

Texas Medicaid

Provider Procedures Manual

November 2026

Volume 2

Provider Handbooks

Outpatient Drug Services Handbook

The Texas Medicaid & Healthcare Partnership (TMHP) is the claims administrator for Texas Medicaid under contract with the Texas Health and Human Services Commission.

OUTPATIENT DRUG SERVICES HANDBOOK

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1 General Information

The information in this handbook provides information about Texas Medicaid's benefits, policies, and procedures applicable to outpatient drugs.

Important: *All providers are required to read and comply with "Section 1: Provider Enrollment and Responsibilities" (Vol. 1, General Information). In addition to required compliance with all requirements specific to Texas Medicaid, it is a violation of Texas Medicaid rules when a provider fails to provide healthcare services or items to Medicaid clients in accordance with accepted medical community standards and standards that govern occupations, as explained in Title 1 Texas Administrative Code (TAC) §371.1659. Accordingly, in addition to being subject to sanctions for failure to comply with the requirements that are specific to Texas Medicaid, providers may also be subject to Texas Medicaid sanctions for failure, at all times, to deliver healthcare items and services to Medicaid clients in full accordance with all applicable licensure and certification requirements including, without limitation, those related to documentation and record maintenance.*

Refer to: "Section 1: Provider Enrollment and Responsibilities" (*Vol. 1, General Information*).

1.1 About the Vendor Drug Program

The Texas Vendor Drug Program (VDP) provides statewide access to prescription drugs as authorized by a prescribing provider for clients enrolled in:

- Medicaid (fee-for-service and managed care).
- Children's Health Insurance Program (CHIP).
- Children with Special Health Care Needs (CSHCN) Services Program.
- Healthy Texas Women (HTW) Program.
- Kidney Health Care (KHC) Program.

VDP manages the Medicaid and CHIP drug formularies and Medicaid Preferred Drug List (PDL).

Note: *Pharmacy services for clients in Medicaid managed care are administered by a client's managed care organization (MCO).*

Refer to: The *Medicaid Managed Care Handbook* (*Vol. 2, Provider Handbooks*) for additional information about managed care prescription drug and pharmacy benefits.

1.2 Pharmacy Enrollment

VDP enrolls any eligible, in-state pharmacy licensed as Class A or C by the Texas State Board of Pharmacy.

Any out-of-state pharmacies or pharmacies holding any other class of pharmacy license are considered for inclusion in the program on a case-by-case basis. Consideration is relative to the benefits made available to the client eligible for pharmacy benefits. Enrollment is not granted unless additional benefits are established.

Pharmacy providers must enroll with Texas Medicaid through the Provider Enrollment and Management System (PEMS) before providing outpatient prescription services and prior to participating in any Medicaid managed care network. To participate in the Medicaid or CHIP managed care networks, the pharmacy must contact the health plan.

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Pharmacy providers enrolled with HHSC should refer to the VDP Pharmacy Provider Procedure Manual for policies and procedures pertaining to fee-for-service outpatient pharmacy claims, including drug benefit guidance, pharmacy prior authorization, coordination of benefits, drug pricing, and reimbursement.

Refer to: The *VDP Pharmacy Provider Procedure Manual* on the VDP website.

Subsection 1.1, "Provider Enrollment" in "Section 1: Provider Enrollment and Responsibilities" (*Vol. 1, General Information*) for more information about procedures for enrolling as a Medicaid provider.

Subsection 2.2, "Provider Enrollment and Responsibilities" in the *Medicaid Managed Care Handbook* (*Vol. 2, Provider Handbooks*).

1.3 Program Contact Information

Vendor Drug Program	Contact
Pharmacy Benefits Access: for questions about outpatient drug and billing (the 800 number is for pharmacy use only and can be used to reach any area within VDP).	1-800-435-4165
Program Policy and Management	vdp-policy@hhs.texas.gov
Drug formulary (Texas listing of national drug codes)	vdp-formulary@hhs.texas.gov
Texas Pharmacy Prior Authorization Center	1-877-728-3927
Texas Pharmacy Third Party Call Center	1-866-389-5594
CAD information	vdp-cad@hhs.texas.gov
Texas Drug Utilization Review Board	vdp-advisory@hhs.texas.gov

1.4 Education

HHSC and TMHP provide several provider education and training opportunities.

1.4.1 Continuing Education

Texas Health Steps offers more than 40 continuing education courses accredited by the Accreditation Council of Pharmacy Education (ACPE). Pharmacy-related continuing education modules.

The Pharmacy module equips pharmacists and pharmacy providers in delivering outpatient pharmacy services to clients enrolled in Texas Medicaid, Children's Health Insurance Program, Children with Special Health Care Needs Services Program, Healthy Texas Women Program, and Kidney Health Care Program.

1.4.2 Texas Health Steps Quick Course

Quick courses are short, targeted training modules available to anyone. Most take 15 minutes or less to complete and do not offer continuing education credit. Outpatient drug-related quick-courses include the following:

- Prescriber's Guide to Medicaid Prior Authorizations
- Texas Medicaid Mosquito Repellent Benefit: What Pharmacy Providers Need to Know

1.4.3 * TMHP Learning Management System

The TMHP Learning Management System is an education portal. To access the LMS, providers must register and obtain a username. Refer to the LMS Registration and Navigation Job Aid to learn more about creating an account and navigating the LMS.

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- [Revised] TMHP LMS
- [Revised] LMS Registration and Navigation Job Aid

Pharmacy-related computer-based training (CBT) modules include the following:

- Durable Medical Equipment
  - The Pharmacy DME CBT provides DME and pharmacy DME providers information and resources necessary to enroll in Texas Medicaid as a DME provider and provide DME and supplies to Texas Medicaid clients.
- NDC Requirements for the Submission of Clinician-Administered Drug Claims
  - Provides information about national drug code (NDC) and healthcare common procedure coding system (HCPCS) requirements on clinician-administered drug (CAD) claims.

2 Clinician-Administered Drugs

2.1 Services, Benefits, Limitations, and Prior Authorization

Clinician-administered drugs or biologicals (CADs), also known as physician-administered drugs, are injectable medications given in an office or outpatient clinic setting when oral medications are not appropriate and may be reimbursable as a medical benefit through Texas Medicaid and CHIP.

Newly released HCPCS codes for CADs and biologicals are reviewed by Texas Medicaid throughout the year. If the CADs are determined to be appropriate benefits for Medicaid, then the HCPCS codes are presented at a rate hearing as part of the process to become a benefit. An application to initiate this review process is not necessary. HHSC's review of any new CAD does not guarantee that the new CAD will become a benefit. If a manufacturer is interested in having a CAD included on the Texas Vendor Drug Program (VDP) formulary list it is necessary to contact VDP for an application.

If a HCPCS code that already is a benefit of Texas Medicaid has a new NDC that needs to be added to the Texas NDC-to-HCPCs crosswalk, contact the Texas Vendor Drug Program. A new NDC for a currently payable HCPCs code generally does not require a new rate hearing.

Refer to: Subsection 10, "Pharmacy Benefit" in this handbook for more information.

The *Medicaid Managed Care Handbook* (*Vol. 2, Provider Handbooks*) for information about the managed care prescription drug and pharmacy benefits.

2.1.1 Clinician-administered Drug Search

The VDP clinician-administered drug search is an online tool available to health-care providers to help clients get access to medications.

Users can search by either brand or generic name of the drug or product, the 11-digit national drug code (NDC), the HCPCS code, or the HCPCS description for products.

Refer to: The VDP CAD Search for more information.

2.1.2 Prior Authorization Requests

Prior authorization requests for CADs must be submitted to the TMHP Prior Authorization Department by mail, fax, or the electronic portal.

To facilitate determination of medical necessity and avoid unnecessary denials, the prescribing provider must submit correct and complete information, including documentation for medical necessity for the equipment or supplies requested, procedure codes, and numerical quantities for services requested. The provider must maintain documentation of medical necessity in the client's medical record.

The requesting provider may be asked for additional information to clarify or complete a request.

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To complete the prior authorization process by paper, the provider must fax or mail the completed Special Medical Prior Authorization (SMPA) Request form to the Special Medical Prior Authorization (SMPA) unit.

To complete the prior authorization process electronically, the provider must complete the prior authorization requirements through any approved electronic methods and retain a copy of the signed and dated SMPA Request form in the client's medical record.

A SMPA Request Form must be completed, signed, and dated by the prescribing provider. The SMPA form will not be accepted beyond 90 days from the date of the prescribing provider's signature.

The completed SMPA Request Form must be maintained by the prescribing provider in the client's medical record and is subject to retrospective review.

Documentation of the client's dosage, administration schedule, number of injections to be administered during the prior authorization period, requested units per injection, and the dosage calculation must be submitted in Section C of the Special Medical Prior Authorization (SMPA) Request Form under Statement of Medical Necessity.

2.1.3 Electronic Signatures in Prior Authorizations

Prior authorization requests may be submitted to the TMHP Prior Authorization Department by mail, fax, or the electronic portal. Prescribing or ordering providers, dispensing providers, clients' responsible adults, and clients may sign prior authorization forms and supporting documentation using electronic or wet signatures.

Refer to: Subsection 5.5.1.2, "Document Requirements and Retention" in "Section 5: Fee-for-Service Prior Authorizations" (*Vol. 1, General Information*) for additional information about electronic signatures.

3 Reimbursement

Clinician-administered drugs, vaccines, and biologicals are reimbursed under Texas Medicaid in accordance with 1 TAC rule §355.8085. Reimbursement for clinician-administered drugs, vaccines, and biologicals are based on the lesser of the billed amount, a percentage of the Medicare rate, or one of the following methodologies:

- If the drug or biological is considered a new drug or biological (that is, approved for marketing by the Food and Drug Administration within 12 months of implementation as a benefit of HHSC-administered programs), it may be reimbursed at an amount equal to 89.5 percent of average wholesale price (AWP).
- If the drug or biological does not meet the definition of a new drug or biological, it may be reimbursed at an amount equal to 85 percent of AWP.
- Vaccines may be reimbursed at an amount equal to 89.5 percent of AWP.
- Infusion drugs furnished through an item of implanted durable medical equipment may be reimbursed at an amount equal to 89.5 percent of AWP.
- Drugs, other than vaccines and infusion drugs, may be reimbursed at a percentage of the Medicare rate.

HHSC may use other data sources or methodologies to establish its fees for physician-administered drugs, vaccines, and biologicals when HHSC determines that the above methodologies are unreasonable or insufficient.

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Texas Medicaid reimburses providers using several different reimbursement methodologies, including fee schedules, reasonable cost with interim rates, hospital reimbursement methodology, provider-specific encounter rates, reasonable charge payment methodology, and manual pricing. Each Texas Medicaid service describes the appropriate reimbursement for each service area.

Note: *If a client is covered by a Medicaid managed care organizations (MCO) or dental plan, providers must contact the client's MCO or dental plan for reimbursement information. The MCOs and dental plans are not required to follow the Texas Medicaid fee schedules, so there may be some differences in reimbursement based on decisions made by the individual health and dental plans.*

When services or products do not have an established reimbursement amount, the detail or claim is manually reviewed to determine an appropriate reimbursement.

Texas Medicaid (FFS and MCO) providers can bill and receive reimbursement for the unused portion of weight-based or variable dosing CADs that are only manufactured in single-dose vials. A multi-dose vial is a vial of liquid medication that is intended for parenteral administration (injection or infusion), contains more than one dose of medication, and may be used for more than one patient preparation or administration. Multi-dose vials are excluded from reimbursement under Texas Medicaid for any unused or discarded portions.

Claims will only be considered for reimbursement if an HHSC review has determined that the medication has a weight-based, variable dosing schedule or that it requires dosing adjustments for pharmacokinetic or pharmacodynamic considerations. The administration of the medication for the recommended dosing must result in a patient dose portion plus a discarded portion of a drug vial. The provider may be eligible for reimbursement up to the amount of drug or biological in accordance with the drug label.

Claims submitted for the unused portion and discarded portion of weight-based or variable dosing clinician-administered drugs (CADs) manufactured only in single-dose vials must include the modifier JW for consideration of reimbursement.

This only applies to medical claims for weight-based or variable dosing CADs billed with Healthcare Common Procedure Coding System (HCPCS) procedure codes, manufactured only in single-dose vials, and provided in a professional or outpatient setting.

Providers must use the modifier JW to identify the unused portion of the vial contents and the discarded amount of the drug or biological. Medicaid and CHIP providers must bill the JW on a separate line.

Example: *A single use vial labeled to contain 100 units of a drug has 95 units administered to the client and 5 units discarded. The 95-unit dose is billed on one line, while the discarded 5 units are billed on another line by using the JW modifier. Both line items are reviewed for reimbursement. The provider must record the discarded amounts of drugs and biologicals in the client's medical record.*

Refer to: Subsection 9.1, "JW Modifier Claims Filing Instructions" in this handbook for further instructions about the JW modifier.

4 Injectable Medications as a Pharmacy Benefit

Some injectable drugs or biologicals are available by prescription and are reimbursable as a pharmacy benefit through the Vendor Drug Program (VDP) under Texas Medicaid.

Refer to: Subsection 10, "Pharmacy Benefit" in this handbook for more information.

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Oral medications that are given in the hospital or physician's office are considered part of the hospital or office visit and cannot be reimbursed separately. Take-home and self-administered drugs may be a pharmacy benefit when they are provided to eligible Texas Medicaid fee-for-service clients through VDP with a valid prescription.

Providers may utilize the "white-bagging" delivery method, in which the treating provider submits prescriptions to pharmacies and the prescription is shipped or mailed to the provider's office.

Refer to: Subsection 11.5.1, "Pharmacy Delivery Method for Clinician-Administered Drugs" in this handbook for additional information on the "white-bagging" delivery method.

Providers must use oral medication in preference to injectable medication in the office and outpatient hospital. If an oral medication cannot be used, the KX modifier must be submitted on the claim. The following situations are acceptable reasons for the use of administering an injectable medication instead of administering an oral medication.

Claim Form	Reason for Injection
Modifier KX	• No acceptable oral equivalent is available. • Injectable medication is the standard treatment of choice. • The oral route is contraindicated. • The client has a temperature over 102 degrees Fahrenheit (documented on the claim and in the medical record) and a high blood level of antibiotic is needed quickly. • The client has demonstrated noncompliance with orally prescribed medication (must be documented on the claim and in the medical record). • Previously attempted oral medication regimens have proven ineffective (must be supported by documentation in the medical record). • Situation is emergent.

The claim and the client's medical record must include documentation of medical necessity to support the need for the service. Retrospective review may be performed to ensure that the documentation supports the medical necessity of the service and any modifier used when billing the claim.

5 National Drug Code (NDC)

The NDC is an 11-digit number on the package or container from which the medication is administered.

Some packages may display less than 11 digits. In those cases, leading zeros can be assumed and are required for billing. For example, 5678-0123-01 becomes 05678-0123-01. In another example, 78513-677-2 becomes 78513-0677-02.

Note: *The NDCs in the examples show hyphens between the segments for easier visualization. NDCs submitted on claims should not include hyphens or spaces between the segments.*

Refer to: Subsection 6.3.4, "National Drug Code (NDC)" in "Section 6: Claims Filing" (*Vol. 1, General Information*) for more information on NDC requirements as well as drug rebates.

5.1 Calculating Billable HCPCS and NDC Units

All drug claims must include HCPCS billing units as well as NDC billing units. HCPCS billing units are calculated by dividing the amount administered by the units found in the procedure code description. The calculated HCPCS billing unit is also needed to determine the correct NDC billing unit. NDC billing units are calculated by multiplying the HCPCS billing unit by the conversion factor. The conversion

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factor is calculated by dividing the HCPCS unit (found in the code description) by the NDC unit (found on the box or packaging). See calculation examples in the following sections. Conversion factors are already computed and included on the Texas NDC-to-HCPCS Crosswalk. The NDC billing unit also requires a unit of measurement. For example, if the NDC is for a liquid medication the submitted units must be in milliliters (ML). If the NDC is for a powder form then the submitted units are Unit (UN). Other allowable NDC units are GR for gram, F2 for international unit, and ME for milligram. For all claims, the HCPCS and NDC billing units are required, along with the specific NDC and HCPCS procedure code. Claims submitted with incorrect unit calculations may cause delayed or incorrect payment.

5.1.1 Single-Dose Vials Calculation Examples

Below are three examples of how to calculate the HCPCS and NDC billing units using single-dose vials.

1) A patient receives 4 mg Zofran IV in the physician's office. The NDC of the product used is 00173-0442-02 (Zofran 2 mg/ml in solution form). There are 2 milliliters per vial. The provider should bill J2405 for ondansetron hydrochloride with 4 HCPCS units and the NDC units submitted should be 2 ML.
2) A patient receives 8mg of Avastin IV in the physician's office. The NDC of the product used is 50242-060-01 (Avastin 25mg/ml). The provider should bill J9035 for bevacizumab with 0.8 HCPCS unit. The NDC unit is 0.32 ML.
3) A patient receives 1 gm Rocephin IM in the physician's office. The NDC of the product used is 00004-1963-02 (Rocephin 500 mg vial in a powder form that is reconstituted prior to the injection). The provider should bill J0696 for ceftriaxone sodium with 4 HCPCS units. The NDC units are 2 UN because this NDC is in powder form.

	Zofran	Avastin	Rocephin
Dose Administered to Patient	4 mg	8mg	1gm = 1000mg
HCPCS Code and Unit found in description	J2405 Per 1 mg	J9035 Per 10 mg	J0696 Per 250 mg
HCPCS CODE BILLING UNIT(s) = Dose divided by units found in HCPCS code description	4mg/1mg=4	8mg/10mg=0.8	1000mg/250mg=4
NDC Information on Vial/Box	2mg/ml	25mg/ml	500mg/vial (powder form)
Determining Conversion Factor (CF) = HCPCS unit from code description divided by NDC unit from vial/box	1mg/2mg=0.5 CF = 0.5	10mg/25mg=0.4 CF = 0.4	250mg/500mg=0.5 CF = 0.5
NDC BILLING UNIT(s) = HCPCS Units x CF	4 x 0.5 = 2 ML	0.8 x 0.4 = 0.32 ML	4 x 0.5 = 2 UN
Quantity Information Required on Claim (HCPCS and NDC)	4 and 2 ML	0.8 and 0.32 ML	4 and 2 UN

5.1.2 Multi-Dose Vials Calculation Examples

Below is an example of calculating the correct billing units for a drug administered from a multi-dose vial. Calculations for multi-dose vials differ from those for single-dose vials.

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A patient receives 8 mg Dexamethasone in the physician's office. A 20 mg multi-dose vial is used. The NDC of the product used is 63323-0165-05 (Dexamethasone 20 MG/5 ml Vial). The provider should bill J1100 for dexamethasone with 8 HCPCS units and the NDC units submitted should be 2 ML. There are 12mg (3 ml) remaining in the vial.

Multi-Dose Calculation Examples for Dexamethasone	
Dose Administered to Patient	8 mg
HCPCS Code and Given Unit	J1100 Per 8 mg
HCPCS CODE BILLING UNIT(s) = Dose divided by units found in HCPCS code	8mg/1mg = 8
NDC Information on Vial/Box	20mg/5ml = 4mg/1ml
NDC BILLING UNIT(s) = Dose divided by NDC unit from vial/box	8/4 = 2
Quantity Information Required on Claim (HCPCS and NDC)	8 and 2 ML

5.1.3 Single and Multi-Use Vials

A single-dose (or single-use) vial of medication intended for administration through injection or infusion contains a single dose of medication. A multi-dose (or multi-use) vial of medication intended for administration through injection or infusion contains more than one dose of medication.

Many drugs have recommended doses that are based on factors such as height, weight, and initial tolerance for the drug. It is important to clearly document how the dosage is calculated so those who review the patient health record can verify the dosage amount when reviewing the claim.

Other resources on clinician-administered drugs may be found online by visiting the TMHP, CDC and CMS websites.

5.1.4 Nonspecific, Unlisted, or Miscellaneous Procedure Codes

Drugs or biologicals that do not have a unique CPT or HCPCS procedure code must be billed using a nonspecific, unlisted, unclassified, or miscellaneous procedure code. All claims for nonspecific, unlisted, unclassified, or miscellaneous procedure codes are processed manually and must be submitted on paper with accompanying documentation. The billing provider must include the following required documentation:

- The name and NDC number of the drug administered.
- The quantity of the drug administered, the amount discarded (if applicable for reimbursement), and the units of measurement.
- A brief description of the recipient's condition(s) that supports the medical need for the drug.
- One of the following pricing information sources:
  - The manufacturer's average wholesale price (AWP)
  - A copy of the invoice for the drug

The claim and attached information will suspend for manual review to determine whether the drug is clinically appropriate based on the information provided and to price the claim using the information provided. Miscellaneous drug or biological procedure codes are reimbursed a percentage of the average wholesale price (AWP). HHSC reserves the option to use other data sources to determine Texas Medicaid fees for drugs when AWP calculations are determined to be unreasonable or insufficient.

The claim will be denied when:

- The information is not sufficient to determine medical necessity.

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- The pricing information is insufficient for pricing the claim.
- There is a more appropriate billing procedure code for the drug or biological.
- The NDC and HCPCs (if applicable) codes are missing.

Providers are responsible for administering drugs based on the U.S. Food and Drug Administration (FDA)-approved guidelines.

Retrospective review may be performed to ensure documentation supports the medical necessity of the service.

Some injectable medications require prior authorization, which is a condition for reimbursement; it is not a guarantee of payment. To avoid unnecessary denials, the physician must provide correct and complete information, including documentation for medical necessity for the service requested. The physician must maintain documentation of medical necessity in the client's medical record. Providers may fax or mail prior authorization requests, including all required documentation, to the TMHP Special Medical Prior Authorization Department at:

Texas Medicaid & Healthcare Partnership
Special Medical Prior Authorization Department
12365-A Riata Trace Parkway
Austin, TX 78727-6418
Fax: 1-512-514-4213

The following injections in the table below are benefits of Texas Medicaid but are subject to the indicated limitations. Those with an asterisk have more information and can be found listed after the table.

6 Outpatient Drugs—Benefits and Limitations

The clinician administered drugs identified throughout this handbook are benefits of Texas Medicaid, but are subject to the indicated limitations.

Clinician administered drugs may be considered for reimbursement in the home, office, or outpatient hospital settings. Certain procedure codes may be restricted for place of service and provider types. Providers should verify the restrictions for specific procedure codes of injectable or infused medications prior to rendering services.

6.1 Abatacept (Orencia)

Abatacept (Orencia) (procedure code J0129) is a selective T-cell costimulation modulator that is indicated for the following:

- Moderate to severe rheumatoid arthritis in adult clients. Concomitant use of abatacept with other immunosuppressives [e.g., biologic disease modifying antirheumatic drugs (bDMARDS), Janus kinase (JAK) inhibitors] is not recommended. Concomitant use with a Tumor necrosis factor (TNF) antagonist can increase the risk of infections and serious infections.
- Moderate to severe juvenile arthritis in adult and pediatric clients who are 2 years of age or older (clients who are 2 years of age or older may receive subcutaneous formulation and clients who are 6 years of age or older may receive intravenous formulation). Abatacept may be used as monotherapy or concomitantly with methotrexate.
- Psoriatic arthritis in clients who are 2 years of age or older.
- The prophylaxis of acute graft versus host disease (aGVHD), in combination with a calcineurin inhibitor and methotrexate, in adults and pediatric clients who are 2 years of age or older undergoing hematopoietic stem cell transplantation (HSCT) from a matched or 1 allele-mismatched unrelated donor.

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6.1.1 Prior Authorization for Abatacept (Orencia)

Prior authorization may be given for an initial six months for eight doses. Prior authorization for an initial request for abatacept injections will be considered when all of the following criteria are met:

- Dates of treatment
- The number of anticipated doses
- The dosage to be administered
- Diagnosis of adult RA, juvenile idiopathic arthritis (JIA), adult psoriatic arthritis (PsA), or as prophylaxis of acute graft versus host disease (aGVHD)

A diagnosis of RA in an adult client must conform to the American College of Rheumatology (ACR) RA classification that requires the following:

- Presence of synovitis in at least one joint
- Absence of an alternative diagnosis to explain the synovitis
- Abatacept will not be used in combination with another biologic agent
- A combined score of at least six out of ten on the level of involved joints, abnormality, and symptom duration from the individual scores in four domains:
    - The number and sites of involved joints
    - Serologic abnormality
    - Elevated acute-phase response
    - Symptom duration

Prior authorization for moderate to severe Juvenile Idiopathic Arthritis (JIA) will be considered when the following criteria are met:

- The client is an adult or pediatric client who is 2 years of age or older.
- Clients who are 2 years of age or older may receive subcutaneous formulation, and clients who are 6 years of age or older may receive intravenous formulation.
- Abatacept (Orencia) may be used as monotherapy or concomitantly with methotrexate.

Prior authorization for adult Psoriatic Arthritis (PsA) will be considered when the following criteria are met:

- The client is 2 years of age or older.
- Abatacept (Orencia) will not be used in combination with another biologic agent.

Prior authorization for prophylaxis acute graft versus host disease will be considered when the following criteria are met:

- The client is 2 years of age or older.
- Abatacept should be used in combination with a calcineurin inhibitor and methotrexate.
- The client is undergoing hematopoietic stem cell transplantation (HSCT) from a matched or 1 allele-mismatched unrelated-donor.

Screening for latent tuberculosis (TB) infection and viral hepatitis should be carried out prior to therapy initiation.

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Prior authorization for subsequent dosing may be given when documentation supports medical necessity for continued treatment with abatacept. Prior authorization for a subsequent request must include all of the following:

- Documentation from the physician stating that there has been at least an improvement
- The number of anticipated doses
- The dosage to be administered

The documentation of medical necessity must be maintained by the requesting provider in the client's medical record and is subject to retrospective review.

6.2 Adalimumab

Adalimumab is a benefit when billed with one of the following procedure codes:

Procedure Codes									
J0139	Q5140	Q5141	Q5142	Q5143	Q5144	Q5145			

Procedure codes Q5141, Q5142, and Q5144 are restricted to clients who are 2 years of age or older.

Procedure codes Q5140, Q5143, and Q5145 are restricted to clients who are 4 years of age or older.

Procedure codes Q5140, Q5142, Q5144, and Q5145 may be reimbursed when billed with diagnosis codes M05A and R7681, in addition to the diagnosis codes listed in the table below.

Procedure code Q5141 may be reimbursed when billed with diagnosis code R7681, in addition to the diagnosis codes listed in the table below.

The procedure codes in the table above may be reimbursed when billed with one of the following diagnosis codes:

Diagnosis Codes							
K5000	K50011	K50012	K50013	K50014	K50018	K5010	K50111
K50112	K50113	K50114	K50118	K5080	K50811	K50812	K50813
K50814	K50818	K5090	K50911	K50912	K50913	K50914	K50918
K50919	K5100	K51011	K51012	K51013	K51014	K51018	K5120
K51211	K51212	K51213	K51214	K51218	K5130	K51311	K51312
K51313	K51314	K51318	K5140	K51411	K51412	K51413	K51414
K51418	K51419	K5150	K51511	K51512	K51513	K51514	K51518
K5180	K51811	K51812	K51813	K51814	K51818	K5190	K51911
K51912	K51913	K51914	K51918	K51919	L400	L401	L402
L403	L404	L4050	L4051	L4052	L4053	L4054	L4059
L408	L409	M00039	M00071	M00072	M00079	M00171	M00172
M00179	M00271	M00272	M00279	M00871	M00872	M00879	M0500
M05011	M05012	M05019	M05021	M05022	M05029	M05031	M05032
M05039	M05041	M05042	M05049	M05051	M05052	M05059	M05061
M05062	M05069	M05071	M05072	M05079	M0509	M05271	M0530
M05411	M05412	M05421	M05422	M05431	M05432	M05441	M05442
M05451	M05452	M05461	M05462	M05471	M05472	M0549	M05511
M05512	M05521	M05522	M05531	M05532	M05541	M05542	M05551

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Diagnosis Codes							
M05552	M05561	M05562	M05571	M05572	M0559	M0560	M05611
M05612	M05619	M05621	M05622	M05629	M05631	M05632	M05639
M05641	M05642	M05649	M05651	M05652	M05659	M05661	M05662
M05669	M05671	M05672	M05679	M0569	M05711	M05712	M05721
M05722	M05731	M05732	M05741	M05742	M05751	M05752	M05761
M05762	M05769	M05771	M05772	M05779	M0579	M057A	M05811
M05812	M05821	M05822	M05831	M05832	M05841	M05842	M05851
M05852	M05861	M05862	M05871	M05872	M0589	M058A	M06011
M06012	M06021	M06022	M06031	M06032	M06041	M06042	M06051
M06052	M06061	M06062	M06071	M06072	M0608	M0609	M060A
M061	M06811	M06812	M06819	M06821	M06822	M06829	M06831
M06832	M06839	M06841	M06842	M06849	M06851	M06852	M06859
M06861	M06862	M06869	M06871	M06872	M06879	M0688	M0689
M068A	M069	M0800	M08011	M08012	M08019	M08021	M08022
M08029	M08031	M08032	M08039	M08041	M08042	M08049	M08051
M08052	M08059	M08061	M08062	M08069	M08071	M08072	M08079
M0808	M0809	M081	M08811	M08812	M08821	M08822	M08831
M08832	M08839	M08841	M08842	M08849	M08851	M08852	M08859
M08861	M08862	M08871	M08872	M0888	M0889	M08911	M08912
M08919	M08921	M08922	M08929	M08931	M08932	M08939	M08941
M08942	M08949	M08951	M08952	M08959	M08961	M08962	M08969
M08971	M08972	M0898	M13871	M13872	M13879	M450	M451
M452	M453	M454	M455	M456	M457	M458	M459
M45A0	M45A1	M45A2	M45A3	M45A4	M45A5	M45A6	M45A7
M45A8	M45AB	M488X1	M488X2	M488X3	M488X4	M488X5	M488X6
M488X7	M488X8	M488X9					

6.3 Ado-trastuzumab entansine (Kadcyla)

Ado-trastuzumab emtansine (Kadcyla), procedure code J9354, is a benefit of Texas Medicaid for clients of any age when all of the following indications are present:

- Individuals have a diagnosis of HER2 positive metastatic breast cancer
- Individuals have previously received trastuzumab and a taxane separately or in combination, and have either:
  - Received prior therapy for metastatic disease
  - Experienced disease reoccurrence during or within six months of completing adjuvant therapy

Documentation must be maintained by the treating physician in the client's medical record to support administration of Ado-trastuzumab emtansine (Kadcyla). Prior authorization is not required for ado-trastuzumab emtansine (Kadcyla).

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At initiation of treatment, documentation must include all of the following:

- Evidence of HER2 positive breast cancer as evidenced by immunochemistry (IHC) test or fluorescent in situ hybridization (FISH) test
- Evidence of metastatic breast cancer
- Evidence demonstrating prior treatment for this diagnosis with trastuzumab and a taxane oncology agent separately or in combination
- Evidence demonstrating receipt of prior therapy for this diagnosis or recurrent disease, including the previous treatment protocol, within six months of completing adjuvant therapy.

6.4 Afamelanotide Implant (Scenesse)

Afamelanotide implant (Scenesse) (procedure code J7352) is a benefit of Texas Medicaid for clients who are 18 years of age or older and is restricted to diagnosis code E800.

6.5 Afamitresgene autoleucel (Tecelra)

Afamitresgene autoleucel (Tecelra) is a melanoma-associated antigen A4 (MAGE-A4)-directed genetically modified autologous T cell immunotherapy indicated to treat adult clients with unresectable or metastatic synovial sarcoma who have received prior chemotherapy, are HLA-A*02:01P, HLA-A*02:02P, HLA-A*02:03P, or HLA-A*02:06P positive and whose tumor expresses the MAGE-A4 antigen as determined by FDA-approved or cleared companion diagnostic devices.

Afamitresgene autoleucel (Tecelra) (procedure code Q2057) is a benefit of Texas Medicaid with prior authorization.

6.5.1 Prior Authorization Requirements

Afamitresgene autoleucel (Tecelra) is administered as a single intravenous infusion and is indicated to treat clients who meet all the following requirements:

- The client is 18 years of age or older.
- The client has a diagnosis of unresectable or metastatic synovial sarcoma with one of the following diagnosis codes:

Diagnosis Codes							
C380	C381	C382	C383	C384	C388	C481	C482
C488	C490	C4910	C4911	C4912	C4920	C4921	C4922
C493	C494	C495	C496	C498	C499		

- The client's tumor is positive for human leukocyte antigen HLA-A*02:01P, HLA-A*02:02P, HLA-A*02:03P, or HLA-A*02:06P.
- The client's tumor expresses the MAGE-A4 antigen (as determined by an FDA-approved or cleared companion diagnostic device).
- The client is not heterozygous or homozygous for HLA-A*02:05P.
- The client has experienced disease progression following at least one or more prior systemic chemotherapy.
- The client has not received prior treatment with CAR-T therapy.
- The client has not had a prior hematopoietic stem cell transplant (HSCT).
- The client does not have any active or clinically significant infections and/or inflammatory disorders.

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Afamitresgene autoleucel (Tecelra) (procedure code Q2057) is limited to one transfusion treatment per lifetime.

Monitoring parameters for Afamitresgene autoleucel (Tecelra) are as follows:

- Monitor for signs and symptoms of cytokine release syndrome (CRS) for at least 7 days following afamitresgene autoleucel (Tecelra) treatment with continued monitoring for at least 4 weeks.
- Monitor for signs and symptoms of immune effector cell-associated neurotoxicity syndrome (ICANS) for at least 7 days following afamitresgene autoleucel (Tecelra) treatment with continued monitoring for at least 4 weeks.

6.5.2 Documentation Requirements

In addition to documentation requirements outlined in the Prior Authorization Requirements section, all services are subject to retrospective review to ensure that the documentation in the client's medical record supports the medical necessity of the service(s) provided.

6.6 Allogeneic Processed Thymus Tissue-agdc (Rethymic)

Allogeneic processed thymus tissue-agdc (Rethymic) is indicated for immune reconstruction in pediatric clients with congenital athymia.

Allogeneic processed thymus tissue-agdc (Rethymic) is a benefit of Texas Medicaid with prior authorization and may be reimbursed using procedure code J3590.

Allogeneic processed thymus tissue-agdc (Rethymic) is limited to once per lifetime.

6.6.1 Prior Authorization Requirements

Providers must submit prior authorization requests for allogeneic processed thymus tissue-agdc (Rethymic) on a Special Medical Prior Authorization (SMPA) Request Form.

The prior authorization request for the one-time surgical procedure for allogeneic processed thymus tissue-agdc (Rethymic) administration must include documentation of the following:

- The client is 18 years of age or younger.
- The client has a diagnosis of congenital athymia that is confirmed by flow cytometry (diagnosis code D821).
- Severe combined immunodeficiency (SCID) has been conclusively ruled out.
- An anti-human leukocyte antigen (HLA) antibody test was conducted prior to treatment. If the client tests positive for anti-HLA antibodies, they must receive allogeneic processed thymus tissue-agdc (Rethymic) from a donor who does not express HLA alleles.
- The prescriber must attest that the benefits and risks of treatment have been evaluated for clients with preexisting cytomegalovirus (CMV) infection or renal impairment.
- The client has not previously received thymus tissue transplantation.

After the surgical implantation of allogeneic processed thymus tissue-agdc (Rethymic), the prescriber must monitor the client for:

- The risk of developing of graft versus host disease (GVHD).
- The possibility of developing autoimmune or lymphoproliferative disorders, which is monitored through complete blood counts (CBC) with differential, liver enzymes, serum creatinine, urinalysis, and thyroid function.
- Renal impairment or failure.

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- The occurrence of an infectious disease, as these may develop due to allogeneic processed thymus tissue-agdc (Rethymic) is derived from human tissue.

In addition to documentation requirements outlined in this section, all services are subject to retrospective review to ensure that the documentation in the client's medical record supports the medical necessity of the service(s) provided.

6.7 Alzheimer's Disease (AD)

Donanemab-azbt (Kisunla) (procedure code J0175) and lecanemab-irmb (Leqembi) (procedure code J0174) are benefits of Texas Medicaid for clients with prior authorization. Procedure codes J0174 and J0175 are limited to diagnosis codes G300, G301, G308, or G309.

Donanemab-azbt (Kisunla) and lecanemab-irmb (Leqembi) are amyloid beta-directed antibodies indicated to treat Alzheimer's disease (AD) by reducing amyloid-beta plaques in clients with mild cognitive impairment (MCI) or mild dementia stage of disease.

This clinical prior authorization applies to Medicaid clients only. Dual eligible clients must follow the Medicare National Coverage Determination policy guidelines for monoclonal antibodies directed against amyloid for the treatment of Alzheimer's disease.

6.7.1 Prior Authorization

Initial Requests

Initial therapy for donanemab-azbt (Kisunla) or lecanemab-irmb (Leqembi) may be approved for a 6-month duration if all the following criteria are met:

- Client has a confirmed diagnosis of Alzheimer's disease (G300, G301, G308, or G309).
- Prescriber attestation that other forms of dementia except Alzheimer's disease have been ruled out by appropriate lab and/or other diagnostic testing.
- Prescriber's confirmation of amyloid beta-plaques presence.
- Clinical testing must confirm client has mild cognitive impairment caused by Alzheimer's disease or mild stage of Alzheimer's disease.
- Documentation that client has received a baseline brain-magnetic resonance imaging (MRI) prior to initiating treatment (within the past year) to evaluate for pre-existing Amyloid Related Imaging Abnormalities (ARIA).
- The prescriber attests to having tested for ApoE ε4 status and counsel ApoE ε4 homozygotes clients on higher incidence of developing ARIA prior to initiation of treatment.
- The following are the monitoring requirements during the donanemab-azbt (Kisunla) treatment period:
  - Prescriber must ensure the client is not currently taking any anti-coagulant (except for aspirin at a prophylactic dose or less) or have a history of clotting disorder.
  - Prescriber must monitor for ARIA during the first 24 weeks of treatment.
  - Prescriber attestation to obtain a brain MRI prior to the 2nd, 3rd, 4th, and 7th infusion to check for asymptomatic ARIA.
  - Clients with severe amyloid-related imaging abnormalities-hemosiderin deposition (ARIA-H) may continue therapy only if radiographic stabilization has been confirmed by a follow-up brain MRI and supported by clinical evaluation.

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The following are the monitoring requirements during the lecanemab-irmb (Leqembi) treatment period:

- Prescriber must monitor for ARIA during the first 14 weeks of treatment.
- Prescriber attestation to obtain a brain MRI prior to the 5th, 7th, and 14th infusion to check for ARIA.
- Clients with severe ARIA-H may continue therapy only if radiographic stabilization has been confirmed by a follow-up brain MRI and supported by clinical evaluation.

Re-certification/Extension

For renewal or continuation therapy of donanemab-azbt (Kisunla) or lecanemab-irmb (Leqembi), the client must meet the following requirements:

- Client continues to meet all the initial authorization approval criteria.
- Client has not progressed to moderate or severe dementia caused by Alzheimer's disease.
- Client experienced positive clinical response to therapy as demonstrated by no increase in amyloid plaque or radiographic stabilization as compared to baseline.
- Documentation of a brain MRI prior to the 2nd, 3rd, 4th, and 7th infusion to check for ARIA with donanemab-azbt (Kisunla) treatment.
- Documentation of brain MRI prior to the 5th, 7th, and 14th infusion to check for ARIA with lecanemab-irmb (Leqembi) treatment.
- Client has not experienced any complications or unacceptable toxicities during donanemab-azbt (Kisunla) or lecanemab-irmb (Leqembi) treatment.

6.8 Amisulpride (Barhemsys)

Amisulpride (procedure code J0184) is a benefit of Texas Medicaid for clients who are 18 years of age or older.

6.9 Antibiotics and Steroids

Injectable antibiotic or steroid medications may be considered for reimbursement even if the same oral medications are appropriate and available. Injected antibiotics or steroid medications, when used in place of oral medications, require the use of the modifier KX.

Physicians billing for injectable antibiotic and steroid medications must indicate the appropriate modifiers with the appropriate injection code and quantity.

Modifier	Use
AT	For acute conditions*
KX	To indicate any of the following: • Oral route contraindicated or an acceptable oral equivalent is not available. • Injectable medication is the accepted treatment of choice. Oral medication regimen has proven ineffective or is not applicable. • The patient has a temperature over 102 degrees and a high level of antibiotic is needed immediately. • Injection is medically necessary into joints, bursae, tendon sheaths, or trigger points to treat an acute condition or the acute flare-up of a chronic condition.

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If a steroid medication is injected into joints, bursae, tendon sheaths, or trigger points, modifier AT must be used to indicate an acute condition. When performed for a chronic condition, these procedures are denied.

6.10 Antineoplastic (Oncology) Agents

6.10.1 Amivantamab-vmjw (Rybervant)

Amivantamab-vmjw (procedure code J9061) is a benefit of Texas Medicaid for clients who are 18 years of age or older.

6.10.2 Cemiplimab-rwlc (Libtayo)

Cemiplimab-rwlc (procedure code J9119) is a benefit for clients who are 18 years of age and older.

6.10.3 Daratumumab and Hyaluronidase-fihj (Darzalex Faspro)

Daratumumab and hyaluronidase-fihj (procedure code J9144) is a benefit of Texas Medicaid for clients who are 18 years of age or older.

6.10.4 Degarelix (Firmagon)

Degarelix injection (procedure code J9155) is a benefit when billed with diagnosis codes C61, C7982, D400.

Refer to: Subsection 6.62.9, "Hormonal Therapy Agents" in this handbook for additional information.

6.10.5 Dostarlimab-gxly (Jemperli)

Dostarlimab-gxly (procedure code J9272) is a benefit of Texas Medicaid for clients who are 18 years of age or older.

6.10.6 Enfortumab Vedotin-ejfv (Padcev)

Enfortumab vedotin-ejfv (procedure code J9177) is a benefit of Texas Medicaid for clients who are 18 years of age or older.

6.10.7 Hydroxyprogesterone Caproate

Hydroxyprogesterone caproate (procedure code J1729) is a benefit and restricted to clients who are nonpregnant women when billed with the following diagnosis codes:

Diagnosis Codes							
C541	N897	N910	N911	N912	N925	N938	

6.10.8 Isatuximab-irfc (Sarclisa)

Isatuximab-irfc (procedure code J9227) is a benefit of Texas Medicaid for clients who are 18 years of age or older.

6.10.9 Loncastuximab Tesirine-lpyl (Zynlonta)

Loncastuximab tesirine-lpyl (procedure code J9359) is a benefit of Texas Medicaid for clients who are 18 years of age or older.

6.10.10 Lurbinectedin (Zepzelca)

Lurbinectedin (procedure code J9223) is a benefit of Texas Medicaid for clients who are 18 years of age or older.

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6.10.11 Margetuximab-cmkb (Margenza)

Margetuximab-cmkb (procedure code J9353) is a benefit of Texas Medicaid for clients who are 18 years of age or older.

6.10.12 Melphalan (Evomela)

Melphalan (procedure codes J9245 and J9246) are a benefit when billed with diagnosis codes C9000, C9001, and C9002.

6.10.13 Mitomycin for Pyelocalyceal Solution (Jelmyto)

Mitomycin for pyelocalyceal solution (procedure code J9281) is a benefit of Texas Medicaid for clients who are 18 years of age or older.

6.10.14 Naxitamab-gqgk (Danyelza)

Naxitamab-gqgk (procedure code J9348) is a benefit of Texas Medicaid for clients who are 1 year of age or older.

6.10.15 Polatuzumab vedotin (Polivy)

Polatuzumab vedotin (procedure code J9309) is a benefit of Texas Medicaid for clients who are 18 years of age or older.

6.10.16 Sacituzumab govitecan-hziy (Trodelvy)

Sacituzumab govitecan-hziy (procedure code J9317) is a benefit of Texas Medicaid for clients who are 18 years of age or older.

6.10.17 Tafasitamab-cxix (Monjuvi)

Tafasitamab-cxix (procedure code J9349) is a benefit of Texas Medicaid for clients who are 18 years of age or older.

6.10.18 Tisotumab Vedotin-tftv (Tivdak)

Tisotumab Vedotin-tftv (procedure code J9273) is a benefit of Texas Medicaid for clients who are 18 years of age or older.

6.11 Antisense Oligonucleotides (eteplirsen, golodirsen, and nusinersen)

Antisense oligonucleotides, casimersen (Amondys 45) (procedure code J1426), eteplirsen (Exondys 51) (procedure code J1428), golodirsen (Vyondys 53) (procedure code J1429), nusinersen (Spinraza) (procedure code J2326), tofersen (Qalsody) (procedure code J1304), or viltolarsen (Viltepso) (procedure code J1427) may be benefits of Texas Medicaid with prior authorization.

An antisense oligonucleotide is a synthetic single stranded nucleic acid that binds to RNA and thereby alters or reduces expression of the target RNA. This may result in an improvement in physical function.

6.11.1 Prior Authorization Requirements

Prior authorization requests for procedure codes J1304, J1426, J1427, J1428, J1429, and J2326 must be submitted by the prescribing provider to the Special Medical Prior Authorization (SMPA) department at TMHP using the Special Medical Prior Authorization (SMPA) Request Form.

Prior authorization is not required for physician services associated with the administration of casimersen, eteplirsen, golodirsen, nusinersen, tofersen, or viltolarsen. Physician services include the procedural costs and the associated supplies for the administration of the medication.

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For situations in which procedure code J1304, J1426, J1427, J1428, J1429, or J2326 are being dispensed by a pharmacy via white bagging, the prescribing provider must provide the dispensing durable medical equipment (DME) pharmacy the authorization approval number.

The dispensing DME pharmacy may not request prior authorization.

The DME pharmacy provider billing for nusinersen (Spinraza) (procedure code J2326) will be responsible for coordinating with the rendering provider to obtain the prior authorization request approval number.

The requesting provider (physician or hospital) may coordinate with the DME Pharmacy provider for the initial or recertification prior authorization request for the specific oligonucleotide. DME Pharmacy providers may assist in providing necessary information such as their National Provider Identifier (NPI) number, fax number, and business address to the requesting provider. However, the Special Medical Prior Authorization (SMPA) form must be signed and dated and submitted by the Medicaid-enrolled requesting provider, not the DME Pharmacy provider.

The dispensing pharmacy must submit the authorization approval number when billing for the drug. Reimbursement for dispensing of the drug by the pharmacy may not occur unless an approved prior authorization for the specific oligonucleotide is in place.

Note: *For additional information on white bag delivery, providers may refer to Subsection 11.5.1, "Pharmacy Delivery Method for Clinician-Administered Drugs" in this handbook.*

Documentation of the client's dosage, administration schedule, the number of injections to be administered during the prior authorization period, the requested units per injection, and the dosage calculation must be submitted in Section C of the SMPA Request Form under Statement of Medical Necessity. When the FDA approves dosing guidelines that require a weight based calculation, the client's current weight must be included.

Refer to: Subsection 2.1.2, "Prior Authorization Requests" in this handbook for additional prior authorization information.

6.11.1.1 Initial Requests (for all Antisense Oligonucleotides)

Initial prior authorization requests for all antisense oligonucleotides will be considered by Medical Director Review for a six month period. The initial request must include documentation supporting medical necessity for the requested antisense oligonucleotide in addition to the SMPA request form completed, signed, and dated by the prescribing provider.

Documentation supporting medical necessity for an initial prior authorization for all requested antisense oligonucleotides must include the following information:

- A diagnosis specific to the requested antisense oligonucleotide
- Genetic testing specific to the requested antisense oligonucleotide
- Documentation of baseline physical function. Testing tools used to measure physical function must be age appropriate for the client being tested.
- Documentation of the requested antisense oligonucleotide dosage and administration schedule, including the number of injections to be administered during the prior authorization period, the requested units per injection, and the dosage calculation. This information must be submitted in Section C of the SMPA request form under Statement of Medical Necessity.

Each antisense oligonucleotide has specific clinical indications and unique documentation requirements.

The initial request for casimersen (Amondys 45) must include the following documentation to support medical necessity for casimersen.

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- Genetic testing must confirm that the client's Duchenne muscular dystrophy (DMD) gene is amenable to exon 45 skipping (diagnosis code G7101).
- Serum cystatin C, urine dipstick, and urine protein-to-creatinine ratio should be measured prior to initiating Amondys 45.
- Monitor baseline renal function (i.e. Glomerulus Filtration Rate, GFR) with therapy initiation and continuation.
- Current client weight, including the date the weight was obtained; the weight must be dated no more than 30 days before the requestdate.

Testing tools that can be used to demonstrate physical function include, but are not limited to:

- Baseline 6MWT (6-minute walk test)
- BrookeUpperExtremity Scale
- North Star Ambulatory Assessment

Amondys 45 should not be used concomitantly with other exon skipping therapies for DMD.

The initial request for eteplirsen (Exondys 51) must include the following documentation to support medical necessity for eteplirsen:

- Genetic testing must confirm that the client's DMD gene is amenable to exon 51 skipping (diagnosis code G7101).
- Current client weight, including the date the weight was obtained; the weight must be dated no more than 30 days before the request date.

Testing tools that can be used to demonstrate physical function include, but are not limited to:

- Brooke Upper Extremity Scale
- Baseline 6-minute walk test (6MWT)
- Pediatric Evaluation of Disability Inventory

Exondys 51 should not be used concomitantly with other exon skipping therapies for DMD.

The initial request for golodirsen (Vyondys 53) must include the following documentation to support medical necessity for golodirsen:

- Genetic testing must confirm that the client's Duchenne muscular dystrophy (DMD) gene is amenable to exon 53 skipping (diagnosis code G7101).
- Baseline renal function test (i.e. Glomerulus Filtration Rate, GFR) with therapy initiation and continuation.
- Current client weight, including the date the weight was obtained; the weight must be dated no more than 30 days before the request date.
- Baseline function testing documented in patient chart or electronic health record.

Testing tools that can be used to demonstrate physical function include, but are not limited to:

- Brooke Upper Extremity Scale
- Baseline 6MWT (6-minute walk test)
- Pediatric Evaluation of Disability Inventory

Vyondys 53 should not be used concomitantly with other exon skipping therapies for DMD.

The initial request for nusinersen (Spinraza) must include the following documentation to support medical necessity for nusinersen:

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- Genetic testing must confirm biallelic pathogenic variants in the client's survival motor neuron 1 (SMN1) gene (diagnosis codes G120, G121, G128, and G129).
- Baseline pulmonary status, including any requirements for invasive or non-invasive ventilation

Testing tools that can be used to demonstrate physical function include, but are not limited to:

- The Hammersmith Infant Neurological Exam (HINE).
- The Hammersmith Functional Motor Scale Expanded (HFMSE).
- The Upper Limb Module (UML).
- Baseline 6MWT.
- Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND).

The initial request for tofersen (Qalsody) must include the following documentation:

- The client is 18 years of age or older.
- Diagnostic testing confirming client has amyotrophic lateral sclerosis (ALS) (diagnosis code G1221).
- Genetic testing must confirm there is the presence of a mutation in the superoxide dismutase1 (SOD1) gene.
- Documentation of baseline measure of the plasma neurofilament light chain (NfL).
- Documentation of baseline functional ability (e.g., climbing stairs, walking, and speech) prior to treatment initiation.

The initial request for viltolarsen (Viltepso) must include the following documentation:

- Genetic testing must confirm that the client's Duchenne muscular dystrophy (DMD) gene is amenable to exon 53 skipping (diagnosis code G7101).
- Current client weight, including the date the weight was obtained; the weight must be dated no more than 30 days before the request date.
- Baseline renal function test (i.e. Glomerulus Filtration Rate) and urine protein-to-creatinine ratio should be measured before starting treatment.

Testing tools that can be used to demonstrate physical function include, but are not limited to:

- Brooke Upper Extremity Scale
- Baseline 6MWT (6-minute walk test)
- Pediatric Evaluation of Disability Inventory

Viltepso should not be used concomitantly with other exon skipping therapies for DMD.

6.11.1.2 Recertification/Extension Requests (for all Antisense Oligonucleotides)

Recertification/extension prior authorization requests for antisense oligonucleotides, excluding nusinersen (Spinraza), will be considered by Medical Director Review for additional six month periods. Recertification/extension prior authorization requests for nusinersen (Spinraza) will be considered by Medical Director Review for additional 12-month periods. All recertification/extension requests must include documentation supporting the ongoing medical necessity for the requested antisense oligonucleotide in addition to a new SMPA request form completed, signed, and dated by the prescribing provider.

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A complete recertification/extension request must be received no earlier than 30 days before the current authorization period expires. Requests for recertification/extension of prior authorization received after the current prior authorization expires will be denied for dates of service that occurred before the date the request is received.

Documentation supporting a recertification/extension prior authorization for all requested antisense oligonucleotide must include the following:

- A diagnosis specific to the requested antisense oligonucleotide
- Current documentation of physical function
- Testing tools used to measure physical function must be age appropriate for the client being tested. Providers must use the same testing instrument as used in the initial evaluation. If re-use of the initial testing instrument is not appropriate, for example, due to change in client status or restricted age range of the testing tool, the provider must explain the reason for the change.
- The physical function testing tool results must include one of the following:
  - An increase in physical function from baseline has been observed
  - Baseline physical function has been maintained
- Statement from prescribing clinician that the client has been compliant with the treatment
- Documentation of the requested antisense oligonucleotide dosage and administration schedule, including the number of injections to be administered during the prior authorization period, the requested units per injection, and the dosage calculation must be submitted in Section C of the Special Medical Prior Authorization (SMPA) Request Form under Statement of Medical Necessity.

The medical necessity documentation for eteplirsen (Exondys 51) recertification/extension requests must include the client's current weight the date on which the weight was obtained. The weight must be dated no more than 30 days before the request date.

The medical necessity documentation for casimersen, golodirsen and viltolarsen recertification/ extension requests must include the client's continual renal function test while on therapy and current client weight, including the date the weight was obtained. The weight must be dated no more than 30 days before the request date.

The medical necessity documentation for nusinersen (Spinraza) recertification/extension requests must include the client's pulmonary status, including any requirements for invasive or non-invasive ventilation. Any changes in pulmonary status that have occurred since the previous prior authorization request must be addressed.

The medical necessity documentation for tofersen (Qalsody) recertification/extension requests must include the following:

- The client has met all initial authorization approval criteria sat the time of initial approval.
- The client has responded positively to therapy as evident by any improvement in the plasma neurofilament light chain (NfL) measurement as compared to baseline.
- Documentation that client has stabilization in disease state and has shown a slowed pattern in disease progression.
- Absence of unacceptable toxicities (aseptic meningitis, serious myelitis and/or radiculitis, papilledema, and elevated cranial pressure) from tofersen therapy.

6.11.1.3 Exclusions

Casimersen (Amondys 45), Eteplirsen (Exondys 51), Golodirsen (Vyondys 53), nusinersen (Spinraza), tofersen (Qalsody), and viltolarsen (Viltepso) should not be continued on clients who experience decreasing physical function while on the medication.

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Casimersen (Amondys 45), Eteplirsen (Exondys 51) and Golodirsen (Vyondys 53) should not be used concomitantly or with other exon skipping therapies for DMD.

Nusinersen (Spinraza) is not a continuing benefit for clients with decreasing pulmonary function while on the medication.

6.12 Aripiprazole (Abilify Asimtufii)

Aripiprazole (Abilify asimtufii) (procedure code J0402) is a benefit of Texas Medicaid for clients who are 18 years of age or older.

6.13 Aripiprazole Lauroxil, (Aristada Initio)

Aripiprazole lauroxil (procedure codes J1943 and J1944) are benefits of Texas Medicaid for clients who are 18 years of age or older.

6.14 Asparginine Specific Enzymes

6.14.1 Calaspargase Pegol-Mknl (Asparlas)

Calaspargase pegol-mknl (procedure code J9118) is a benefit of Texas Medicaid for clients who are birth through 21 years of age.

Procedure code J9118 is limited to diagnosis codes C9100, C9101, and C9102.

6.14.2 Pegaspargase (Oncaspar)

Pegaspargase injection (procedure code J9266) is a benefit of Texas Medicaid when billed with diagnosis codes C9100, C9101, or C9102.

6.15 Atidarsagene Autotemcel (Lenmeldy)

Atidarsagene Autotemcel (Lenmeldy) (procedure code J3391) is a benefit of Texas Medicaid with prior authorization.

Atidarsagene Autotemcel (Lenmeldy) is an autologous hematopoietic stem cell-based gene therapy indicated for the treatment of clients with pre-symptomatic late infantile (PSLI), pre-symptomatic early juvenile (PSEJ), or early symptomatic early juvenile (ESEJ) metachromatic leukodystrophy.

6.15.1 Prior Authorization Requirements

Atidarsagene Autotemcel (Lenmeldy) is a once per lifetime infusion therapy indicated for the treatment of a client for whom hematopoietic stem cell therapy (HSCT) is appropriate and must meet all the following requirements:

- The client is 7 years of age or younger or the client is between 7 years and 17 years of age with the onset of symptoms before 7 years of age.
- The client has a documented biochemical and molecular diagnosis of one of the following forms of metachromatic leukodystrophy (MLD) (diagnosis code E7525):
  - Pre-symptomatic late infantile
  - Pre-symptomatic early juvenile (PSEJ)
  - Early symptomatic early juvenile
- The client has an MLD diagnosis that is confirmed by:
  - Biochemical testing indicating Arylsulfatase A (ARSA) activity below the normal range.
  - Genetic testing confirming two disease causing ARSA alleles.

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  - If ARSA mutations are present, a 24-hour urine collection showing elevated sulfatide levels.
- The client is a candidate for and has not previously received HSCT.
- The client will not take prophylactic human immunodeficiency virus (HIV) anti-retroviral medications for at least one month prior to mobilization or for the expected duration of time needed for the elimination of medications.

The required monitoring parameters following atidarsagene autotemcel (Lenmeldy) are:

- Monitor for signs and symptoms of encephalitis, thrombocytopenia and/or serious infection after atidarsagene autotemcel (Lenmeldy) infusion.
- Monitor for signs and symptoms of veno-occlusive disease including liver function tests during the first month post atidarsagene autotemcel (Lenmeldy) infusion.
- Monitor life-long for hematologic malignancies, including a complete blood count (with differential) annually and integration site analysis, as warranted, for at least 15 years after treatment.

In addition to the documentation requirements outlined in the Prior Authorization Requirements section, all services outlined in this section are subject to retrospective review to ensure that the documentation in the client's medical record supports the medical necessity of the service(s) provided.

6.16 Axatilimab-csfr (Niktimvo)

Axatilimab-csfr (Niktimvo) (procedure code J9038) is a benefit of Texas Medicaid with prior authorization.

Axatilimab-csfr (Niktimvo) is a colony stimulating factor-1 receptor (CSF-1R)-blocking antibody indicated for the treatment of chronic graft-versus-host disease (cGVHD) after failure of at least two prior lines of systemic therapy in adult and pediatric clients weighing at least 40 kilograms.

6.16.1 Prior Authorization Requirements

Axatilimab-csfr (Niktimvo) is an intravenous infusion indicated for clients who meet the following requirements:

- The client weighs at least 40 kg (88 pounds).
- The client has a confirmed diagnosis of cGVHD (diagnosis codes D89811 and D89812).
- The client has undergone allogenic stem cell transplantation.
- The client has previously had at least two failed systemic therapies for cGVHD.
- The prescribing provider attests to counseling female clients of childbearing age regarding the use of an effective method of contraception to prevent pregnancy during treatment of axatilimab-csfr (Niktimvo) and for 30 days after the last dose of therapy.

Clients who are taking axatilimab-csfr (Niktimvo) must be monitored prior to starting axatilimab-csfr (Niktimvo) therapy, every two weeks for the first month of axatilimab-csfr (Niktimvo) therapy, and one to two months after completing axatilimab-csfr (Niktimvo) therapy. Clients will be monitored for aspartate aminotransferase (AST), alanine aminotransferase (ALT), alkaline phosphatase (ALP), creatine phosphokinase (CPK), amylase, and lipase.

For continuation therapy, the client must meet the following requirements:

- The client must meet the initial requirements for prior authorization.
- The client must be undergoing treatment with axatilimab-csfr (Niktimvo) with the absence of unacceptable toxicity (e.g., severe infusion-related reactions).
- The client must experience a positive clinical response to therapy.

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In addition to the documentation requirements outlined in the Prior Authorization Requirements section, all services outlined in this section are subject to retrospective review to ensure that the documentation in the client's medical record supports the medical necessity of the service(s) provided.

6.17 Azacitidine (Vidaza)

Procedure code J9025 is a benefit when billed with one of the following diagnosis codes:

Diagnosis Codes							
C9200	C9202	C9210	C9212	C9220	C9222	C9232	C9242
C9252	C9262	C9290	C9292	C92A2	C92Z2	C9310	C9312
C9330	C9332	C9502	C9510	C9512	C9592	D460	D461
D4620	D4621	D4622	D464	D469	D46A	D46B	D46C
D46Z	D640	D641	D642	D643			

6.18 Beremagene geperpavec-svdt (Vyjuvek)

Beremagene geperpavec-svdt (Vyjuvek) is a herpes-simplex virus type 1 (HSV-1) vector-based gene therapy indicated to treat wounds in adults and pediatric clients with dystrophic epidermolysis bullosa (DEB) with mutation in the collagen type VII alpha 1 chain (COL7A1) gene.

Beremagene geperpavec-svdt (Vyjuvek) (procedure code J3401) is a benefit of Texas Medicaid for clients who are 6 months of age or older with prior authorization and restricted to diagnosis code Q812.

6.18.1 Prior Authorization Requirements

Prior authorization is required for beremagene geperpavec-svdt (Vyjuvek) therapy and must be submitted with a Special Medical Prior Authorization (SMPA) Request Form.

Initial therapy for beremagene geperpavec-svdt (Vyjuvek) may be approved for a 6-month duration if all the following criteria are met:

- The client has a confirmed diagnosis of DEB (diagnosis code Q812).
- Genetic test confirming client has a mutation in the collagen type VII alpha 1 chain (COL7A1) gene.
- The client does not have current evidence or history of squamous cell carcinoma or active infection in the area requiring beremagene geperpavec-svdt (Vyjuvek) application.
- The prescriber attests to counseling female clients of childbearing age regarding the use of an effective method of contraception to prevent pregnancy during treatment with beremagene geperpavec-svdt (Vyjuvek).

For renewal or continuation of beremagene geperpavec-svdt (Vyjuvek) therapy, the client must meet the following requirements:

- The client continues to meet all the initial requirements for prior authorization and is currently treated with beremagene geperpavec-svdt (Vyjuvek) with no severe adverse reactions.
- The client has experienced positive clinical response to therapy as documented by any of the following:
  - Reduction in the number of wounds, decrease in wound size, increase in granulation tissue, and/or complete wound closure.
  - The client has not experienced any complications while being treated with beremagene geperpavec-svdt (Vyjuvek).

All services outlined in this section are subject to retrospective review to ensure that the documentation in the client's medical record supports the medical necessity of the service(s) provided.

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Refer to: Subsection 2.1.2, "Prior Authorization Requests" in this handbook for additional prior authorization information.

Subsection 5.5.1.2, "Document Requirements and Retention" in "Section 5: Fee-for-Service Prior Authorizations" (*Vol. 1, General Information*) for additional information about electronic signatures.

6.19 Betibeglogene Autotemcel (Zynteglo)

Betibeglogene autotemcel (Zynteglo) (procedure code J3393) is a benefit of Texas Medicaid for clients who are 4 years of age or older with prior authorization. Prior authorization may be approved for a duration of 12 months.

Betibeglogene autotemcel (Zynteglo) is an autologous hematopoietic stem cell-based gene therapy indicated for treating adult and pediatric clients with β-thalassemia who require regular red blood cell (RBC) transfusions.

Betibeglogene autotemcel (Zynteglo) (procedure code J3393) is limited to one transfusion treatment per lifetime and may be infused as a single infusion in one or more infusion bags.

6.19.1 Prior Authorization Requirements

Betibeglogene autotemcel (Zynteglo) is a one-time infusion therapy indicated for the treatment of clients with β-thalassemia who meet the following requirements:

- The client is 4 years of age or older.
- The client has a documented diagnosis of β-thalassemia (diagnosis code D561) and other forms of thalassemia have been ruled out.
- The client is RBC transfusion dependent and has documented history of receiving RBC transfusions of at least 100 ml per kilogram per year (pRBC/kg/yr) or at least 8 or more transfusions of regular RBCs per year for two years.
- The client has not had a prior hematopoietic stem cell transplant (HSCT) and is unable to find a matched related donor.
- The client is stable and eligible for HSCT, according to the following criteria:
  - No advanced liver disease
  - No human immunodeficiency virus (HIV) positive diagnosis
  - No hepatitis B virus (HBV) and hepatitis C virus (HCV)
  - No prior or current malignancies
  - No bleeding disorders
  - Normal iron levels in the heart
  - Normal levels of white blood cells
  - Normal platelet counts
- The prescriber attests to avoid the use of anti-retroviral medications or hydroxyurea for one month prior to mobilization and until all cycles of apheresis are completed
- The prescriber attests to discontinue iron chelators at least seven days prior to initiation of myeloablative conditioning and the use of myelosuppressive iron chelators should be avoided for 6 months after betibeglogene autotemcel (Zynteglo) infusion

In addition to the documentation requirements outlined in the Prior Authorization Requirements section, the prescriber must monitor the following:

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- The client's platelet count for thrombocytopenia and bleeding during the treatment period with betibeglogene autotemcel (Zynteglo)
- The client for at least 15 years post betibeglogene autotemcel (Zynteglo) infusion for possible hematologic malignancies

All services outlined in this section are subject to retrospective review to ensure that the documentation in the client's medical record supports the medical necessity of the service(s) provided.

6.20 * Botulinum Toxin Type A and Type B

OnabotulinumtoxinA (Botox brand of botulinum toxin type A), abobotulinumtoxinA (Dysport brand of botulinum toxin type A), incobotulinumtoxin A (Xeomin brand of botulinum toxin type A), rimabotulinumtoxinB (Myobloc brand of botulinum toxin type B), and daxibotulinumtoxinA-lanm (Daxxify brand toxin type A) are benefits of Texas Medicaid.

Botulinum toxins are potent neuromuscular blocking agents that are useful in treating various focal muscle spastic disorders and excessive muscle contractions, such as dystonia, spasms, and twitches. They produce a presynaptic neuromuscular blockade by preventing the release of acetylcholine from the nerve endings. Since the resulting chemical denervation of muscle produces local paresis or paralysis, selected muscles can be treated. Two of the seven naturally occurring serotypes of botulinum toxin have been approved by the FDA for human use in the United States-type A and type B.

Due to the unique manufacturing process of each toxin, botulinum toxins are chemically, clinically, and pharmacologically distinct; as a consequence, these products are not interchangeable. The units of biological activity of one botulinum toxin product cannot be compared to, nor converted into, units of any other botulinum toxin product. The established drug names of the botulinum products emphasize the differing dose-to-potency ratios of these products.

Procedure code J0585 is a benefit when billed with one of the following diagnosis codes:

[Revised] Diagnosis Codes							
G114	G2401	G241	G243	G244	G245	G248	G250
G251	G252	G253	G35A	G35B0	G35B1	G35B2	G35C0
G35C1	G35C2	G35D	G360	G370	G371	G372	G374
G375	G3781	G3789	G379	G43701	G43709	G43711	G43719
G800	G801	G802	G803	G804	G808	G809	G8110
G8111	G8112	G8113	G8114	G8220	G8221	G8222	G8250
G8251	G8252	G8253	G8254	G830	G8310	G8311	G8312
G8313	G8314	G8320	G8321	G8322	G8323	G8324	G8330
G8331	G8332	G8333	G8334	G834	H4901	H4902	H4903
H4911	H4912	H4913	H4921	H4922	H4923	H4931	H4932
H4933	H4941	H4942	H4943	H499	H5000	H50011	H50012
H50021	H50022	H50031	H50032	H50041	H50042	H5005	H5006
H5007	H5008	H5010	H50111	H50112	H50121	H50122	H50131
H50132	H50141	H50142	H5015	H5016	H5017	H5018	H5021
H5022	H5030	H50311	H50312	H5032	H50331	H50332	H5034
H5040	H50411	H50412	H5042	H5043	H5050	H5051	H5052
H5053	H5054	H5055	H5060	H50611	H50612	H50621	H50622
H50629	H50631	H50632	H50639	H50641	H50642	H50649	H50651
H50652	H50659	H50661	H50662	H50669	H50671	H50672	H50679

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[Revised] Diagnosis Codes							
H50681	H50682	H50689	H5069	H50811	H50812	H5089	H510
H5111	H5112	H5121	H5122	H5123	H518	H519	I69031
I69032	I69033	I69034	I69041	I69042	I69043	I69044	I69051
I69052	I69053	I69054	I69061	I69062	I69063	I69064	I69065
I69098	I69131	I69132	I69133	I69134	I69141	I69142	I69143
I69144	I69151	I69152	I69153	I69154	I69161	I69162	I69163
I69164	I69165	I69198	I69231	I69232	I69233	I69234	I69241
I69242	I69243	I69244	I69251	I69252	I69253	I69254	I69261
I69262	I69263	I69264	I69265	I69298	I69331	I69332	I69333
I69334	I69341	I69342	I69343	I69344	I69351	I69352	I69353
I69354	I69361	I69362	I69363	I69364	I69365	I69398	I69831
I69832	I69833	I69834	I69841	I69842	I69843	I69844	I69851
I69852	I69853	I69854	I69861	I69862	I69863	I69864	I69865
I69898	J385	K117	K220	K600	K601	K602	M436
M62838	N318	N319	N3281	N3644	R490	R498	

Procedure code J0586 is a benefit when billed with one of the following diagnosis codes:

[Revised] Diagnosis Codes for J0586							
G114	G241	G243	G244	G245	G248	G35	G360
G370	G371	G372	G374	G375	G3781	G3789	G379
G800	G801	G802	G804	G808	G809	G8110	G8111
G8112	G8113	G8114	G8253	G8254	G830	G8320	G8321
G8322	G8323	G8324	I69059	I69259	I69359	I69859	I69959
I69051	I69052	I69151	I69152	I69251	I69252	I69351	I69352
I69851	I69852	I69951	I69952	I69053	I69054	I69153	I69154
I69253	I69254	I69353	I69354	I69853	I69854	I69953	I69954
I69039	I69139	I69239	I69339	I69839	I69939	I69031	I69032
I69131	I69132	I69231	I69232	I69331	I69332	I69831	I69832
I69931	I69932	I69033	I69034	I69133	I69134	I69233	I69234
I69333	I69334	I69833	I69834	I69933	I69934	J385	M436
M62838							

Procedure code J0587 is a benefit when billed with diagnosis code G243 or K117.

Procedure code J0589 is a benefit when billed with diagnosis code G243.

Procedure code J0588 is a benefit when billed with one of the following diagnosis codes:

Diagnosis Codes for J0588							
G243	G245	G800	G801	G802	G830	G8110	G8111
G8112	G8113	G8114	G8253	G8254	G8320	G8321	G8322
G8323	G8324	I69059	I69259	I69359	I69859	I69959	I69051
I69052	I69151	I69152	I69251	I69252	I69351	I69352	I69851

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Diagnosis Codes for J0588							
I69852	I69951	I69952	I69053	I69054	I69153	I69154	I69253
I69254	I69353	I69354	I69853	I69854	I69953	I69954	I69039
I69139	I69239	I69339	I69839	I69939	I69031	I69032	I69131
I69132	I69231	I69232	I69331	I69332	I69831	I69832	I69931
I69932	I69033	I69034	I69133	I69134	I69233	I69234	I69333
I69334	I69833	I69834	I69933	I69934			

Procedure codes J0586, J0587, J0588, and J0589 are denied when billed on the same date of service by any provider as procedure code J0585. Procedure codes J0587, J0588, and J0589 are denied when billed on the same date of service by any provider as procedure code J0586. Procedure code J0587 and J0589 are denied when billed on the same date of service by any provider as procedure code J0588. Procedure code J0588 is denied when billed on the same date of service by any provider as procedure code J0589.

IncobotulinumtoxinA, procedure code J0588, is FDA-approved for the treatment of adults with blepharospasm previously treated with onabotulinumtoxinA (J0585).

Physicians, hospitals, and other providers and suppliers should care for and administer drugs to patients in such a way that they can use drugs or biologicals most efficiently, in a clinically appropriate manner. Texas Medicaid encourages scheduling patients to make the most efficient use of the drugs administered. Safe handling guidelines per manufacturer must be observed (e.g., shelf life, cold chain requirements). The smallest size vial to cover the dose is encouraged to be used.

Claims for botulinum toxin type A and B must indicate the number of units used. If the number of units is not specified, the claim will be paid a quantity of one. Claims that exceed the following quantity limitations, per day, may be considered on appeal with documentation of medical necessity:

Procedure Codes	Quantity Limitations of Medication	Billing Units
J0585	400 units	One billing unit is equal to 1 unit of medication. ***Example:*** *A provider that administers 400 units of medication would submit a claim for a quantity of 400.*
J0586	1,500 units	One billing unit is equal to 5 units of medication. ***Example:*** *A provider that administers 1,500 units of medication would submit a claim for a quantity of 300.*
J0587	10,000 units	One billing unit is equal to 100 units of medication. ***Example:*** *A provider that administers 10,000 units of medication would submit a claim for a quantity of 100.*
J0588	400 units	One billing unit is equal to 1 unit of medication. ***Example:*** *A provider that administers 400 units of medication would submit a claim for a quantity of 400.*

Procedures performed in conjunction with botulinum toxin injections are subject to guidelines set forth in the policies specific for those procedures. Any supplies billed by the provider for the administration of botulinum toxin type A or B are not separately payable.

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Botulinum toxins administered more frequently than every 12 weeks must include documentation of medical necessity justifying why the medication was given at an interval sooner than 12 weeks.

Documentation in the client's medical record must include the following elements:

- Support for the medical necessity of the botulinum toxin injection:
- A covered diagnosis
- Dosage and frequency of the injections
- Support of the clinical effectiveness of the injections
- Specific site(s) injected

All documentation is subject to retrospective review.

6.21 Brolucizumab-DBLL (Beovu)

Brolucizumab-dbll (procedure code J0179) is a benefit of Texas Medicaid for clients who are 18 years of age or older.

6.22 Bupivacaine

Bupivacaine (procedure code J0665) is a benefit of Texas Medicaid for clients who are 18 years of age or older.

6.23 Burosumab-Twza (Crysvita)

Burosumab-Twza (Crysvita) (procedure code J0584) is a benefit of Texas Medicaid with prior authorization. Burosumab-Twza (Crysvita) may be approved for a duration of every 12 months per prior authorization request.

Burosumab-twza (Crysvita) is a fibroblast growth factor 23 (FGF23) blocking antibody, indicated to treat the following:

- X-linked hypophosphatemia (XLH, a rare, inherited form of rickets) in adult and pediatric clients who are 6 months of age and older
- FGF23-related hypophosphatemia in tumor-induced osteomalacia associated with phosphaturic mesenchymal tumors that cannot be localized or is not amenable by surgical excision in adult and pediatric clients who are two years of age and older

The initial therapy for X-linked hypophosphatemia (XLH) must meet the following criteria:

- The client is 6 months of age or older.
- The client has a diagnosis of X-linked hypophosphatemia (XLH) (diagnosis code E8331 or E8339) that is supported by one of the following:
  - Confirmed phosphate regulating gene with homology to endopeptidases located on the X chromosome (PHEX-gene) mutation
  - Serum fibroblast growth factor-23 (FGF23) level >30 pg/ml
- The prescriber discontinues any oral phosphate or active vitamin D analog supplementation at least one week prior to starting burosumab-twza (Crysvita) therapy.
- The prescriber agrees to measure serum phosphate throughout therapy and withhold medication when serum phosphorus is above 5 mg/dl.

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The initial therapy for FGF23-related hypophosphatemia in tumor-induced osteomalacia must meet the following criteria:

- The client is 2 years of age or older.
- The client has a diagnosis of FGF23-related hypophosphatemia produced by an underlying tumor that cannot be localized or is not amenable to surgical excision (diagnosis code M838).
- The prescriber discontinues any oral phosphate or vitamin D analog supplement at least two weeks prior to starting burosumab-twza (Crysvita) therapy.
- The prescriber agrees to measure serum phosphate throughout therapy.

For renewal or continuation therapy, the following criteria must be met:

- The client has previously received treatment with burosumab-twza (Crysvita).
- Documentation from the physician that the client has demonstrated a positive clinical response to burosumab-twza (Crysvita) (e.g., enhanced height velocity, improvement in a skeletal deformity, reduction of fractures, reduction of generalized bone pain).
- The physician continues to monitor serum phosphate level.

Burosumab-twza (Crysvita) is not a benefit for the following:

- Clients who currently use oral phosphates and active vitamin D analogs.
- Clients whose serum phosphorus is within or above the normal range for client's age.
- Clients with severe renal impairment or end stage renal disease.

Refer to: Subsection 2.1.2, "Prior Authorization Requests" in this handbook for additional prior authorization information.

6.24 Cabotegravir and Rilpivirine (Cabenuva)

Cabotegravir and Rilpivirine (Cabenuva) (procedure code J0741) is a benefit of Texas Medicaid for clients who are 12 years of age or older.

Cabotegravir (Apretude) (procedure code J0739) is a benefit of Texas Medicaid for clients who are 10 years of age or older.

6.25 Caffeine Citrate (Cafcit)

Caffeine citrate (procedure code J0706) is a benefit of Texas Medicaid for clients who are birth through 6 months of age.

6.26 Calcitonin Gene Related Peptide (CGRP) agents

6.26.1 Eptinezumab-JJMR (Vyepti)

Eptinezumab-jjmr (procedure code J3032) is a benefit of Texas Medicaid for clients who are 18 years of age or older.

6.26.2 Ajovy (Fremanezumab-vfrm)

Ajovy (fremanezumab-vfrm) (procedure code J3031) is a benefit of Texas Medicaid for clients who are 6 years of age or older.

6.27 Cantharidin

Cantharidin (procedure code J7354) is a benefit of Texas Medicaid for clients who are 2 years of age or older and is restricted to diagnosis code B081.

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6.28 Cefiderocol (Fetroja)

Cefiderocol (procedure code J0699) is a benefit of Texas Medicaid for clients who are 18 years of age or older.

6.29 Chelating Agents

Chelating agent procedure code J0895 is a benefit of Texas Medicaid when billed with an appropriate diagnosis code.

6.29.1 Deferoxamine Mesylate (Desferal)

Procedure code J0895 must be billed with one of the following diagnosis codes:

Diagnosis Codes							
D560	D561	D562	D563	D568	D569	D5700	D5701
D5702	D5703	D5704	D5709	D571	D5720	D57211	D57212
D57213	D57214	D57218	D57219	D5740	D57411	D57412	D57413
D57414	D57418	D57419	D5742	D57431	D57432	D57433	D57434
D57438	D57439	D5744	D57451	D57452	D57453	D57454	D57458
D57459	D5780	D57811	D57812	D57813	D57814	D57818	D57819
E83111	E83118	N181	N182	N1830	N1831	N1832	N184
N185	N186	N189	N19	T454X1A	T454X1D	T454X1S	T454X2A
T454X2D	T454X2S	T454X3A	T454X3D	T454X3S	T454X4A	T454X4D	T454X4S
T470X1A	T470X1D	T470X1S	T470X2A	T470X2D	T470X2S	T470X3A	T470X3D
T470X3S	T470X4A	T470X4D	T470X4S	T471X1A	T471X1D	T471X1S	T471X2A
T471X2D	T471X2S	T471X3A	T471X3D	T471X3S	T471X4A	T471X4D	T471X4S
T564X1A	T564X1D	T564X1S	T564X2A	T564X2D	T564X2S	T564X3A	T564X3D
T564X3S	T564X4A	T564X4D	T564X4S	T565X1A	T565X1D	T565X1S	T565X2A
T565X2D	T565X2S	T565X3A	T565X3D	T565X3S	T565X4A	T565X4D	T565X4S
T566X1A	T566X1D	T566X1S	T566X2A	T566X2D	T566X2S	T566X3A	T566X3D
T566X3S	T566X4A	T566X4D	T566X4S	T56811A	T56811D	T56811S	T56812A
T56812D	T56812S	T56813A	T56813D	T56813S	T56814A	T56814D	T56814S
T56821A	T56821D	T56821S	T56822A	T56822D	T56822S	T56823A	T56823D
T56823S	T56824A	T56824D	T56824S	T56891A	T56891D	T56891S	T56892A
T56892D	T56892S	T56893A	T56893D	T56893S	T56894A	T56894D	T56894S
T5691XA	T5691XD	T5691XS	T5692XA	T5692XD	T5692XS	T5693XA	T5693XD
T5693XS	T5694XA	T5694XD	T5694XS				

6.30 Chimeric Antigen Receptor (CAR) T-Cell Therapy

Axicabtagene ciloleucel (Yescarta) (procedure code Q2041), brexucabtagene autoleucel (Tecartus) (procedure code Q2053), ciltacabtagene autoleucel (Carvykti) (procedure code Q2056), idecabtagene vicleucel (ABECMA) (procedure code Q2055), lisocabtagene maraleucel (Breyanzi) (procedure code Q2054), obecabtagene autoleucel (Aucatzyl) (procedure code Q2058), and tisagenlecleucel (Kymriah) (procedure code Q2042) are benefits of Texas Medicaid with prior authorization.

Procedure codes Q2041, Q2042, Q2053, Q2054, Q2055, Q2056, and Q2058 are limited to once per lifetime, any provider.

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Axicabtagene ciloleucel (Yescarta) is a CD-19-directed genetically modified autologous T-cell immunotherapy indicated to treat the following:

- Adult clients with relapsed or refractory large B-cell Lymphoma after two or more lines of systemic therapy, including diffuse large B-cell lymphoma (DLBCL) not otherwise specified, primary mediastinal large B-cell lymphoma, high grade B-cell lymphoma, and DLBCL arising from follicular lymphoma.
- Adult clients with large B-cell lymphoma that is refractory to first-line chemoimmunotherapy or that relapses within 12 months of first-line chemoimmunotherapy.
- Adult clients with relapsed or refractory follicular lymphoma (FL) after two or more lines of systemic therapy.

Brexucabtagene autoleucel (Tecartus) is a CD-19-directed genetically modified autologous T-cell immunotherapy indicated to treat adult clients with relapsed or refractory mantel cell lymphoma (MCL). Brexucabtagene autoleucel is also indicated to treat adult clients with relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL).

Ciltacabtagene autoleucel (Carvykti) is a B-cell maturation antigen-directed genetically modified autologous T-cell immunotherapy indicated to treat adult clients with relapsed or refractory multiple myeloma after one or more lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and are refractory to lenalidomide.

Idecabtagene vicleucel (ABECMA) is a B-cell maturation antigen directed genetically modified autologous T-cell immunotherapy indicated to treat adult clients with relapsed or refractory multiple myeloma after two or more prior lines of therapy including an immunomodulatory agent, a proteasome inhibitor and an anti-CD38 monoclonal antibody.

Lisocabtagene maraleucel (Breyanzi) is a CD-19 directed genetically modified autologous T-cell immunotherapy indicated to treat adult clients with the following:

- Large B-cell lymphoma, including diffuse large B-cell lymphoma (DLBCL) not otherwise specified (including DLBCL arising from indolent lymphoma), high-grade B-cell lymphoma, primary mediastinal large B-cell lymphoma, and follicular lymphoma grade 3B who have:
  - Refractory disease to first-line chemoimmunotherapy or relapse within 12 months of first- line chemoimmunotherapy.
  - Refractory disease to first-line chemoimmunotherapy or relapse after first-line chemoimmunotherapy and are not eligible for hematopoietic stem cell transplant (HSCT) due to comorbidities or age.
  - Relapsed or refractory disease after two or more lines of systemic therapy.
- Relapsed or refractory chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) who have received at least two prior lines of therapy, including a Bruton tyrosine kinase (BTK) inhibitor and a B-cell lymphoma 2 (BCL-2) inhibitor.
- Relapse or refractory follicular lymphoma who has received two or more lines of systemic therapy.
- Relapse or refractory mantle cell lymphoma (MCL) who have received at least two prior lines of systemic therapy.

Obecabtagene autoleucel (Aucatzyl) is a CD19-directed genetically modified autologous T-cell immunotherapy indicated to treat adult clients with relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL).

Tisagenlecleucel (Kymriah) is a CD-19-directed genetically modified autologous T-cell immunotherapy indicated to treat the following:

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- Clients who are 25 years of age or younger who have acute lymphoblastic leukemia (ALL) that is refractory or second/later relapse.
- Adult clients who have relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy, including diffuse large B-cell lymphoma (DLBCL) not otherwise specified, high grade B-cell lymphoma, and DLBCL arising from follicular lymphoma.
- Adult clients with relapsed or refractory follicular lymphoma (FL) after two or more lines of systemic therapy.

Providers and facilities must ensure that the client:

- Receives the recommended pre-medications before treatment.
- Is closely monitored for at least two weeks, including daily monitoring for at least one week.
- Is instructed to remain within proximity of a certified healthcare facility for at least two weeks and to avoid driving for two weeks following product administration.

6.30.1 Prior Authorization Criteria for Axicabtagene Ciloleucel (Yescarta)

Prior authorization approval of axicabtagene ciloleucel (Yescarta) (procedure code Q2041) infusion therapy will be considered for the following:

- The client is 18 years of age or older.
- The client has one of the following:
  - Relapsed or refractory disease, defined as progression after two or more lines of systemic therapy (which may or may not include therapy supported by autologous stem cell transplant)
  - Large B-cell lymphoma that is refractory to first-line chemoimmunotherapy or that relapses within 12 months of first-line chemoimmunotherapy
- The client does not have primary central nervous system lymphoma/disease.
- The client does not have an active infection or inflammatory disorder.
- The client has not received prior CD-19 directed CAR-T therapy.
- The client must have a histologically confirmed diagnosis of one of the following types of aggressive non-Hodgkin's lymphoma diagnosis codes:

Diagnosis Codes							
C8330	C8331	C8332	C8333	C8334	C8335	C8336	C8337
C8338	C83398	C833A	C8510	C851A	C8520	C852A	

Prior authorization approval for clients with relapsed or refractory follicular lymphoma (FL) after two or more lines of systemic therapy will be considered when all of the following criteria are met:

- The client is 18 years of age or older.
- The client has relapsed or refractory disease defined as progression after two or more lines of systemic therapy (which may or may not include therapy supported by autologous stem cell transplant).
- The client does not have primary central nervous system lymphoma/disease.
- The client does not have an active infection or inflammatory disorder.
- The client has not received prior CD-19 directed CAR-T therapy.
- The client has a histologically confirmed diagnosis of one of the following types of follicular lymphoma:

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Diagnosis Codes							
C8200	C8201	C8202	C8203	C8204	C8205	C8206	C8207
C8208	C8209	C820A	C8210	C8211	C8212	C8213	C8214
C8215	C8216	C8217	C8218	C8219	C821A	C8220	C8221
C8222	C8223	C8224	C8225	C8226	C8227	C8228	C8229
C822A	C8230	C8231	C8232	C8233	C8234	C8235	C8236
C8237	C8238	C8239	C823A	C8240	C8241	C8242	C8243
C8244	C8245	C8246	C8247	C8248	C8249	C824A	C8250
C8251	C8252	C8253	C8254	C8255	C8256	C8257	C8258
C8259	C825A	C8260	C8261	C8262	C8263	C8264	C8265
C8266	C8267	C8268	C8269	C826A	C8280	C8281	C8282
C8283	C8284	C8285	C8286	C8287	C8288	C8289	C828A
C8290	C8291	C8292	C8293	C8294	C8295	C8296	C8297
C8298	C8299	C829A					

6.30.2 Prior Authorization Criteria for Brexucabtagene Autoleucel (Tecartus)

Prior authorization approval for brexucabtagene autoleucel (Tecartus) (procedure code Q2053) infusion therapy for mantel cell lymphoma will be considered when all of the following criteria are met:

- The client has histologically confirmed diagnosis of relapse or refractory mantel cell lymphoma (diagnosis codes C8310, C8311, C8312, C8313, C8314, C8315, C8316, C8317, C8318, C8319, and C831A).
- The client is 18 years of age or older.
- The client does not have primary central nervous system lymphoma/disease.
- The client has not received prior CD-19 directed CAR-T therapy.

Prior authorization approval for clients with B-cell Precursor Acute Lymphoblastic Leukemia (ALL) will be considered once all of the following criteria are met:

- The client has histologically confirmed diagnosis of relapse or refractory B-cell precursor Acute Lymphoblastic Leukemia (ALL) (diagnosis codes C9100, C9101, C9102).
- The client is 18 years of age or older.
- The client does not have primary central nervous system lymphoma/disease.
- The client does not have an active infection or inflammatory disorder.
- The client has not received prior CD-19 directed CAR-T therapy.

6.30.3 Prior Authorization Criteria for Ciltacabtagene Autoleucel (Carvykti)

Prior authorization approval for ciltacabtagene autoleucel (Carvykti) (procedure code Q2056) infusion therapy will be considered when all of the following criteria are met:

- The client is 18 years of age or older.
- The client has histologically confirmed diagnosis of relapse or refractory multiple myeloma (diagnosis codes C9000 and C9002).
- The client has relapsed or refractory disease and has received at least one line of the following systemic therapies before treatment with ciltacabtagene autoleucel (Carvykti) and are refractory to lenalidomide, which must include:

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  - A proteasome inhibitor
  - An immunomodulatory agent
- The client does not have primary central nervous system lymphoma/disease.
- The client does not have an active infection or inflammatory disorder.
- The client has not received prior CAR-T therapy.
- Ciltacabtagene autoleucel (Carvykti) (procedure code Q2056) is limited to once per lifetime.

6.30.4 Prior Authorization Criteria for Idecabtagene Vicleucel (ABECMA)

Prior authorization approval of idecabtagene vicleucel (ABECMA) (procedure code Q2055) infusion therapy will be considered when all of the following criteria are met:

- The client is 18 years of age or older.
- The client has a histologically confirmed diagnosis of relapse or refractory multiple myeloma (diagnosis codes C9000 and C9002).
- The client must have received two or more prior lines of the following therapies before treatment with idecabtagene vicleucel:
  - An immunomodulatory agent
  - A proteasome inhibitor
  - An anti-CD-38 monoclonal antibody
- The client does not have primary central nervous system lymphoma/disease.
- The client does not have an active infection or inflammatory disorder.
- The client has not received prior CAR-T therapy.

Idecabtagene vicleucel (ABECMA) (procedure code Q2055) is limited to once per lifetime.

6.30.5 Prior Authorization Criteria for Lisocabtagene Maraleucel (Breyanzi)

Prior authorization approval of lisocabtagene maraleucel (Breyanzi) (procedure code Q2054) infusion therapy will be considered when the client has one of the diagnoses listed below, and also meets the following criteria:

- The client has a histologically confirmed diagnosis of large B-cell lymphoma, including diffuse large B-cell lymphoma not otherwise specified (including DLBCL arising from indolent lymphoma), high-grade B-cell lymphoma, primary mediastinal large B-cell lymphoma, or follicular lymphoma grade 3B with one of the following:
  - Refractory disease to first-line chemoimmunotherapy or relapse within 12 months of first line chemoimmunotherapy; or
  - Refractory disease to first-line chemoimmunotherapy or relapse after first line chemoimmunotherapy, and are not eligible for hematopoietic stem cell transplant (HSCT) due to comorbidities or age; or
  - Relapsed or refractory disease after two or more lines of systemic therapy.
- The client has confirmed diagnosis of relapsed or refractory chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) who has received at least two prior lines of therapy, including a Bruton tyrosine kinase (BTK) inhibitor and a B-cell lymphoma 2 (BCL-2) inhibitor.
- The client has confirmed diagnosis of relapsed or refractory follicular lymphoma who has received two or more lines of systemic therapy.

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- The client has confirmed diagnosis of relapsed or refractory mantle cell lymphoma (MCL) who has received at least two prior lines of systemic therapy.
- The client is 18 years of age or older.
- The client does not have primary central nervous system lymphoma/disease.
- The client does not have an active infection or inflammatory disorder.
- The client has not received prior CD-19 directed CAR-T therapy.
- The client has one of the following lymphoma diagnosis codes:

Diagnosis Codes							
C8200	C8201	C8202	C8203	C8204	C8205	C8206	C8207
C8208	C8209	C820A	C8210	C8211	C8212	C8213	C8214
C8215	C8216	C8217	C8218	C8219	C821A	C8220	C8221
C8222	C8223	C8224	C8225	C8226	C8227	C8228	C8229
C822A	C8230	C8231	C8232	C8233	C8234	C8235	C8236
C8237	C8238	C8239	C823A	C8240	C8241	C8242	C8243
C8244	C8245	C8246	C8247	C8248	C8249	C824A	C8250
C825A	C8280	C8281	C8282	C8283	C8284	C8285	C8286
C8287	C8288	C8289	C828A	C8290	C8291	C8292	C8293
C8294	C8295	C8296	C8297	C8298	C8299	C829A	C8300
C8301	C8302	C8303	C8304	C8305	C8306	C8307	C8308
C8309	C830A	C8310	C8311	C8312	C8313	C8314	C8315
C8316	C8317	C8318	C8319	C831A	C8330	C8331	C8332
C8333	C8334	C8335	C8336	C8337	C8338	C83398	C833A
C8390	C8391	C8392	C8393	C8394	C8395	C8396	C8397
C8398	C8399	C839A	C8510	C8511	C8512	C8513	C8514
C8515	C8516	C8517	C8518	C8519	C851A	C8520	C8521
C8522	C8523	C8524	C8525	C8526	C8527	C8528	C8529
C852A	C8580	C8581	C8582	C8583	C8584	C8585	C8586
C8587	C8588	C8589	C858A	C9110	C9112		

Lisocabtagene maraleucel (Breyanzi) (procedure code Q2054) is limited to once per lifetime.

6.30.6 Prior Authorization Criteria for Obecabtagene Autoleucel (Aucatzyl)

Obecabtagene autoleucel (Aucatzyl) may be approved for a duration of 12 months.

Obecabtagene autoleucel (Aucatzyl) is a once in a lifetime cell suspension therapy with split dose infusion and is indicated for clients who meet all the following requirements:

- The client is 18 years of age or older.
- The client has a confirmed diagnosis of relapsed or refractory B-cell precursor ALL (diagnosis codes C9100 and C9102).
- The client has adequate cardiac, hepatic, pulmonary, and renal function.
- A bone marrow blast assessment was conducted, and results from the sample were obtained in order to start lymphodepleting chemotherapy.

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- The client does not have a clinically significant active infection or inflammatory disorder.
- The client has been screened and does not have active/latent Hepatitis B virus, active Hepatitis C virus or human immunodeficiency virus (HIV).
- The client has not previously received CAR-T therapy.

Obecabtagene autoleucel (Aucatzyl) (procedure code Q2058) is limited to a one-time split dose transfusion treatment.

The required monitoring parameters following obecabtagene autoleucel (Aucatzyl) are:

- Monitor for signs and symptoms of cytokine release syndrome (CRS), neurologic toxicities/ immune effector cell-associated neurotoxicity syndrome (ICANS), and other acute toxicities daily for at least 14 days at the healthcare facility following Aucatzyl infusion.
- Monitor blood counts for cytopenia (e.g., anemia, neutropenia, thrombocytopenia) and secondary malignancies.

6.30.7 Prior Authorization Criteria for Tisagenlecleucel (Kymriah)

Prior authorization approval of tisagenlecleucel (Kymriah) (procedure code Q2042) infusion for the treatment of clients with refractory or second relapse B-cell precursor acute lymphoblastic leukemia will be considered when all of the following criteria are met:

- The client has a confirmed diagnosis of B-cell acute lymphoblastic leukemia (diagnosis codes C9100, C9101, and C9102).
- The client is 25 years of age or younger.
- The client has a confirmed CD-19 tumor expression.
- The client has not received prior CAR-T therapy.

Prior authorization approval of tisagenlecleucel (Kymriah) infusion for the treatment of clients with relapsed or refractory diffuse large B-cell lymphoma will be considered when all of the following criteria are met:

- The client has a confirmed diagnosis of relapsed or refractory large B-cell lymphoma (diagnosis codes C8330, C8331, C8332, C8333, C8334, C8335, C8336, C8337, C8338, C83398, and C833A):
  - Diffuse large B-cell lymphoma, not otherwise specified
  - High grade B-cell lymphoma
  - Diffuse large B-cell lymphoma arising from follicular lymphoma
- The client is 18 years of age or older.
- The client must have relapsed or refractory disease defined as progression after two or more lines of systemic therapy (which may or may not include therapy supported by autologous stem cell transplant).
- The client does not have primary central nervous system lymphoma
- The client has not received prior CD-19 directed CAR-T therapy

Prior authorization approval for clients with relapsed or refractory follicular lymphoma (FL) after two or more lines of systemic therapy will be considered once all the following criteria are met:

- The client is 18 years of age or older
- The client has relapsed, or refractory disease defined as progression after two or more lines of systemic therapy.
- The client does not have primary central nervous system lymphoma/disease

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- The client does not have an active infection or inflammatory disorder
- The client has not received prior CD-19 directed CAR-T therapy
- The client has histologically confirmed diagnosis of one of the following types of follicular lymphoma:

Diagnosis Codes							
C8200	C8201	C8202	C8203	C8204	C8205	C8206	C8207
C8208	C8209	C820A	C8210	C8211	C8212	C8213	C8214
C8215	C8216	C8217	C8218	C8219	C821A	C8220	C8221
C8222	C8223	C8224	C8225	C8226	C8227	C8228	C8229
C822A	C8230	C8231	C8232	C8233	C8234	C8235	C8236
C8237	C8238	C8239	C823A	C8240	C8241	C8242	C8243
C8244	C8245	C8246	C8247	C8248	C8249	C824A	C8250
C8251	C8252	C8253	C8254	C8255	C8256	C8257	C8258
C8259	C825A	C8260	C8261	C8262	C8263	C8264	C8265
C8266	C8267	C8268	C8269	C826A	C8280	C8281	C8282
C8283	C8284	C8285	C8286	C8287	C8288	C8289	C828A
C8290	C8291	C8292	C8293	C8294	C8295	C8296	C8297
C8298	C8299	C829A					

Refer to: Subsection 2.1.2, "Prior Authorization Requests" in this handbook for additional prior authorization information.

6.31 Clofarabine

Clofarabine is used for the treatment of relapsed or refractory acute lymphoblastic leukemia for clients who are 1 through 21 years of age. Clofarabine is administered by IV infusion once daily for five days and is repeated every two to six weeks, as needed.

6.31.1 Prior Authorization for Clofarabine

Prior authorization is required for treatment with clofarabine (procedure code J9027) and may be granted for a maximum of six weeks.

Clofarabine may be prior authorized for the treatment of relapsed or refractory acute lymphoblastic leukemia. The following criteria apply to requests for prior authorization:

- The number of anticipated injections needed as well as the dosage per injection must be submitted with the request for prior authorization.
- Prior authorization must be obtained before services are rendered whenever possible. If authorization cannot be obtained prior to the rendering of the service, the authorization request must be submitted within three business days from the date the treatment is initiated.

Prior authorization requests may be considered with documentation of the following:

- The client is 1 through 21 years of age.
- A diagnosis of refractory or relapsed acute lymphoblastic leukemia
- A history of at least two prior failed chemotherapy regimens

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The prior authorization number must be included on the claim along with the number of units, based on the dosage given. Failure to place the prior authorization number on the claim or to obtain prior authorization within the allotted timeframe will result in denied claims.

Refer to: Subsection 2.1.2, "Prior Authorization Requests" in this handbook for additional prior authorization information.

6.32 Coagulation Factor IX (Ixinity)

Coagulation factor IX (Ixinity) (procedure code J7213) is a benefit of Texas Medicaid for clients who are 12 years of age or older.

6.33 * Colony Stimulating Factors (Filgrastim and Pegfilgrastim)

Colony stimulating factors (CSFs) are growth factors (glycoproteins) that support survival, clonal expansion and differentiation of blood forming cells and are a benefit of Texas Medicaid. CSFs reduce the likelihood of neutropenic complications due to chemotherapy and bone marrow transplant.

Filgrastim (Neupogen) (procedure code J1442), tbo-filgrastim (Granix) (procedure code J1447), pegfilgrastim (Neulasta) (procedure code J2506), sargramostim (Leukine) (procedure code J2820), eflapegrastim-xnst (Rolvedon) (procedure code J1449), and efbemalenograstim alfa-vuxw (Ryzneuta) (procedure code J9361) are granulocyte colony stimulating factors (G-CSFs).

[Revised] Filgrastim (Neupogen) (procedure code J1442) biosimilars are filgrastim-aafi (Nivestym) (procedure code Q5110), filgrastim-ayow (Releuko) (procedure code Q5125), filgrastim-sndz (Zarxio) (procedure code Q5101), filgrastim-txid (Nypozi) (procedure code Q5148), and filgrastim-laha (Filkri) (procedure code Q5172).

[Revised] Pegfilgrastim (Neulasta) (procedure code J2506) biosimilars are pegfilgrastim-jmdb (Fulphila) (procedure code Q5108), pegfilgrastim-pbbk (Fylnetra) (procedure code Q5130), pegfilgrastim-apgf (Nyvepria) (procedure code Q5122), pegfilgrastim-fpgk (Stimufend) (procedure code Q5127), pegfilgrastim-cbqv (Udenyca) (procedure code Q5111), pegfilgrastim-bmez (Ziextenzo) (procedure code Q5120), and pegfilgrastim-unne (Armlupeg) (procedure code Q5169).

To submit claims for reimbursement of colony stimulating factors, providers must submit the most appropriate procedure code with the number of units administered.

Procedure code J2506 will be denied if billed on the same date of service as procedure codes J1442, J1449, and J2820.

Procedure code J1442 will be denied if billed on the same date of service as procedure codes J1449, J2506, and J2820.

Procedure code J1449 will be denied if billed on the same date of service as procedure codes J1442, J2506, and J2820.

Procedure code J2820 will be denied if billed on the same date of service as procedure codes J1442, J1449, and J2506.

Procedure code 96377 must be billed with procedure code J2506 on the same day by the same provider.

Procedure code J1449 is restricted to clients who are 18 years of age or older.

Procedure code J9361 is restricted to clients who are 18 years of age or older.

6.34 Crizanlizumab-tmca (Adakveo)

Crizanlizumab-tmca (Adakveo) (procedure code J0791) is a benefit of Texas Medicaid for clients who are 16 years of age and older.

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Crizanlizumab-tmca (Adakveo) is indicated for clients with sickle cell disease to reduce the frequency of vaso-occlusive crises (VOCs).

6.34.1 Prior Authorization

Prior authorization is required for crizanlizumab-tmca (Adakveo) and may be approved for a duration of 12 months.

Initial therapy requests for Crizanlizumab-tmca (Adakveo) may be approved for a 12-month duration if all of the following criteria are met:

- The client must be 16 years of age or older.
- The client has a diagnosis of sickle cell disease of any genotype.
- The client has experienced two or more vaso-occlusive events in the past 12 months.

For renewal or continuation therapy requests, the client must meet all of the following requirements:

- The client continues to meet the following initial approval criteria:
  - The client must be 16 years of age or older.
  - The client has a diagnosis of sickle cell disease of any genotype.
- The client experienced positive clinical response to therapy as demonstrated by reduced frequency of vaso-occlusive crisis.
- The client has previously received treatment with Crizanlizumab-tmca (Adakveo) without complications.

Refer to: Subsection 2.1.2, "Prior Authorization Requests" in this handbook for additional prior authorization information.

6.35 * Delandistrogene moxeparvovec-rokl (Elevidys)

[Revised] Delandistrogene moxeparvovec-rokl (Elevidys) is an adeno-associated virus vector-based gene therapy indicated for the treatment of ambulatory clients who are 4 years of age or older with Duchenne muscular dystrophy (DMD) with a confirmed mutation in the DMD gene.

Delandistrogene moxeparvovec-rokl (Elevidys) (procedure code J1413) is a benefit of Texas Medicaid and limited to one transfusion treatment per lifetime. Procedure code J1413 is restricted to diagnosis code G7101.

6.35.1 * Prior Authorization Requirements

Prior authorization is required for delandistrogene moxeparvovec-rokl (Elevidys) therapy and must be submitted with a Special Medical Prior Authorization (SMPA) Request Form.

Delandistrogene moxeparvovec-rokl (Elevidys) is a one-time intravenous infusion therapy indicated for the treatment of clients with Duchenne muscular dystrophy who meet the following requirements:

- [Revised] The client is 4 years of age or older and ambulatory.
- The client has a confirmed mutation in the DMD gene (diagnosis code G7101). Prescribers should monitor clients with a mutation in exon0s 1-17 and/or 59-71 of the DMD gene, for immune-mediated myositis.
- The client does not have any deletion in exon 8 or exon 9 in the DMD gene.
- The client is not on concomitant DMD antisense oligonucleotide therapy (e.g., golodirsen, casimersen, viltolarsen, eteplirsen, etc.).
- Documentation of client's baseline testing for presence of anti-AAVrh74 total binding antibody titers of <1:400.

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- The client has no current infection. If there are signs of infection prior to infusion, treatment with delandistrogene moxeparvovec-rokl (Elevidys) should be postponed until the infection clears.
- Due to the possibility of acute serious liver injury, client's liver function must be monitored prior and post delandistrogene moxeparvovec-rokl (Elevidys) therapy.
- Documentation of client's platelet count and troponin-l level should be obtained prior to infusion.
- The client does not have a history of previously receiving treatment with delandistrogene moxeparvovec-rokl (Elevidys) infusion.

The required monitoring parameters following delandistrogene moxeparvovec-rokl (Elevidys) infusion are:

- Liver function should be monitored upon initiation of therapy and continued on a weekly schedule for the first 3 months after delandistrogene moxeparvovec-rokl (Elevidys) infusion.
- Troponin-l level should be monitored weekly for the first month after treatment with delandistrogene moxeparvovec-rokl (Elevidys).

All services outlined in this section are subject to retrospective review to ensure that the documentation in the client's medical record supports the medical necessity of the service(s) provided.

Refer to: Subsection 2.1.2, "Prior Authorization Requests" in this handbook for additional prior authorization information.

Subsection 5.5.1.2, "Document Requirements and Retention" in "Section 5: Fee-for-Service Prior Authorizations" (*Vol. 1, General Information*) for additional information about electronic signatures.

6.36 Denileukin Diftitox-cxdl (Lymphir)

Denileukin diftitox-cxdl (Lymphir) (procedure code J9161) is a benefit of Texas Medicaid for clients with prior authorization.

Denileukin diftitox-cxdl (Lymphir) is an IL-2 receptor directed cytotoxin indicated for the treatment of adult patients with relapsed or refractory stage I–III cutaneous T-cell lymphoma (CTCL) after at least one prior systemic therapy.

6.36.1 Prior Authorization Requirements

6.36.1.1 Initial Requests

Denileukin diftitox-cxdl (Lymphir) is a subcutaneous injection and the initial prior authorization for this drug will be approved for 12 months for clients who meet the following requirements:

- The client is 18 years of age or older.
- The client has a confirmed diagnosis of cutaneous T-cell lymphoma (CTCL).
  - The client's lymphoma is categorized as Stage I to III.
  - The client's CTCL is relapsed or refractory after at least one prior systemic treatment.

Diagnosis Codes							
C8400	C8401	C8402	C8403	C8404	C8405	C8406	C8407
C8408	C8409	C8410	C8411	C8412	C8413	C8414	C8415
C8416	C8417	C8418	C8419	C84A0	C84A1	C84A2	C84A3
C84A4	C84A5	C84A6	C84A7	C84A8	C84A9	C84AA	

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- The client's serum albumin level must be > 3 g/dL prior to treatment cycle.
- The prescriber attests to counseling female clients of childbearing age regarding the use of an effective method of contraception during treatment with denileukin diftitox-cxdl (Lymphir) as there may be potential risk to the fetus.

The required monitoring parameters following denileukin diftitox-cxdl (Lymphir) are:

- Monitor the client for signs and symptoms of capillary leak syndrome (e.g., low blood pressure, severe swelling).
- Monitor the client's liver enzymes and bilirubin at baseline and during treatment as hepatotoxicity may occur.
- Monitor the client's renal function prior to starting each treatment. If serum albumin is less than 3 g/dL, delay administration of Lymphir until serum albumin is ≥ 3 g/dL.
- Monitor and evaluate the client for any visual impairment throughout treatment.

6.36.1.2 Recertification/Extension

For renewal or continuation of denileukin diftitox-cxdl (Lymphir) therapy, the client must meet the following requirements:

- The client meets the initial requirements for prior authorization and is currently treated with denileukin diftitox-cxdl (Lymphir) with the absence of severe adverse reactions or unacceptable toxicity (e.g., visual impairment, infusion related reactions, or hepatotoxicity).
- The client demonstrates partial/complete response to treatment or stabilization of disease, as shown by a decrease in spread or size of the tumor.

6.36.2 Documentation Requirements

In addition to the documentation requirements outlined in this section, all services are subject to retrospective review to ensure that the documentation in the client's medical record supports the medical necessity of the services provided.

6.37 Dexamethasone (Hemady)

Dexamethasone (Hemady) (procedure code J8541) is a benefit of Texas Medicaid for clients who are 18 years of age or older.

6.38 Dexmedetomidine

Dexmedetomidine (procedure code J1105) is a benefit of Texas Medicaid for clients who are 18 years of age or older.

6.39 Dimethyl sulfoxide

Dimethyl sulfoxide (procedure code J1212) is a benefit of Texas Medicaid and is limited to diagnosis codes N3010 and N3011.

6.40 Eculizumab (Soliris)

Eculizumab (Soliris) (procedure code J1299) is a benefit of Texas Medicaid and is limited to the following diagnosis codes:

Diagnosis Codes							
D5932	D5939	D595	G360	G7000	G7001		

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6.41 Edaravone (Radicava)

Procedure code J1301 is a benefit of Texas Medicaid for clients who are 18 years of age and older with prior authorization. Client must have a diagnosis of amyotrophic lateral sclerosis (ALS).

6.42 Efgartigimod

Efgartigimod alfa-fcab (Vyvgart) (procedure code J9332) and efgartigimod alfa (Vyvgart Hytrulo) (procedure code J9334) are benefits of Texas Medicaid and are limited to clients who are 18 years of age or older and restricted to diagnosis codes G700 and G7001. Procedure code J9334 is also restricted to diagnosis code G6181.

6.43 Elivaldogene Autotemcel (Skysona)

Elivaldogene autotemcel (Skysona) (procedure code J3387) is a benefit of Texas Medicaid for male clients who are 4 through 17 years of age with prior authorization.

Elivaldogene autotemcel (Skysona) is indicated to slow the progression of neurological dysfunction in boys who are 4 through 17 years of age with early, active cerebral adrenoleukodystrophy (CALD).

Elivaldogene autotemcel (Skysona) (procedure code J3387) is limited to one transfusion treatment per lifetime.

6.43.1 Prior Authorization Requirements

Elivaldogene autotemcel (Skysona) is a one-time infusion therapy indicated for the treatment of clients who meet the following requirements:

- The client is male who is 4 through 17 years of age.
- The client has a documented diagnosis of CALD (diagnosis code E71511, E71520, E71521, E71528, or E71529).
- The client has a variant in the ABCD1 gene as evident by a genetic test.
- The client's CALD is caused by the presence of a variant of the ABCD1 gene causing elevated very long chain fatty acid (VLCFA) and not secondary to head trauma.
- The client has early, active CALD as defined by all the following:
  - The client is asymptomatic or mildly symptomatic with neurologic function score (NFS) of less than or equal to 1.
  - The client has gadolinium enhancement on brain magnetic resonance imaging (MRI).
  - The client has a Loes score ranging from 0.5 to 9.
- The client has not had a hematopoietic stem cell transplant (HSCT), is eligible for HSCT, and is unable to find a matched related donor.
- The client's screening result is negative for hepatitis B virus (HBV), hepatitis C virus (HCV), human immunodeficiency virus (HIV)-1 and HIV-2, and Human T-lymphotropic virus type I (HTLV-I) and type II (HTLV-II) prior to the collection of cells for manufacturing.
- The prescriber must attest to monitor the client closely for evidence of life-threatening hematological malignancy through complete blood counts (CBC) at least every six months and through assessment for possible clonal expansion a least twice in the first year and annually thereafter.
- The prescriber must attest to monitor the client for signs of bleeding and infections after the treatment with elivaldogene autotemcel (Skysona) as life-threatening bacterial or viral infections may occur as well as thrombocytopenia and prolonged cytopenia.

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- The client must avoid taking anti-retroviral medications for at least one month prior to initiating medication for stem cell mobilization and for the expected duration for elimination of the medications, and until all cycles of apheresis are complete.

In addition to the documentation requirements outlined in the Prior Authorization Requirements section, all services outlined in this section are subject to retrospective review to ensure that the documentation in the client's medical record supports the medical necessity of the service(s) provided.

6.44 Elranatamab-bcmm (Elfrexio)

Elranatamab-bcmm (Elfrexio) (procedure code J1323) is a benefit of Texas Medicaid for clients who are 18 years of age or older.

6.45 Emapalumab-lzsg (Gamifant)

Emapalumab-lzsg (Gamifant) is an interferon gamma (IFNy) blocking antibody that is indicated for the treatment of the following:

- Adult and pediatric (newborn and older) clients with primary hemophagocytic lymphohistiocytosis (HLH) with refractory, recurrent, or progressive disease or intolerance with conventional HLH therapy.
- Adult and pediatric (newborn and older) clients with HLH/macrophage activation syndrome (MAS) in known or suspected Still's disease, including systemic juvenile idiopathic arthritis (sJIA), with an inadequate response or intolerance to glucocorticoids, or with recurrent MAS.

Emapalumab-lzsg (Gamifant) (procedure code J9210) is a benefit of Texas Medicaid for clients (newborn and older) with prior authorization.

Prescriber must administer dexamethasone concomitantly with emapalumab-lzsg (Gamifant) therapy.

Emapalumab-lzsg (Gamifant) is administered as part of the induction/maintenance phase of hematopoietic stem cell transplant (HSCT) and therapy will be discontinued once client is at the initiation phase for HSCT and no longer requires emapalumab-lzsg (Gamifant) therapy for HLH.

6.45.1 Prior Authorization Requirements

Prior authorization is required for emapalumab-lzsg (Gamifant) (procedure code J9210).

Prior authorization for initial therapy will be approved for a duration of six months when the client has one of the diagnoses listed below and meets the following criteria:

- Client has a documented diagnosis of primary HLH (diagnosis code D761) based on the following:
  - Genetic mutation of the gene known to cause primary HLH (e.g., PRF1, UNC13D, STX11, or STXBP2) or a family history consistent with primary HLH or
  - Confirmation of least 5 of the following criteria:
    - Fever ≥101.3 °F
    - Splenomegaly
    - Cytopenia defined by at least 2 of the following: Hemoglobin <9 g/dl; OR platelet count <100 x 10^9/L; OR neutrophils <1 x 10 Fasting triglycerides >265 mg/dl OR fibrinogen ≤1.5 g/L
    - Hemophagocytosis in the liver, bone marrow, spleen or lymph node
    - Low or absent natural killer (NK) cell activity
    - Serum ferritin concentration ≥ 500 mg/L

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    - High plasma concentration of soluble CD25 (i.e., soluble interleukin-2 receptor) >2,400 U/mL
- Client has refractory, recurrent or progressive disease or intolerance with conventional HLH therapy (e.g., etoposide, cyclosporine A, or anti-thymocyte globulin).
- Client has been tested/screened for latent tuberculosis infection prior to initiation of emapalumab-lzsg (Gamifant) therapy.
- Client has not undergone hematopoietic stem cell transplant and is candidate for HSCT once emapalumab-lzsg (Gamifant) therapy has been discontinued.
- Client has a documented diagnosis of HLH/MAS in Still's disease based on the following:
    - Client has a diagnosis of HLH along with a confirmed or suspected diagnosis of systemic juvenile idiopathic arthritis or adult onset of Still's disease.

Diagnosis Codes							
D761	M061	M0820	M08211	M08212	M08219	M08221	M08222
M08229	M08231	M08232	M08239	M08241	M08242	M08249	M08251
M08252	M08259	M08261	M08262	M08269	M08271	M08272	M08279
M0828	M0829						

    - Client has a diagnosis of active MAS with ferritin level greater than 684 ng/mL and any two of the four laboratory criteria listed below:
        - Platelet count ≤ 181×109/L
        - Aspartate aminotransferase (AST) > 48 U/L
        - Triglycerides > 156 mg/dL
        - Fibrinogen levels ≤ 360 mg/dL
    - Client has an inadequate response to high-dose IV glucocorticoids.
    - Client does not have any active infections caused by specific pathogens favored by IFNγ neutralization (e.g., mycobacteria and Histoplasma capsulatum).

For renewal or continuation therapy with emapalumab-lzsg (Gamifant), the client must meet all of the following requirements:

- Client continues to meet the initial approval criteria.
- Client continues to require emapalumab-lzsg (Gamifant) as HLH treatment pending the initiation of HSCT or when treatment is no longer needed for HLH/MAS.

Refer to: Subsection 2.1.2, "Prior Authorization Requests" in this handbook for additional prior authorization information.

6.46 * Enzyme Replacement Therapy (ERT)

ERT is a medical treatment that replaces a specific enzyme that is deficient or absent in the body.

The following ERT therapies are benefits of Texas Medicaid:

- Agalsidase beta (Fabrazyme) is indicated in clients who are 2 years of age or older with Fabry disease and may be reimbursed with diagnosis code E7521.
- Alglucosidase alfa (Lumizyme) is indicated for clients with Pompe disease (GAA deficiency) and may be reimbursed with diagnosis code E7402.

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- Apadamtase alfa (Adzynma) is indicated in pediatric and adult clients for prophylactic or on demand ERT for congenital thrombotic thrombocytopenic purpura (cTTP) and may be reimbursed with diagnosis code D6942.
- Avalglucosidase alfa-ngpt (Nexviazyme) is indicated for clients who are 1 year of age or older with late onset Pompe disease (lysosomal acid alpha-glucosidase [GAA] deficiency) and may be reimbursed with diagnosis code E7402.
- Cerliponase alfa (Brineura) is indicated to slow the loss of ambulation in pediatric clients with late neuronal ceroid lipofuscinosis type 2 (CLN2) and may be reimbursed with diagnosis code E754.
- Cipaglucosidase alfa-atga (Pombiliti) is indicated to treat adult clients who are 18 years of age or older with Pompe disease (lysosomal acid alpha-glucosidase [GAA] deficiency) who weigh over 40 kilograms, are not improving on current ERT, and may be reimbursed with diagnosis code E7402.
- Elosulfase alfa (Vimizim) is a hydrolytic lysosomal glycosaminoglycan- (GAG) specific enzyme indicated for clients who are 5 years of age or older with mucopolysaccharidosis type IVA and may be reimbursed with diagnosis code E76210.
- [Revised] Galsulfase (Naglazyme) is a hydrolytic lysosomal glycosaminoglycan- (GAG) specific enzyme indicated for clients who are 5 years of age or older with mucopolysaccharidosis VI (MPS VI; Maroteaux-Lamy syndrome) and may be reimbursed with diagnosis code E7629.
- Idursulfase (Elaprase) is a hydrolytic lysosomal glycosaminoglycan- (GAG) specific enzyme indicated for clients with Hunter syndrome (mucopolysaccharidosis II [MPS II]) and may be reimbursed with diagnosis code E761.
- [Revised] Imiglucerase (Cerezyme) is indicated for long-term ERT for adult and pediatric clients with a confirmed diagnosis of Type 1 Gaucher disease (diagnosis code E7522) that results in one or more of the following conditions:
  - Anemia (low red blood cell count)
  - Thrombocytopenia (low blood platelet count)
  - Bone disease
  - Hepatomegaly or splenomegaly (enlarged liver or spleen)
- Laronidase (Aldurazyme) is indicated in clients with Hurler and Hurler-Scheie forms of mucopolysaccharidosis I (MPS I) and clients with the Scheie form who have moderate to severe symptoms and may be reimbursed with diagnosis codes E7601, E7602, and E7603.
- Olipudase alfa-rpcp (Xenpozyme) is indicated for the treatment of non-central nervous system manifestations of acid sphingomyelinase deficiency (ASMD) in adult and pediatric patients and may be reimbursed with diagnosis codes E75240, E75241, E75244, E75248, and E75249. The following requirements must be met:
  - Pregnancy status of female clients of reproductive potential must be verified prior to initiating treatment.
  - Client's baseline transaminase level must be obtained.
  - Assessment of alanine transaminase (ALT) and aspartate aminotransferase (AST) must be conducted within one month prior to initiation of Olipudase alfa-rpcp, within 72 hours prior to any infusion during dose escalation, or prior to the next scheduled Olipudase alfarpcp infusion upon resuming treatment following a missed dose.
- Pegunigalsidase alfa-iwxj (Elfabrio) is indicated for the treatment of adult clients with confirmed Fabry disease and may be reimbursed with diagnosis code E7521.

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- [Revised] Pegzilarginase-nbln (Loargys) is indicated to treat hyperargininemia in clients who are 2 years of age or older with arginase 1 deficiency (ARG1-D) in conjunction with dietary protein restriction with diagnosis code E7221.
- Protein C concentrate, human (Ceprotin) is indicated in pediatric and adult clients with severe congenital protein C deficiency for the prevention and treatment of venous thrombosis and purpura fulminans and may be reimbursed with diagnosis cod D6859.
- Sebelipase alfa (Kanuma) is indicated for the treatment of pediatric and adult clients with a diagnosis of lysosomal acid lipase (LAL) deficiency and may be reimbursed with diagnosis code E755.
- [Revised] Taliglucerace alfa (Elelyso) is indicated for long-term ERT for adult and pediatric clients who are 4 years of age or older with Type 1 Gaucher disease and may be reimbursed with diagnosis code E7522.
- [Revised] Tividenofusp alfa-eknm (Avlayah) is indicated for the treatment of neurologic manifestations of Hunter syndrome (Mucopolysaccharidosis type II, MPS II) in presymptomatic or symptomatic pediatric clients weighing at least five kilograms before advanced neurologic impairment with diagnosis code E761.
- Velaglucerase alfa (VPRIV) is indicated for long-term ERT for clients with Type 1 Gaucher disease and may be reimbursed with diagnosis code E7522.
- Velmanase alfa-tycv (Lamzede) is indicated to treat non-central nervous system manifestation of alpha-mannosidosis in adult and pediatric clients and may be reimbursed with diagnosis code E771. The following requirement must be met:
    - Pregnancy status of female clients of reproductive potential must be verified prior to initiating treatment.

Vestronidase alfa-vjbk (Mepsevii) is indicated to treat Mucopolysaccharidosis VII (MPS VII, Sly syndrome) in pediatric and adult clients with prior authorization. Vestronidase alfa-vjbk (Mepsevii) may be approved for a duration of every 12 months per prior authorization request.

For initial therapy, the following criteria must be met:

- Documentation of clinical signs and symptoms of Mucopolysaccharidosis VII (MPS VII) (e.g., skeletal deformities; enlarged liver, spleen, or both; airway obstruction or pulmonary problems; joint limitations; etc.)
- Diagnosis of Mucopolysaccharidosis VII (MPS VII, Sly syndrome) (diagnosis code E7629 or E763) supported by elevated urine glycosaminoglycans excretion at a minimum of 3-fold over the mean normal for age at screening and either or the following:
    - Beta-glucuronidase enzyme deficiency in peripheral blood based on leukocytes or cultured fibroblasts
    - Mutation in the glucuronidase beta (GUSB) gene, confirmed by molecular genetic testing

For renewal or continuation of therapy, the following criteria must be met:

- Client has previously received treatment with vestronidase alfa-vjbk without an adverse reaction.
- Documentation from physician confirms the client has experienced an improvement in clinical response compared to pretreatment baseline (e.g., stability in skeletal deformities; reduction in liver volume; reduction in spleen volume, or both; stable or improved pulmonary function; improved endurance; and functional capacity, etc.).

Refer to: Subsection 2.1.2, "Prior Authorization Requests" in this handbook for additional prior authorization information.

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6.46.1 * Reimbursement for ERT

The following procedure codes may be reimbursed for ERT services:

[Revised] Procedure Codes									
J0180	J0217	J0218	J0219	J0221	J0567	J1203	J1322	J1458	J1743
J1757	J1786	J1818	J1931	J2508	J2724	J2840	J3060	J3385	J3397
J7171									

6.46.2 Prior Authorization

Prior authorization is required for enzyme replacement therapy and documentation must include all of the following:

- A request for the specific enzyme replacement therapy.
- Laboratory evidence of the enzyme deficiency, (i.e., below the laboratory-defined cut-off value as determined by the laboratory).

The requesting provider may be asked for additional information to clarify or complete a request for enzyme replacement therapy.

Retrospective review may be performed to ensure documentation supports the medical necessity of the requested equipment or supplies.

6.47 Epcoritamab-bysp (Epkinly)

Epcoritamab-bysp (procedure code J9321) is a benefit of Texas Medicaid for clients who are 18 years of age or older.

6.48 Eravacycline (Xerava)

Eravacycline (procedure code J0122) is a benefit of Texas Medicaid for clients who are 18 years of age or older.

6.49 Esketamine (Spravato)

Esketamine (Spravato) is a benefit of Texas Medicaid for clients who are 18 years of age or older with prior authorization. Providers must submit claims for esketamine (Spravato) with procedure code J0013.

Esketamine (Spravato) nasal spray is an N-methyl-D-aspartate (NMDA) receptor antagonist that is indicated for any of the following treatments:

- Treatment-resistant depression (TRD) in adult clients, as monotherapy or in conjunction with an oral antidepressant
- Depressive symptoms in adult clients with major depressive disorder (MDD) with acute suicidal ideation or behavior in conjunction with an oral antidepressant

Esketamine (Spravato) is only available through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS).

Providers/health-care settings must be certified in the Spravato REMS program to administer Spravato to clients enrolled in the REMS program. Administration of the drug must take place in a health-care facility under the direct observation of a health-care provider.

Pharmacies must be certified in the Spravato REMS program to dispense to health-care settings who are authorized to administer the drug.

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Clients must be enrolled in the Spravato REMS program and comply with the ongoing requirements for Spravato treatment.

Esketamine (Spravato) is not a benefit for clients who have aneurysmal vascular disease, arteriovenous malformation or history of intracerebral hemorrhage.

6.49.1 Prior Authorization

Prior authorization is required for esketamine (Spravato) (procedure code J0013) and may be approved for a duration of six months.

Initial therapy for esketamine (Spravato) nasal spray may be approved when all of the following criteria is met:

- The client is 18 years of age or older.
- The client has a diagnosis of major depressive disorder (MDD) with one of the following diagnosis codes:

Diagnosis Codes							
F0631	F0632	F0634	F320	F321	F322	F323	F324
F325	F3289	F329	F32A	F330	F331	F332	F333
F3340	F3341	F3342	F338	F339	F341	F350	

- Client has either of the following:
  - A treatment-resistance depression (as monotherapy or in combination with an oral antidepressant) that has been confirmed as an inadequate response/failure to previous antidepressant treatment.
  - A major depressive disorder with acute suicidal ideation or behavior (in conjunction with an oral antidepressant) and the prescriber's evaluation shows that the client:
    - Has suicidal ideation with intent.
    - Needs acute psychiatric hospitalization due to an imminent risk of suicide.
- Esketamine (Spravato) must be administered under the direct observation of a health-care provider and the client must be monitored for at least 2 hours after each treatment.
- Prior to starting esketamine (Spravato) treatment, there must be an attestation of baseline scoring of clinical assessment of MDD.
- The client must not have contraindications to esketamine (Spravato), such as aneurysmal vascular disease, arteriovenous malformation, or intracerebral hemorrhage.

For renewal or continuation therapy, the client must meet all of the following requirements:

- The client continues to meet the initial prior authorization approval criteria.
- The client demonstrates positive clinical response to esketamine (Spravato) therapy by an improvement from baseline assessment.
- The client has previously received treatment esketamine (Spravato) without complications.

Refer to: Subsection 2.1.2, "Prior Authorization Requests" in this handbook for additional prior authorization information.

6.50 Esmolol Hydrochloride

Esmolol hydrochloride (procedure code J1805 and J1806) is a benefit of Texas Medicaid for clients who are 18 years of age or older.

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6.51 Etranacogene Dezaparvovec-drlb (Hemgenix)

Etranacogene dezaparvovec-drlb (Hemgenix) is an adeno-associated virus vector-based gene therapy indicated to treat adult clients with Hemophilia B (congenital Factor IX deficiency).

Etranacogene dezaparvovec-drlb (Hemgenix) (procedure code J1411) is a benefit of Texas Medicaid for adult clients who are 18 years of age or older with prior authorization.

6.51.1 Prior Authorization Requirements

Prior authorization is required for etranacogene dezaparvovec-drlb (Hemgenix) therapy.

Etranacogene dezaparvovec-drlb (Hemgenix) is a one-time infusion therapy indicated for the treatment of clients who meet the following requirements:

- The client is 18 years of age or older.
- The client has a confirmed diagnosis of Hemophilia B (Hereditary factor IX deficiency) (diagnosis code D67) and all other bleeding disorders not related to Hemophilia B have been ruled out.
- The client must meet one of the following criteria:
  - Is currently using Factor IX prophylaxis therapy, or
  - Has current or historical life-threatening hemorrhage, or
  - Has a history of repeated, serious spontaneous bleeding episodes.
- A Factor IX inhibitor titer testing must be performed, and client must have a baseline anti-AAV5 antibody titer of ≤1:678.
- The client must be tested for Factor IX inhibitor presence and testing result must be negative.
  - If testing yields a positive result, a second Factor IX inhibitor titer test should be performed within two weeks.
  - Etranacogene dezaparvovec-drlb (Hemgenix) should not be administered if the results for the initial and second test for human Factor IX inhibitor are positive.
- Baseline liver condition and function assessment must be assessed prior to etranacogene dezaparvovec-drlb (Hemgenix) infusion.
  - Documentation includes, but is not limited to alanine aminotransferase (ALT), aspartate aminotransferase (AST), alkaline phosphatase (ALP), and total bilirubin
  - Documentation of hepatic ultrasound and elastography must be provided.
- The client does not have a history of previously receiving treatment with etranacogene dezaparvovec-drlb (Hemgenix) infusion.

Etranacogene dezaparvovec-drlb (Hemgenix) (procedure code J1411) is limited to one infusion per lifetime.

These are the required monitoring parameters following etranacogene dezaparvovec-drlb (Hemgenix) infusion:

- Liver transaminase levels must be assessed once weekly for at least three months after etranacogene dezaparvovec-drlb (Hemgenix) infusion to monitor for any signs of potential hepatotoxicity.
- Factor IX activity must be monitored weekly for at least three months post-infusion.

In addition to the documentation requirements outlined in this section, if any, all services are subject to retrospective review to ensure that the documentation in the client's medical record supports the medical necessity of the service(s) provided.

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6.52 Evinacumab-dgnb (Evkeeza)

Evinacumab-dgnb (procedure code J1305) is a benefit of Texas Medicaid for clients who are 1 year of age or older.

6.53 Fam-trastuzumab Deruxtecan-nxki

Fam-trastuzumab Deruxtecan-nxki (procedure code J9358) is a benefit of Texas Medicaid for clients who are 18 years of age or older.

6.54 * Fecal Microbiota

[Revised] Fecal microbiota (procedure code J1440) is a benefit of Texas Medicaid for clients who are 18 years of age or older and restricted to diagnosis codes A0471, A0472, and Z8617.

6.55 Fluocinolone Acetonide (Retisert)

Procedure code J7311 is a benefit of Texas Medicaid for clients of all ages but is only considered for reimbursement with a posterior uveitis diagnosis of more than six months in duration and only when the condition has been unresponsive to oral or systemic medication treatment.

Refer to: Subsection 4.2.11, "Fluocinolone Acetonide" in the *Inpatient and Outpatient Hospital Services Handbook* (*Vol. 2, Provider Handbooks*) for additional prior authorization requirements.

6.56 Furosemide (Furoscix)

Furosemide (Furoscix) (procedure code J1941) is a benefit of Texas Medicaid for clients who are 18 years of age or older.

6.57 Givosiran (Givlaari)

Givosiran (procedure code J0223) is a benefit of Texas Medicaid for clients who are 18 years of age or older and when billed with diagnosis codes E8020, E8021, and E8029.

6.58 Glofitamab-gxbm

Glofitamab-gxbm (procedure code J9286) is a benefit of Texas Medicaid for clients who are 18 years of age or older.

6.59 Granisetron Hydrochloride

Granisetron hydrochloride (procedure code J1626) is a benefit of Texas Medicaid and is limited to diagnosis codes Z510, Z5111, Z5112, and Z5189.

6.60 Hematopoietic Injections

Hematopoietic agents erythropoietin alfa, epoetin alfa (EPO), methoxy polyethylene glycol-epoetin beta (Mircera), and darbepoetin alfa are benefits of Texas Medicaid and reimbursed using procedure codes J0881, J0885, and J0888 with an appropriate diagnosis code.

Providers must maintain medical records in their offices that document regular monitoring of hemoglobin or hematocrit levels and explain the rationale for the dosing of epoetin alfa, methoxy polyethylene glycol-epoetin beta, and darbepoetin alfa. These records are subject to retrospective review to determine appropriate utilization and reimbursement for this service.

EPO, Mircera, and darbepoetin alfa injections are limited to specific diagnosis codes as indicated in this section.

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Refer to: Subsection 7.2.7.1, "Hematopoietic Injections" in the *Clinics and Other Outpatient Facility Services Handbook* (*Vol. 2, Provider Handbooks*) for information about outpatient facility criteria.

6.60.1 Darbepoetin Alfa

Darbepoetin alfa (procedure code J0881) is an erythropoiesis-stimulating protein closely related to erythropoietin. Darbepoetin stimulates erythropoiesis by the same mechanism as EPO. Darbepoetin alfa has approximately a three-fold longer half-life than EPO, resulting in a sustained erythropoietic effect and less frequent dosing. Darbepoetin alfa is indicated for:

- Treatment of anemia associated with chronic renal failure (CRF), including clients on dialysis and clients not on dialysis.
- Treatment of anemia in clients who have non-myeloid malignancies where anemia is due to the effect of chemotherapy.

Procedure code J0881 must be billed with one of the following diagnosis codes:

Diagnosis Codes							
C9000	C9001	C9002	D460	D461	D4621	D464	D46A
D46B	D611	D612	D613	D6189	D619	D630	D631
D644	D6481	D6489	D649	N181	N182	N1830	N1831
N1832	N184	N189	N19	Z5111	Z5112		

Darbepoetin alfa injections are limited to once weekly (Sunday through Saturday).

6.60.2 Epoetin Alfa (EPO)

EPO (procedure code J0885) is a glycoprotein that stimulates the formation of red blood cells and the production of the precursor red blood cells of the bone marrow. EPO is indicated for:

- Anemia associated with chronic renal failure (CRF), including clients not on dialysis.
- Anemia related to therapy with zidovudine (AZT) in HIV-infected clients.
- Anemia due to the effects of concomitantly administered chemotherapy in clients who have non-myeloid malignancies.
- Anemia of prematurity.
- Clients scheduled to undergo elective noncardiac, nonvascular surgery to decrease need for allogenic blood transfusion.

Procedure code J0885 must be billed with one of the following diagnosis codes:

Diagnosis Codes							
B20	C9000	C9001	C9002	D460	D461	D4621	D4622
D464	D469	D46A	D46B	D46C	D46Z	D471	D479
D47Z9	D611	D612	D613	D6189	D619	D630	D631
D644	D6481	D6489	D649	I120	N181	N182	N1830
N1831	N1832	N184	N189	N19	P612		

EPO may be considered for reimbursement when the dose is titrated consistent with prevailing, evidence-based clinical guidelines, as published by the National Kidney Foundation Kidney Disease Outcomes Quality Initiative, including appropriate monitoring of the rise and fall of the hemoglobin or hematocrit levels.

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EPO is limited to three injections per calendar week (Sunday through Saturday).

6.60.3 Methoxy Polyethylene Glycol-Epoetin Beta (Mircera)

Methoxy polyethylene glycol-epoetin beta (Mircera) is indicated for the treatment of anemia associated with chronic kidney disease (CKD) and may be administered subcutaneously or intravenously. Mircera is not indicated for use in the treatment of anemia due to cancer chemotherapy or as a substitute for red blood cell transfusions in clients who require immediate correction of anemia. Mircera is indicated for the following:

- Treatment of anemia associated with CKD in adult clients on hemodialysis and adult clients not on hemodialysis.
- Treatment of anemia associated with CKD in pediatric clients who are 5 through 17 years of age. These clients must be on hemodialysis and converting from another erythropoiesis-stimulating agent (ESA) after their hemoglobin level was stabilized with an ESA.

Note: *In pediatric clients, Mircera is administered by intravenous injection only.*

Methoxy polyethylene glycol-epoetin beta (Mircera) (procedure code J0888) is limited to the following diagnosis codes:

Diagnosis Codes							
D631	I129	I130	N181	N182	N1830	N1831	N1832
N184							

Methoxy polyethylene glycol-epoetin beta (Mircera) may be considered for reimbursement when the dose is titrated consistent with prevailing, evidence-based, clinical guidelines as published by the National Kidney Foundation Kidney Disease Outcomes Quality Initiative, including appropriate monitoring of the rise and fall of the hemoglobin or hematocrit levels.

Methoxy polyethylene glycol-epoetin beta (Mircera) is limited to one injection every 2 calendar weeks, any provider (Sunday through Saturday).

6.61 Hemophilia Drugs

6.61.1 Alhemo (Concizumab-mtci)

Alhemo (Concizumab-mtci) (procedure code J7173) is a benefit of Texas Medicaid for clients who are 12 years of age or older.

6.61.2 Coagulation factor Xa (Recombinant), Inactivated-zhzo (Andexxa)

Coagulation factor XA (recombinant), inactivated-zhzo (procedure code J7169) is a benefit of Texas Medicaid for clients who are 18 years of age or older.

6.61.3 Factor VIIa (Antihemophilic factor, Recombinant-JNCW) (Sevenfact)

Factor VIIa (Antihemophilic factor, recombinant-jncw) (procedure code J7212) is a benefit of Texas Medicaid for clients who are 12 years of age or older.

6.61.4 Prothrombin complex concentrate (Human-lans), per I.U. of factor 1x activity

Prothrombin complex concentrate, human-lans, (procedure code J7165) is a benefit of Texas Medicaid for clients who are 18 years of age or older.

6.61.5 Prothrombin complex (Human), per I.U. of factor 1x activity (Kcentra)

Prothrombin complex, human (procedure code J7168) is a benefit of Texas Medicaid for clients who are 18 years of age or older.

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6.61.6 Qfitlia (Fitusiran)

Qfitlia (Fitusiran) (procedure code J7174) is a benefit of Texas Medicaid for clients who are 12 years of age or older.

6.62 Hereditary Angioedema (HAE) agents

6.62.1 C1 Esterase Inhibitor (Human) (Berinert)

C-1 esterase inhibitor (human) (Berinert) (procedure code J0597) is a benefit of Texas Medicaid for clients who are 5 years of age or older when billed with diagnosis code D841.

6.62.2 C1 Esterase Inhibitor (Human) (Cinryze)

C-1 esterase inhibitor (human) (Cinryze) (procedure code J0598) is a benefit of Texas Medicaid for clients who are 6 years of age or older when billed with diagnosis code D841.

6.62.3 C1 Esterase Inhibitor (Human) (Haegarda)

C1 esterase inhibitor (human) (Haegarda) (procedure code J0599) is a benefit of Texas Medicaid for clients who are 6 years of age or older when billed with diagnosis code D841.

6.62.4 C1 Esterase Inhibitor (Recombinant) (Ruconest)

C1 esterase inhibitor (recombinant) (procedure code J0596) is a benefit of Texas Medicaid for clients who are 13 years of age or older when billed with diagnosis code D841.

6.62.5 Ecallantide (Kalbitor)

Ecallantide (Kalbitor) (procedure code J1290) is a benefit of Texas Medicaid for clients who are 12 years of age or older when billed with diagnosis code D841.

6.62.6 Hympavzi (Marstacimab-hncq)

Hympavzi (Marstacimab-hncq) (procedure code J7172) is a benefit of Texas Medicaid for clients who are 6 years of age or older.

6.62.7 Icatibant (Firazyr)

Icatibant (Firazyr) (procedure code J1744) is a benefit of Texas Medicaid for clients who are 18 years of age or older when billed with diagnosis code D841.

6.62.8 Lanadelumab-flyo (Takhzyro)

Lanadelumab-flyo (Takhzyro) (procedure code J0593) is a benefit of Texas Medicaid for clients who are 2 years of age or older when billed with diagnosis code D841.

6.62.9 Hormonal Therapy Agents

The following hormonal therapy agent procedure codes require prior authorization. Hormonal therapy agents are not a benefit when submitted with diagnosis codes F640, F641, F642, F648, and F649.

Procedure Codes									
J1000	J1071	J1072	J1073	J1380	J1950	J1951	J3121	J3145	J3315
J3316	J9155	J9217	J9218	J9226					

6.63 Ibalizumab-uiyk (Trogarzo)

Ibalizumab-uiyk (Trogarzo) (procedure code J1746) is a benefit of Texas Medicaid for clients who are 18 years of age and older with prior authorization. Ibalizumab-uiyk (Trogarzo) may be approved for a duration of every 12 months per prior authorization request.

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For initial therapy, all of the following criteria must be met:

- The client is 18 years of age or older.
- The client has a documented diagnosis of multi-drug resistant human immunodeficiency virus (diagnosis code B20) from the provider and meets the following criteria:
  - Has received antiretroviral treatment for at least 6 months and is failing or has recently failed therapy
  - Has documented resistance, measured by resistance testing, to at least one antiretroviral medication from each of the following 3 classes of ARV:
    - Nucleoside reverse transcriptase inhibitors (NRTI)
    - Non-Nucleoside reverse transcriptase inhibitors (NNRTI)
    - Protease inhibitor (PI)
- The client has documented RNA viral load greater than 1,000 copies/mL.

Providers must use ibalizumab-uiyk (Trogarzo) concomitantly with another antiretroviral medication to which the client's virus is susceptible.

For renewal or continuation of therapy, all of the following criteria must be met:

- The client has previously received treatment with ibalizumab-uiyk (Trogarzo).
- Documentation from the physician confirming that the client has achieved a clinical viral response defined as one of the following:
  - Decrease in viral load
  - Sustained viral load reduction
- The physician continues ibalizumab-uiyk (Trogarzo) therapy with another antiretroviral.

Trogarzo is not a benefit for clients who fail to demonstrate heavily treated multi-drug resistance.

Refer to: Subsection 2.1.2, "Prior Authorization Requests" in this handbook for additional prior authorization information.

6.64 Imetelstat (Rytelo)

Imetelstat (Rytelo) is an oligonucleotide telomerase inhibitor indicated for the treatment of adult clients meeting both of the following criteria:

- The client has low- to intermediate-1 risk myelodysplastic syndromes (MDS) with transfusion-dependent anemia requiring four or more red blood cell (RBC) units over eight weeks.
- The client has not responded to, has lost response to, or is ineligible for erythropoiesis-stimulating agents (ESA).

Imetelstat (Rytelo) (procedure code J0870) is a benefit of Texas Medicaid for clients with prior authorization.

6.64.1 Prior Authorization Requirements

Prior authorization requests for imetelstat (Rytelo) must be submitted with a Special Medical Prior Authorization (SMPA) Request Form and documentation of all the following.

Imetelstat (Rytelo) is an intravenous infusion indicated for the treatment of a client who meets all of the following requirements:

- The client is 18 years of age or older.

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- The client has a confirmed diagnosis of low- to intermediate-1 risk MDS (diagnosis codes D460, D461, D464, D469, D46A, D46B, D46C, and D46Z).
- The client has transfusion-dependent anemia requiring regular RBC transfusions defined as >4 RBC units over eight weeks.
- The prescriber has ruled out or addressed other causes of anemia (e.g., abnormal bleeding, hemolysis, nutritional deficiency, renal disease)
- The prescriber attests that the client has not responded to, has lost response to, or is ineligible for ESAs.
- The client does not have deletion 5q cytogenic abnormalities.
- Imetelstat (Rytelo) will not be prescribed concomitantly with other erythropoiesis stimulating agents.
- The prescriber attests to counseling female clients of childbearing age regarding the use of an effective method of contraception to prevent pregnancy during treatment with imetelstat (Rytelo).

The required monitoring parameters following imetelstat (Rytelo) infusion are:

- Monitor for thrombocytopenia and neutropenia.
- Monitor liver function tests prior to imetelstat (Rytelo) administration, then weekly for the first cycle, and prior to each cycle thereafter.

6.64.2 Documentation Requirements

In addition to documentation requirements outlined in this section, all services are subject to retrospective review to ensure that the documentation in the client's medical record supports the medical necessity of the service(s) provided.

6.65 Imipenem, Cilastatin, and Relebactam (Recarbrio)

Imipenem, Cilastatin, and Relebactam (procedure code J0742) is a benefit of Texas Medicaid for clients who are 18 years of age or older.

6.66 * Immunosuppressive Drugs

Immunosuppressive drugs weaken or modulate the activity of the immune system and are most often used in organ transplantation to prevent rejection or to treat autoimmune diseases such as rheumatoid arthritis.

The following procedure codes are benefits of Texas Medicaid:

[Revised] Procedure Codes									
J0202	J0257	J0480	J0485	J0717	J1595	J1602	J7501	J7516	J7524
J7525	J7526	J7529	J7530						

The following procedure codes may be indicated for, but are not limited to, treatment of the following conditions:

[Revised] Procedure Code	Conditions
J0202	Multiple sclerosis (MS): For treatment of relapsing forms of MS and should be reserved for adult clients who have had an inadequate response to two or more drugs indicated for the treatment of MS.

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[Revised] Procedure Code	Conditions
J0257	Alpha-1 proteinase inhibitor deficiency: For the treatment of adult clients who have a deficiency of the alpha-1 proteinase inhibitor enzyme (also known as alpha-1 antitrypsin deficiency) in the treatment of emphysema.
J0480	Organ rejection: For the prophylaxis of acute organ rejection in clients receiving renal transplantation when used as part of an immunosuppressive regimen that includes cyclosporine and corticosteroids.
J0485	Organ rejection: For the prophylaxis of organ rejection in adult clients receiving a kidney transplant, to be used in combination with basiliximab injection, mycophenolate mofetil, and corticosteroids.
J0717	Psoriatic arthritis, ankylosing spondylitis, Crohn's disease, rheumatoid arthritis, polyarticular juvenile idiopathic arthritis, non-radiographic axial spondylarthritis, and plaque psoriasis.
J1595	Multiple sclerosis (MS): For the reduction of the frequency of relapses in adult clients with relapsing remitting MS, including clients who have experienced a first clinical episode and have magnetic resonance imaging (MRI) features consistent with MS.
J1602	Psoriatic arthritis, rheumatoid arthritis, ankylosing spondylitis, and polyarticular juvenile idiopathic arthritis.
J7501	Renal homotransplantations: Adjunct for the prevention of rejection in renal homotransplantation. Rheumatoid arthritis: Azathioprine is indicated only in clients meeting the criteria for classic or definite rheumatoid arthritis as specified by the American Rheumatism Association.
J7516, J7524, J7526, J7529, J7530	Allogeneic transplants: For prophylaxis of organ rejection in kidney, liver, and heart allogeneic transplants.
J7525	Organ rejection prophylaxis: For the prophylaxis of organ rejection in clients receiving allogeneic liver, kidney, or heart transplants.

Note: *Oral, self-administered immunosuppressive drugs may be reimbursed for Medicaid fee-for-service clients through the Texas Vendor Drug Program (VDP).*

Retrospective review may be performed to ensure documentation supports the medical necessity of the service. Authorization is not required for immunosuppressive drugs.

6.67 Inclisiran (Leqvio)

Inclisiran (Leqvio) (procedure code J1306) is a benefit of Texas Medicaid for clients who are 18 years of age or older.

6.68 * Inebilizumab-cdon (Uplizna)

Inebilizumab-cdon (Uplizna) (procedure code J1823) is a benefit of Texas Medicaid for clients who are 18 years of age or older with prior authorization.

Inebilizumab-cdon (Uplizna) is indicated for the treatment of adult clients with the following:

- Neuromyelitis optica spectrum disorder (NMOD/NMOSD) who are anti-aquaporin-4 antibody positive

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- Immunoglobulin G4-related disease (IgG4-RD)
- [Revised] Generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) or anti-muscle-specific tyrosine kinase (MuSK) antibody positive.

6.68.1 * Prior Authorization Criteria

Prior authorization approval for initial therapy for inebilizumab-cdon (Uplizna) will be considered and approved for a 12-month duration when the client has one of the diagnoses listed below and meets the following criteria:

Neuromyelitis Optica Spectrum Disorder

- Client must be 18 years of age or older.
- Client has a diagnosis of neuromyelitis optica spectrum disorder (diagnosis code G360).
- Client is anti-aquaporin 4 (AQP4) antibody seropositive.
- Client has been screened for hepatitis B virus (HBV), quantitative serum immunoglobulins, and tuberculosis (TB) prior to initiating treatment.
- Client has at least one attack requiring rescue therapy in the last year OR two attacks requiring rescue therapy in the last 2 years.
- Client is not receiving Inebilizumab-cdon (Uplizna) concomitantly with the following therapies:
  - Anti-CD20 monoclonal antibody treatments
  - Complement inhibitors (e.g. Eculizumab, Ravulizumab)
  - Immunosuppressant drugs (e.g. Cyclosporine, Methotrexate)
  - Satralizumab

Immunoglobulin Related Disease

- Client must be 18 years of age or older.
- Client has a diagnosis of immunoglobulin G4-related disease (diagnosis code D8984) and other conditions that mimic IgG4-RD have been ruled out (e.g., malignancy, infection, other autoimmune disorders).
- Client experiences (or recently experienced) an IgG4-RD flare that requires initiation or continuation of glucocorticoid treatment.
- Client has history of IgG4-RD affecting at least two organs.

For renewal or continuation of therapy, the client must meet all of the following requirements:

- Client continues to meet the following initial approval criteria.
- Client experienced positive clinical response to therapy as demonstrated by decreased attacks or disease stabilization.
- Client has previously received inebilizumab-cdon (Uplizna) treatment without complications or unacceptable toxicity (e.g., infusion reactions, serious infections).

*** Generalized myasthenia gravis (gMG)**

- [Revised] Client must be 18 years of age or older.
- [Revised] Client has a diagnosis of gMG, Myasthenia Gravis Foundation of America (MGFA) clinical classification of II, III, or IV (diagnosis codes G7000 and G7001).

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- [Revised] Client is anti-acetylcholine receptor (AChR) or anti-muscle-specific tyrosine kinase (MuSK) antibody positive.
- [Revised] Client's Myasthenia Gravis-Activities of Daily Living (MG-ADL) score is between six and ten.
- [Revised] Client has a Quantitative Myasthenia Gravis (QMG) score greater than 11.
- [Revised] Client is on a stable dose of corticosteroid, a specific non-steroidal immunosuppressive therapy, or a combination of both.
- [Revised] Client is not receiving inebilizumab-cdon (Uplizna) to treat myasthenia gravis concomitantly with the following therapies:
  - [Revised] Anti-CD20 monoclonal antibody treatments
  - [Revised] Complement inhibitors (e.g., ravulizumab-cwvz (Ultomiris), or zilucoplan (Zilbrysq))
  - [Revised] A neonatal Fc receptor (FcRn) blocker (e.g., nipocalimab-aahu (Imaavy), rozanolixizumab-noli (Rystiggo), efgartigimod alfa-fcab (Vyvgart), efgartigimod alfa or hyaluronidase-qvfc (Vyvgart Hytrulo))

6.69 Infliximab (Remicade), Avsola, Inflectra, Renflexis, and Zymfentra

Procedure codes J1745, Q5103, Q5104, and Q5121 are benefits of Texas Medicaid, and may not be reimbursed for the same date of service by any provider. Procedure codes J1745, Q5103, Q5104, and Q5121 are limited to the following diagnosis codes:

Diagnosis Codes							
K5000	K50011	K50012	K50013	K50014	K50018	K5010	K50111
K50112	K50113	K50114	K50118	K5080	K50811	K50812	K50813
K50814	K50818	K5090	K50911	K50912	K50913	K50914	K50918
K50919	K5100	K51011	K51012	K51013	K51014	K51018	K5120
K51211	K51212	K51213	K51214	K51218	K5130	K51311	K51312
K51313	K51314	K51318	K5150	K51511	K51512	K51513	K51514
K51518	K5180	K51811	K51812	K51813	K51814	K51818	K5190
K51911	K51912	K51913	K51914	K51918	K6030	K60311	K60312
K60313	K60319	K60321	K60322	K60323	K60329	K632	L400
L401	L402	L403	L404	L4050	L4051	L4052	L4053
L4054	L4059	L408	M05011	M05012	M05021	M05022	M05031
M05032	M05041	M05042	M05051	M05052	M05061	M05062	M05071
M05072	M0509	M05411	M05412	M05421	M05422	M05431	M05432
M05441	M05442	M05451	M05452	M05461	M05462	M05471	M05472
M0549	M05511	M05512	M05521	M05522	M05531	M05532	M05541
M05542	M05551	M05552	M05561	M05562	M05571	M05572	M0559
M05611	M05612	M05621	M05622	M05631	M05632	M05641	M05642
M05651	M05652	M05661	M05662	M05671	M05672	M0569	M05711
M05712	M05721	M05722	M05731	M05732	M05741	M05742	M05751
M05752	M05761	M05762	M05769	M05771	M05772	M05779	M0579
M057A	M05811	M05812	M05821	M05822	M05831	M05832	M05841

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Diagnosis Codes							
M05842	M05851	M05852	M05861	M05862	M05871	M05872	M0589
M058A	M06011	M06012	M06021	M06022	M06031	M06032	M06041
M06042	M06051	M06052	M06061	M06062	M06071	M06072	M0608
M0609	M060A	M06811	M06812	M06819	M06821	M06822	M06829
M06831	M06832	M06839	M06841	M06842	M06849	M06851	M06852
M06859	M06861	M06862	M06869	M06871	M06872	M06879	M0688
M0689	M068A	M069	M08011	M08012	M08021	M08022	M08031
M08032	M08041	M08042	M08051	M08052	M08061	M08062	M08071
M08072	M0809	M08811	M08812	M08821	M08822	M08831	M08832
M08841	M08842	M08851	M08852	M08861	M08862	M08871	M08872
M0888	M0889	M08931	M08932	M08941	M08942	M08951	M08952
M08961	M08962	M08971	M08972	M0898	M450	M451	M452
M453	M454	M455	M456	M457	M458	M45A0	M45A1
M45A2	M45A3	M45A4	M45A5	M45A6	M45A7	M45A8	M45AB

Procedure code J1745 is also limited to diagnosis code M05A.

Procedure code J1748 is a benefit for clients who are 18 years of age or older and limited to the following diagnosis codes:

Diagnosis Codes							
K5000	K50011	K50012	K50013	K50014	K50018	K50019	K5010
K50111	K50112	K50113	K50114	K50118	K5080	K50811	K50812
K50813	K50814	K50818	K50819	K5090	K50911	K50912	K50913
K50914	K50918	K5100	K51011	K51012	K51013	K51014	K51018
K51019	K5120	K51211	K51212	K51213	K51214	K51218	K5130
K51311	K51312	K51313	K51314	K51318	K5180	K51811	K51812
K51813	K51814	K51818	K5190	K51911	K51912	K51913	K51914
K51918	K51919						

6.70 Inotuzumab ozogamicin (Besponsa)

Inotuzumab ozogamicin (Besponsa) (procedure code J9229) is a benefit of Texas Medicaid for pediatric and adult clients who are 1 year of age or older with prior authorization.

Inotuzumab ozogamicin (Besponsa) is a CD22-directed antibody-drug conjugate (ADC) that has 3 components:

- The antibody inotuzumab
- N-acetyl-gamma-calicheamicin dimethylhydrazide (a cytotoxic agent)
- An acid cleavable linker

Besponsa is indicated for the treatment of relapsed or refractory precursor B-cell acute lymphoblastic leukemia (ALL).

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6.70.1 Prior Authorization Requirements for Inotuzumab ozogamicin (Besponsa)

Prior authorization approval for Besponsa intravenous injection (procedure code J9229) will be considered when all of the following criteria are met:

- Client is 1 year of age or older
- Client has a confirmed diagnosis of precursor B-cell acute lymphoblastic leukemia (ALL) that is refractory or in relapse
- The prescriber must agree to monitor the client for signs and symptoms of hepatic veno-occlusive disease (VOD) for the duration of Besponsa therapy

Refer to: Subsection 2.1.2, "Prior Authorization Requests" in this handbook for additional prior authorization information.

6.70.2 Documentation Requirements

In addition to documentation requirements outlined above all services are subject to retrospective review to ensure that the documentation in the client's medical record supports the medical necessity of the service(s) provided.

6.70.3 Exclusions

Besponsa is not a benefit for patients who have hepatic veno-occlusive disease.

6.71 Insulin

Insulin [Fiasp (procedure code J1812) and Lyumjev (procedure code J1814)] is a benefit of Texas Medicaid for clients who are 18 years of age or older.

6.72 Invega Hafyera

Invega hafyera (procedure code J2427) is a benefit of Texas Medicaid for clients who are 18 years of age or older.

6.73 Iron Injections

Ferric derisomaltose (procedure code J1437) is a benefit of Texas Medicaid for clients who are 18 years of age or older.

Ferric carboxymaltose (procedure code J1439) is a benefit of Texas Medicaid for clients who are 1 year of age or older.

Iron Dextran injection (procedure code J1750) is a benefit of Texas Medicaid for clients who are 4 months of age or older.

Iron Sucrose injection (procedure code J1756) is a benefit of Texas Medicaid for clients who are 2 years of age or older.

Sodium Ferric Gluconate Complex injection (procedure code J2916) is a benefit of Texas Medicaid for clients who are 6 years of age or older.

Ferumoxytol injection (procedure code Q0138) is a benefit of Texas Medicaid for clients who are 18 years of age or older.

6.74 Eladocagene Exuparvovec-tneq (Kebilidi)

Eladocagene exuparvovec-tneq (Kebilidi) is an adeno-associated virus (AAV) vector-based gene therapy indicated to treat adult and pediatric clients with aromatic L-amino acid decarboxylase (AADC) deficiency.

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Eladocagene exuparvovec-tneq (Kebilidi) is a benefit of Texas Medicaid with prior authorization.

Eladocagene exuparvovec-tneq (Kebilidi) may be reimbursed using procedure code J3590 and is limited to once per lifetime.

6.74.1 Prior Authorization Requirements

Providers must submit prior authorization requests for eladocagene exuparvovec-tneq (Kebilidi) on a Special Medical Prior Authorization (SMPA) Request Form.

Eladocagene exuparvovec-tneq (Kebilidi) is a single-dose intraputaminal infusion indicated for clients who meet the following requirements:

- The client is 16 months of age or older.
- The client has a confirmed diagnosis of AADC deficiency (diagnosis code E7081).
- The client has presence of biallelic mutations in the dopa decarboxylase (DDC) gene identified by molecular genetic testing.
- There is documentation of skull assessment confirming that the client has achieved skull maturity by neuroimaging, which is necessary for stereotactic neurosurgical administration of eladocagene exuparvovec-tneq (Kebilidi) therapy.
- The client has not previously received eladocagene exuparvovec-tneq (Kebilidi) infusion for AADC deficiency.

After eladocageneexuparvovec-tneq (Kebilidi) infusion, providers must monitor the client for the following:

- Post-procedural complications, which may include events of respiratory and cardiac arrest after administration
- Additional procedure-related adverse events, such as cerebrospinal fluid leak, intracranial bleeding, neuroinflammation, acute infarction, and infection
- Signs of dyskinesia or involuntary movements of the face, arm, leg, or entire body (fidgeting, writhing, wriggling, head bobbing, or body swaying) after administration

In addition to documentation requirements outlined in this section, all services are subject to retrospective review to ensure that the documentation in the client's medical record supports the medical necessity of the service(s) provided.

6.75 Labetalol Hydrochloride

Labetalol hydrochloride [(procedure code J1920) and Hikma (procedure code J1921)] is a benefit of Texas Medicaid for clients who are 1 year of age or older.

6.76 Lactated Ringer's

Lactated Ringer's (procedure code J7121) is a benefit of Texas Medicaid for clients who are birth through 20 years of age.

6.77 Lenacapavir (Sunlenca)

Lenacapavir (Sunlenca) (procedure code J1961) is a benefit of Texas Medicaid for clients who are 18 years of age or older.

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6.78 Leuprolide Acetate (Lupron Depot)

Procedure codes J1950, J9217, or J9218 may be reimbursed for leuprolide acetate injections with prior authorization. The following limitations apply to procedure codes J1950 and J9217:

Procedure Code	Limitation(s)
J1950	Reimbursed once every 28 days

Procedure code J9217 may be reimbursed in monthly, three-month, four-month, and six-month doses as follows:

Frequency	Dosage	Limitations
Monthly	7.5 mg	Billed with a quantity of 1 Reimbursed once every 28 days
3-month	22.5 mg	Billed with a quantity of 3 Reimbursed once every 84 days
4-month	30 mg	Billed with a quantity of 4 Reimbursed once every 112 days
6-month	45 mg	Billed with a quantity of 6 Reimbursed once every 168 days

The total dosage allowed within a 6-month period is 45 mg.

Procedure codes J1950, J9217, and J9218 will be denied if billed on the same date of service by the same provider.

Refer to: Subsection 6.62.9, "Hormonal Therapy Agents" in this handbook for additional information.

6.79 Lumasiran (Oxlumo)

Lumasiran (procedure code J0224) is a benefit of Texas Medicaid for clients when billed with diagnosis code E72530.

6.80 Lupus Treatment Agents

Anifrolumab-fnia (Saphnelo) (procedure code J0491) and Belimumab (Benlysta) (procedure code J0490) are benefits of Texas Medicaid for clients with prior authorization.

Anifrolumab-fnia (Saphnelo) is indicated to treat moderate to severe systemic lupus erythematosus (SLE) in adult clients who are receiving standard therapy.

Belimumab (Benlysta) is indicated to treat the following:

- Active, autoantibody-positive, systemic lupus erythematosus (SLE) in clients who are 5 years of age or older, and receiving standard therapy.
- Adult clients with active Lupus Nephritis who are receiving standard therapy.

6.80.1 Initial Requests

Initial therapy for anifrolumab-fnia (Saphnelo) may be approved for a 12-month duration if all the following criteria are met:

- The client is 18 years of age or older.
- The client has a confirmed diagnosis of systemic lupus erythematosus (M3210, M3211, M3212, M3213, M3214, M3215, M3219, M328, M329).
- The client does not have active lupus nephritis or severe active central nervous lupus.

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- The client is currently receiving at least one stable standard-of-care treatment for active systemic lupus erythematosus.
- The client is not receiving anifrolumab-fina (Saphnelo) in combination with a biologic agent.

Initial therapy for belimumab (Benlysta) may be approved for a 12-month duration if all the following criteria are met:

- Diagnosis of SLE:
  - The client is 5 years of age or older.
  - The client has a confirmed diagnosis of SLE (M320, M3210, M3211, M3212, M3213, M3214, M3215, M3219, M328, M329).
  - The client has laboratory testing confirming the presence of autoantibodies.
  - The client is currently receiving at least one standard-of-care treatment for active SLE.
  - The client is not receiving belimumab (Benlysta) in combination with a biologic disease-modifying antirheumatic drug (DMARD) agent.
- Diagnosis of active lupus nephritis:
  - The client is 18 years of age or older.
  - The adult client has a confirmed diagnosis of active lupus nephritis.
  - The client has laboratory testing confirming the presence of autoantibodies.
  - The client is currently receiving at least one standard-of-care treatment.
  - The client is not receiving belimumab (Benlysta) in combination with a biologic DMARD agent.

6.80.2 Recertification or Extension

For renewal or continuation therapy for anifrolumab-fnia (Saphnelo), the client must meet the following criteria:

- The client continues to meet the initial authorization approval criteria.
- The client has experienced a positive clinical response to therapy as demonstrated by stabilization of the disease or absence of disease progression.
- The client has not experienced any complications or unacceptable toxicities during anifrolumab-fnia (Saphnelo) treatment.

For renewal or continuation therapy for belimumab (Benlysta), the client must meet the following criteria:

- The client continues to meet the initial authorization approval criteria.
- The client has experienced a positive clinical response to therapy as demonstrated by stabilization of the disease or absence of disease progression.
- The client has not experienced any complications or unacceptable toxicities during belimumab (Benlysta) treatment.

6.81 Luspatercept-aamt (Reblozyl)

Luspatercept-aamt (Reblozyl) (procedure code J0896) is a benefit of Texas Medicaid with prior authorization.

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Luspatercept-aamt (Reblozyl) is restricted to clients who are 18 years of age or older, and may be approved for treatment of the following:

- Anemia in adult clients with beta thalassemia requiring red blood cell (RBC) transfusions
- Anemia failing an erythropoiesis stimulating agent and requiring two or more red blood cell units over eight weeks in adult clients with low to intermediate-risk myelodysplastic syndrome with ring sideroblasts (MDS-RS) or with myelodysplastic/myeloproliferative neoplasm with ring sideroblasts and thrombocytosis (MDS/MPN-RS-T)

6.81.1 Prior Authorization for Luspatercept-aamt (Reblozyl)

Prior authorization requests for procedure code J0896 must be submitted with a Special Medical Prior Authorization (SMPA) Request Form.

For initial prior authorization requests for Luspatercept-aamt (Reblozyl), the client must be 18 years of age or older and meet the following criteria:

- Client who has anemia with beta thalassemia requiring regular RBC transfusions:
  - The client must have a diagnosis of beta thalassemia.
  - The client requires regular RBC transfusions of six or more units within the previous 24 weeks and has had no transfusion-free period for 35 days or longer during the review period.
- Client who has anemia failing an erythropoiesis stimulating agent:
  - The client must have a diagnosis of myelodysplastic syndrome classified as low to intermediate risk disease.
  - The client must require RBC transfusions of two or more units over a period of eight weeks.
  - The client must be ineligible or must have failed prior erythropoietin stimulating agent treatment.

For renewal or continuation of therapy, the client must meet the initial age and diagnosis criteria, in addition to the following requirements:

- Client who has anemia with beta thalassemia requiring regular RBC transfusions:
  - The client had a positive response/hematological improvement demonstrated by a reduction in RBC transfusion as indicated by the prescribing physician.
  - The client previously received treatment with luspatercept-aamt (Reblozyl) without complications.
- Client who has anemia failing an erythropoiesis stimulating agent:
  - The client had a positive response demonstrated by RBC transfusion independence during any consecutive eight-week period or a decrease in transfusion requirement as indicated by the prescribing physician.
  - The client previously received treatment with luspatercept-aamt (Reblozyl) without complications.

6.82 Medroxyprogesterone Acetate (Depo Provera)

Refer to: The *Gynecological, Obstetrics, and Family Planning Title XIX Services Handbook* (*Vol. 2, Provider Handbooks*) for information about procedure code J1050.

6.83 Meloxicam (Anjeso)

Meloxicam (procedure code J1738) is a benefit of Texas Medicaid for clients who are 18 years of age or older.

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6.84 Methotrexate

Methotrexate (Jylamvo) (procedure code J8611) is a benefit of Texas Medicaid for clients who are 18 years of age or older.

Methotrexate (Xatmep) (procedure code J8612) is a benefit of Texas Medicaid for clients who are 18 years of age or younger.

6.85 Mirikizumab-mrkz

Mirikizumab-mrkz (procedure code J2267) is a benefit of Texas Medicaid for clients who are 18 years of age or older and is restricted to the following diagnosis codes:

Diagnosis Codes							
K5100	K51011	K51012	K51013	K51014	K51018	K51019	K5120
K51211	K51212	K51213	K51214	K51218	K51219	K5130	K51311
K51312	K51313	K51314	K51318	K51319	K5180	K51811	K51812
K51813	K51814	K51818	K51819	K5190	K51911	K51912	K51913
K51914	K51918	K51919					

6.86 Mirvetuximab Soravtansine-gynx (Elahere)

Mirvetuximab Soravtansine-gynx (Elahere) (procedure code J9063) is a benefit of Texas Medicaid for clients who are 18 years of age or older.

6.87 Mogamulizumab-kpkc (Poteligeo)

Mogamulizumab-kpkc (Poteligeo) procedure code J9204 is a benefit of Texas Medicaid. Mogamulizumab-kpkc (Poteligeo) is a CCR4-directed monoclonal antibody indicated for the treatment of an adult client with relapsed or refractory mycosis fungoides or Sézary syndrome after at least one prior systemic therapy.

Mogamulizumab-kpkc (Poteligeo) (procedure code J9204) may be approved for a duration of every 12 months.

6.87.1 Prior Authorization Criteria

Prior authorization for initial therapy using mogamulizumab-kpkc (Poteligeo) infusion will be considered when all of the following criteria are met:

- The client is 18 years of age or older
- The client has relapsed or refractory disease
- The client has received at least one prior systemic therapy
- The client has a histologically confirmed diagnosis of Mycosis fungoides or Sézary syndrome

One of the following diagnosis codes must be submitted with procedure code J9204 if the diagnosis is mycosis fungoides:

Diagnosis Codes for Mycosis Fungoides							
C8400	C8401	C8402	C8403	C8404	C8405	C8406	C8407
C8408	C8409						

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One of the following diagnosis codes must be submitted with procedure code J9204 if the diagnosis is sézary syndrome:

Diagnosis for Sézary Syndrome							
C8410	C8411	C8412	C8413	C8414	C8415	C8416	C8417
C8418	C8419						

For renewal or continuation of therapy, the client must meet all the following requirements:

- The client demonstrates partial or complete response to treatment or stabilization of disease, shown by a decrease in spread or size of the tumor
- The absence of unacceptable drug toxicity, such as dermatological toxicity, severe infection, infusion reactions (Stevens-Johnson Syndrome or toxic epidermal necrolysis), and life-threatening autoimmune complications

Refer to: Subsection 2.1.2, "Prior Authorization Requests" in this handbook for additional prior authorization information.

6.88 Monoclonal Antibodies

Monoclonal antibodies omalizumab (Xolair) (procedure code J2357), benralizumab (Fasenra) (procedure code J0517), mepolizumab (Nucala) (procedure code J2182), reslizumab (Cinqair) (procedure code J2786), tezepelumab-ekko (Tezspire) (procedure code J2356), or depemokimab-ulaa (Exdensur) (procedure code J2361) are benefits of Texas Medicaid when medically necessary with prior authorization. Clients who are younger than the FDA-approved age indicated for each medication will be considered on a case-by-case basis and determined by the TMHP medical director.

6.88.1 Omalizumab (Xolair)

Omalizumab (Xolair) (procedure code J2357) is an injectable drug that is FDA-approved for the following treatments:

- Clients who are 6 years of age or older with moderate to severe persistent asthma (as defined by the National Heart, Lung, and Blood Institute's Guidelines for the Diagnosis and management of Asthma).
- Clients who are 12 years of age or older and have chronic spontaneous urticaria (CSU) who remain symptomatic despite H1 antihistamine treatment.
- Add-on maintenance treatment of chronic rhinosinusitis with nasal polyps (CRwNP) in adult clients who are 18 years of age or older with inadequate response to nasal corticosteroids.
- IgE-mediated food allergy in adult and pediatric clients who are 1 year of age or older for the reduction of allergic reactions (Type I), including anaphylaxis, that may occur with accidental exposure to one or more foods.

6.88.2 Benralizumab (Fasenra)

Benralizumab (Fasenra) (procedure code J0517) is an injectable drug that is FDA-approved and indicated for the following treatment:

- Add-on maintenance treatment of clients who are 6 years of age or older and have severe asthma with an eosinophilic phenotype
- Adult clients who are 18 years of age or older with eosinophilic granulomatosis with polyangiitis (EGPA)
- Adult and pediatric clients who are 12 years of age or older with hypereosinophilic syndrome (HES) without an identifiable non-hematologic secondary cause.

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6.88.3 Mepolizumab (Nucala)

Mepolizumab (Nucala) (procedure code J2182) is an injectable drug that is approved by the FDA and indicated for the following treatments:

- Add-on maintenance treatments for clients who are 6 years of age or older and have severe asthma with an eosinophilic phenotype
- Adult clients who are 18 years of age or older with eosinophilic granulomatosis with polyangiitis (EGPA)
- Adult and pediatric clients who are 12 years of age or older with hypereosinophilic symptoms (HES) for 6 months or longer without identifiable non-hematologic secondary cause
- Add-on maintenance treatment of chronic rhinosinusitis with nasal polyps (CRSwNP) in adult clients who are 18 years of age or older with inadequate response to nasal corticosteroids
- Add-on maintenance treatment for adult clients who are 18 years of age or older with inadequately controlled chronic obstructive pulmonary disease (COPD) and an eosinophilic phenotype

6.88.4 Reslizumab (Cinqair)

Reslizumab (Cinqair) (procedure code J2786) is an injectable drug that is FDA-approved and indicated for the treatment of clients who are 18 years of age or older and have severe asthma (as defined by the National Heart, Lung, and Blood Institute's Guidelines for the Diagnosis and Management of Asthma) with an eosinophilic phenotype.

6.88.5 Tezepelumab-ekko (Tezspire)

Tezepelumab-ekko (Tezspire) (procedure code J2356) is an injection drug that is FDA-approved and indicated as an add-on maintenance treatment of adult and pediatric clients who are 12 years of age or older with severe asthma or inadequately controlled chronic rhinosinusitis with nasal polyps (CRSwNP).

6.88.6 Depemokimab-ulaa (Exdensur)

Depemokimab-ulaa (Exdensur) (procedure code J2361) is a subcutaneous injection that is FDA-approved and indicated as an add-on maintenance treatment of severe asthma characterized by an eosinophilic phenotype in adult and pediatric clients who are 12 years of age or older.

6.88.7 Prior Authorization for Omalizumab, Benralizumab, Mepolizumab, Reslizumab, Tezepelumab-ekko, and Depemokimab-ulaa

Prior authorization for omalizumab (Xolair) will be considered for the following:

- Moderate to severe persistent asthma
  - Client is 6 years of age or older.
  - Client has a diagnosis of moderate to severe asthma (as defined by the National Heart, Lung, and Blood Institute's Guidelines for the Diagnosis and management of Asthma) (diagnosis code J4540 or J4550).
  - Client has a positive skin test or radioabsorbent assay test (RAST) to a perennial (not seasonal) aeroallergen within the past 36 months.
  - Client has a total IgE level greater than 30 IU/ml but less than 1300 IU/ml within the past 12 months.
- Chronic Spontaneous Urticaria (CSU)
  - Client is 12 years of age or older

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    - Client has a diagnosis of CSU with symptomats despite H1 antihistamine treatment (diagnosis code L501).
    - Documentation supporting medical necessity for the treatment of CSU with omalizumab (Xolair) must be submitted with request and include the following:
        - Documented failure of, or contraindication to, antihistamine
        - Evidence of an evaluation that excludes other medical diagnosis associated with chronic urticaria
- Add-on maintenance treatment of chronic rhinosinusitis with nasal polyps (CRwNP)
    - Client is 18 years of age or older
    - Client has a diagnosis of CRwNP (diagnosis code J330, J331, J338, or J339) with inadequate response to nasal corticosteroids
    - Documentation supporting medical necessity for maintenance treatment of nasal polyps with omalizumab (Xolair) must be submitted with the request and include the following:
        - Client has bilateral nasal polyposis confirmed by physical examination or nasal endoscopy
        - Documented failure of, or contraindication to, prior corticosteroids as monotherapy
        - Documented inadequate response to prior corticosteroid treatments
- IgE-mediated food allergy to reduce allergic reactions (Type I)
    - Client has a diagnosis of IgE-mediated food allergy (diagnosis code Z91010, Z910110, Z910111, Z910112, Z910120, Z910121, Z910122, Z91013, or Z91018)
    - Client is 1 year of age or older
    - Must use drug in conjunction with food allergen avoidance

Prior authorization for benralizumab (Fasenra) will be considered for the following:

- Severe asthma with eosinophilic phenotype
    - Client is 6 years of age or older
    - Client has a diagnosis of severe asthma with eosinophilic phenotype (as defined by the National Heart, Lung, and Blood Institute's Guidelines for the Diagnosis and Management of Asthma) (diagnosis code J4550, J4551, J4552, or J8283)
- Eosinophilic Granulomatosis with Polyangiitis (EGPA)
    - Client is 18 years of age or older
    - Client has a medical history of asthma
    - Client has a diagnosis of EGPA (diagnosis code M301)
    - Client has a refractory disease or has had a history of EGPA relapse
- Hypereosinophilic Symptoms (HES)
    - Client is 12 years of age or older
    - Client has a diagnosis of HES without identifiable non-hematologic secondary cause (diagnosis code D72110, D72111, D72118, or D72119)
    - Documents supporting medical necessity for treatment of benralizumab must be submitted with the request and meet the following:
        - Diagnosis or sign, and symptoms of HES without any non-hematologic secondary cause

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- History of two or more HES flares (flare defined as worsening clinical symptoms or blood eosinophil counts requiring an increase in prior therapy) within the past 12 months prior to the initiation of benralizumab therapy
- Prescriber's attestation that the client has been on a stable dose of HES therapy which includes, but is not limited to, oral corticosteroids, immunosuppressive and cytotoxic therapy.

Prior authorization for mepolizumab (Nucala) will be considered for the following:

- Severe asthma with eosinophilic phenotype
  - Client is 6 years of age or older
  - Client has a diagnosis of severe asthma with eosinophilic phenotype (as defined by the National Heart, Lung, and Blood Institute's Guidelines for the Diagnosis and management of Asthma) (diagnosis code J4550, J4551, J4552, or J8283).
- Eosinophilic granulomatosis with polyangiitis (EGPA)
  - Client is 18 years of age or older
  - Confirmed diagnosis of eosinophilic granulomatosis with polyangiitis (diagnosis code M301)
  - Documentation supporting medical necessity for treatment of EGPA with mepolizumab (Nucala) must be submitted with the requestand meet the following:
    - Diagnosis of EGPA
    - Medical history of asthma
    - Presence of at least 2 of the following EGPA characteristics below:
      - Histopathological findings of eosinophilic vascularitis, perivascularitis eosinophilic infiltration or eosinophil-rich granulomatous inflammation
      - Neuropathy
      - Pulmonary infiltrates, non-fixed; Sino-nasal abnormality
      - Cardiomyopathy
      - Glomerulonephritis
      - Alveolar hemorrhage
      - Palpable purpura
      - Anti-neutrophils cytoplasmic antibody
    - Client use of an oral glucocorticoid and/or cyclophosphamide, azathioprine, methotrexate, or leflunomide
    - Refractory disease or has had a history of EGPA relapse
- Hypereosinophilic Symptoms (HES)
  - Client is 12 years of age or older
  - Client has a diagnosis of hypereosinophilic symptoms (HES) for 6 months or longer without identifiable non-hematologic secondary cause (diagnosis code D72110, D72111, D72118, or D72119)

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- Documents supporting medical necessity for treatment of HES in clients who are 12 years of age or older with mepolizumab (Nucala) must be submitted with the request and meet all of the following:
  - Diagnosis of HES for 6 months or longer without any non-hematologic secondary cause
  - History of two or more HES flares (flare defined as worsening clinical symptoms or blood eosinophil counts requiring an increase in prior therapy) within the past 12 months prior to the initiation of mepolizumab (Nucala) therapy
  - Prescriber's attestation that client has been on a stable dose of HES therapy which includes, but no limited to corticosteroids, immunosuppressive and cytotoxic therapy

Prior authorization for mepolizumab (Nucala) will be considered for clients as an add-on maintenance treatment of:

- Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)
  - Client is 18 years of age or older
  - Confirmed diagnosis of chronic rhinosinusitis with nasal polyps (diagnosis code J330, J331, J338, or J339)
  - Evidence of inadequate response to nasal corticosteroid
- Eosinophilic Chronic Obstructive Pulmonary Disease (COPD)
  - The client is 18 years of age or older.
  - The client has a diagnosis of inadequately controlled COPD (diagnosis codes J440, J441, J4489, or J449), confirmed by either spirometry or classic signs and symptoms.
  - The client's COPD is uncontrolled despite treatment with triple therapy, which includes an inhaled corticosteroid (ICS), long-acting beta agonist (LABA), and long-acting muscarinic antagonist (LAMA).
  - The client's inadequately controlled COPD is demonstrated by one or both of the following within the previous year:
    - At least two moderate exacerbations despite treatment with triple inhaled therapy.
    - One or more severe exacerbations despite treatment with triple inhaled therapy.
  - The client has an eosinophilic phenotype defined by a baseline blood eosinophil level of at least ≥ 150 cells per microliter prior to treatment with mepolizumab (Nucala).

Mepolizumab (Nucala) will be used as an add-on maintenance therapy and not as the primary treatment for COPD.

Prior authorization for reslizumab (Cinqair®) will be considered for clients who are 18 years of age or older with severe asthma (as defined by the National Heart, Lung and Blood Institute's Guidelines for the Diagnosis and management of Asthma) (diagnosis code J4550, J4551, J4552, or J8283).

Prior authorization for tezepelumab-ekko (Tezspire) will be considered for the following:

- Add-on maintenance for severe asthma or chronic rhinosinusitis with nasal polyps
  - Client is 12 years of age or older.
  - Client has one of the following diagnoses:
    - Severe asthma (as defined by the National Heart, Lung, and Blood Institute's Guidelines for the Diagnosis and Management of Asthma) (diagnosis code J4550 or J4551)
    - Chronic rhinosinusitis with nasal polyps (diagnosis code J330, J331, J338, or J339)

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- Tezepelumab-ekko (Tezspire) is being used as an add-on maintenance therapy and not to be used as a single or primary therapy.
- For severe asthma client is currently on the following as a regular treatment and compliant on the therapy:
  - Medium or high-dose inhaled corticosteroid therapy, and
  - An additional asthma controller
- Tezepelumab-ekko (Tezspire) should not be used for relief of acute bronchospasm or status asthmaticus.
- Tezepelumab-ekko (Tezspire) may not be used in combination with anti-IgE, anti-IL4 or anti-IL5 monoclonal antibody agents (i.e., benralizumab [Fasenra], omalizumab [Xolair], mepolizumab [Nucala], reslizumab [Cinqair], etc.)
- Tezepelumab-ekko (Tezspire) should not be administered concurrently with live attenuated vaccination.

Prior authorization for depemokimab-ulaa (Exdensur) will be considered when the following criteria are met:

- The client is 12 years of age or older.
- The client has a diagnosis of severe asthma (as defined by the National Heart, Lung, and Blood Institute's Guidelines for the Diagnosis and Management of Asthma) (diagnosis code J4550, J4551, or J8283).
- The client's asthma is characterized by an eosinophilic phenotype with baseline blood eosinophilic count of at least 150 cells/microliter or greater.
- The client has asthma that is uncontrolled before administration of depemokimab-ulaa (Exdensur) as add-on treatment.
- The client has adhered to at least three consecutive months of inhaled corticosteroid therapy and used at least one additional asthma controller or asthma maintenance medication.
- The client's asthma is inadequately controlled despite the use of controller therapy, i.e., medium- to high-dose inhaled corticosteroid (ICS) plus at least one asthma controller with or without maintenance oral corticosteroids (OCS), indicated by either of the following within the previous year:
  - At least two or more asthma exacerbations that required treatment with systemic corticosteroids (SCS)
  - Reduced lung function with forced expiratory volume in one second (FEV1) that was less than 80% of predicted
- Depemokimab-ulaa (Exdensur) will be used as an add-on maintenance therapy to the client's medication for asthma and may not be used as a single or primary therapy.
- Depemokimab-ulaa (Exdensur) may not be used in combination with anti-IgE, anti-IL4 or anti-IL5 monoclonal antibody agents (i.e., omalizumab (Xolair), benralizumab (Fasenra), mepolizumab (Nucala), reslizumab (Cinqair), etc.).

A client with preexisting helminth infections should be treated prior to receiving omalizumab (Xolair), benralizumab (Fasenra), mepolizumab (Nucala), reslizumab (Cinqair), tezepelumab-ekko (Tezspire), or depemokimab-ulaa (Exdensur) therapy.

- If there is active helminth infection, the client should be treated with anti-helminth treatment.
- If there is no response, treatment should be discontinued until the parasitic infection resolves.

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Refer to: Subsection 2.1.2, "Prior Authorization Requests" in this handbook for additional prior authorization information.

6.88.8 Prior Authorization Criteria for Asthma — Moderate to Severe (Omalizumab) and Severe (Benralizumab, Mepolizumab, Reslizumab, Tezepelumab-ekko, and Depemokimab-ulaa)

Requests for prior authorization must be submitted by the treating physician to the Special Medical Prior Authorization (SMPA) department by mail or approved electronic method using the SMPA request form.

Documentation supporting medical necessity for treatment of asthma with omalizumab (Xolair), benralizumab (Fasenra), mepolizumab (Nucala), reslizumab (Cinqair), tezepelumab-ekko (Tezspire), or depemokimab-ulaa (Exdensur) must be submitted with the request and must indicate the following:

- Symptoms are inadequately controlled with use of any of the following combination therapies:
    - A minimum of 3 months of controller medication (which includes but is not limited to a long-acting beta2-agonist [LABA], an inhaled or oral corticosteroid, leukotriene receptor antagonist [LTRA], or theophylline), unless the individual is intolerant of or has a medical contraindication to these agents

Note: *Exceptions to the criteria above will be considered on a case-by-case basis, which will require a letter from the prescribing provider stating the medical necessity for these monoclonal antibodies, the client's asthma severity level, and the duration of current and past therapies and lack of asthma control. Consideration for these exceptions will be reviewed by the TMHP medical director.*

Prior authorization approvals for omalizumab (Xolair), benralizumab (Fasenra), mepolizumab (Nucala), reslizumab (Cinqair), or tezepelumab-ekko (Tezspire) are for intervals of six months at a time. Prior authorization approvals for Depemokimab-ulaa (Exdensur) are for intervals of 12 months. Clients must be compliant with their regimen in order to qualify for additional prior authorizations. The provider must submit a statement documenting compliance with the requests for each renewal.

Treatment of benralizumab (Fasenra), mepolizumab (Nucala), or reslizumab (Cinqair) may not be used concurrently with omalizumab (Xolair) or any other interleukin-5 antagonist.

Tezepelumab-ekko (Tezspire) may not be used in combination with anti-IgE, anti-IL4 or anti-IL5 monoclonal antibody agents (i.e., benralizumab [Fasenra], omalizumab [Xolair], mepolizumab [Nucala], reslizumab [Cinqair], dupilumab [Dupixent], depemokimab-ulaa [Exdensur], etc.).

6.88.9 Requirements for Continuation of Therapy for Omalizumab, Benralizumab, Mepolizumab, Reslizumab, Tezepelumab-ekko, or Depemokimab-ulaa

For continuation of therapy with omalizumab (Xolair), benralizumab (Fasenra), mepolizumab (Nucala), reslizumab (Cinqair), tezepelumab-ekko (Tezspire), or depemokimab-ulaa (Exdensur), the requesting provider must submit the following documentation of the client's compliance and satisfactory clinical response to omalizumab (Xolair), benralizumab (Fasenra), mepolizumab (Nucala), reslizumab (Cinqair), tezepelumab-ekko (Tezspire), or depemokimab-ulaa (Exdensur):

- Documentation of clinical improvement must include one or more of the following:
- Decreased utilization of rescue medications; or
- Increase in predicted FEV1 (forced expiratory volume) from pretreatment baseline; or
- Reduction in reported asthma-related symptoms, as evidenced by decreases in frequency or magnitude of one or more of the following symptoms:
    - Asthma attacks

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- Chest tightness or heaviness
- Coughing or clearing throat
- Difficulty taking deep breath or difficulty breathing out
- Shortness of breath
- Sleep disturbance, night wakening, or symptoms upon awakening
- Tiredness
- Wheezing/heavy breathing/fighting for air, and

- Member has not exhibited symptoms of hypersensitivity or anaphylaxis (bronchospasm, hypotension, syncope, urticaria, and/or angioedema) after administration of omalizumab (Xolair), benralizumab (Fasenra), mepolizumab (Nucala), reslizumab (Cinqair), tezepelumab-ekko (Tezspire), or depemokimab-ulaa (Exdensur).

After lapses in treatment of 3 months or greater, prior authorization requests submitted with documentation will be reviewed by the TMHP medical director.

Requests for clients who do not meet the above criteria will be reviewed for medical necessity by the TMHP medical director.

6.88.10 Reimbursement

Procedure codes J0517, J2182, J2356, J2357, J2361, and J2786 may not be billed in any combination for the same date of service by any provider.

Providers may not bill for an office visit if the only reason for the visit is an omalizumab (Xolair), benralizumab (Fasenra), mepolizumab (Nucala), reslizumab (Cinqair), tezepelumab-ekko (Tezspire), or depemokimab-ulaa (Exdensur) injection.

6.89 Mosunetuzumab-axgb

Mosunetuzumab-axgb (procedure code J9350) is a benefit of Texas Medicaid for clients who are 18 years of age or older.

6.90 Nadofaragene Firadenovec-vncg (Adstiladrin)

Nadofaragene firadenovec-vncg (Adstiladrin) is an adenoviral vector-based gene therapy indicated to treat adult clients with high-risk Bacillus Calmette-Guérin (BCG)-unresponsive non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) with or without papillary tumors.

Nadofaragene firadenovec-vncg (Adstiladrin) (procedure code J9029) is a benefit of Texas Medicaid for clients who are 18 years of age or older with prior authorization.

6.90.1 Prior Authorization Requirements

Prior authorization is required for nadofaragene firadenovec-vncg (Adstiladrin) therapy and must be submitted with a Special Medical Prior Authorization (SMPA) Request Form.

Initial therapy for nadofaragene firadenovec-vncg (Adstiladrin) may be approved for a 6-month duration for clients who meet the following requirements:

- The client is 18 years of age or older.
- The client has a confirmed diagnosis of non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) with or without papillary tumors.
- The client's disease is high-risk and BCG unresponsive as defined as persistent disease following adequate BCG therapy, disease recurrence after an initial tumor-free state following adequate BCG therapy, or T1 disease following a single induction course of BCG.

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- The client does not have any metastatic urothelial carcinoma.
- The client does not have a hypersensitivity to interferon alfa.
- The client is not immunocompromised or immunodeficient.

For renewal or continuation of therapy, the client continues to meet the requirements listed above and must:

- Have been treated with nadofaragene firadenovec-vncg (Adstiladrin) with no adverse reactions.
- Have no signs of unacceptable toxicity (e.g., risk of disseminated adenovirus infection) while on treatment with nadofaragene firadenovec-vncg (Adstiladrin).

All services outlined in this section are subject to retrospective review to ensure that the documentation in the client's medical record supports the medical necessity of the service(s) provided.

Refer to: Subsection 2.1.2, "Prior Authorization Requests" in this handbook for additional prior authorization information.

Subsection 5.5.1.2, "Document Requirements and Retention" in "Section 5: Fee-for-Service Prior Authorizations" (*Vol. 1, General Information*) for additional information about electronic signatures.

6.91 Natalizumab

Procedure code J2323 is a benefit when billed with one of the following diagnosis codes:

Diagnosis Codes							
G35A	G35C0	G35D	G35C1	K5000	K50011	K50012	K50013
K50014	K50018	K5010	K50111	K50112	K50113	K50114	K50118
K5080	K50811	K50812	K50813	K50814	K50818	K5090	K50911
K50912	K50913	K50914	K50918	K50919			

6.92 Nitroglycerin

Nitroglycerin (procedure code J2305) is a benefit of Texas Medicaid for clients who are 18 years of age or older.

6.93 Nivolumab and Relatlimab-rmbw

Nivolumab and relatlimab-rmbw (procedure code J9298) is a benefit of Texas Medicaid for clients who are 12 years of age or older.

6.94 Nogapendekin Alfa Inbakicept-pmln (Anktiva)

Nogapendekin alfa inbakicept-pmln (Anktiva) is an interleukin-15 (IL-15) receptor agonist indicated to treat adult clients with Bacillus Calmette-Guérin (BCG)-unresponsive non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) with or without papillary tumors.

Nogapendekin alfa inbakicept-pmln (Anktiva) is a benefit of Texas Medicaid (procedure code J9028) for adult clients with prior authorization.

6.94.1 Initial Requests

Initial therapy for nogapendekin alfa inbakicept-pmln (Anktiva) may be approved for a 6-month duration for clients who meet the following requirements:

- The client is at least 18 years of age or older.

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- The client has a confirmed diagnosis of NMIBC with CIS with or without papillary tumors.
- The client's disease is high-risk and BCG unresponsive, defined as persistent disease following adequate BCG therapy, disease recurrence after an initial tumor-free state following adequate BCG therapy, or T1 disease following a single induction course of BCG.
- Nogapendekin alfa inbakicept-pmln (Anktiva) is used in combination with BCG.
- The client has undergone transurethral resection of bladder tumor (TURBT) to remove all resectable disease (Ta and T1 components).
- The client does not have any metastatic urothelial carcinoma.

6.94.2 Recertification or Extension

For renewal or continuation of therapy of nogapendekin alfa inbakicept-pmln (Anktiva), the client must meet the following requirements:

- The client continues to have a diagnosis as listed in the initial authorization section above and has been treated with nogapendekin alfa inbakicept-pmln (Anktiva) in the past with no adverse reactions.
- The client has no signs of unacceptable toxicity (e.g., hematuria, dysuria, or micturition urgency) while on treatment with nogapendekin alfa inbakicept-pmln (Anktiva).

All services outlined in this section are subject to retrospective review to ensure that the documentation in the client's medical record supports the medical necessity of the service(s) provided.

6.95 * Omidubicel-onlv (Omisirge)

Omidubicel-onlv (Omisirge) is a nicotinamide modified allogeneic hematopoietic progenitor cell therapy derived from cord blood and indicated for the following:

- Hematologic malignancies in clients who are 12 years of age or older and are scheduled for umbilical cord blood transplantation (UCBT) following myeloablative conditioning to reduce the time to neutrophil recovery and the risk of developing infection.
- Severe aplastic anemia (SAA) in clients who are 6 years of age or older, following reduced intensity conditioning.

[Revised] Omidubicel-onlv (Omisirge) is a benefit of Texas Medicaid with prior authorization and may be reimbursed using procedure code J3406.

Omidubicel-onlv (Omisirge) is administered as a one-time infusion treatment per lifetime.

6.95.1 Prior Authorization Requirements

Providers must submit prior authorization requests for omidubicel-onlv (Omisirge) on the Special Medical Prior Authorization (SMPA) Request Form.

Prior authorization for omidubicel-onlv (Omisirge) may be approved for 12 months for clients who have one of the following diagnoses:

- Hematologic malignancies in clients who meet all the following criteria:
  - The client is 12 years of age or older.
  - The client has a confirmed diagnosis of a high-risk hematologic malignancy and is scheduled for UCBT after undergoing a myeloablative conditioning regimen such as radiation and chemotherapy (diagnosis code D701, D708, D709, or Z9481).
  - The client is receiving therapy to reduce the time to neutrophil recovery and the risk of developing infection.

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- The client does not have a matched related or unrelated donor for allogeneic hematopoietic stem cell transplantation (HSCT).
- The client does not have a history of receiving prior allogeneic HSCT.

- SAA in clients who meet all the following criteria:
  - The client is 6 years of age or older.
  - The client has a confirmed diagnosis of SAA following a reduced intensity conditioning regimen (diagnosis code D611, D612, D6189, or D619).
  - The client has a history of intolerance or failure to respond to immunosuppressive therapy.
  - The client does not have a matched related or unrelated donor.

Note: *Regardless of the diagnosis, the client does not have known sensitivity to dimethyl sulfoxide (DMSO), Dextran 40, gentamicin, human serum albumin, or bovine material.*

After omidubicel-onlv (Omisirge) infusion, providers must monitor the client for the following:

- Allergic reactions, particularly in clients with a history of allergic reactions to antibiotics
- Graft failure
- Graft-versus-host disease
- Engraftment syndrome
- Infections
- Secondary malignancies
- Other post-transplant complications

In addition to documentation requirements outlined in this section, all services are subject to retrospective review to ensure that the documentation in the client's medical record supports the medical necessity of the service(s) provided.

6.96 Onasemnogene Abeparvovec-brve (Itvisma)

Onasemnogene abeparvovec-brve (Itvisma) is an adeno-associated virus (AAV) vector-based gene therapy indicated for the treatment of spinal muscular atrophy (SMA) in adult and pediatric clients who are 2 years of age or older with confirmed mutation in the survivor motor neuron 1 (SMN1) gene.

Onasemnogene abeparvovec-brve (Itvisma) is a benefit of Texas Medicaid with prior authorization.

Onasemnogene abeparvovec-brve (Itvisma) (procedure code J3405) is limited to once per lifetime.

Onasemnogene abeparvovec-brve (Itvisma) is not a benefit for clients with tracheostomy or invasive ventilator support.

6.96.1 Prior Authorization Requirements

Providers must submit prior authorization requests for onasemnogene abeparvovec-brve (Itvisma) on the Special Medical Prior Authorization (SMPA) Request Form.

A prior authorization request for onasemnogene abeparvovec-brve (Itvisma) single-dose intrathecal injection must include documentation of all the following:

- The client is 2 years of age or older.
- The client has a confirmed diagnosis of SMA (diagnosis code G120, G121, G1225, G128, or G129).
- An SMA diagnostic test has confirmed SMN1 deletion, or the client has documentation of a previous test that confirmed SMN1 deletion.

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- The client's medical record supports any one of the following mutations or deletions of genes in chromosome 5q:
  - Homozygous gene deletion of the SMN1 gene (e.g., absence of the SMN1 gene)
  - Homozygous mutation of the SMN1 gene (e.g., biallelic mutation of exon 7)
  - Compound heterozygous mutation in the SMN1 gene (e.g., deletion of SMN1 exon 7 [allele 1] and mutation of SMN1 [allele 2])
- The client has a baseline documentation of AAV serotype 9 (AAV9) antibody titer of 1:50 or lower as determined by enzyme-linked immunosorbent assay (ELISA) binding immunoassay.
- The client's overall baseline health status is stable, as evidenced by the following:
  - The client's complete blood count, liver function, and creatinine are within normal limits.
  - The client has no signs or symptoms of active infection.
- The prescriber attests to counseling female clients of childbearing age regarding the use of an effective method of contraception to prevent pregnancy during treatment and to refrain from egg donation for up to six months after dose administration of onasemnogene abeparvovecbrve (Itvisma) therapy.

Important: *Male clients should refrain from fathering a child or donating sperm for three months following therapy.*

- Physician attests that the client has not previously received onasemnogene abeparvovec-brve (Itvisma), onasemnogene abeparvovec-xioi (Zolgensma), or any other gene therapy for SMA.

If nusinersen (Spinraza) or risdiplam (Evrysdi) have been previously prescribed, the prescriber must provide documentation of one of the following prior to switching to onasemnogene abeparvovec-brve (Itvisma) therapy:

- The client's clinical deterioration (e.g., decreased physical function and motor skill/function test scores) while receiving nusinersen (Spinraza) or risdiplam (Evrysdi) therapy
- Discontinuation of nusinersen (Spinraza) or risdiplam (Evrysdi) therapy

6.96.1.1 Requirements for Safe Drug Administration

The administration of onasemnogene abeparvovec-brve (Itvisma) may cause acute serious liver injury or failure. To administer the drug, providers must:

- Examine the client's liver function using clinical examination and laboratory testing such as hepatic aminotransferases (aspartate aminotransferase [AST] and alanine aminotransferase [ALT]), total bilirubin, and prothrombin time prior to infusion of onasemnogene abeparvovec-brve (Itvisma).
- Administer a systemic corticosteroid before and after the infusion.
- Continue to monitor client's liver function for at least three months after the infusion.

6.96.1.2 Required Monitoring Parameters

After administering onasemnogene abeparvovec-brve (Itvisma) intrathecal injection, the prescriber must monitor the client for signs of the following:

- Hepatotoxicity
- Thrombocytopenia
- Peripheral sensory neuropathy
- Thrombotic microangiopathy

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- Elevated cardiac troponin I levels

In addition to documentation requirements outlined in this section, all services are subject to retrospective review to ensure that the documentation in the client's medical record supports the medical necessity of the service(s) provided.

6.97 Onasemnogene abeparvovec-xioi (Zolgensma)

Onasemnogene abeparvovec-xioi (Zolgensma) is a benefit of Texas Medicaid, with prior authorization. Claims for onasemnogene abeparvovec-xioi (Zolgensma) must be submitted with unlisted procedure code J3399.

Onasemnogene abeparvovec-xioi (Zolgensma) (procedure code J3399) is limited to one treatment per lifetime, per client.

Onasemnogene abeparvovec-xioi (Zolgensma) is a one-time infusion therapy indicated for the treatment of a client who meets all of the following requirements:

- Has spinal muscular atrophy (SMA)
- Has biallelic mutations in the survival motor neuron 1 (SMN1) gene
- Is 24 months of age or younger

Onasemnogene abeparvovec-xioi (Zolgensma) is not a benefit for clients with a tracheostomy or invasive ventilator support.

6.97.1 Prior Authorization Requirements

To be considered for the approval of a one-time intravenous infusion, prior authorization requests for onasemnogene abeparvovec-xioi (Zolgensma) (unlisted procedure code J3399) must be submitted with a Special Medical Prior Authorization (SMPA) Request Form.

All of the following must be included in Section C (located under Statement of Medical Necessity) of the Special Medical Prior Authorization (SMPA) Request Form:

- Documentation of the client's dosage
- Administration schedule
- Number of injections to be administered during the prior authorization period
- Requested units per injection
- Dosage calculation

The Special Medical Prior Authorization (SMPA) Request Form must be completed, signed, and dated by the prescribing provider. The completed form must be maintained by the prescribing provider in the client's medical record and is subject to retrospective review. The form will not be accepted beyond 90 days from the date of the prescribing provider's signature.

6.97.2 Documentation Requirements

The prior authorization request for an onasemnogene abeparvovec-xioi (Zolgensma) single-dose intravenous infusion must include documentation of all of the following:

- Client is 24 months of age or younger.
- Medical record supports any of the following mutation or deletion of genes in chromosome 5q:
  - Homozygous gene deletion of the SMN1 gene (e.g., absence of SMN1 gene)
  - Homozygous mutation of the SMN1 gene (e.g., biallelic mutation of exon 7)

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  - Compound heterozygous mutation in the SMN1 gene (e.g., deletion of SMN1 exon 7 [allele 1] and mutation of SMN1 [allele 2])
- Confirmed diagnosis of SMA (diagnosis codes G120, G121, G128, and G129) based on gene mutation analysis with biallelic SMN1 mutation (deletion or point mutation).
- The administration of onasemnogene abeparvovec-xioi (Zolgensma) may cause serious liver injury or failure. Providers must also complete the following to administer the drug:
  - Examine the client's liver function by clinical examination and laboratory testing (e.g., hepatic aminotransferases [aspartate aminotransferase (AST) and alanine aminotransferase (ALT)], total bilirubin, and prothrombin time) before infusion of onasemnogene abeparvovec-xioi (Zolgensma).
  - Administer a systemic corticosteroid before and after the administration of the drug.
  - Continue to monitor the client's liver function at least 3 months after the infusion of the drug.
- Evaluation of motor skill and function must be documented using a standardized test. However, it is not a prerequisite of therapy and should not delay treatment. Standardized testing tools that may be used to evaluate motor skill/function include, but are not limited to:
  - Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorder (CHOP-INTEND) score
  - Bayley scale of infant and toddler development screening test
  - WHO Multicenter Growth Reference Study (WHO MGRS)
- Baseline documentation supports an AAV9 antibody titer of 1:50 or lower, as determined by enzyme-linked immunosorbent assay (ELISA) binding immunoassay.
- Baseline platelet counts, and the provider must assess safety by continually checking weekly counts for the first month and then every other week for the second and third months until platelet counts return to baseline.

  Note: *In addition to the documentation requirements outlined in the Prior Authorization section, post-monitoring requirements like liver function tests and platelet counts must be part of the client's record and are subject to retrospective review.*
- Physician attestation supports that the client has not received prior onasemnogene abeparvovec-xioi (Zolgensma) therapy.

If nusinersen (Spinraza) (procedure code J2326) or risdiplam (Evrysdi) have been previously prescribed, the prescriber must provide documentation of one of the following before switching to onasemnogene abeparvovec-xioi (Zolgensma) therapy:

- Evidence of clinical deterioration (e.g., decreased physical function and motor skill/function test scores) while on nusinersen (Spinraza) or risdiplam (Evrysdi) therapy
- Prescriber's attestation that nusinersen (Spinraza) or risdiplam (Evrysdi) therapy has been discontinued

6.98 Panhematin

Panhematin (procedure code J1640) is a benefit of Texas Medicaid and is limited to diagnosis code E8021.

6.99 Pegcetacoplan (Syfovre)

Pegcetacoplan (Syfovre) (procedure code J2781) is a benefit of Texas Medicaid for clients who are 18 years of age or older.

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6.100 Phenylephrine Hydrochloride (Immphentiv)

Phenylephrine hydrochloride (Immphentiv) (procedure code J2373) is a benefit of Texas Medicaid for clients who are 18 years of age or older.

6.101 * Polyneuropathy of Hereditary Transthyretin-mediated (hATTR) Amyloidosis

[Revised] Eplontersen (Wainua), patisiran (Onpattro), and vutrisiran (Amvuttra) are benefits of Texas Medicaid with prior authorization for the treatment of the polyneuropathy of hereditary transthyretin-mediated (hATTR) amyloidosis in adult clients. Patisiran (Onpattro) and vutrisiran (Amvuttra) are transthyretin-directed small interfering ribonucleic acid (RNA), while eplontersen (Wainua) is an antisense oligonucleotide.

[Revised] Prior authorization requests for eplontersen (Wainua) (procedure code C9311), patisiran (Onpattro) (procedure code J0222), and vutrisiran (Amvuttra) (procedure code J0225) must be submitted with a Special Medical Prior Authorization (SMPA) Request Form and may be approved for 12 months per prior authorization request.

For initial therapy of patisiran (Onpattro), all of the following criteria must be met:

- The client is 18 years of age or older.
- The client has a diagnosis of hATTR amyloidosis (diagnosis code E851), supported by the following:
  - Transthyretin (TTR) mutation proven by genetic testing
  - [Revised] Clinical signs and symptoms of the disease (e.g., peripheral autonomic neuropathy, or motor disability)
- [Revised] The client will not receive patisiran (Onpattro) therapy in combination with other polyneuropathy hATTR amyloidosis therapies (e.g., eplontersen, inotersen, tafamidis, meglumine, or vutrisiran).
- The client has not had a liver transplant.

For initial therapy of vutrisiran (Amvuttra), all of the following criteria must be met:

- The client is 18 years of age or older
- The client has a diagnosis of hATTR amyloidosis (diagnosis code E851), supported by the following:
  - Transthyretin (TTR) mutation proven by genetic testing
  - [Revised] Clinical signs and symptoms of the disease (e.g., peripheral autonomic neuropathy, or motor disability)
- [Revised] The client will not receive vutrisiran (Amvuttra) therapy in combination with other therapies for polyneuropathy caused by hATTR amyloidosis (e.g., eplontersen, inotersen, patisiran, or tafamidis meglumine).
- The client will receive vitamin A supplementation at the recommended daily allowance while on vutrisiran (Amvuttra) therapy.
- The client has not had a liver transplant.

[Revised] For initial therapy of eplontersen (Wainua), all of the following criteria must be met:

- [Revised] The client must be 18 years of age or older.
- [Revised] The client has a diagnosis of polyneuropathy of hereditary transthyretin (hATTR) amyloidosis (diagnosis code E851), supported by the following:
  - [Revised] Transthyretin (TTR) mutation proven by genetic testing

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- [Revised] Clinical signs and symptoms of the disease (e.g., peripheral autonomic neuropathy, or motor disability)

- [Revised] The client will not receive eplontersen (Wainua) therapy in combination with other polyneuropathy hATTR amyloidosis therapies (e.g., inotersen, patisiran, vutrisiran, or tafamidis meglumine).
- [Revised] The client will receive vitamin A supplementation at the recommended daily allowance while on eplontersen (Wainua) therapy.

For renewal or continuation of therapy, all of the following criteria must be met:

- [Revised] The client has previously received treatment with eplontersen (Wainua), patisiran (Onpattro) or vutrisiran (Amvuttra) without an adverse reaction.
- [Revised] The client has a positive clinical response to eplontersen (Wainua), patisiran (Onpattro) or vutrisiran (Amvuttra) (e.g., improved neurologic impairment, improved motor function, or slowing of disease progression).

Documentation of the client's dosage, administration schedule, number of injections to be administered during the prior authorization period, requested units per injection, and the dosage calculation must be submitted in Section C of the Special Medical Prior Authorization (SMPA) Request Form under Statement of Medical Necessity.

Refer to: Subsection 2.1.2, "Prior Authorization Requests" in this handbook for additional prior authorization information.

6.102 Plasminogen Human-tvmh (Ryplazim)

Plasminogen human-tvmh (Ryplazim) (procedure code J2998) is a benefit of Texas Medicaid and is limited to diagnosis code E8802.

6.103 Plazomicin

Plazomicin (procedure code J0291) is a benefit of Texas Medicaid for clients who are 18 years of age or older.

6.104 Prademagene Zamikeracel (Zevaskyn)

Prademagene zamikeracel (Zevaskyn) (procedure code J3389) is a benefit of Texas Medicaid for clients with prior authorization.

Prademagene zamikeracel (Zevaskyn) is an autologous cell sheet-based gene therapy indicated to treat wounds in adult and pediatric clients with recessive dystrophic epidermolysis bullosa (RDEB).

6.104.1 Prior Authorization Requirements

6.104.1.1 Initial Requests

Prademagene zamikeracel (Zevaskyn) is indicated as a surgical topical application for treating wounds.

Prior authorization may be approved for 12 months for clients who:

- Are at least 6 years of age or older.
- Have a confirmed diagnosis of RDEB (diagnosis code Q812) that has been confirmed by biopsy and by genetic testing that detected biallelic mutations in the COL7A1 gene.
- Have chronic cutaneous stage 2 wounds that are adequate for treatment and:
  - Have been open/present for at least 6 months.
  - Have an area of ≥ 20 cm2.

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- Have not previously been treated with prademagene zamikeracel (Zevaskyn).
- Are not infected.

- Have a wound area that shows no current evidence or history of squamous cell carcinoma.
- Do not have severe hypersensitivity (i.e., anaphylaxis) to vancomycin or amikacin.

Authorization will not be approved for administration to wounds that have previously been treated with prademagene zamikeracel (Zevaskyn).

6.104.1.2 Recertification or Extension

For continued therapy, the client must meet the following requirements:

- Reauthorization for the same wound is not permitted. The client must meet the initial approval criteria if the request is for previously untreated or newly developed wounds.
- Absence of unacceptable toxicity from prademagene zamikeracel (Zevaskyn) (e.g., severe hypersensitivity reactions and development of new malignance).
- The client shows a positive response to treatment as defined by improvement (healing) of treated wound sites or reduction in skin infections.

6.104.2 Documentation Requirements

In addition to the documentation requirements outlined in this section, all services are subject to retrospective review to ensure that the documentation in the client's medical record supports the medical necessity of the services provided.

6.105 Ravulizumab-cwvz (Ultomiris)

Ravulizumab-cwvz (procedure code J1303) is a benefit of Texas Medicaid and is limited to the following diagnosis codes:

Diagnosis Codes							
D588	D5930	D5932	D5939	D594	D595	D598	G360
G7000	G7001						

6.106 Remestemcel-L-rknd (Ryoncil)

Remestemcel-L-rknd (Ryoncil) (procedure code J3402) is a benefit of Texas Medicaid with prior authorization.

Remestemcel-L-rknd (Ryoncil) is an allogeneic bone marrow-derived mesenchymal stromal cell (MSC) therapy approved to treat steroid-refractory acute graft versus host disease (SR-aGVHD) in pediatric clients who are 2 months of age or older.

6.106.1 Prior Authorization Requirements

6.106.1.1 Initial Requests

Remestemcel-L-rknd (Ryoncil) is an intravenous infusion which may be approved for clients who meet all of the following requirements:

- The client is at least 2 months of age or older.
- The client has a confirmed diagnosis of aGVHD (diagnosis code D89810) following an allogenic hematopoietic stem cell transplant.
- The client's aGVHD is steroid refractory, as documented by the following:

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- Progression of acute GVHD within three days of consecutive treatment with 2 mg/kg/day of methylprednisolone or equivalent.
- No signs of improvement within 7 days of therapy with 2mg/kg/day of methylprednisolone or equivalent treatment.

- The client has no known hypersensitivity to dimethyl sulfoxide or porcine and bovine proteins.

6.106.1.2 Re-certification or Extension

For renewal or continuation of therapy, the client must meet the following requirements:

- The client has received remestemcel-L-rknd (Ryoncil) for at least 28 days.
- The client has documentation of partial or mixed response to remestemcel-L-rknd (Ryoncil) treatment.
- The client is currently receiving or has received remestemcel-L-rknd (Ryoncil) without any serious or life-threatening reactions.

6.106.2 Documentation Requirements

In addition to documentation requirements outlined in this section, all services are subject to retrospective review to ensure that the documentation in the client's medical record supports the medical necessity of the service(s) provided.

6.107 Remimazolam

Remimazolam (procedure code J2249) is a benefit of Texas Medicaid for clients who are 18 years of age or older.

6.108 Retifanlimab-dlwr (Zynyz)

Retifanlimab-dlwr (procedure code J9345) is a benefit of Texas Medicaid for clients who are 18 years of age or older.

6.109 Revakinagene taroretcel-lwey (Encelto)

Revakinagene taroretcel-lwey (Encelto) (procedure code J3403) is a benefit of Texas Medicaid with prior authorization.

Revakinagene taroretcel-lwey (Encelto) is an allogeneic encapsulated cell-based gene therapy indicated for the treatment of adults with idiopathic macular telangiectasia type 2 (MacTel).

6.109.1 Prior Authorization Requirements

6.109.1.1 Initial Requests

Revakinagene taroretcel-lwey (Encelto) is administered as an intravitreal implantation under aseptic conditions and is indicated for clients who meet all the following requirements:

- The client is 18 years of age or older.
- The client has a confirmed diagnosis of retinal telangiectasis in at least one eye (diagnosis codes H35071, H35072, H35073, or H35079).
- The client has type 2 MacTel in at least one eye.
- The client does not have neovascular or proliferative MacTel.
- The client has no ocular and/or periocular infections.
- The client has no known hypersensitivity to endothelial serum-free media (Endo-SFM).

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- The client has temporarily discontinued any antithrombotic medication prior to revakinagene taroretcel-lwey (Encelto) insertion surgery.
- The client has not previously received revakinagene taroretcel-lwey (Encelto) insertion.

Prior authorization is limited to one revakinagene taroretcel-lwey (Encelto) treatment per eye per lifetime.

Clients must be monitored for signs and symptoms of vision loss, infectious endophthalmitis, and retinal tear or detachment.

6.109.1.2 Re-certification or Extension

Re-authorization of revakinagene taroretcel-lwey (Encelto) is not permitted for previously treated eyes.

If the request is for treatment of an eye that has not previously received an ocular implant, the client must meet the approval criteria listed in the prior authorization requirement section.

6.109.2 Documentation Requirements

In addition to documentation requirements outlined in this section, all services are subject to retrospective review to ensure that the documentation in the client's medical record supports the medical necessity of the service(s) provided.

6.110 Rilonacept (Arcalyst)

Rilonacept (procedure code J2793) is a benefit of Texas Medicaid for clients who are 12 years of age or older.

6.111 Risperidone

Risperidone (Perseris) (procedure code J2798) and (Uzedy) (procedure code J2799) are benefits of Texas Medicaid for clients who are 18 years of age or older.

6.112 Rituximab-Abbs, (Truxima)

Rituximab-abbs (Truxima) (procedure code Q5115) is a benefit of Texas Medicaid for clients who are 18 years of age or older.

6.113 Romosozumab

Romosozumab (procedure code J3111) is a benefit of Texas Medicaid for clients who are 18 years of age or older.

6.114 Ronzanolixizum-noli (Rystiggo)

Ronzanolixizum-noli (procedure code J9333) is a benefit of Texas Medicaid for clients who are 18 years of age or older and is restricted to diagnosis codes G7000 and G7001.

6.115 Sickle Cell Disease Gene Therapy

Exagamglogene autotemcel (Casgevy) is an autologous genome edited hematopoietic stem cell-based gene therapy indicated for the treatment of clients who are 12 years of age or older with one of the following:

- Sickle cell disease (SCD) with recurrent vaso-occlusive crises, or
- Transfusion-dependent ß-thalassemia

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Exagamglogene autotemcel (Casgevy) (procedure code J3392) and lovotibeglogene autotemcel (Lyfgenia) (procedure code J3394) are benefits of Texas Medicaid with prior authorization. Prior authorization is approved for a duration of 12 months.

Exagamglogene autotemcel (Casgevy) (procedure code J3392) is limited to one transfusion treatment per lifetime.

Lovotibeglogene autotemcel (Lyfgenia) is an autologous hematopoietic stem cell-based gene therapy indicated for the treatment of clients who are 12 years of age or older with sickle cell disease and a history of vaso-occlusive events with at least four vaso-occlusive events in the past 24 months or currently receiving chronic transfusion therapy for recurrent vaso-occlusive events.

Lovotibeglogene autotemcel lovotibeglogene autotemcel (Lyfgenia) (procedure code J3394) is limited to one transfusion treatment per lifetime.

6.115.1 Prior Authorization Requirements

Exagamglogene Autotemcel (Casgevy)

Prior authorization requests for exagamglogene autotemcel (Casgevy) and lovotibeglogene autotemcel (Lyfgenia) must be submitted using the Special Medical Prior Authorization (SMPA) Request Form.

Exagamglogene autotemcel (Casgevy) is a one-time infusion therapy indicated for the treatment of clients for whom autologous hematopoietic stem cell transplantation is appropriate and who meet all the following criteria:

- The client is 12 years of age or older and has been diagnosed with sickle cell disease.
- The client has a diagnosis of sickle cell disease as confirmed by genetic testing with recurrent vaso-occlusive crises, with at least two vaso-occlusive crisis events per year in the past 2 years, as documented with one of the following diagnosis codes or provider attestation:

Diagnosis Codes							
D5700	D5701	D5702	D5703	D5704	D5709	D571	D5720
D57211	D57212	D57213	D57214	D57218	D57219	D5740	D57411
D57412	D57413	D57414	D57418	D57419	D5742	D57431	D57432
D57433	D57434	D57438	D57439	D5744	D57451	D57452	D57453
D57454	D57458	D57459	D5780	D57811	D57812	D57813	D57814
D57818	D57819						

- The client has inadequate response to hydroxyurea or crizanlizumab.
- The client is 12 years of age or older and has been diagnosed with transfusion-dependent ß-thalassemia, and the following additional criteria must be met:
  - Genetic testing confirms the client's diagnosis of transfusion-dependent ß-thalassemia, as documented with diagnosis code D561 or D565.
  - The client has a history of requiring at least 100 mL/kg/year or ten units/year of red blood cell (RBC) transfusions in the past 24 months.
- The client has not previously received allogeneic or autologous hematopoietic stem cell transplantation.
- The client has not previously received exagamglogene autotemcel (Casgevy) or any other gene therapy.
- The client has a confirmed negative serum pregnancy test.
- The client does not have active HIV-1, HIV-2, HBV, or HCV.

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- The client does not have advanced liver or chronic kidney disease.
- For transfusion-dependent ß-thalassemia diagnosis, prescriber attestation will be required to discontinue iron chelators at least 7 days prior to initiation of myeloablative conditioning.

For diagnosis of sickle cell disease, the prescriber attestation is required for the following:

- Hydroxyurea is discontinued at least eight weeks before mobilization and conditioning.
- Crizanlizumab is discontinued at least eight weeks before mobilization or conditioning.
- Iron chelators are discontinued at least seven days before initiation of myeloablative conditioning.

Monitoring parameters for exagamglogene autotemcel (Casgevy) are as follows:

- Monitor for bleeding and conduct frequent platelet counts until platelet engraftment and platelet recovery are achieved.
- Monitor absolute neutrophil counts until engraftment has been achieved.

Lovotibeglogene autotemcel (Lyfgenia)

Lovotibeglogene autotemcel (Lyfgenia) is a one-time infusion therapy indicated for the treatment of clients for whom autologous hematopoietic stem cell transplantation is appropriate and who meets the following requirements:

- The client is 12 years of age or older at the expected time of gene therapy administration.
- The client has a diagnosis of sickle cell disease confirmed by genetic testing and a history of vaso-occlusive events, with at least four vaso-occlusive events in the past 24 months, or currently receiving chronic transfusion therapy for recurrent vaso-occlusive events, as documented with one of the following diagnosis codes or provider attestation:

Diagnosis Codes							
D5700	D5701	D5702	D5703	D5704	D5709	D571	D5720
D57211	D57212	D57213	D57214	D57218	D57219	D5740	D57411
D57412	D57413	D57414	D57418	D57419	D5742	D57431	D57432
D57433	D57434	D57438	D57439	D5744	D57451	D57452	D57453
D57454	D57458	D57459	D5780	D57811	D57812	D57813	D57814
D57818	D57819						

- The client has not previously received allogeneic or autologous hematopoietic stem cell transplantation.
- The client has inadequate response or contraindication to hydroxyurea per the healthcare provider's discretion.
- The client has not previously received lovotibeglogene autotemcel (Lyfgenia) or any other gene therapy.
- The client has a confirmed negative serum pregnancy test and is not breastfeeding.
- The client has confirmed negative serology test for HIV-1 or HIV-2.
- The client does not have advanced liver or chronic kidney disease.
- Prescribers must attest and document the following:
  - Hydroxyurea is discontinued two months before mobilization and two days before conditioning.

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- Anti-retroviral medication is discontinued at least one month before mobilization and until all cycles of apheresis are completed.
- Iron chelators are discontinued at least seven days before initiation of myeloablative conditioning.

Monitoring parameters for lovotibeglogene autotemcel (Lyfgenia) are as follows:

- Monitor for evidence of malignancy through complete blood counts at least every six months and through integration site analysis at month 6, month 12, and as warranted.
- Monitor for thrombocytopenia and bleeding.
- Monitor neutrophil counts until engraftment has been achieved.

6.115.2 Documentation Requirements

In addition to documentation requirements outlined in this section, all services are subject to retrospective review to ensure that the documentation in the client's medical record supports the medical necessity of the service(s) provided.

6.116 Secukinumab (Cosentyx)

Secukinumab (Cosentyx) (procedure code J3247) is a benefit of Texas Medicaid for clients who are 18 years of age or older and is restricted to the following diagnosis codes:

Diagnosis Codes							
L400	L401	L402	L403	L404	L405	L4050	L4051
L4052	L4053	L4054	L4059	L408	L409	M0880	M450
M451	M452	M453	M454	M455	M456	M457	M458
M459	M4680	M4681	M4682	M4683	M4684	M4685	M4686
M4687	M4688	M4689					

6.117 Sirolimus Protein-bound Particles (Fyarro)

Sirolimus protein-bound particles (Fyarro) (procedure code J9331) is a benefit of Texas Medicaid for clients who are 18 years of age or older.

6.118 Spesolimab-sbzo (Spevigo)

Spesolimab-sbzo (Spevigo) (procedure code J1747) is a benefit of Texas Medicaid for clients who are 12 years of age or older and restricted to diagnosis code L401.

6.119 Sutimlimab-jome (Enjaymo)

Sutimlimab-jome (Enjaymo) (procedure code J1302) is a benefit of Texas Medicaid for clients who are 18 years of age or older.

6.120 Sumatriptan succinate (Imitrex)

Procedure code J3030 is a benefit when billed with one of the following diagnosis codes:

Diagnosis Codes							
G43001	G43009	G43011	G43019	G43101	G43109	G43111	G43119
G43401	G43409	G43411	G43419	G43501	G43509	G43511	G43519
G43601	G43609	G43611	G43619	G43701	G43709	G43711	G43719

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Diagnosis Codes							
G43801	G43809	G43811	G43819	G43821	G43829	G43831	G43839
G43901	G43909	G43911	G43919	G43A0	G43A1	G43B0	G43B1
G43C0	G43C1	G43D0	G43D1				

6.121 * Blastic Plasmacytoid Dendritic Cell Neoplasm Therapy (Elzonris and Decnupaz)

[Revised] Tagraxofusp-erzs (Elzonris) and pivekimab sunirine-pvzy (Decnupaz) are indicated to treat blastic plasmacytoid dendritic cell neoplasm (BPDCN). Tagraxofusp-erzs (Elzonris) is a CD 123-directed cytotoxin while pivekimab sunirine-pvzy (Decnupaz) is a CD 123-directed antibody and alkylating agent conjugate indicated to treat BPDCN.

[Revised] Tagraxofusp-erzs (Elzonris) (procedure code J9269) and pivekimab sunirine-pvzy (Decnupaz) (procedure code C9313) are benefits of Texas Medicaid with prior authorization.

6.121.1 * Prior Authorization Requirements

[Revised] Prior authorization is required for tagraxofusp-erzs (Elzonris) (procedure code J9269) and pivekimab sunirine-pvzy (Decnupaz) (procedure code C9313), and may be approved for a duration of every 12 months.

Prior authorization approval for tagraxofusp-erzs (Elzonris) infusion will be considered once all of the following criteria are met for initial therapy:

- [Revised] Client is 2 years of age or older
- Client has a diagnosis of blastic plasmacytoid dendritic cell neoplasm (diagnosis code C8640) excluding, acute promyelocytic leukemia (APL, FAB, M3)
- Client has a CD-123 positive/expressing disease
- Client has adequate serum albumin level and baseline organ function, including cardiac, renal, and hepatic function prior to each course of therapy:
  - Baseline serum albumin level of 3.2 g/dl or greater
  - Left ventricular ejection fraction (LVEF) of 40% or greater
  - Serum creatinine (Scr) of 1.5 mg/dl or less
  - Bilirubin level of 1.5 mg/dl or less

[Revised] Prior authorization approval for pivekimab sunirine-pvzy (Decnupaz) therapy will be considered once all of the following criteria are met for initial therapy:

- [Revised] Client is 18 years of age or older
- [Revised] Client has a diagnosis of blastic plasmacytoid dendritic cell neoplasm excluding acute promyelocytic leukemia (APL, FAB, M3) (diagnosis code C8640)
- [Revised] Client has a CD-123 positive/expressing disease
- [Revised] Client does not have moderate-to-severe hepatic impairment. Baseline aspartate amino-transferase (AST), alanine aminotransferase (ALT), and total bilirubin must be obtained and reviewed prior to treatment with pivekimab sunirine-pvzy (Decnupaz)
- [Revised] Pivekimab sunirine-pvzy (Decnupaz) may cause hepatotoxicity, including veno-occlusive disease (VOD), a severe form of hepatotoxicity.
  - [Revised] The client's hepatic function must be monitored prior to each course of therapy to mitigate the risk of severe or fatal VOD.

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  - [Revised] Treatment with pivekimab sunirinepvzy (Decnupaz) should be delayed with liver test elevations and permanently discontinued therapy in clients who experience VOD
- [Revised] Prescriber attests to closely monitor for signs and symptoms of VOD including elevations in liver tests, hepatomegaly, rapid weight gain, and ascites
- For renewal or continuation therapy, the client must meet all of the following criteria:
  - Client continues to meet initial approval criteria
  - [Revised] Client has previously received treatment with tagraxofusp-erzs (Elzonris) or pivekimab sunirine-pvzy (Decnupaz) with absence of adverse drug reactions or drug toxicity
  - Client has a positive clinical response demonstrated by disease stabilization

Refer to: Subsection 2.1.2, "Prior Authorization Requests" in this handbook for additional prior authorization information.

6.122 Talquetamab-tgvs (Talvey)

Talquetamab-tgvs (procedure code J3055) is a benefit of Texas Medicaid for clients who are 18 years of age or older.

6.123 Tarlatamab-dlle (Imdelltra)

Tarlatamab-dlle (Imdelltra) is a bispecific delta-like ligand 3 (DLL3)-directed CD3 T-cell engager indicated for the treatment of adult clients with extensive stage small cell lung cancer (ES-SCLC) with disease progression on or after platinum-based chemotherapy.

Tarlatamab-dlle (Imdelltra) (procedure code J9026) is a benefit of Texas Medicaid with prior authorization.

Tarlatamab-dlle (Imdelltra) infusion is to be administered by a qualified healthcare professional in a healthcare setting with appropriate medical support.

6.123.1 Initial Requests

Tarlatamab-dlle (Imdelltra) is an intravenous infusion indicated for the treatment of a client who meets the following requirements:

- The client is 18 years of age or older.
- The client has a confirmed diagnosis of extensive stage small cell lung cancer with one of the following diagnosis codes:

Diagnosis Codes							
C3400	C3401	C3402	C3410	C3411	C3412	C342	C3430
C3431	C3432	C3480	C3481	C3482	C3490	C3491	C3492

- The client has previously received platinum-based chemotherapy (e.g., cisplatin, or carboplatin).
- The client does not have a clinically significant active systemic infection.
- The prescriber attests to counseling female clients of childbearing age regarding the risk of embryo-fetal toxicity and counseling to prevent pregnancy during treatment period and two months after the last infusion of tarlatamab-dlle (Imdelltra) by using an effective method of contraception.

Providers should monitor the following parameters:

- Signs and symptoms of severe reactions such as cytokine release syndrome (CRS).
- Neurologic toxicity, including immune effector cell-associated neurotoxicity syndrome (ICANS).

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- Cytopenia including neutropenia, thrombocytopenia, and anemia. Perform complete blood counts before each tarlatamab-dlle (Imdelltra) treatment.
- Signs and symptoms of hepatotoxicity. Monitor liver enzymes and bilirubin before each tarlatamab-dlle (Imdelltra) treatment.

6.123.2 Recertification or Extension

For renewal or continuation therapy of tarlatamabdlle (Imdelltra), the client must meet the following requirements:

- The client continues to meet the requirements listed above and has been treated with tarlatamabdlle (Imdelltra) in the past.
- The client experienced positive clinical response to treatment, as documented by stabilization of disease, and/or decrease in tumor size or spread.
- The client has not experienced any unacceptable, clinically significant adverse reactions or toxicity (e.g., severe cytopenia, hepatotoxicity, neurotoxicity, etc.) while on tarlatamab-dlle (Imdelltra) therapy.

All services outlined in this section are subject to retrospective review to ensure that the documentation in the client's medical record supports the medical necessity of the service(s) provided.

6.124 Tebentafusp-tebn (Kimmtrak)

Tebentafusp-tebn (Kimmtrak) (procedure code J9274) is a benefit of Texas Medicaid for clients who are 18 years of age or older.

6.125 Teclistamab-cqyv (Tecvayli)

Teclistamab-cqyv (Tecvayli) (procedure code J9380) is a benefit of Texas Medicaid for clients who are 18 years of age or older.

6.126 Teplizumab-mzwv (Tzield)

Teplizumab-mzwv (Tzield) is a cluster of differentiation 3 (CD3)-directed antibody that is indicated to:

- Delay the onset of stage 3 type 1 diabetes (T1D) in adult and pediatric clients who are 1 year of age or older with stage 2 T1D.
- Delay the decline in endogenous insulin production in pediatric clients who are 8 through 17 years of age who have recently been diagnosed with stage 3 T1D.

Teplizumab-mzwv (Tzield) (procedure code J9381) is a benefit of Texas Medicaid with prior authorization.

Teplizumab-mzwv (Tzield) therapy may be approved for up to 14-day treatment duration when the client meets the following criteria:

- The request is to delay the onset of stage 3 T1D
  - The client is 1 year of age or older.
  - The client is given teplizumab-mzwv (Tzield) to delay the onset of stage 3 T1D. The use of teplizumab-mzwv (Tzield) is not approved in type 2 diabetes or any other stages of T1D other than stage 2 TID.
  - The client has a diagnosis of stage 2 T1D confirmed by documentation of at least two positive pancreatic islet autoantibodies:
    - Islet cell autoantibody (ICA)

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    - Insulinoma-associated antigen 2 autoantibody (IA-2A)
    - Insulin autoantibody (IAA)
    - Zinc transporter 8 autoantibody (ZnT8A)
    - Glutamic acid decarboxylase 65 (GAD) autoantibodies
  - Documentation of dysglycemia without overt hyperglycemia using oral glucose tolerance test (OGTT), or another appropriate test for dysglycemia may be used if OGTT is not available.
- The request is to delay the decline in endogenous insulin production in pediatric clients recently diagnosed with stage 3 T1D.
  - The client is 8 through 17 years of age
  - The client has a diagnosis of stage 3 T1D confirmed by the documentation of at least one positive pancreatic islet cell autoantibody:
    - Islet cell autoantibody (ICA)
    - Insulinoma-associated antigen 2 autoantibody (IA-2A)
    - Insulin autoantibody (IAA)
    - Zinc transporter 8 autoantibody (ZnT8A)
    - Glutamic acid decarboxylase 65 (GAD) autoantibodies
  - The client has residual beta cell function, as indicated by peak stimulated C-peptide > 0.2 pmol/mL on a mixed-meal tolerance test (MMTT) or alternative method if appropriate and MMTT is not available.
- The clinical history does not suggest that the client has type 2 diabetes.
- The prescriber must obtain and assess a complete blood count and liver enzyme tests prior to the initiation of treatment with teplizumab-mzwv (Tzield) because the use of teplizumab-mzwv (Tzield) is not recommended in clients with certain lab abnormalities.
- The prescriber must assess client's history of chronic infection and monitor for any signs of active serious infection while on teplizumab-mzwv (Tzield). If a serious infection develops, teplizumab-mzwv (Tzield) therapy should be discontinued.

6.127 Teprotumumab-trbw (Tepezza)

Teprotumumab-trbw (Tepezza) (procedure code J3241) is a benefit of Texas Medicaid and prior authorization is required. Teprotumumab-trbw (Tepezza) is indicated for the treatment of thyroid eye disease (TED) regardless of TED activity or duration.

6.127.1 Prior Authorization Requirements

Prior authorization requests for procedure code J3241 must be submitted with a Special Medical Prior Authorization (SMPA) Request Form.

The client must meet all of the following requirements for approval of Teprotumumab-trbw (Tepezza):

- The client has a diagnosis of Graves' disease associated with TED.
- The client is euthyroid, or the client has either mild hypothyroidism or mild hyperthyroidism.
- The client has no history of prior surgical intervention for TED and does not plan to have surgical treatment while on Teprotumumab-trbw (Tepezza).
- The client may not exceed the course of eight total infusions per lifetime.

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6.127.2 Exclusions

Teprotumumab-trbw (Tepezza) should not be used in pregnancy as it may potentially lead to fetal loss. Females of reproductive potential should use effective contraception prior to initiation, during treatment with Teprotumumab-trbw (Tepezza) and for 6 months after the last dose of Teprotumumab-trbw (Tepezza).

6.128 Thyrotropin alpha for injection (Thyrogen)

Thyrotropin alpha for injection (Thyrogen) (procedure code J3240) is a benefit of Texas Medicaid and is limited to the following diagnosis codes:

Diagnosis Codes							
C323	C73	D020	D093	D098	D380	D440	D442
D449	D497	E010	E011	E012	E040	E042	E048
E049	E0500	E0520	Z85850				

6.129 Tildrakizumab (Ilumya)

Tildrakizumab (procedure code J3245) is a benefit of Texas Medicaid for clients who are 18 years of age or older, and is limited to diagnosis code L400.

6.130 Tisotumab Vedotin-tftv

Tisotumab Vedotin-tftv (procedure code J9273) is a benefit of Texas Medicaid for clients who are 18 years of age or older.

6.131 Tocilizumab-aazg (Tyenne)

Tocilizumab-aazg (Tyenne) (procedure code Q5135) is a benefit of Texas Medicaid for clients who are 2 years of age or older, and is limited to the following diagnosis codes:

Diagnosis Codes							
M0500	M05011	M05012	M05019	M05021	M05022	M05029	M05031
M05032	M05039	M05041	M05042	M05049	M05050	M05052	M05059
M05061	M05062	M05069	M05071	M05072	M05079	M0509	M0510
M05111	M05112	M05119	M05121	M05122	M05129	M05131	M05132
M05139	M05141	M05142	M05149	M05151	M05152	M05159	M05161
M05162	M05169	M05171	M05172	M05179	M0519	M0520	M05211
M05212	M05219	M05221	M05222	M05229	M05231	M05232	M05239
M05241	M05242	M05249	M05251	M05252	M05259	M05261	M05262
M05269	M05271	M05272	M05279	M0529	M0530	M05311	M05312
M05319	M05321	M05322	M05329	M05331	M05332	M05339	M05341
M05342	M05349	M05351	M05352	M05359	M05361	M05362	M05369
M05371	M05372	M05379	M0539	M0540	M05411	M05412	M05419
M05421	M05422	M05429	M05431	M05432	M05439	M05441	M05442
M05449	M05451	M05452	M05459	M05461	M05462	M05469	M05471
M05472	M05479	M0549	M0550	M05511	M05512	M05519	M05521
M05522	M05529	M05531	M05532	M05539	M05541	M05542	M05549
M05551	M05552	M05559	M05561	M05562	M05569	M05571	M05572

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Diagnosis Codes							
M05579	M0559	M0560	M05611	M05612	M05619	M05621	M05622
M05629	M05631	M05632	M05639	M05641	M05642	M05649	M05651
M05652	M05659	M05661	M05662	M05669	M05671	M05672	M05679
M0569	M0570	M05711	M05712	M05719	M05721	M05722	M05729
M05731	M05732	M05739	M05741	M05742	M05749	M05751	M05752
M05759	M05761	M05762	M05769	M05771	M05772	M05779	M0579
M057A	M0580	M05811	M05812	M05819	M05821	M05822	M05829
M05831	M05832	M05839	M05841	M05842	M05849	M05851	M05852
M05859	M05861	M05862	M05869	M05871	M05872	M05879	M0589
M058A	M059	M05A	M0600	M06011	M06012	M06019	M06021
M06022	M06029	M06031	M06032	M06039	M06041	M06042	M06049
M06051	M06052	M06059	M06061	M06062	M06069	M06071	M06072
M06079	M0609	M060A	M0680	M06811	M06812	M06819	M06821
M06822	M06829	M06831	M06832	M06839	M06841	M06842	M06849
M06851	M06852	M06859	M06861	M06862	M06869	M06871	M06872
M06879	M0689	M068A	M069	M0820	M08211	M08212	M08219
M08221	M08222	M08229	M08231	M08232	M08239	M08241	M08242
M08249	M08251	M08252	M08259	M08261	M08262	M08269	M08271
M08272	M08279	M0829	M082A	M083	M315	M316	R7681

6.132 Tocilizumab-bavi (Tofidence)

Tocilizumab-bavi (Tofidence) (procedure code Q5133) is a benefit of Texas Medicaid and is limited to the following diagnosis codes:

Diagnosis Codes							
M0510	M05111	M05112	M05119	M05121	M05122	M05129	M05131
M05132	M05139	M05141	M05142	M05149	M05151	M05152	M05159
M05161	M05162	M05169	M05171	M05172	M05179	M0519	M0520
M05211	M05212	M05219	M05221	M05222	M05229	M05231	M05232
M05239	M05241	M05242	M05249	M05251	M05252	M05259	M05261
M05262	M05269	M05271	M05272	M05279	M0529	M0530	M05311
M05312	M05319	M05321	M05322	M05329	M05331	M05332	M05339
M05341	M05342	M05349	M05351	M05352	M05359	M05361	M05362
M05369	M05371	M05372	M05379	M0539	M0540	M05411	M05412
M05419	M05421	M05422	M05429	M05431	M05432	M05439	M05441
M05442	M05449	M05451	M05452	M05459	M05461	M05462	M05469
M05471	M05472	M05479	M0549	M0550	M05511	M05512	M05519
M05521	M05522	M05529	M05531	M05532	M05539	M05541	M05542
M05549	M05551	M05552	M05559	M05561	M05562	M05569	M05571
M05572	M05579	M0559	M0560	M05611	M05612	M05619	M05621
M05622	M05629	M05631	M05632	M05639	M05641	M05642	M05649

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Diagnosis Codes							
M05651	M05652	M05659	M05661	M05662	M005669	M05671	M05672
M05679	M0569	M0570	M05711	M05712	M05719	M05721	M05722
M05729	M05731	M05732	M05739	M05741	M05742	M05749	M05751
M05752	M05759	M05761	M05762	M05769	M05771	M05772	M05779
M0579	M057A	M0580	M05811	M05812	M05819	M05821	M05822
M05829	M05831	M05832	M05839	M05841	M05842	M05849	M05851
M05852	M05859	M05861	M05862	M05869	M05871	M05872	M05879
M0589	M058A	M059	M05A	M0600	M06011	M06012	M06019
M06021	M06022	M06029	M06031	M06032	M06039	M06041	M06042
M06049	M06051	M06052	M06059	M06061	M06062	M06069	M06071
M06072	M06079	M0609	M060A	M0680	M06811	M06812	M06819
M06821	M06822	M06829	M06831	M06832	M06839	M06841	M06842
M06849	M06851	M06852	M06859	M06861	M06862	M06869	M06871
M06872	M06879	M0689	M068A	M069	M0800	M0820	M08211
M08212	M08219	M08221	M08222	M08229	M08231	M08232	M08239
M08241	M08242	M08249	M08251	M08252	M08259	M08261	M08262
M08269	M08271	M08272	M08279	M0829	M082A	M083	M0880
M0890	R7681						

6.133 Toripalimab-tpzi

Toripalimab-tpzi (procedure code J3263) is a benefit of Texas Medicaid for clients who are 18 years of age or older.

6.134 Trastuzumab

Procedure code J9355 is a benefit of Texas Medicaid. Reimbursement for this drug is considered when it is used as a single agent for the treatment of clients who have metastatic breast cancer whose tumors overexpress the Her-2 protein and who have received one or more chemotherapy regimens for their metastatic disease. Trastuzumab may also be reimbursed when:

- Used in combination with paclitaxel for the treatment of clients who have metastatic breast cancer whose tumors overexpress the Her-2 protein and who have not received chemotherapy for their metastatic disease.
- Used as part of a treatment regimen containing doxorubicin, cyclophosphamide, and paclitaxel for the adjuvant treatment of clients who have Her-2-overexpressing, node-positive breast cancer.

Trastuzumab is a benefit for clients whose tumors have Her-2 protein overexpression.

When billing for the test used to determine whether a client overexpresses the Her-2 protein, use procedure code 83950. Diagnosis of overexpression of the Her-2 protein must be made before Texas Medicaid will consider reimbursement for trastuzumab. This test may be reimbursed only once in a client's lifetime to the same provider. An additional test by the same provider requires documentation to support the medical necessity.

6.135 Travoprost

Travoprost (procedure code J7355) is a benefit of Texas Medicaid for clients who are 18 years of age or older.

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6.136 Tremelimumab-actl (Imjudo)

Tremelimumab-actl (Imjudo) (procedure code J9347) is a benefit of Texas Medicaid for clients who are 18 years of age or older.

6.137 Treosulfan (Grafapex)

Treosulfan (Grafapex) (procedure code J0614) is a benefit of Texas Medicaid with prior authorization.

Treosulfan (Grafapex) is an alkylating drug indicated for use in combination with fludarabine as a preparative regimen for allogeneic hematopoietic stem cell transplantation (HSCT) in adult and pediatric clients who are 1 year of age or older with acute myeloid leukemia (AML) or myelodysplastic syndrome (MDS).

6.137.1 Prior Authorization Requirements

Treosulfan (Grafapex) is an intravenous infusion, given on three consecutive days in conjunction with fludarabine prior to hematopoietic stem cell infusion. It is indicated for clients who meet the following requirements:

- The client is 1 year of age or older.
- The client has a confirmed diagnosis of one of the following:
  - Acute myeloid leukemia (diagnosis code C9200)
  - Myelodysplastic syndrome (diagnosis code D469)
- The client is undergoing allogeneic hematopoietic stem cell transplantation.
- Fludarabine must be administered in conjunction with treosulfan (Grafapex) as a preparative regimen for allogeneic HSCT.
- The prescriber attests to counseling female clients of childbearing age regarding the use of an effective method of contraception to prevent pregnancy during treatment and up to six months after the last dose of therapy. Male clients with female partners of reproductive potential should also be counseled.

The required monitoring parameters following treosulfan (Grafapex) are:

- Monitor hematologic laboratory parameters, as treosulfan (Grafapex) can cause severe and prolonged myelosuppression.
- Monitor for signs of neurological adverse reactions (e.g., seizures).
- Monitor for extravasation and tissue necrosis.
- Monitor for infections, anemia, thrombocytopenia, and secondary malignancies.

In addition to the documentation requirements outlined in the Prior Authorization Requirements section, all services outlined in this section are subject to retrospective review to ensure that the documentation in the client's medical record supports the medical necessity of the service(s) provided.

6.138 Triamcinolone Acetonide

Procedure code J3304 is a benefit of Texas Medicaid and is restricted to the following diagnosis codes:

Diagnosis Codes							
M170	M1711	M1712	M172	M1731	M1732	M174	M175
M1909	M1919	M1929					

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6.139 Trilaciclib (Cosela)

Trilaciclib (procedure code J1448) is a benefit of Texas Medicaid for clients who are 18 years of age or older.

6.140 Ublituximab-xiiy (Briumvi)

Ublituximab-xiiy (Briumvi) (procedure code J2329) is a benefit of Texas Medicaid for clients who are 18 years of age or older.

6.141 Valrubicin sterile solution for intravesical instillation (Valstar)

Procedure code J9357 valrubicin sterile solution for intravesical instillation (Valstar), is a benefit for clients with the diagnosis of bladder cancer in situ who have been treated unsuccessfully with BCG therapy and have an unacceptable morbidity or mortality risk if immediate cystectomy should be performed. Documentation of diagnosis and treatment must be submitted with the claim.

6.142 Vasopressin

Vasopressin (procedure codes J2598, J2599, and J2601) is a benefit of Texas Medicaid for clients who are 18 years of age or older.

6.143 Vitamin B12 (Cyanocobalamin) Injections

Vitamin B12 injections (procedure code J3420) are a benefit of Texas Medicaid. Vitamin B12 injections should only be considered for clients with conditions that are refractory to, or have a contraindication to, oral therapy.

6.144 Voretigene neparvovec-rzyl (Luxturna)

Voretigene neparvovec-rzyl (Luxturna) is an adeno-associated virus vector-based gene therapy indicated for the treatment of patients with confirmed biallelic RPE65 mutation-associated retinal dystrophy, who have viable retinal cells in each eye as determined by the treating physician.

Luxturna (procedure code J3398) is a benefit of Texas Medicaid for clients who are 1 year through 65 years of age with prior authorization.

Voretigene neparvovec-rzyl (Luxturna) must be prescribed and administered by a retinal surgeon at an ocular gene therapy treatment center with experience performing intraocular surgery.

6.144.1 Prior Authorization Requirements

Prior authorization is not required for the physician services associated with administration of Luxturna. Physician services include the procedural costs and the associated supplies for administration of the medication.

Prior authorization is required for voretigene neparvovec-rzyl (Luxturna) (procedure code J3398).

For situations in which voretigene neparvovec-rzyl (Luxturna) is being dispensed by a pharmacy via white bagging, the prescribing provider must provide the dispensing DME pharmacy the authorization approval number. The dispensing DME pharmacy may not request prior authorization.

The DME Pharmacy provider billing for voretigene neparvovec-rzyl (Luxturna) will be responsible for coordinating with the rendering provider to obtain the prior authorization request approval number.

The requesting provider (physician or hospital) may coordinate with the DME Pharmacy provider for the initial request for voretigene neparvovec-rzyl (Luxturna). DME Pharmacy providers may assist in providing necessary information, such as their NPI number, fax number, and business address, to the requesting provider. However, the Special Medical Prior Authorization (SMPA) form must be signed, dated, and submitted by the Medicaid-enrolled requesting provider, not the DME Pharmacy provider.

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The dispensing pharmacy must submit the authorization approval number when billing for the drug. Reimbursement for dispensing of the drug by the pharmacy may not occur unless an approved prior authorization for voretigene neparvovec-rzyl (Luxturna) is in place.

Refer to: Subsection 11.5.1, "Pharmacy Delivery Method for Clinician-Administered Drugs" in this handbook for additional information on the "white bagging" delivery method.

Subsection 2.1.2, "Prior Authorization Requests" in this handbook for additional prior authorization information.

Prior authorization request for Luxturna injections will be considered when all of the following criteria are met:

- Client is 1 year of age through 65 years of age
- A documented diagnosis of a confirmed biallelic RPE65 mutation-associated retinal dystrophy (e.g., Leber's congenital amaurosis subtype 2, retinitis pigmentosa, or early onset severe retinal dystrophy)
- Genetic testing documenting biallelic mutations of the RPE65 gene
- Systemic corticosteroids equivalent to prednisone 1 mg/kg/day are administered for a total of 7 days, starting 3 days before administration of voretigene neparvovec-rzyl to each eye and followed by a tapering dose
- Client has viable retinal cells in each eye as determined by the treating physician and assessed in the previous 6 months. Verification of viable retinal cells must be documented and evident by one of the following:
- An area of retina within the posterior pole of greater than 100 μm thickness shown on optimal coherence tomography (OCT)
- Greater than or equal to 3 disc areas of retina without atrophy or pigmentary degeneration within the posterior pole
    - Remaining visual field within 30 degrees of fixation as measured by a III4e isopter or equivalent
- Prescribed and administered by retinal surgeon at an ocular gene therapy treatment center with experience performing intraocular surgery
- Patient has not previously received RPE65 gene therapy in intended eye
- Injection of the second eye must be administered at least 6 days after the first eye
- Have not had intraocular surgery within 6 months in either eye indicated for treatment

Benefit not to exceed more than 1 injection per eye per lifetime.

Authorization is valid for a period of 6 months from approval.

All services outlined in this section are subject to retrospective review to ensure that the documentation in the client's medical record supports the medical necessity of the services provided.

6.144.2 Exclusions

Luxturna is not a benefit for patients who have previously received RPE65 gene therapy and who do not have viable retinal cells in each eye as determined by the treating physician.

6.145 Zopapogene Imadenovec-drba (Papzimeos)

Zopapogene imadenovec-drba (Papzimeos) (procedure code J3404) is a benefit of Texas Medicaid for clients with prior authorization.

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Zopapogene imadenovec-drba (Papzimeos) is a non-replicating adenoviral vector-based immunotherapy indicated to treat adults with recurrent respiratory papillomatosis.

6.145.1 Prior Authorization Requirements

6.145.1.1 6.142.1.1 Initial Requests

Zopapogene imadenovec-drba (Papzimeos) is a subcutaneous injection, and the initial prior authorization will be approved for 6 months for clients who meet the following requirements:

- The client is 18 years of age or older.
- The client has a confirmed diagnosis of recurrent respiratory papillomatosis (diagnosis code D141).
- The client has documented human papillomavirus (HPV) serotype 6 or 11.
- The prescriber must perform a surgical debulking of visible papilloma prior to the initiation of zopapogene imadenovec-drba (Papzimeos) treatment (Day 1) to establish minimal residual disease.
- The prescriber attests to remove visible papilloma prior to the third and fourth zopapogene imadenovec-drba (Papzimeos) administration to maintain minimal residual disease during treatment.

Authorization will be issued for no more than one treatment course (i.e., four doses).

Monitor the client for signs and symptoms of thrombotic events, including shortness of breath, chest pain, leg swelling, persistent abdominal pain, or neurological symptoms such as severe or persistent headache or blurred vision.

6.145.1.2 Documentation Requirements

In addition to the documentation requirements outlined in this section, all services are subject to retrospective review to ensure that the documentation in the client's medical record supports the medical necessity of the services provided.

7 * Separate Reimbursement of Certain Inpatient HCCADs

Inpatient high-cost clinician-administered drugs (HCCADs) are drugs or biologics that HHSC has approved to be "carved out" of the All-Patient Refined Diagnosis Related Group (APR-DRG) and can be billed on an outpatient claim.

This section allows for the use of specialty pharmacy billing for the HCCAD if it is available for the drug or bill for the HCCAD on a separate outpatient claim.

Refer to: Section 6, "Outpatient Drugs—Benefits and Limitations" in this handbook for the prior authorization criteria for the HCCADs.

The section below contains the list of HCCADs and procedure codes approved by HHSC:

HCCADs	[Revised] Procedure Codes
Abecma	Q2055
Aucatzyl	Q2058
Breyanzi	Q2054
Carvykti	Q2056
Casgevy	J3392
Elevidys	J1413
Hemgenix	J1411
Itvisma	J3405

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HCCADs	[Revised] Procedure Codes
Kebilidi	J3590
Kymriah	Q2042
Lenmeldy	J3391
Lyfgenia	J3394
Omisirge	J3406
Rethymic	J3590
Skysona	J3387
Tecartus	Q2053
Tecelra	Q2057
Yescarta	Q2041
Zevaskyn	J3389
Zolgensma	J3399
Zynteglo	J3393

Refer to: Subsection 9.2, "HCCADs Claims Processing Requirements" in this handbook" for claims processing requirements.

8 Cell and Gene Therapy Access Model (CGT)

The CGT Access Model is a Centers for Medicare & Medicaid Services (CMS) led multi-year initiative focusing on potentially lifesaving gene therapies for sickle cell disease.

Unique to this model, clients have access to fertility preservation services that otherwise are not a covered Texas Medicaid benefit. The drug manufacturers will cover the cost of these services.

Medications

In alignment with CMS, only the following gene therapies are part of the CGT Access Model:

- Lyfgenia by bluebird bio, Inc.
- Casgevy by Vertex Pharmaceuticals, Inc.

The CGT Access Model is only for the treatment of sickle cell disease (beta-thalassemia indication is not included).

As part of the CGT Access Model, the prior authorizations for the gene therapy and related care (i.e., genetic and laboratory testing, prescription) are authorized until the end of the original authorization period regardless of whether the client transitions between fee-for-service and managed care or from amongst MCOs. Additionally, the client must have access to the same qualified treatment center that administered the medication for at least one year after receiving their gene therapy infusion.

Eligibility

Clients who are eligible to participate must meet the following conditions:

- Be actively enrolled in Texas Medicaid and have Medicaid as their primary insurance
- Meet the clinical prior authorization criteria outlined in section "6.115 Sickle Cell Disease Gene Therapy" in this handbook.

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Billing

Providers submitting a claim under the CGT Access Model must:

- Be a member of the CMS Designated Registry through the Center for International Blood and Marrow Transplant Research (CIBMTR) prior to administering the gene therapy.
- Participate in the study related to this model; providers will receive study information directly from CIBMTR.
- Adhere to billing requirements outlined in section "7 * Separate Reimbursement of Certain Inpatient HCCADs" in this handbook and subsection "9.2 HCCADs Claims Processing Requirements" in this handbook for claims submission guidelines.
- Submit the invoice of the actual acquisition cost of the drug.

Resources

CGT Access Model:

- CMS: Cell and Gene Therapy Access Model
- CMS: Improved Access to Gene Therapy for Sickle Cell Disease: Maya's Care Journey
- CMS: CMS Expands Access to Lifesaving Gene Therapies Through Innovative State Agreements

For information and enrollment information related to additional client support in navigating through the client's journey, including the fertility preservation services, see:

- Lyfgenia: my bluebird support
- Casgevy: Vertex Connects

For fee-for-service, providers may contact the following:

- TMHP: Provider Enrollment
- TMHP: Prior Authorization

9 Claims Filing Information

Claims for clinician-administered drugs must be submitted to TMHP in an approved electronic format or on the CMS-1500 paper claim form. Providers may purchase CMS-1500 paper claim forms from the vendor of their choice. TMHP does not supply them.

When completing a CMS-1500 paper claim form, all required information must be included on the claim, as information is not keyed from attachments. Superbills and itemized statements are not accepted as claim supplements.

Refer to: "Section 3: TMHP Electronic Data Interchange (EDI)" (*Vol. 1, General Information*) for information on electronic claims submissions.

"Section 6: Claims Filing" (*Vol. 1, General Information*) for general information about claims filing.

Subsection 6.5, "CMS-1500 Paper Claim Filing Instructions" in "Section 6: Claims Filing" (*Vol. 1, General Information*) for instructions on completing paper claims. Blocks that are not referenced are not required for processing by TMHP and may be left blank.

9.1 JW Modifier Claims Filing Instructions

Providers must not use the JW modifier for medications manufactured in a multi-dose vial format.

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Providers must choose the most appropriate vial size(s) required to prepare a dose to minimize the discarded portion of the vial payable.

Claims considered for reimbursement must not exceed the package size of the vial used for preparation of the dose. Providers must not bill for vial contents overfill.

Providers must not use the JW modifier when the actual dose of the drug or biological administered is less than the billing unit.

Example: *One billing unit for a drug is equal to 10mg of the drug in a single use vial. A 7mg dose is administered to a client while 3mg of the remaining drug is discarded. The 7mg dose is billed using one billing unit that represents 10mg on a single line item. The single line item of 1 unit would process for payment of the total 10mg of drug administered and discarded. Billing another unit on a separate line item with the JW modifier for the discarded 3mg of drug is not permitted because it would result in overpayment. Therefore, when the billing unit is equal to or greater than the total actual dose and the amount discarded, the use of the JW modifier is not permitted.*

Reimbursement for JW modifier claims is only available for drugs covered in an outpatient setting.

Inpatient and diagnostic radiopharmaceuticals claims are not eligible for reimbursement, and may not include the JW modifier.

Coverage is for "buy and bill" providers only. Specialty pharmacies billing through the medical benefit must not submit claims with a JW modifier because they are unaware of how much the provider administered or discarded.

Federally Qualified Health Center (FQHC) and Rural Healthcare Clinic RHC) are not eligible to bill with the JW modifier because these providers do not bill for the coverage of drugs or biologicals separately.

Critical Access Hospitals (CAH) are eligible to bill with the JW modifier because these providers bill for the coverage of drugs or biologicals separately.

The JW modifier is not allowed for medications prepared in an institutional setting via "batch processing or bulk productions" methods. An example of a batch processing method is when a hospital or repackaging facility produces multiple non-patient specific doses of medications in advance of anticipated use. These preparations are labeled and distributed with client specific information only when orders are received. Because these doses may be recycled for other client use, they are not eligible.

Providers may utilize automatic systems to calculate dose and discard amounts. However, providers must continue to document the exact usage/discard accurately.

Providers must enter the dose administered (used portion) line item detail of the CAD and also enter the dose discarded (unused portion) line item detail of the CAD on the same claim. The dose discarded (unused portion) line item detail must include the JW modifier to be considered for reimbursement. When billing for reimbursement of wastage on an outpatient claim, the HCPCS and Current Procedural Terminology (CPT) code should always be provided along with the revenue code.

9.2 HCCADs Claims Processing Requirements

The following special requirements apply when billing the HCCAD on a separate outpatient claim.

Providers must claim separate payment for the HCCAD on an outpatient claim. Payment for the HCCAD must not be bundled with any other service.

The claim for the HCCAD must be separate from any facility or institutional claim the hospital submits for all other hospital services delivered to the member during the same visit. The associated inpatient or outpatient charges with the same date(s) of service are billed separately and remain part of the APR-DRG.

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The date of administration of the drug should be used on the HCCAD outpatient claim along with the member's name and other required information. The HCCAD claim must include:

- The NDC qualifier of N4 (paper claims only).
- The appropriate 11-digit National Drug Code (NDC) and corresponding HCPCS code for the drug.
- The number of units of the drug administered to the member that is covered by the claim.
- The NDC unit of measurement. There are five allowed values: F2, GR, ML, UN, or ME.

Drugs administered in an inpatient setting do not qualify for 340B discounts.

9.2.1 * Claims Submissions for HCCADs Covered Under Procedure Code J3590

Hospitals that have prior authorization can submit a separate outpatient claim for HCCADs when the drug is provided in an inpatient setting. In addition to the criteria listed in section 9.2, HCCADs Claims Processing Requirements, providers must submit modifier U3 on a fee-for service (FFS) outpatient claim so that TMHP can easily identify the HCCAD under (procedure code J3590) for claims, and reimburse them appropriately for the following drugs:

- Rethymic
- Kebilidi

Note: *Providers should not submit these HCCADs on the related inpatient services claim.*

Providers can refer to the current National Drug Codes fee schedule on the Online Fee Lookup (OFL) on the TMHP website at www.tmhp.com.

10 Pharmacy Benefit

The Texas Drug Code Index, or formulary (or list of available drugs), includes non-legend (over-the counter) drugs. Additionally, certain supplies and select vitamin and mineral products are also available as a pharmacy benefit. Some drugs are subject to one or both types of prior authorization, clinical and non-preferred. VDP does not reimburse claims for nutritional products (enteral or parenteral), medical supplies, or equipment other than a limited set of home health supplies.

The PDL is arranged by drug therapeutic class, and contains a subset of many, but not all, drugs that are on the Medicaid formulary. Most drugs are identified as preferred or non-preferred. Drugs listed on the PDL as preferred or not listed at all are available without prior authorization unless there is a clinical prior authorization associated with that drug. For more information about prior authorization, refer to Subsection 13, "Pharmacy Prior Authorization" in this handbook.

10.1 Drug and Product Search

The Drug and Product Searches are online tools available to health-care providers to help clients get access to medications.

Users can search by either brand or generic name of the drug or product, the 11-digit national drug code (NDC), the PDL drug class, or HCPCS description (for products).

Detailed filters allow searches as follows:

- By program:
  - Medicaid
  - CHIP
  - CSHCN Services Program

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  - HTW Program
  - HTW Plus Program
  - KHC Program (e.g., CHIP, CSHCN, HTW, and KHC)
- By prior authorization status:
  - PDL prior authorization
  - Clinical prior authorization
- By drug types:
  - Family planning
  - Diabetic supplies
  - Injectable drugs
  - LARCs
  - Over-the-counter (OTC)
  - Drugs requiring 90% utilization before refilling (refer to section 10.4)
- By product types:
  - Flu vaccines
  - Mosquito repellents
  - COVID-19 vaccines

Refer to: The Drug Search and Product Search on the VDP website for more information.

10.1.1 Epocrates

The Texas Medicaid formulary and Preferred Drug List are available on the Epocrates drug information system. Epocrates (epocrates.com) is the publisher of mobile device software applications designed to provide information about drugs to doctors and other health care professionals.

Once registered, providers can utilize Epocrates Rx, the free drug reference, and search for brand, generic, or over-the-counter medicines. Providers can select the "Texas Medicaid" formulary option, allowing searches by drug name to find products identified as preferred or non-preferred or are subject to clinical prior authorization criteria. In addition to listing a drug's preferred status, Epocrates includes drug monographs, dosing information, and warnings.

Epocrates does not mirror the HHSC designations differentiated by dosage form. In these situations, the designation includes an explanatory message.

10.2 Drug Shortages

HHSC encourages prescribing providers to notify HHSC about potential drug shortages impacting prescribing choice and pharmacy claim processing using the Drug Shortage Notification and Expedited Formulary or Preferred Drug List Request (HHS Form 1315).

Significant drug shortages affecting multiple pharmacies and distributors can have a continuing adverse impact on people enrolled in Medicaid if not resolved promptly. The process ensures notification of alternatives to the shorted drug, the timeline of the shortage, and the drug's availability for use.

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10.3 Hepatitis C Direct-Acting Antiviral Treatment Products

The Texas Health and Human Services Commission (HHSC) launched a public health initiative called Texas Medicaid HepCure to reduce the rate of Hepatitis C virus (HCV) in Texas. No HCV medication is required to be prescribed by or in consultation with a hepatologist, gastroenterologist, or infectious disease specialist. All providers with prescriptive authority can prescribe this treatment to their clients with HCV.

HHSC allows prescribers to write prescriptions for the entire course of therapy for DAAs, and clients do not need to request additional refills throughout their treatment duration. Prescribers may choose to write a prescription for the entire treatment cycle or have the client return for further testing if warranted. This applies to all Hepatitis C DAA medications.

10.3.1 Background on Hepatitis C

Hepatitis C is a liver infection caused by HCV. It spreads through contact with blood from an infected person. For some people, hepatitis C is a short-term illness that resolves spontaneously, but it becomes a chronic infection for most people who become infected with HCV. Chronic HCV can result in serious, even life-threatening, health problems like cirrhosis and liver cancer.

People with HCV often have no symptoms and do not feel sick. When symptoms appear, they often are a sign of advanced liver disease. The number of people unknowingly living with undiagnosed HCV infection is why broad population-based HCV screening is important. Screening, testing and treatment can save and prolong life.

DAA medications use molecules that target specific nonstructural proteins of the virus which results in disruption of viral replication and infection. They are oral medications taken once per day for several weeks. With cure rates above 90%, these drugs can virtually eliminate the disease. The medications can be prescribed using simplified treatment algorithms for most clients and do not require specialized clinical oversight or management.

10.3.2 HCV Screening and Testing

The Centers for Disease Control and Prevention (CDC) recommends that all adults who are 18 years of age or older be screened for HCV at least once in a lifetime. They also recommend that people with certain risk factors, including people who inject drugs, be tested regularly. The US Preventative Services Task Force recommends screening for Hepatitis C infection in adults who are 18 through 79 years of age and gives a “B” recommendation (moderate certainty of substantial net benefit).

Screening for HCV involves measuring antibodies to HCV in a client’s serum. A reactive or positive test (detection of the antibody) is not a disease diagnosis; it only indicates that a person was previously exposed to the virus. If the antibody test is reactive, a nucleic acid test (also known as a polymerase chain reaction [PCR] test) for HCV ribonucleic acid (RNA) is needed to determine whether the client currently has active HCV infection. Often, the antibody test and the RNA test can be performed on a single blood draw, with a positive antibody test automatically reflexing to the HCV RNA test. The client can be prescribed HCV treatment if the HCV RNA test is positive. In most instances, a simplified HCV treatment algorithm can be followed.

10.3.3 Treatment Coverage

After confirmatory testing, individuals may not have previously received treatment for Hepatitis C. HHSC encourages Medicaid providers to evaluate their clients at risk for Hepatitis C or previously ineligible for HCV treatment to assess if they would benefit from treatment.

Prior authorization is required for PDL non-preferred agents.

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10.3.4 Follow-Up After Treatment

Clients who have received treatment should be tested for HCV RNA 12 weeks (or longer) after treatment completion. Undetectable or unquantifiable HCV RNA 12 weeks or longer after treatment completion is defined as a sustained virologic response (SVR) consistent with the cure of HCV infection.

10.3.5 Pregnant Clients

The CDC recommends that all pregnant clients should be screened for HCV during each pregnancy, regardless of age. This will aid providers in identifying HCV-infected pregnant clients, which can lead to treatment for the birthing client during the postpartum period. It can also help identify infants with perinatal exposure who should receive testing at a pediatric visit. There are currently no approved curative treatments available for pregnant clients or children who are 3 years of age or younger, but curative treatments are available for non-pregnant clients and for children who are 3 years of age or older.

10.3.6 Resources for Providers

HCV DAAs are safe, associated with high rates of cure, and have few side effects and contraindications. Some HCV clients may need to have their treatment managed by a specialist, such as those with hepatitis B virus or HIV co-infection, those who previously failed HCV treatment, or those with liver cancer or who have had a liver transplant. However, most cases of HCV can be treated by primary care physicians or advanced practice providers. Providers may find the following resources helpful, and can also visit the Hepatitis C Treatment page for more information on Texas Medicaid HepCure and Hepatitis C:

- CDC Resources:
  - Recommended Testing Sequence for Identifying Current HCV Infection: www.cdc.gov/hepatitis/hcv/pdfs/hcv_flow.pdf
  - Testing Recommendations for HCV infection: www.cdc.gov/hepatitis-c/hcp/diagnosis-testing/
  - Hepatitis C Questions and Answers for Health Professionals: www.cdc.gov/hepatitis-c/hcp/clinical-overview/
- Prescriber Resources: www.hcv.com/resources
- Resources from the American Association for the Study of Liver Diseases: www.hcvguidelines.org
- Texas Hepatitis C Report Card: stateofhepc.org/states/texas/

10.4 Home Health Supplies

Pharmacies enrolled with VDP can dispense a limited set of home health supplies that are commonly found in a pharmacy to clients enrolled in traditional Medicaid. These supplies are also available to clients enrolled in Medicaid managed care, provided the dispensing pharmacy is contracted by the client's health plan.

The list of supplies that can be dispensed at a pharmacy and information about the provisions of these supplies for clients enrolled in traditional Medicaid can be found on the VDP Product Search page. Users can search by product NDC or name or the HCPCS description.

Providers should contact the appropriate health plan or pharmacy benefit manager for more information about providing these supplies to clients enrolled in managed care.

10.5 Long-Acting Reversible Contraception Products

Long-acting reversible contraception (LARC) products are available to clients through either a Medicaid or HTW pharmacy or medical benefit.

The list of LARC drugs dispensed at a pharmacy can be found on the VDP Drug Search page. Users can select the "LARC" check-box for a list of all drugs.

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Providers can obtain LARC products with no upfront cost by submitting a completed and signed prescription request form to certain specialty pharmacies. The specialty pharmacy will dispense the LARC product by shipping it to the practice address in care of the client and bill Medicaid or HTW for the product. Providers can only bill for product administration at the time of service. LARC products obtained by providers from specialty pharmacies must be returned if unused and unopened.

10.5.1 Product Billing

The specialty pharmacy bills Medicaid or HTW for LARC products when obtained from a specialty pharmacy. Providers will continue to bill Medicaid or HTW for insertion of the LARC product. Providers may only bill for the LARC product if it was obtained through the buy-and-bill process.

For clients enrolled in traditional Medicaid (fee-for-service (FFS)) or HTW, providers bill HHSC for the insertion of the LARC product using procedure code 58300.

For clients enrolled in Medicaid managed care, providers bill the patient's managed care organization for the insertion of the LARC product. Contact the patient's MCO for specific billing instructions.

10.5.2 Specialty Pharmacy Participation

Providers do not need to enroll with specialty pharmacies to obtain LARC products. Any provider currently enrolled with Medicaid or HTW may prescribe and obtain a LARC product and bill Medicaid or HTW for insertion of the LARC product. The participating pharmacies ship statewide.

Prescribing providers should identify whether the patient is enrolled in traditional Medicaid or managed care. For clients enrolled in managed care, the provider's office should coordinate with the managed care organization (MCO) to determine which pharmacy should receive the prescription because the MCO may be contracted with a single specialty pharmacy. The name, phone number, and national provider identifier (NPI) is provided for each specialty pharmacy is listed in the "Manufacturer Information" section.

10.5.3 Product Returns and Abandoned Units

Manufacturers offer abandoned unit return programs that allow a provider to return an abandoned LARC product. An "abandoned unit" is an unused and unopened product that was shipped by a participating specialty pharmacy with a prescription label that includes the name of the patient. In order to be returnable, the LARC product should be in its original packaging.

10.5.4 Manufacturer Information

10.5.4.1 Bayer (Kyleena, Mirena, and Skyla)

10.5.4.1.1 Specialty Pharmacy Participation

Products are available from CVS CarePlus Specialty Pharmacy or Walgreens Specialty Pharmacy, both shipping statewide.

Walgreens Specialty Pharmacy
Frisco, TX
1-800-424-9002
NPI 1851463087

CVS Caremark Specialty Pharmacy
Fort Worth, TX
817-336-7281
NPI 1366551848

10.5.4.1.2 Obtaining Products

Providers use Bayer's Specialty Pharmacy Prescription Request Form. This form is available on the VDP website at https://www.txvendordrug.com/resources/forms.

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Complete the Bayer's Specialty Pharmacy Prescription Request Form as follows:

- Enter the patient and prescriber information, including the patient's pharmacy drug benefit and medical insurance information and copies of the patient's pharmacy benefit and medical insurance cards.
- Complete the prescribing information and keep a copy for future use.
- Identify the drug to be administered in the prescription section, including the appropriate diagnosis code, and sign the prescription. Advanced Practice Registered Nurses, Physician Assistants, and Nurse Practitioners should identify who their collaborative agreement is with to write prescriptions, if necessary
- Have the patient read and sign the "Patient Authorization" section of the form.
- Fax the form, including the "Patient Authorization" section, to the pharmacy.
- The pharmacy will call the patient to confirm the patient's intent to receive an intrauterine device (IUD). This is done to limit potentially abandoned IUD units. The pharmacy will not mail the IUD to the provider until confirmation from the patient is received.

10.5.4.1.3 Returning Products

Providers may return abandoned units. The box must be sealed and have been abandoned for at least 60 days (2 months) from the dispensing date but no more than 210 days (7 months) past the fill date. Only LARC products obtained through a specialty pharmacy can be returned through this program.

To return abandoned units complete the Bayer Abandoned Unit Program Return Form. This form is available on the VDP website at https://www.txvendordrug.com/resources/forms.

The Bayer Abandoned Unit Program Return Form may be submitted by mail or fax as follows:

- Fax the form to the dispensing specialty pharmacy for verification.
- Wait for an authorization number and return mailing label, and then
- Confirm the specialty pharmacy identification number matches the ID number listed on the return authorization form.
- Package the unit in one of the cardboard boxes the drug was initially shipped in or a large envelope.
- Mail the unit to the specialty pharmacy.

10.5.4.2 Organon (Nexplanon)

10.5.4.2.1 Specialty Pharmacy Participation

Nexplanon is available from CVS CarePlus Specialty Pharmacy or Accredo Specialty Pharmacy, both of which ship statewide.

CVS Caremark Specialty Pharmacy
Fort Worth, TX
817-336-7281
NPI 1366551848

Accredo Specialty Pharmacy
Irving, TX
972-929-6800
NPI 1073569034

10.5.4.2.2 Obtaining Products

Providers use Organon's Nexplanon Direct Service Request Form. Request the form from Organon Customer Support Center for Nexplanon (CSCN) at 1-844-639-4321.

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Complete the CSCN Direct Service Request Form as follows:

- At the top of the first page of the form, check the "Prescription Order" box and select a specialty pharmacy.
- Complete the patient and prescriber information including the patient's pharmacy drug benefit and medical insurance information. Include copies of the patient's insurance card and prescription drug card.
- Have the patient read and sign the "Patient Authorization" section.
- Ensure the physician signs both the Dispense as Written and prescriber signature lines, and the appropriate diagnosis code is selected.
- Fax the completed form to the CSCN at 1-844-232-2618.
- The CSCN will forward the prescription to the specialty pharmacy you selected after confirming the benefits of the patient.

10.5.4.2.3 Returning Products

Providers may return an abandoned unit. The Nexplanon box must be sealed and been abandoned for at least 120 days (4 months) from date of dispense but no more than 180 days (6 months) past the fill date.

Complete the Organon Abandoned Unit Program Return Form. This form is available on the VDP website at https://www.txvendordrug.com/resources/forms.

The Organon Abandoned Unit Program Return Form may be submitted by mail or fax as follows:

- Fax the form to the specialty pharmacy for verification.
- Wait to receive the return identification number from the specialty pharmacy and return mailing label and instructions, which will be provided by C3i, Organon's third-party processor.
- Confirm the specialty pharmacy return identification number matches the ID number listed in the return mailing label provided by C3i.
- Package the unit in the box in which the Nexplanon was originally shipped or other appropriately sized shipping box or envelope.
- Mail the unit along with the Organon Abandoned Unit Program for Nexplanon Return Form to Cardinal Health 3PL. A pre-paid shipping label and address will be provided by C3i.

Only LARC products obtained through a specialty pharmacy can be returned through this program.

10.5.4.3 Cooper Surgical (Paragard)

10.5.4.3.1 Specialty Pharmacy Participation

Paragard is available from the following specialty pharmacy, which ships statewide:

Biologics by McKesson Specialty Pharmacy
Cary, NC 27513
1-888-275-8596
NPI 1487640314

10.5.4.3.2 Obtaining Products

To obtain products providers should use the Cooper Surgical Patient Authorization Form and Patient Referral Form:

- Patients should complete the Patient Authorization Form and return to the provider.

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- Providers should ensure the box next to "PARAGARD T 380A Qty: 1" is checked on the Teva Patient Authorization Form and Patient Referral Form.
- Forms may be returned to the Specialty Pharmacy by fax to 1-855-215-5315 for Biologics by McKesson or fax to 1-212-988-4501 for City Drugs. Upon receipt of your completed forms, Cooper Surgical will send you written confirmation by fax.

10.5.4.3.3 Returning Products

The original Paragard box must be sealed and have been abandoned at least 90 days since it was shipped.

The following will occur ninety days following shipment:

- Paragard will follow-up with your office to confirm the product was placed into the intended Medicaid client.
- If the product was not placed, the Paragard Specialist will obtain your email address to send you the return shipping label.
- Place the original unused and unopened Paragard unit and original packaging with affixed prescription label into a shipping box. You can reuse the original shipping box.
- Print the return shipping label and ship the unused and unopened Paragard unit back to Paragard as soon as possible.
- For additional questions regarding Cooper Surgical Abandoned Unit Return program contact Paragard at 1-877-727-2427.

10.5.4.3.4 Loss of Client Eligibility

If the client was eligible for Medicaid or HTW on the date of service when the LARC product was prescribed and ordered, but the client loses eligibility before the LARC product is inserted, the provider is not required to return the LARC product. If the client is no longer eligible for Medicaid or HTW, the provider may insert the LARC device, but reimbursement for all care and services provided must be resolved between the provider and the client.

If a provider accepts a client as a private pay client, the provider must advise the client she is accepted as a private pay client at the time the service is provided and is responsible for paying for all services received. In this situation, HHSC strongly encourages the provider to ensure the client signs written notification so there is no question how the client was accepted.

10.5.4.3.5 Questions

Contact the specialty pharmacy for questions related to obtaining LARC products. Further questions may be directed to the client's health plan or the TMHP provider help line for FFS Medicaid or HTW clients at 1-800-925-9126.

10.6 Mosquito Repellent Benefit

HHSC covers mosquito repellent year-round for the prevention of the Zika virus.

A list of products is available through the VDP Product Search page. Users can search by product name, the 11-digit National Drug Code (NDC), or click the "mosquito repellent" checkbox to view all products.

Clients that are eligible for the benefit include the following demographics:

- Females who are 10 through 55 years of age
- Pregnant females of any age
- Males who are 14 years of age and older

HHSC requires a prescription for all clients.

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10.7 Palivizumab (Synagis)

Palivizumab is available to physicians for administration to clients in Medicaid and the CSHCN Services Program through VDP. This enables physicians to have palivizumab shipped directly to their office from a network pharmacy, and not purchase the drug.

Physicians who obtain palivizumab through VDP may not submit claims to TMHP for the drug. The administering provider may submit a claim to TMHP for an injection administration fee and any medically necessary office-based evaluation and management service provided at time of injection.

10.7.1 Schedule

The following sections provide information about the forms used for prior authorization requests.

Refer to: The Synagis page on the VDP website for the current season's schedule.

10.7.2 Forms

Note: *Palivizumab is also available for clients enrolled in the Children with Special Health Care Needs (CSHCN) Services Program. Providers can refer to the CSHCN Services Program Provider Manual for details.*

10.7.2.1 Managed Care

Medicaid managed care and CHIP require the Texas Standard Prior Authorization Request Form for Prescription Drug Benefits (Texas Department of Insurance Form NOFR002). Prescribing providers should contact the MCO for prior authorization requirements and forms. MCOs may require additional information in addition to the MCO-specific addendum form. The MCO's form will reflect the appropriate MCO contact information and reconsideration request process.

10.7.2.2 Traditional Medicaid

The prescribing provider must send the Texas Standard Prior Authorization Request Form for Prescription Drug Benefits (TDI NOFR002), the Palivizumab (Synagis) Standard Prior Authorization Request (HHS 1321), the prescription for Synagis, and any supporting information to the Medicaid-enrolled pharmacy. Pharmacy staff will submit the form to the Texas Prior Authorization Call Center.

10.8 Vitamin and Mineral Products

HHSC-enrolled pharmacies with VDP can dispense vitamin and mineral products to clients who are 20 years of age and younger and enrolled in traditional Medicaid. These products are also available to clients enrolled in Medicaid managed care, if the dispensing pharmacy is contracted with the client's health plan.

To expedite pharmacy claim processing for vitamin and mineral products, prescribing providers are encouraged to include the diagnosis on the prescription.

The list of products that can be dispensed at a pharmacy and information about the provision of these products to clients enrolled in fee-for-service can be found on the VDP Product Search page. Users can search by product NDC or name or the HCPCS description.

For clients enrolled in Medicaid managed care or CHIP, claims are submitted to the clients' health plans. Pharmacy staff must work with the health plan's pharmacy benefit manager to determine the billing requirements, reimbursement rates, and coverage limitations for these products.

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11 Prescribing Information

The federal Patient Protection and Affordable Care Act and the Code of Federal Regulations Title 42 §455.410(b) require all physicians or other professionals who order, refer, or prescribe drugs, supplies and services for a recipient of traditional Medicaid, CHIP, CSHCN, and HTW Program to be enrolled as participating Medicaid providers.

Refer to: "Section 1: Provider Enrollment and Responsibilities" (*Vol. 1, General Information*) for more information.

11.1 Tamper-Resistant Prescription Pads

Providers are required by federal law (Public Law 110-28) to use a tamper-resistant prescription pad when writing a prescription for any drug for Medicaid clients. Pharmacies are required to ensure that all written Medicaid prescriptions submitted for payment to the VDP were written on a compliant tamper resistant pad.

The Centers for Medicare & Medicaid Services (CMS) has stated that special copy-resistant paper is not a requirement for electronic medical records (EMRs) or e-prescribing-generated prescriptions and prescriptions that are faxed directly to the pharmacy. These prescriptions may be printed on plain paper and will be fully compliant if they contain at least one feature from each of the following three categories:

- Prevents unauthorized copying of completed or blank prescription forms
- Prevents erasure or modification of information written on the prescription form
- Prevents the use of counterfeit prescription forms

Two features that can be incorporated into computer-generated prescriptions printed on plain paper to prevent passing a copied prescription as an original prescription are as follows:

- Use a very small font that is readable when viewed at 5x magnification or greater and illegible when copied.
- Use a "void" pantograph accompanied by a reverse "Rx," which causes a word such as "Void" to appear when the prescription is photocopied.

Refer to: The *VDP Pharmacy Provider Procedure Manual* on the VDP website.

11.2 Prescription Refills and Expirations

Medicaid prescriptions for non-controlled substances are valid for one year from the date written and up to 11 refills if authorized by prescriber.

Medicaid prescriptions for controlled substances in Schedules III, IV, and V are valid for six months from the date written and up to five refills if authorized by prescriber provider. Controlled substance prescriptions written by advanced practice registered nurses and physicians assistants are valid for 90 days.

Medicaid prescriptions for Schedule II drugs cannot be refilled and must be dispensed within 21 days of the date on which the prescription was written.

Prescriptions for Schedule II drugs may be written as multiples of three for a total of a 90 day supply subject to federal and state law.

Refer to: The *VDP Pharmacy Provider Procedure Manual* on the VDP website.

Pharmacy Laws and Rules page of the Texas State Board of Pharmacy (TSBP) website for rules about issuance of identical sets of Schedule II prescriptions.

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11.3 Prescription Monitoring of Controlled Substances

The Substance Use–Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act requires states to have a qualified prescription drug monitoring program. The SUPPORT Act also requires certain Medicaid providers to check beneficiaries' prescription drug history before prescribing or dispensing controlled substances.

The Texas Prescription Monitoring Program (PMP) collects and monitors prescription data for all Schedule II, III, IV and V controlled substances dispensed by a pharmacy in Texas or to a Texas resident from a pharmacy located in another state. The PMP also provides a venue for monitoring patient prescription history for practitioners and the ordering of Schedule II Texas Official Prescription Forms.

Prescribers are required to check a Medicaid member's PMP history before prescribing Schedule II, III, IV, and V controlled substances.

Pharmacies that dispense Schedule II, III, IV, and V drugs are required to report the information directly to the Texas State Board of Pharmacy's contracted vendor. Prescription data is reported by the prescriber's federal Drug Enforcement Administration (DEA) number. Prescribers and pharmacies are required by statute to have a valid, active DEA numbers in order to possess, administer, prescribe or dispense controlled substances.

Refer to: The Texas Prescription Monitoring Program page of TSBP website.

11.4 Requirements for Early Refills

A refill is considered too soon, or early, if the client has not used at least 75 percent of the previous fill of the medication.

For clients enrolled in traditional Medicaid or the CSHCN Services Program, a refill for certain controlled substances is considered too soon if the client has not used at least 90 percent of the previous fill of the medication.

Note: *Some drugs, such as attention deficit hyperactivity disorder drugs and certain seizure medications, are excluded from this change.*

To identify drugs that require 90 percent utilization, refer to the VDP Drug Search and select the "90% Utilization" filter. The returned results will include only those drugs that meet this requirement.

Refer to: The VDP Drug Search on the VDP website for more information.

Justifications for early refills include, but are not limited to, the following:

- A verifiable dosage increase
- An anticipated prolonged absence from the state

If a client requests an early refill of a drug, the pharmacy must contact VDP to request an override of the early refill restriction. Prescribing providers may be asked to verify the reason for the early refill by the dispensing pharmacy or VDP staff.

Note: *Providers who are members of Medicaid managed care plans should contact the appropriate health plan or pharmacy benefits manager for specific requirements and processes related to dispensing early refills.*

11.5 Clinician-Administered Drugs

All Texas Medicaid providers must submit a rebate-eligible NDC for professional or outpatient claims submitted to TMHP with a clinician-administered drug procedure code.

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The NDC is an 11-digit number on the package or container from which the medication is administered. Providers must enter identifier N4 before the NDC code. The NDC unit and the NDC unit of measure must be entered on all professional or outpatient claims that are submitted to TMHP and Medicaid managed care plans.

Clinician-administered drugs that do not have a rebate-eligible NDC will not be reimbursed by Texas Medicaid.

Refer to: Subsection 6.3.4, "National Drug Code (NDC)" in "Section 6: Claims Filing" (*Vol. 1, General Information*) for additional information on claim filing using NDC.

The VDP CAD Search for more information.

11.5.1 Pharmacy Delivery Method for Clinician-Administered Drugs

Providers administering clinician-administered drugs in an outpatient setting for clients enrolled in Medicaid (both traditional and managed care) can send a prescription to a pharmacy and wait for the drug to be shipped or mailed to their office. This delivery method is called "white-bagging."

Providers should use the following steps for this delivery method:

1) The treating provider identifies that the client is enrolled in Medicaid.
2) The treating provider or treating provider's agent sends a prescription to a Texas Medicaid-enrolled pharmacy and obtains any necessary prior authorizations.
3) If any prior authorization is approved, the dispensing pharmacy fills the prescription and overnight ships an individual dose of the medication, in the client's name, directly to the treating provider.
4) The treating provider administers the medication in the office setting. The provider bills for an administration fee and any medically necessary service provided at time of administration. The provider should not bill Medicaid for the drug.

The pharmacy contacts the provider each month, prior to dispensing any refills, to ensure that the client received all previously dispensed medication. Auto-refills are not allowed.

These medications cannot be used on any other client and cannot be returned to the pharmacy for credit.

Exception: *Unused long-acting reversible contraceptives may be returned in certain circumstances.*

Note: *Physicians who use this delivery method will not have to buy the clinician-administered drug, therefore, the physician is allowed to administer the drug and should only bill for the administration of the drug.*

11.6 Opioid Limitations

For many people, substance use disorder starts after initially receiving opioid prescriptions for an episode of acute pain. To encourage the appropriate use of opioids and reduce the over-prescribing of opioids, Texas Medicaid has implemented the requirements in this section.

11.6.1 Affected Clients

The requirements in this section do not apply to clients who are:

- Receiving hospice care or palliative care
- Being treated for cancer
- Residing in a long-term care facility
- Residing in a facility in which residents receive opioid substitution therapy for the treatment of opioid use disorder (OUD).

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The requirements also do not apply to other clients that HHSC elects to exempt based on an objective, confirmable physical pathology known to cause severe chronic pain that is not ameliorated by other therapies and for which opioid treatment is appropriate (e.g., sickle cell disease). If diagnoses are not available in the medical data, prescribers can request exemptions on a case-by-case basis through the pharmacy prior authorization process.

11.6.2 Morphine Milligram Equivalents

Morphine milligram equivalents (MME) per day is used to compare the potency of one opioid to another. The clinical decision for the MME per day recommendations varies depending on the person's opioid use. Additionally, the Centers for Disease Control and Prevention (CDC) recommends starting opioid treatment with an immediate-release/short-acting formulation at the lowest effective dose instead of an extended-release/long-acting formulation.

A client is considered "opioid naive" if the client has taken opioids for a duration that is less than or equal to seven days in the last 60 days. For clients who are opioid naive, providers must submit a one-time prior authorization request for:

- An opioid prescription that exceeds a ten-day supply.
- A prescription for a long-acting opioid formulation.
- A claim or combination of claims in which the total daily dose of opioids exceeds 90.

The one-time requirement for prior authorization does not apply to subsequent claims because the member will no longer be opioid naive. The duration of the prior authorization is equal to the days' supply of the claim.

For clients who are not opioid naïve, prior authorization is required for opioid prescriptions if the total daily dose of opioids exceeds 90 MME. For those patients who may require a tapering plan, providers would determine the development and management of a patient specific course of therapy to help manage withdrawal symptoms. A prescriber may request a tapering plan through the pharmacy prior authorization process on a case-by-case basis. Prior authorization approvals last for six-months.

11.6.3 Days' Supply Limit

Opioid prescriptions for the treatment of acute pain are rarely required for more than ten days. To reduce the risk of addiction and the diversion of unused opioids, opioid prescriptions for clients who are opioid naïve are limited to a maximum ten-day supply without prior authorization.

11.6.4 Fee-For-Service Three Prescription Limit

Prescriptions for opioids to treat acute pain for clients who are 21 years of age and older are exempt from the three-prescription-per-month limit for members in fee-for-service.

12 Patient Information

12.1 Medicaid Drug Benefits

Clients enrolled in traditional Medicaid are limited to three prescriptions per month with the following exceptions:

- Clients enrolled in waiver programs such as Community Living Assistance (CLASS) and Community-Based Alternatives (CBA)
- Texas Health Steps (THSteps)-eligible clients (clients who are 20 years of age and younger)
- Clients in skilled nursing facilities

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The following categories of drugs do not count against the three prescription per month limit:

- Family planning drugs and supplies
- Smoking cessation drugs
- Insulin syringes

Note: *Prescriptions for family planning drugs and limited home health supplies are not subject to the three-prescription limit.*

Though TMHP reimburses family planning agencies and physicians for family planning drugs and supplies, the following family planning drugs and supplies are also available through the VDP and are not subject to the three-prescription limit:

- Oral contraceptives
- Long-acting injectable contraceptives
- Vaginal ring
- Hormone patch
- Certain drugs used to treat sexually transmitted diseases (STDs)

12.2 Cost Avoidance Coordination of Benefits

Cost avoidance coordination of benefits for pharmacy claims ensures compliance with CMS regulations. Under federal rules, Medicaid agencies must be the payer of last resort. The cost avoidance model checks for other known insurance at point of sale, preventing Medicaid from paying a claim until the pharmacy attempts to obtain payment from the client's primary third party insurance.

12.3 Medicaid Children's Services Comprehensive Care Program

Medically-necessary drugs and supplies that are not covered by the VDP may be available to children and adolescents (birth through 20 years of age) through the Medicaid Comprehensive Care Program (CCP). Drugs and supplies not covered could include, as examples, some over-the-counter drugs, nutritional products, diapers, and disposable or expendable medical supplies.

The Prior Authorization fax number is 1-512-514-4212.

Refer to: Subsection 2.8.1.1, "Pharmacies (CCP)" in the *Children's Services Handbook* (*Vol. 2, Provider Handbooks*) for more information about pharmacy enrollment in CCP.

12.4 Pharmacy Lock-In

Clients enrolled in traditional Medicaid can be "locked-in" to a specific primary care pharmacy. Those clients will have "Lock-in" identified on the face of their Your Texas Benefits Medicaid card. Clients who are not "locked-in" to a specific pharmacy may obtain their drugs or supplies from any enrolled Medicaid pharmacy.

Refer to: Subsection 4.3.2, "Client Lock-in Program" in "Section 4: Client Eligibility" (*Vol. 1, General Information*) for more information about lock-in limitations.

Family planning services are excluded from lock-in limitation.

12.5 Free Delivery of Medicaid Prescriptions

Many Medicaid pharmacies offer free delivery of prescriptions to clients enrolled in Medicaid.

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To find out which pharmacies offer delivery services:

- Refer clients enrolled in traditional Medicaid to the VDP Pharmacy Search. Click the "Delivers" indicator on the search. The returned results will include only those pharmacies that provide a delivery service. These HHSC-enrolled pharmacies have certified their delivery services meet the minimum conditions for the payment of the delivery fee. These certified delivery pharmacies are reimbursed a delivery fee that is included in the medication dispensing formula.
- Refer clients enrolled in Medicaid managed care to their respective health plan. Each health plan develops its own participating pharmacy network for the delivery service.

Deliveries are made to client's home and not institutions, such as nursing homes. Delivery service is not applicable for mail-order prescriptions and not is available for over-the-counter drugs.

Refer to: The VDP Pharmacy Search on the VDP website.

12.6 Medication Synchronization

12.6.1 Overview

Medication Synchronization establishes processes for early refills in order to align the filling or refilling of multiple medications for a client with chronic illnesses.

The Texas Insurance Code §1369(j) allows a client enrolled in Medicaid, their prescribing physician, or the dispensing pharmacist to initiate the medication synchronization request. This process allows for clients to pick up all their medication on a single day each month versus requiring clients to make multiple pharmacy visits to obtain different prescription medications with different refill dates.

12.6.2 Eligible Medications

A drug is eligible for medication synchronization if it meets the following conditions:

- It is listed on the Medicaid, CHIP, KHC or CSHCN formulary.
- It is used for treatment and management of chronic illnesses.
- It is a formulation or dosage form that can be effectively dispensed in a medication synchronization protocol.
- It must meet all prior authorization criteria applicable to the medication on the date the synchronization request is made. This includes clinical prior authorizations, non-preferred prior authorizations, and drug utilization review edits.
- The original prescription must have refills.

Exception: *The prescription could be new but the drug is categorized with the same Generic Code Number (GCN) class, and if the pharmacy uses the override code, the claim will pay. Having available refills is not required.*

A claim cannot be synchronized if it is a Schedule II controlled substance or a Schedule III controlled substance containing hydrocodone.

12.6.3 Chronic Illness

Medications eligible for synchronization must be used to treat chronic illnesses. A chronic illness is defined as an illness or physical condition that is:

- Reasonably expected to continue for an uninterrupted period of at least three months, and
- Controlled, but not cured by medical treatment. This includes drugs used to treat mental health conditions and substance use.

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12.6.4 Traditional Medicaid Claims Processing

A synchronized claim will count as one of the three prescriptions Medicaid will pay if a client is limited.

12.6.5 Medicaid Managed Care and CHIP Claims Processing

Each health plan has an HHSC-approved process for medication synchronization for clients eligible for Medicaid or CHIP. In CHIP, cost sharing or co-payment amounts will be prorated. Dispensing fees will not be prorated.

Pharmacy staff should contact the client's health plan for medication synchronization requirements using the contact information on the MCO Search page.

Refer to: The VDP MCO Search on the VDP website.

13 Pharmacy Prior Authorization

Some Medicaid drugs are subject to one or both types of prior authorization, clinical and non-preferred.

13.1 Clinical Prior Authorization

Clinical prior authorizations utilize evidence-based clinical criteria and nationally recognized peer-reviewed information. These prior authorizations may apply to an individual drug or a drug class on the formulary, including some preferred and non-preferred drugs. There are specific clinical prior authorizations that all health plans are required to perform. Usage of all other clinical prior authorizations will vary between health plans and at the discretion of each health plan.

Some clinical prior authorizations require prescribing providers to submit forms for clients enrolled in traditional Medicaid. Refer to each form's instruction page linked below for submission requirements and instructions. Prescribing providers must submit each form below with the Texas Standard Prior Authorization Request Form for Prescription Drug Benefits (TDI Form NOFR002). and submit by fax to the Texas Prior Authorization Call Center at 866-469-8590.

Health plans may require prior authorization for these drugs. Providers should contact the appropriate health plan for specific requirements and forms.

Drug Name	Number
Cystic Fibrosis Treatment Agents (Kalydeco, Orkambi, and Symdeko)	HHS Form 1338
Increlex	HHS Form 1357
Phosphate Binders	HHS Form 1348
Synagis Refer to: Subsection 10.7, "Palivizumab (Synagis)" in this section for information about Synagis prior authorizations.	HHS Form 1321
Xyrem	HHS Form 1356

Refer to: The Clinical Prior Authorization Assistance Chart is available on the VDP website https://www.txvendordrug.com/sites/default/files/docs/cpa-assistance-chart.pdf. It identifies each health plans prior authorization and how those authorizations relate to the authorizations used for traditional Medicaid claim processing. The chart is updated quarterly.

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13.2 Non-preferred Prior Authorization

The PDL is arranged by drug therapeutic class and contains a subset of many, but not all, drugs that are on the Medicaid formulary. Drugs are identified as preferred or non-preferred on the PDL. Drugs listed on the PDL as preferred, or those not listed at all, are available without PDL prior authorization. Drugs identified as non-preferred on the PDL require a PDL prior authorization.

Refer to: Medicaid health plans are required to adhere to the Texas Medicaid Preferred Drug List.

Note: *CHIP does not have a PDL.*

Refer to: The PDL Prior Authorization Criteria Guide that explains the criteria that are used to evaluate the PDL prior authorization requests.

13.3 Obtaining Prior Authorization

Prior authorization for clients enrolled in traditional Medicaid is requested through the Texas Prior Authorization Call Center.

The Texas Prior Authorization Call Center accepts prior authorization requests by phone at 1-877-PA-TEXAS (1-877-728-3927) (Monday through Friday, between 7:00 a.m. to 7:00 p.m., Central time) or online through the VDP Provider Portal. Online submissions are only available for non-preferred prior authorization requests. The prescriber can submit both clinical and non-preferred prior authorization requests online.

Refer to: The VDP Provider Portal Registration User Manual and the VDP Provider Portal User Manual.

The VDP Prescriber Prior Authorization Manual.

Note: *Pharmacists cannot obtain prior authorization for medications. If the client arrives at the pharmacy without prior authorization for a non-preferred drug and/or a drug requiring clinical prior authorization, the pharmacist will alert the provider's office and ask the provider to get prior authorization.*

13.4 Prior Authorization Reconsideration

The prescribing provider may request reconsideration if the prior authorization request is denied.

13.4.1 Managed Care

Prescribing providers should refer to the VDP MCO Search to find each MCO's prior authorization call center to learn about their reconsideration or appeal processes.

13.4.2 Fee-for-service Medicaid

The Texas Prior Authorization Call Center will notify prescribing providers of their right to request a reconsideration of the decision rendered. Providers should complete the Medicaid Fee-for-Service Prior Authorization Reconsideration Request (HHS Form 1322) and submit it to the Texas Prior Authorization Call Center. Refer to the form's instruction page for requirements and submission instructions. Providers may also include supporting documentation with their form submission, including:

- Medication documentation, such as the patient's medical records or lab results supporting the medical reason for the treatment
- Peer-reviewed literature supporting the safety, efficacy, and rationale for using the medication outside the current Medicaid criteria, if applicable

The Texas Prior Authorization Call Center will mail a copy of the reconsideration determinations to the requesting provider and client. The client's letter will include the HHSC prior authorization appeal process if the reconsideration request is denied.

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13.5 72-Hour Emergency Supply

Federal and Texas law allows for a 72-hour emergency supply of a prescribed drug to be provided when a medication is needed without delay and prior authorization is not available. This rule applies to non-preferred drugs on the PDL and any drug that is affected by a clinical prior authorization.

Drugs not on the PDL may also be subject to clinical prior authorization.

14 Retrospective Drug Utilization Reviews

Retrospective DUR provides for the ongoing periodic examination of claims data and other records to identify patterns of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care among prescribing providers, pharmacists, and people associated with specific drugs or groups of drugs.

The retrospective review also allows for active and ongoing educational outreach in the form of letters or face-to-face discussions to educate prescribing providers on common drug therapy problems with the aim of improving prescribing or dispensing practices.

The Texas Drug Utilization Review Board reviews and recommends interventions for traditional Medicaid claims. A fixed-number of interventions are performed each calendar year. MCOs are required to create and perform interventions and education of their population.

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