Texas Medicaid
Provider Procedures Manual

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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 clinician-administered 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.

Clinician-administered drugs or biologicals, 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 Healthcare Common Procedure Coding System (HCPCS) codes for CADs are reviewed throughout the year. If a CAD is determined to be an appropriate benefit for Medicaid, then the HCPCS code is presented at a rate hearing as part of the process to become a benefit. CADs may become a benefit prior to issuance of a HCPCS code. In this instance, the CAD may be listed on the Texas NDC-to-HCPCS Crosswalk with an unclassified HCPCS code. VDP manages the CAD benefit and crosswalk. The Texas NDC-to-HCPCS Crosswalk identifies relationships between National Drug Codes (NDC) and payable Healthcare Common Procedure Coding System (HCPCS) codes in Medicaid and CHIP The crosswalk assists with billing and coding and is a reference for converting HCPCS billing units to valid NDC unit calculations. The crosswalk is published quarterly and based on revisions to the CMS list of rebate-eligible drugs and new drugs and biologicals added to First Databank.

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 that hold 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 be enrolled with VDP prior to 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.

Pharmacy providers enrolled with VDP 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.

1.3 Program Contact Information

Vendor Drug Program	Telephone Number
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 Management	1-512-707-6108
Program Policy	1-512-707-6108
Drug formulary (Texas listing of national drug codes)	1-512-462-6390
Texas Pharmacy Prior Authorization Center Hotline	1-877-728-3927
Texas Pharmacy Third Party Call Center	1-866-389-5594

2 Enrollment

Refer to: 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*).

3 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 Medicaid 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 Medicaid Vendor Drug Program. A new NDC for a currently payable HCPCs code generally does not require a new rate hearing.

Refer to: Subsection 9, "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.

3.1 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.

To complete the prior authorization process by paper, the provider must fax or mail the completed prior authorization 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.

3.2 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.

4 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 Texas Medicaid), 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 an amount equal to 106 percent of the average sales price (ASP).

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

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 8.1, "JW Modifier Claims Filing Instructions" in this handbook for further instructions about the JW modifier.

5 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 9, "Pharmacy Benefit" in this handbook for more information.

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 10.5.1, "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.

6 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.

6.1 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 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.

6.1.1 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

	Zofran	Avastin	Rocephin
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

6.1.2 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.

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

6.1.3 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.

6.1.4 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.
- 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. In the absence of FDA indications, a drug needs to meet the following criteria:

- The drug is recognized by the American Medical Association Drug Evaluations (AMA-DE), American Hospital Formulary Service Drug Information, the U.S. Pharmacopoeia Dispensing Information, Volume I, or two articles from major peer-reviewed journals that have validated and uncontested data supporting the proposed use for the specific medical condition as safe and effective.
- It is medically necessary to treat the specific medical condition, including life-threatening conditions or chronic and seriously debilitating conditions.
- The off-label use of the drug is not investigational or experimental.

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
12357-B Riata Trace Parkway, Suite 100
Austin, TX 78727
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.

7 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.

7.1 Abatacept (Orencia)

Abatacept is a synthetic protein produced by recombinant deoxyribonucleic acid (DNA) technology that is used for treating rheumatoid arthritis. Abatacept slows the damage to bones and cartilage and relieves the symptoms and signs of arthritis. Abatacept (procedure code J0129) is a benefit of Texas Medicaid for clients who have moderately to severely active rheumatoid arthritis. These clients may also have an inadequate response to one or more non-biological, disease modifying antirheumatic drugs (DMARDs).

7.1.1 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 or juvenile idiopathic arthritis (JIA)

  Note: *A diagnosis of adult RA 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
- 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 an initial request for abatacept injections may be granted for six months for eight doses. Prior authorization will be considered when the client has an inadequate response after 12 weeks to a nonbiological DMARD such as methotrexate or sulfasalazine or one or more biological (injectable) DMARDs, such as adalimumab, etanercept, or tumor necrosis factor (TNF) antagonists. The inadequate response must be indicated by all of the following commonly used prognostic factors:

- Visual Analogue scale (VAS) (4 or greater on a pain scale from 0-10)
- Global Arthritis Score (GAS) (3 or greater with remission defined as less than 3)
- Health Assessment Questionnaire Disability Index (HAQDI) score (greater than 1)
- Evidence of radiographic erosions
- Elevated erythrocyte sedimentation rate (greater than 20 millimeters/hour)
- Elevated C-reactive protein level (greater than zero milligrams/deciliter)
- Elevated rheumatoid factor (RF) level (greater than 60 units/millimeter or a titer greater than 1:80 titer)
- Elevated anti-cyclic citrullinated peptide (anti-CCP) antibody level (20 units/millimeter or greater)

Prior authorization for subsequent dosing may be given for a maximum of six doses 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 a 20-percent improvement as defined by the ACR
- 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.

7.2 Adalimumab

Procedure code J0135 is a benefit 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

Diagnosis Codes							
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
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	M05811	M05812
M05821	M05822	M05831	M05832	M05841	M05842	M05851	M05852
M05861	M05862	M05871	M05872	M0589	M06011	M06012	M06021
M06022	M06031	M06032	M06041	M06042	M06051	M06052	M06061
M06062	M06071	M06072	M0608	M0609	M061	M06811	M06812
M06819	M06821	M06822	M06829	M06831	M06832	M06839	M06841
M06842	M06849	M06851	M06852	M06859	M06861	M06862	M06869
M06871	M06872	M06879	M0688	M0689	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	M488X1	M488X2	M488X3	M488X4
M488X5	M488X6	M488X7	M488X8	M488X9			

7.3 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).

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.

7.4 Alglucosidase Alfa (Myozyme)

Alpha-glucosidase, a recombinant human enzyme alpha-glucosidase (rhGAA), is an essential enzyme for normal muscle development and function. Aglucosidase alfa may be a benefit of Texas Medicaid for clients of any age who are diagnosed with glycogen storage disease Type II (GSD Type II, also known as Pompe disease), using procedure codes J0220 and J0221. The most appropriate diagnosis code must be indicated on the prior authorization request and on the claim.

Prior authorization is required for alglucosidase alfa and documentation must include all of the following:

- A request for alglucosidase alfa.
- Laboratory evidence of acid alpha-glucosidase (GAA) deficiency, (i.e., below the laboratory-defined cut-off value as determined by the laboratory performing the GAA enzyme activity assay). Tissues used for determination of GAA deficiency may include blood, muscle, or skin fibroblasts.

The physician must maintain supporting documentation in the client's medical record.

7.5 Amifostine

Amifostine is a benefit of Texas Medicaid for the reduction of the cumulative renal toxicity associated with administration of cisplatin in clients who have advanced ovarian cancer or non-small cell lung cancer with documentation of a creatinine clearance of 50 or less and where no other chemotherapeutic agent can be used.

Amifostine may also be used to reduce the incidence of moderate-to-severe xerostomia in clients undergoing postoperative radiation treatment for head and neck cancers where the radiation port includes a substantial portion of the parotid glands.

Amifostine may be reimbursed for the following indications:

- Bone marrow toxicity
- Cisplatin- and cyclophosphamide-induced (prophylaxis)
- Advanced solid tumors
- Head and neck carcinoma
- Malignant lymphoma
- Non-small cell lung cancer
- Myelodysplastic syndromes
- Nephrotoxicity
- Advanced ovarian carcinoma
- Melanoma

- Advanced solid tumors of non-germ cell origin
- Neurotoxicity
- Reduction in the incidence of mucositus in clients receiving radiation therapy, or radiation combined with chemotherapy
- Reduction in the incidence of xerostomia associated with postoperative radiation treatment of head and neck cancer, where the radiation port includes a substantial portion of the parotid glands

Providers must use procedure code J0207 with one of the following diagnosis codes:

Diagnosis Codes							
A690	A691	C000	C001	C002	C003	C004	C005
C006	C008	C01	C020	C021	C022	C023	C024
C028	C029	C030	C031	C039	C040	C041	C048
C049	C050	C051	C052	C058	C059	C060	C061
C062	C0689	C069	C07	C080	C081	C089	C090
C091	C098	C099	C100	C101	C102	C103	C104
C108	C109	C110	C111	C112	C113	C118	C119
C12	C130	C131	C132	C138	C139	C140	C142
C148	C153	C154	C155	C158	C159	C160	C161
C162	C163	C164	C165	C166	C168	C169	C170
C171	C172	C173	C178	C179	C180	C181	C182
C183	C184	C185	C186	C187	C188	C189	C19
C20	C210	C211	C218	C220	C221	C222	C223
C227	C228	C229	C23	C240	C241	C248	C249
C250	C251	C252	C253	C254	C257	C258	C259
C260	C261	C269	C300	C301	C310	C311	C312
C313	C318	C319	C320	C321	C322	C323	C328
C329	C33	C3400	C3401	C3402	C3410	C3411	C3412
C342	C3430	C3431	C3432	C3480	C3481	C3482	C3490
C3491	C3492	C37	C380	C381	C382	C383	C384
C388	C390	C399	C4000	C4001	C4002	C4010	C4011
C4012	C4020	C4021	C4022	C4030	C4031	C4032	C4081
C4082	C410	C411	C412	C413	C414	C419	C430
C4310	C4311	C4312	C4320	C4321	C4322	C4330	C4331
C4339	C434	C4351	C4352	C4359	C4360	C4361	C4362
C4370	C4371	C4372	C438	C439	C4491	C4492	C4499
C460	C461	C462	C463	C464	C4650	C4651	C4652
C467	C469	C478	C480	C481	C482	C488	C490
C4910	C4911	C4912	C4920	C4921	C4922	C493	C494
C495	C496	C498	C499	C50011	C50012	C50019	C50021
C50022	C50029	C50111	C50112	C50119	C50121	C50122	C50211
C50212	C50219	C50221	C50222	C50311	C50312	C50319	C50321
C50322	C50411	C50412	C50419	C50421	C50422	C50511	C50512

Diagnosis Codes							
C50519	C50521	C50522	C50611	C50612	C50619	C50621	C50622
C50811	C50812	C50819	C50821	C50822	C50911	C50912	C50919
C50921	C50922	C50929	C510	C511	C512	C519	C52
C530	C531	C538	C539	C540	C541	C542	C543
C548	C549	C55	C561	C562	C569	C5700	C5701
C5702	C5710	C5711	C5712	C5720	C5721	C5722	C573
C574	C577	C578	C579	C58	C600	C601	C602
C608	C609	C61	C6200	C6201	C6202	C6210	C6211
C6212	C6290	C6291	C6292	C6300	C6301	C6302	C6310
C6311	C6312	C632	C637	C638	C639	C641	C642
C649	C651	C652	C659	C661	C662	C669	C670
C671	C672	C673	C674	C675	C676	C677	C678
C679	C680	C681	C688	C689	C6900	C6901	C6902
C6910	C6911	C6912	C6920	C6921	C6922	C6930	C6931
C6932	C6940	C6941	C6942	C6950	C6951	C6952	C6960
C6961	C6962	C6980	C6981	C6982	C6990	C6991	C6992
C700	C701	C709	C710	C711	C712	C713	C714
C715	C716	C717	C718	C719	C720	C721	C7221
C7222	C7231	C7232	C7241	C7242	C7250	C7259	C729
C73	C7401	C7402	C7411	C7412	C7490	C750	C751
C752	C753	C754	C755	C758	C759	C760	C761
C762	C763	C7640	C7641	C7642	C7650	C7651	C7652
C768	C770	C771	C772	C773	C774	C775	C778
C779	C7800	C7801	C7802	C781	C782	C7839	C784
C785	C786	C787	C7889	C7900	C7901	C7902	C7911
C7919	C792	C7931	C7932	C7949	C7951	C7952	C7960
C7961	C7962	C7970	C7971	C7972	C7981	C7982	C7989
C800	C801	C802	C8100	C8101	C8102	C8103	C8104
C8105	C8106	C8107	C8108	C8109	C8110	C8111	C8112
C8113	C8114	C8115	C8116	C8117	C8118	C8119	C8120
C8121	C8122	C8123	C8124	C8125	C8126	C8127	C8128
C8129	C8130	C8131	C8132	C8133	C8134	C8135	C8136
C8137	C8138	C8139	C8140	C8141	C8142	C8143	C8144
C8145	C8146	C8147	C8148	C8149	C8170	C8171	C8172
C8173	C8174	C8175	C8176	C8177	C8178	C8179	C8190
C8191	C8192	C8193	C8194	C8195	C8196	C8197	C8198
C8199	C8201	C8202	C8203	C8204	C8205	C8206	C8207
C8208	C8209	C8211	C8212	C8213	C8214	C8215	C8216
C8217	C8218	C8219	C8221	C8222	C8223	C8224	C8225
C8226	C8227	C8228	C8229	C8231	C8232	C8233	C8234

Diagnosis Codes							
C8235	C8236	C8237	C8238	C8239	C8241	C8242	C8243
C8244	C8245	C8246	C8247	C8248	C8249	C8251	C8252
C8253	C8254	C8255	C8256	C8257	C8258	C8259	C8261
C8262	C8263	C8264	C8265	C8266	C8267	C8268	C8269
C8280	C8281	C8282	C8283	C8284	C8285	C8286	C8287
C8288	C8289	C8290	C8291	C8292	C8293	C8294	C8295
C8296	C8297	C8298	C8299	C8330	C8331	C8332	C8333
C8334	C8335	C8336	C8337	C8338	C8339	C8350	C8351
C8352	C8353	C8354	C8355	C8356	C8357	C8358	C8359
C8370	C8371	C8372	C8373	C8374	C8375	C8376	C8377
C8378	C8379	C8380	C8381	C8382	C8383	C8384	C8385
C8386	C8387	C8388	C8389	C8391	C8392	C8393	C8394
C8395	C8396	C8397	C8398	C8399	C8400	C8401	C8402
C8403	C8404	C8405	C8406	C8407	C8408	C8409	C8410
C8411	C8412	C8413	C8414	C8415	C8416	C8417	C8418
C8419	C8491	C8492	C8493	C8494	C8495	C8496	C8497
C8498	C8499	C84A1	C84A2	C84A3	C84A4	C84A5	C84A6
C84A7	C84A8	C84A9	C84Z1	C84Z2	C84Z3	C84Z4	C84Z5
C84Z6	C84Z7	C84Z8	C84Z9	C8511	C8512	C8513	C8514
C8515	C8516	C8517	C8518	C8519	C8521	C8522	C8523
C8524	C8525	C8526	C8527	C8528	C8529	C8580	C8581
C8582	C8583	C8584	C8585	C8586	C8587	C8588	C8589
C8591	C8592	C8593	C8594	C8595	C8596	C8597	C8598
C8599	C860	C861	C862	C863	C864	C865	C866
C880	C882	C883	C888	C889	C9000	C9001	C9002
C9010	C9011	C9012	C9020	C9021	C9022	C9030	C9031
C9032	C9140	C9141	C9142	C960	C964	C965	C966
C969	C96A	C96Z	D030	D0310	D0311	D0312	D0320
D0321	D0322	D0330	D0339	D034	D0351	D0352	D0359
D0360	D0361	D0362	D0370	D0371	D0372	D038	D039
D588	D589	D590	D591	D592	D593	D594	D595
D596	D598	D599	D6101	D6109	D61810	D61811	D61818
D6182	D619	D62	D630	D631	D638	D640	D641
D642	D643	D644	D6481	D6489	D649	G620	H903
H905	H933X1	H933X2	H933X3	H933X9	K117	N059	T451X1A
T451X1D	T451X1S	T451X2A	T451X2D	T451X2S	T451X3A	T451X3D	T451X3S
T451X4A	T451X4D	T451X4S	T4591xA	T4591xD	T4591xS	T4592xA	T4592xD
T4592xS	T4593xA	T4593xD	T4593xS	T4594xA	T4594xD	T4594xS	T50905A
T50905D	T50905S	T66xxxA	T66xxxD	T66xxxS	Z510	Z5111	

7.6 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.

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.

7.7 Antisense Oligonucleotides (eteplirsen, golodirsen, and nusinersen)

Antisense oligonucleotides, eteplirsen (Exondys 51) (procedure code J1428), golodirsen (Vyondys 53) (procedure code J1429), nusinersen (Spinraza) (procedure code J2326), or viltolarsen (Viltepso) (procedure code C9071)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.

7.7.1 Prior Authorization Requirements

Prior authorization requests for procedure codes J1428, J1429, J2326, and C9071 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 eteplirsen, golodirsen, nusinersen, or viltolarsen. Physician services include the procedural costs and the associated supplies for the administration of the medication.

For situations in which procedure code J1428, J1429, J2326, or C9071 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 10.5.1, "Pharmacy Delivery Method for Clinician-Administered Drugs" in this handbook.*

A neurologist's consultation must be dated no more than six months prior to an initial request and no more than one rolling year prior to a recertification or extension request. The consultation must include the neurologist's name, credentials, contact information, and a recommendation for treatment with the specific antisense oligonucleotide.

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 3.1, "Prior Authorization Requests" in this handbook for additional prior authorization information.

7.7.1.1 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
- Client age 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.
- A neurologist's consultation dated no more than six months prior to the initially requested authorization start date. The consultation must include the neurologist's name, credentials, contact information, and a recommendation for treatment with the requested antisense oligonucleotide.
- 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 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.
- Client age
- 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.
- 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:

- Genetic testing must confirm biallelic pathogenic variants in the client's survival motor neuron 1 (SMN1) gene
- Client age
- 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 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.
- 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.

7.7.1.2 Recertification/Extension Requests (for all Antisense Oligonucleotides)

Recertification/extension prior authorization requests for antisense oligonucleotides will be considered by Medical Director Review for additional six month periods. The recertification/extension request 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.

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
- Client age
- 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
- A neurology consultation dated no more than one rolling year of the recertification/extension date that includes the name, credentials, and contact information for the consulting neurologist recommending ongoing treatment with the requested antisense oligonucleotide
- 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 golodirsen (Vyondys 53) and viltolarsen (Viltepso) 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.

7.7.1.3 Exclusions

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

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.

7.8 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.

7.9 Azacitidine (Vidaza)

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

Diagnosis Codes							
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				

7.10 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), and rimabotulinumtoxinB (Myobloc brand of botulinum toxin type B) 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 dystonias, 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:

Diagnosis Codes							
G114	G2401	G241	G243	G244	G245	G248	G250
G251	G252	G253	G35	G360	G370	G371	G372
G374	G375	G378	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
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	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
M722	N318	N3281	N3644	R490	R498		

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

Diagnosis Codes for J0586							
G114	G241	G243	G244	G245	G248	G35	G360

Diagnosis Codes for J0586							
G370	G371	G372	G374	G375	G378	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
M722							

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

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

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.

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.

7.11 Brexanolone (Zulresso)

Brexanolone (Zulresso) (procedure code J1632) is a benefit for female clients who are 18 years of age and older, and is indicated for the treatment of postpartum depression in adults. Brexanolone (Zulresso) must be prescribed by, or in consultation with, a psychiatrist or obstetrics/gynecologist.

Prior authorization is required for brexanolone (Zulresso) (procedure code J1632).

Brexanolone (Zulresso) is not a benefit for clients with active psychosis or history of bipolar disorder or schizophrenia.

7.11.1 Risk Evaluation and Mitigation Strategy Program

Brexanolone (Zulresso) is only available through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) due to the risk of excessive sedation or sudden loss of consciousness.

Health-care facilities must enroll in the brexanolone (Zulresso) REMS program.

Prior to brexanolone (Zulresso) treatment, clients must also be enrolled in the brexanolone (Zulresso) REMS program. Certified facilities must ensure that brexanolone (Zulresso) is only administered to clients who are enrolled in the brexanolone (Zulresso) REMS program.

Pharmacies must be certified in the brexanolone (Zulresso) REMS program and must only dispense to health-care facilities certified to administer brexanolone (Zulresso).

7.11.2 Prior Authorization Requirements

Prior authorization requests for procedure code J1632 must be submitted with a Special Medical Prior Authorization Request Form, and may be approved for one continuous 60-hour intravenous infusion per pregnancy or postpartum period.

For treatment of postpartum depression with brexanolone (Zulresso) therapy, all of the following criteria must be met:

- The client has a diagnosis of postpartum depression (diagnosis code F530) with a HAM-D total score of at least 20, or as scored by an alternative comparable rating scale that measures depressive symptoms.
- The onset of the major depressive episode is within the third trimester and no later than the first four weeks postpartum.
- The client is six months or less postpartum at screening.
- The client does not have active psychosis or history of bipolar disorder or schizophrenia.
- The client has not received treatment with brexanolone (Zulresso) for the current postpartum depressive episode.
- The client must have continuous pulse oximetry monitoring during the infusion period due to risk of serious harm, and must be accompanied when interacting with their children as the drug can cause loss of consciousness.
- A health-care provider must be available on site for continuous monitoring of the client for the duration of the infusion.

Refer to: Subsection 3.1, "Prior Authorization Requests" in this handbook for additional prior authorization information.

7.12 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 E8330 or E8331) 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.

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

- The client is two 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.
- 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 physician confirming one of the following:
  - The client has achieved normal level of serum phosphate.
  - The client has demonstrated a positive clinical response to burosumab-twza (Crysvita) (e.g., enhanced height velocity, improvement in askeletal deformity, reduction of fractures, and reduction of generalized bone pain).
- The physician continues to monitor serum phosphate level.

Burosumab-twza (Crysvita) must be prescribed by a nephrologist or endocrinologist, or be in consultation with a nephrologist or endocrinologist.

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 3.1, "Prior Authorization Requests" in this handbook for additional prior authorization information.

7.13 Calaspargase Pegol-Mknl

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, C9102.

7.14 Cemiplimab-rwlc

Cemiplimab-rwlc (procedure code J9119) is a benefit for clients who are 18 years of age and older and is limited to the following diagnosis codes:

Diagnosis Codes							
C4402	C44121	C441221	C441222	C441291	C441292	C44221	C44222
C44229	C44320	C44321	C44329	C4442	C44520	C44521	C44529
C44621	C44622	C44629	C44721	C44722	C44729	C4482	C4492

7.15 Chelating Agents

Chelating agent procedure codes J0470, J0600, and J0895 are benefits of Texas Medicaid when billed with an appropriate diagnosis code.

7.15.1 Dimercaprol

Procedure code J0470 is a benefit when billed with one of the following diagnosis codes:

Diagnosis Codes							
T560X1A	T560X1D	T560X1S	T560X2A	T560X2D	T560X2S	T560X3A	T560X3D
T560X3S	T560X4A	T560X4D	T560X4S	T561X1A	T561X1D	T561X1S	T561X2A
T561X2D	T561X2S	T561X3A	T561X3D	T561X3S	T561X4A	T561X4D	T561X4S
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
T56891A	T56891D	T56891S	T56892A	T56892D	T56892S	T56893A	T56893D
T56893S	T56894A	T56894D	T56894S	T5691XA	T5691XD	T5691XS	T5692XA
T5692XD	T5692XS	T5693XA	T5693XD	T5693XS	T5694XA	T5694XD	T5694XS
T570X1A	T570X1D	T570X1S	T570X2A	T570X2D	T570X2S	T570X3A	T570X3D
T570X3S	T570X4A	T570X4D	T570X4S				

7.15.2 Edetate calcium disodium

Procedure code J0600 is a benefit when billed with one of the following diagnosis codes:

Diagnosis Codes							
T560X1A	T560X1D	T560X1S	T560X2A	T560X2D	T560X2S	T560X3A	T560X3D
T560X3S	T560X4A	T560X4D	T560X4S	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	T56891A	T56891D	T56891S	T56892A
T56892D	T56892S	T56893A	T56893D	T56893S	T56894A	T56894D	T56894S

Diagnosis Codes							
T5691XA	T5691XD	T5691XS	T5692XA	T5692XD	T5692XS	T5693XA	T5693XD
T5693XS	T5694XA	T5694XD	T5694XS				

7.15.3 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	D5709	D571	D5720	D57211	D57212	D57213
D57218	D57219	D5740	D57411	D57412	D57413	D57418	D57419
D5742	D57431	D57432	D57433	D57438	D57439	D5744	D57451
D57452	D57453	D57458	D57459	D5780	D57811	D57812	D57813
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	T56891A	T56891D	T56891S	T56892A	T56892D	T56892S
T56893A	T56893D	T56893S	T56894A	T56894D	T56894S	T5691XA	T5691XD
T5691XS	T5692XA	T5692XD	T5692XS	T5693XA	T5693XD	T5693XS	T5694XA
T5694XD	T5694XS						

7.16 Chimeric Antigen Receptor (CAR) T-Cell Therapy

Axicabtagene ciloleucel (Yescarta) (procedure code Q2041), Brexucabtagene autoleucel (Tecartus) (procedure code C9073), and Tisagenlecleucel (Kymriah) (procedure code Q2042) are benefits of Texas Medicaid with prior authorization and must be prescribed by an oncologist or in consultation with an oncologist.

Procedure codes C9073, Q2041, and Q2042 are limited to once per lifetime, any provider.

Axicabtagene ciloleucel (Yescarta) and tisagenlecleucel (Kymriah) infusions must take place at a certified healthcare facility. Certified healthcare facilities must enroll with the Risk Evaluation and Mitigation Strategies (REMS) and comply with its requirements for each drug administered within this section.

Certified healthcare facilities must ensure that providers that prescribe, dispense, or administer axicabtagene ciloleucel (Yescarta) and tisagenlecleucel (Kymriah) receive training for the management of cytokine release syndrome (CRS) and neurological toxicities.

It is recommended that severe or life-threatening CRS be treated with tocilizumab. Facilities must have on-site at least 2 doses of tocilizumab per patient for administration within 2 hours of infusion if needed for treatment of CRS.

Providers and facilities must ensure that the client:

- Receives the recommended pre-medications before treatment.
- Is closely monitored for toxicity post infusion.
- Is instructed to remain within proximity of the certified healthcare facility for at least 4 weeks post-infusion.

7.16.1 Prior Authorization Criteria for Axicabtagene Ciloleucel (Yescarta)

Prior authorization approval of axicabtagene ciloleucel (Yescarta) (procedure code Q2041) infusion therapy will be considered when all of the following criteria are met:

- The client must have a histologically confirmed diagnosis of one of the following types of aggressive non-Hodgkin's lymphoma (diagnosis codes C8330, C8331, C8332, C8333, C8334, C8335, C8336, C8337, C8338, and C8339):
  - Diffuse large B-cell lymphoma, not otherwise specified
  - High-grade B-cell lymphoma
  - Primary mediastinal large B-cell lymphoma
  - Transformed 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 must have received adequate prior therapy including, at a minimum, all of the following:
  - An anthracycline-containing chemotherapy regimen
  - For CD20+ disease, anti-CD20 monoclonal antibody
  - For clients with transformed follicular lymphoma, prior chemotherapy for follicular lymphoma with chemotherapy refractory disease after transformation to DLBCL
- There must be documentation of all of the following clinical findings:
  - Client has an Eastern Cooperative Oncology Group performance status of 0 or 1.
  - Client does not have primary central nervous system lymphoma/disease.
  - Client does not have an active infection or inflammatory disorder.
  - Client has not received prior CD-19 directed CAR-T therapy.

7.16.2 Prior Authorization for Brexucabtagene autoleucel (Tecartus)

Prior authorization approval for Brexucabtagene autoleucel (Tecartus) (procedure code C9073) infusion therapy 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 and C8319).
- The client is 18 years of age or older.
- The client has received adequate therapy and has had at least one of the following systemic treatment for MCL prior to brexucabtagene autoleucel therapy:

  - Anthracycline or bendamustine-containing chemotherapy
  - Anti-CD 20 monoclonal antibody therapy
  - Bruton Tyrosine Kinase inhibitors (e.g. ibrutinib or acalabrutinib)
- 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.

7.16.3 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 does not have an active infection or inflammatory disorder.
- The Eastern Cooperative Oncology Group performance status is between 0 to 3.
- 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, and C8339):
  - 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 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 must have received adequate prior therapy including, at a minimum, the following:
  - An anthracycline-containing chemotherapy regimen
  - For CD20+ disease, an anti-CD20 monoclonal antibody
  - For clients with transformed follicular lymphoma, prior chemotherapy refractory disease after transformation to DLBCL
- The client has an Eastern Cooperative Oncology Group performance status of 0 or 1
- The client does not have primary central nervous system lymphoma
- The client does not have an active infection or inflammatory disorder
- The client has not received prior CD-19 directed CAR-T therapy

Refer to: Subsection 3.1, "Prior Authorization Requests" in this handbook for additional prior authorization information.

7.16.4 Exclusions

Axicabtagene ciloleucel (Yescarta), Brexucabtagene autoleucel (Tecartus), and Tisagenlecleucel (Kymriah) are not benefits for clients who have any of the following:

- An active infection
- An inflammatory disorder
- Primary central nervous system lymphoma

7.17 Clofarabine

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

7.17.1 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 both of the following:

- A diagnosis of refractory or relapsed acute lymphoblastic leukemia
- A history of at least two prior failed chemotherapy regimens

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 3.1, "Prior Authorization Requests" in this handbook for additional prior authorization information.

7.18 Colony Stimulating Factors (Filgrastim, Pegfilgrastim, and Sargramostim)

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 (procedure codes J1442, J1447, and Q5101) and pegfilgrastim (procedure code J2505) are granulocyte colony stimulating factors (G-CSFs). The biosimilars to filgastrim, nivestym (procedure code Q5110), pegfilgrastim-bmez (Ziextenzo) (procedure code Q5120), and pegfilgrastim (Fulphila) (procedure code Q5108) are G-CSFs. Sargramostim (procedure code J2820) is a granulocyte- macrophage colony stimulating factor (GM-CSF). GM-CSF and G-CSF stimulate neutrophil production after autologous bone marrow transplant and significantly reduce the duration and impact of neutropenia. 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 J2505 will be denied if billed on the same date of service as procedure code J1442.

Procedure code 96377 must be billed with procedure code J2505 on the same day by the same provider.

One of the following diagnosis codes must be billed with the appropriate procedure code:

Diagnosis Codes							
C000	C001	C002	C003	C004	C005	C006	C008
C01	C020	C021	C022	C023	C024	C028	C029
C030	C031	C039	C040	C041	C048	C049	C050
C051	C052	C059	C060	C061	C062	C0689	C069
C07	C080	C081	C089	C090	C091	C099	C100
C101	C102	C103	C104	C108	C109	C110	C111
C112	C113	C118	C119	C12	C130	C131	C132
C138	C139	C140	C142	C148	C153	C154	C155
C158	C159	C160	C161	C162	C163	C164	C165
C166	C168	C169	C170	C171	C172	C173	C178
C179	C180	C181	C182	C183	C184	C185	C186
C187	C188	C189	C19	C20	C210	C211	C218
C220	C221	C222	C223	C227	C228	C229	C23
C240	C241	C248	C249	C250	C251	C252	C253
C254	C257	C258	C259	C260	C261	C269	C300
C301	C310	C311	C312	C313	C318	C319	C320
C321	C322	C323	C328	C329	C33	C3401	C3402
C3411	C3412	C342	C3431	C3432	C3481	C3482	C3491
C3492	C37	C380	C381	C382	C383	C384	C388
C390	C399	C4001	C4002	C4011	C4012	C4021	C4022
C4031	C4032	C4081	C4082	C410	C411	C412	C413
C414	C430	C43111	C43112	C43121	C43122	C4321	C4322
C4331	C4339	C434	C4351	C4352	C4359	C4361	C4362
C4371	C4372	C438	C439	C460	C461	C462	C463
C464	C4651	C4652	C467	C469	C478	C480	C481
C482	C488	C490	C4911	C4912	C4921	C4922	C493
C494	C495	C496	C498	C499	C49A0	C49A1	C49A2
C49A3	C49A4	C49A5	C49A9	C4A0	C4A111	C4A112	C4A121
C4A122	C4A21	C4A22	C4A31	C4A39	C4A4	C4A51	C4A52
C4A59	C4A61	C4A62	C4A71	C4A72	C4A8	C50011	C50012
C50021	C50022	C50111	C50112	C50121	C50122	C50211	C50212
C50221	C50222	C50311	C50312	C50321	C50322	C50411	C50412
C50421	C50422	C50511	C50512	C50521	C50522	C50611	C50612
C50621	C50622	C50811	C50812	C50821	C50822	C50911	C50912
C50921	C50922	C510	C511	C512	C519	C52	C530
C531	C538	C539	C540	C541	C542	C543	C548
C55	C561	C562	C5701	C5702	C5711	C5712	C5721
C5722	C573	C574	C577	C578	C579	C58	C600

Diagnosis Codes							
C601	C602	C608	C609	C61	C6201	C6202	C6211
C6212	C6291	C6292	C6301	C6302	C6311	C6312	C632
C637	C638	C639	C641	C642	C651	C652	C661
C662	C670	C671	C672	C673	C674	C675	C676
C677	C678	C679	C680	C681	C688	C689	C6901
C6902	C6911	C6912	C6921	C6922	C6931	C6932	C6941
C6942	C6951	C6952	C6961	C6962	C6981	C6982	C6991
C6992	C700	C701	C710	C711	C712	C713	C714
C715	C716	C717	C718	C719	C720	C721	C7221
C7222	C7231	C7232	C7241	C7242	C7259	C729	C73
C7401	C7402	C7411	C7412	C750	C751	C752	C753
C754	C755	C758	C759	C760	C761	C762	C763
C7641	C7642	C7651	C7652	C768	C770	C771	C772
C773	C774	C775	C778	C779	C7801	C7802	C781
C782	C7839	C784	C785	C786	C787	C7889	C7901
C7902	C7911	C7919	C792	C7931	C7949	C7951	C7952
C7961	C7962	C7971	C7972	C7981	C7982	C7989	C7A010
C7A011	C7A012	C7A020	C7A021	C7A022	C7A023	C7A024	C7A025
C7A026	C7A090	C7A091	C7A092	C7A093	C7A094	C7A095	C7A096
C7A098	C7A1	C7A8	C7B01	C7B02	C7B03	C7B04	C7B09
C7B1	C7B8	C800	C801	C802	C8101	C8102	C8103
C8104	C8105	C8106	C8107	C8108	C8109	C8111	C8112
C8113	C8114	C8115	C8116	C8117	C8118	C8119	C8121
C8122	C8123	C8124	C8125	C8126	C8127	C8128	C8129
C8131	C8132	C8133	C8134	C8135	C8136	C8137	C8138
C8139	C8141	C8142	C8143	C8144	C8145	C8146	C8147
C8148	C8149	C8171	C8172	C8173	C8174	C8175	C8176
C8177	C8178	C8179	C8191	C8192	C8193	C8194	C8195
C8196	C8197	C8198	C8199	C8201	C8202	C8203	C8204
C8205	C8206	C8207	C8208	C8209	C8211	C8212	C8213
C8214	C8215	C8216	C8217	C8218	C8219	C8221	C8222
C8223	C8224	C8225	C8226	C8227	C8228	C8229	C8231
C8232	C8233	C8234	C8235	C8236	C8237	C8238	C8239
C8241	C8242	C8243	C8244	C8245	C8246	C8247	C8248
C8249	C8251	C8252	C8253	C8254	C8255	C8256	C8257
C8258	C8259	C8261	C8262	C8263	C8264	C8265	C8266
C8267	C8268	C8269	C8281	C8282	C8283	C8284	C8285
C8286	C8287	C8288	C8289	C8291	C8292	C8293	C8294
C8295	C8296	C8297	C8298	C8299	C8301	C8302	C8303
C8304	C8305	C8306	C8307	C8308	C8309	C8311	C8312

Diagnosis Codes							
C8313	C8314	C8315	C8316	C8317	C8318	C8319	C8331
C8332	C8333	C8334	C8335	C8336	C8337	C8338	C8339
C8351	C8352	C8353	C8354	C8355	C8356	C8357	C8358
C8359	C8371	C8372	C8373	C8374	C8375	C8376	C8377
C8378	C8379	C8381	C8382	C8383	C8384	C8385	C8386
C8387	C8388	C8389	C8391	C8392	C8393	C8394	C8395
C8396	C8397	C8398	C8399	C8401	C8402	C8403	C8404
C8405	C8406	C8407	C8408	C8409	C8411	C8412	C8413
C8414	C8415	C8416	C8417	C8418	C8419	C8441	C8442
C8443	C8444	C8445	C8446	C8447	C8448	C8449	C8461
C8462	C8463	C8464	C8465	C8466	C8467	C8468	C8469
C8471	C8472	C8473	C8474	C8475	C8476	C8477	C8478
C8479	C8491	C8492	C8493	C8494	C8495	C8496	C8497
C8498	C8499	C84A1	C84A2	C84A3	C84A4	C84A5	C84A6
C84A7	C84A8	C84A9	C84Z1	C84Z2	C84Z3	C84Z4	C84Z5
C84Z6	C84Z7	C84Z8	C84Z9	C8511	C8512	C8513	C8514
C8515	C8516	C8517	C8518	C8519	C8521	C8522	C8523
C8524	C8525	C8526	C8527	C8528	C8529	C8581	C8582
C8583	C8584	C8585	C8586	C8587	C8588	C8589	C8591
C8592	C8593	C8594	C8595	C8596	C8597	C8598	C8599
C860	C861	C862	C863	C864	C865	C866	C880
C882	C883	C884	C888	C9000	C9001	C9002	C9010
C9011	C9012	C9020	C9021	C9022	C9030	C9031	C9032
C9100	C9101	C9102	C9110	C9111	C9112	C9130	C9131
C9132	C9140	C9141	C9142	C9150	C9151	C9152	C9160
C9161	C9162	C91A0	C91A1	C91A2	C91Z0	C91Z1	C91Z2
C9200	C9201	C9202	C9210	C9211	C9212	C9220	C9221
C9222	C9230	C9231	C9232	C9240	C9241	C9242	C9250
C9251	C9252	C9260	C9261	C9262	C9290	C9291	C92Z0
C92Z1	C92Z2	C9292	C92A0	C92A1	C92A2	C9300	C9301
C9302	C9310	C9311	C9312	C9330	C9331	C9332	C93Z0
C93Z1	C93Z2	C9400	C9401	C9402	C9420	C9421	C9422
C9430	C9431	C9432	C9440	C9441	C9442	C946	C9480
C9481	C9482	C9500	C9501	C9502	C9510	C9511	C9512
C9590	C9591	C9592	C960	C9620	C9621	C9622	C9629
C964	C965	C966	C96A	C96Z	D0001	D0002	D0003
D0004	D0005	D0006	D0007	D0008	D001	D002	D010
D011	D012	D013	D0149	D015	D017	D020	D021
D0221	D0222	D023	D030	D03111	D03112	D03121	D03122
D0321	D0322	D0339	D034	D0351	D0352	D0359	D0361

Diagnosis Codes							
D0362	D0371	D0372	D038	D039	D040	D04111	D04112
D04121	D04122	D0421	D0422	D0439	D044	D045	D0461
D0462	D0471	D0472	D048	D0501	D0502	D0511	D0512
D0581	D0582	D060	D061	D067	D070	D071	D072
D0739	D074	D075	D0761	D0769	D090	D0919	D0921
D0922	D093	D098	D45	D4701	D4702	D4709	D49511
D49512	D49519	D4959	D4981	D4989	D600	D601	D608
D6109	D611	D612	D613	D6189	D700	D701	D702
D703	D704	D8940	D8941	D8942	D8943	D8949	P615
T451X1A	T451X1D	T451X1S	T451X2A	T451X2D	T451X2S	T451X3A	T451X3D
T451X3S	T451X4A	T451X4D	T451X4S	T8601	T8602	T8603	T8609
Z5111	Z5112	Z5189	Z9481	Z9484			

7.19 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.

Crizanlizumab-tmca (Adakveo) is indicated for clients with sickle cell disease to reduce the frequency of vaso-occlusive crises (VOCs) and must be prescribed by, or in consultation with, a hematologist or a sickle cell disease specialist.

7.19.1 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.
- Clients will not receive crizanlizumab-tmca (Adakveo) therapy concomitantly with voxelotor (Oxbryta).

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 is not receiving crizanlizumab-tmca (Adakveo) therapy concomitantly with voxelotor (Oxbryta).
- 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 3.1, "Prior Authorization Requests" in this handbook for additional prior authorization information.

7.20 Denileukin diftitox (Ontak)

Denileukin diftitox (Ontak) (procedure code J9160) is a benefit for clients who have advanced or recurrent cutaneous T-cell lymphoma with the CD25 component of IL-2 and failure of at least one type of traditional therapy. Documentation of diagnosis and treatment must be submitted with the claim.

7.21 Dimethyl sulfoxide

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

7.22 Eculizumab

Eculizumab (procedure code J1300) is a benefit of Texas Medicaid and is limited to the following diagnosis codes:

Diagnosis Codes							
D588	D591	D594	D595	D596	D598	G360	G7000
G7001							

7.23 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).

7.24 Emapalumab-lzsg (Gamifant)

Emapalumab-lzsg (Gamifant) is an interferon gamma (IFNy) blocking antibody that is indicated for the treatment of adult and pediatric (newborn and older) clients with primary Hemophagocytic Lymphohistiocytosis (HLH) with refractory, recurrent or progressive disease or intolerance with conventional HLH therapy.

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

Emapalumab-lzsg (Gamifant) must be prescribed by, or in consultation with, a hematologist, oncologist or a specialist in hemophagocytic lymphohistiocytosis disorder.

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 HCST and no longer requires emapalumab-lzsg (Gamifant) therapy for HLH.

7.24.1 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 for clients who meet 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 $10^{I\ should}$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
- 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.

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.

Refer to: Subsection 3.1, "Prior Authorization Requests" in this handbook for additional prior authorization information.

7.25 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.

7.26 Eravacycline (Xerava)

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

7.27 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 S0013.

Esketamine (Spravato) nasal spray is an N-methyl-D-aspartate (NMDA) receptor antagonist that is indicated in conjunction with an oral antidepressant in adult clients for the treatment of the following:

- Treatment-resistant depression (TRD)
- Depressive symptoms in clients with major depressive disorder (MDD) with acute suicidal ideation or behavior

Esketamine (Spravato) must be prescribed by, or in consultation with a psychiatrist.

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.

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.

7.27.1 Prior Authorization

Prior authorization is required for esketamine (Spravato) (procedure code S0013) 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) (diagnosis code F320, F321, F322, F324, F325, F329, F330, F331, F332, F3340, F3341, F3342 or F339).
- Client has either of the following:
  - A treatment-resistance depression that has been confirmed as an inadequate response/failure to previous antidepressant treatment.
  - A major depressive disorder with acute suicidal ideation or behavior, 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.
- The client must receive esketamine (Spravato) nasal spray concomitantly with an oral antidepressant agent (esketamine [Spravato] should not be used as monotherapy).
- 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 3.1, "Prior Authorization Requests" in this handbook for additional prior authorization information.

7.28 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.

7.29 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. Prior authorization is required.

7.30 Fremanezumab-vfrm

Fremanezumab-vfrm (procedure code J3031) is a benefit of Texas Medicaid for clients who are 18 years of age or older.

7.31 Galsulfase

Galsulfase (procedure code J1458) is a benefit of Texas Medicaid and is limited to the following diagnosis codes:

Diagnosis Codes							
E7601	E7602	E7603	E761	E76210	E76211	E76219	E7622
E7629	E763	E768	E769				

7.32 Granisetron Hydrochloride

Granisetron hydrochloride is a benefit of Texas Medicaid and is limited to diagnosis codes Z5189, Z510, Z5111, and Z5112.

7.33 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, J0882, J0885, J0887, 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.

When billing procedure code J0882 providers must submit the client's most recent dated hemoglobin or hematocrit levels in the comments section of the claim form.

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

Refer to: Subsection 6.2.9.4, "Hematopoietic Injections" in the *Clinics and Other Outpatient Facility Services Handbook* (*Vol. 2, Provider Handbooks*) for information about outpatient facility criteria.

7.33.1 Darbepoetin Alfa

Darbepoetin alfa (procedure codes J0881 and J0882) 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 erythopoietic 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	D46A	D46B
D611	D612	D613	D6189	D619	D630	D631	D644
D6481	D6489	D649	N181	N182	N1830	N1831	N1832
N184	N185	N186	N189	N19	Z5111	Z5112	

Procedure code J0882 must be billed with one of the following diagnosis codes:

Diagnosis Codes							
D631	N181	N182	N1830	N1831	N1832	N184	N185
N186	N189	N19					

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

7.33.2 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 on dialysis (end-stage renal disease or ESRD) and 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	N181	N182	N1830	N1831
N1832	N184	N185	N186	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.

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

7.33.3 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 J0887) is limited to diagnosis codes D631 and N186.

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

Diagnosis Codes							
D631	I120	I129	I130	I1311	I132	N181	N182
N1830	N1831	N1832	N184	N185	N186		

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).

7.34 Hydroxyprogesterone Caproate

Refer to: The *Gynecological, Obstetrics, and Family Planning Title XIX Services Handbook* (*Vol. 2, Provider Handbooks*) for information about procedure codes J1726 and J1729.

7.35 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.

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.

Ibalizumab-uiyk (Trogarzo) must be prescribed by a physician, in consultation with an infectious disease physician or a physician who specializes in the treatment of HIV infection.

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

Refer to: Subsection 3.1, "Prior Authorization Requests" in this handbook for additional prior authorization information.

7.36 Ibutilide fumarate

Ibutilide fumarate (procedure code J1742) is a benefit of Texas Medicaid and is limited to diagnosis codes I480, I481, I482, I483, and I484.

7.37 Idursulfase (Elaprase)

Idursulfase (procedure code J1743) is a benefit of Texas Medicaid and is limited to the following diagnosis codes:

Diagnosis Codes							
E7601	E7602	E7603	E761	E76210	E76211	E76219	E7622
E7629	E763	E768	E769				

7.38 * Immune Globulin

Immune globulins may be indicated for treatment of certain immune disorders and states of immunodeficiency. The following immune globulin procedure codes are benefits of Texas Medicaid:

[Revised] Procedure Codes									
90284	90291	C9072	J0850	J1459	J1460	J1555	J1556	J1557	J1559
J1561	J1566	J1568	J1569	J1572	J1575	J1599	J1670	J2788	J2791
J2792	J7504	J7511							

Note: *Procedure codes 90291 and J0850 may only be reimbursed when billed with diagnosis code Z940, Z941, Z942, Z943, Z944, or Z9483.*

7.39 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:

Procedure Codes									
J0202	J0257	J0480	J0485	J0490	J0717	J1595	J1602	J7501	J7516
J7525									

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

Procedure Code	Conditions
J0202	Multiple sclerosis (MS): For treatment of relapsing forms of MS and should be reserved for clients who have had an inadequate response to two or more drugs indicated for the treatment of MS.
J0257	Alpha-1 proteinase inhibitor deficiency: For the treatment of 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 patients 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 adults receiving a kidney transplant, to be used in combination with basiliximab injection, mycophenolate mofetil, and corticosteroids.
J0490	Systemic lupus erythematosus (SLE): For use in clients with moderate to severe SLE when other forms of treatment have failed to control moderate to severe symptoms
J0717	Psoriatic arthritis, Ulcerative colitis, Ankylosing spondylitis, Crohn's disease
J1595	Multiple sclerosis (MS): For the reduction of the frequency of relapses in clients with relapsing remitting MS, including clients who have experienced a first clinical episode and have magnetic resonance imaging (MRI) features consistent with MS.

Procedure Code	Conditions
J1602	Psoriatic arthritis, Rheumatoid arthritis, Ankylosing spondylitis
J7501	Renal homotransplantations: Adjunct for the prevention of rejection in renal homotransplantation. Rheumatoid arthritis: Azathioprine is indicated only in adult patients meeting the criteria for classic or definite rheumatoid arthritis as specified by the American Rheumatism Association.
J7516	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 Medicaid 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.

7.40 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 and must be prescribed by or in consultation with a neurologist.

Inebilizumab-cdon (Uplizna) is indicated for the treatment of adult clients with neuromyelitis optica spectrum disorder (NMOD/NMOSD) who are anti-aquaporin-4 antibody positive.

7.40.1 Prior Authorization Criteria

Prior authorization for initial therapy for inebilizumab-cdon (Uplizna) may be approved for a 12-month duration if all of the following criteria are met:

- Client must be 18 years of age or older.
- Client has a diagnosis of neuromyelitis optica spectrum disorder (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

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.

7.41 Infliximab (Remicade), Inflectra*, Renflexis*

Procedure code J1745, Q5103, and Q5104 are benefits of Texas Medicaid, and may not be reimbursed for the same date of service by any provider. Procedure codes J1745, Q5103, and Q5104 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	K603	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
M05811	M05812	M05821	M05822	M05831	M05832	M05841	M05842
M05851	M05852	M05861	M05862	M05871	M05872	M0589	M06011
M06012	M06021	M06022	M06031	M06032	M06041	M06042	M06051
M06052	M06061	M06062	M06071	M06072	M0608	M0609	M06811
M06812	M06819	M06821	M06822	M06829	M06831	M06832	M06839
M06841	M06842	M06849	M06851	M06852	M06859	M06861	M06862
M06869	M06871	M06872	M06879	M0688	M0689	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

Diagnosis Codes							
M08941	M08942	M08951	M08952	M08961	M08962	M08971	M08972
M0898	M450	M451	M452	M453	M454	M455	M456
M457	M458						

7.42 Inotuzumab ozogamicin (Besponsa)

Inotuzumab ozogamicin (Besponsa) (procedure code J9229) is a benefit of Texas Medicaid for clients who are 18 years of age and older with prior authorization, and must be prescribed by an oncologist or be in consultation with an oncologist.

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).

7.42.1 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 18 years 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 3.1, "Prior Authorization Requests" in this handbook for additional prior authorization information.

7.42.2 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.

7.42.3 Exclusions

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

7.43 * Interferon

Interferons are a family of naturally-occurring proteins that are produced by cells of the immune system. Three classes of interferons have been identified: alfa, beta, and gamma. Each class has different effects, though their activities overlap. Together, the interferons direct the immune system's attack on viruses, bacteria, tumors, and other foreign substances that may invade the body. Once interferons have detected and attacked a foreign substance, they alter it by slowing, blocking, or changing its growth or function.

The following interferon procedure codes are benefits of Texas Medicaid:

[Revised] Procedure Codes						
J1826	J1830	J9214	J9216	S0145	Q3027	Q3028

[Revised] Interferon Alfa-2B (procedure code J9214) may be indicated for, but is not limited to, treatment of the conditions listed below:

- Acute leukemias
- AIDs-related Kaposi sarcoma Basal- and squamous-cell cancer Behcet syndrome
- Bladder tumors (local use for superficial tumors) Carcinoid tumor
- Chronic granulocytic leukemia Chronic hepatitis B virus Chronic hepatitis C virus Chronic myelogenous leukemia Condylomata acuminata Cutaneous T- cell lymphoma Cytolomegavirus
- Essential thrombocytopenia Essential thrombocytosis Follicular lymphoma Hairy cell leukemia Herpes simplex Hodgkin's disease
- Hypereosinophilic syndrome Melanoma Multiple myeloma Mycosis fungoides
- Non-Hodgkin's lymphoma Ovarian and cervical carcinoma Papilloma viruses Polycythemia vera
- Renal cell carcinoma Rhino viruses Varicella zoster

[Revised] Interferon Gamma-1B (procedure code J9216) may be indicated for, but is not limited to, treatment of the following:

- Chronic granulomatous disease
- Malignant osteoporosis

[Revised] Interferon Beta-1A (procedure codes J1826, Q3027, and Q3028), and Interferon Beta-1B (procedure code J1830) may be indicated for, but are not limited to, treatment of relapsing forms of multiple sclerosis.

> ***Note:*** *Pegylated interferons are self-administered weekly and are available through Texas Medicaid Vendor Drug Program for Medicaid fee-for-service clients.*

7.44 Iron Injections

Iron is a hematinic, essential to the synthesis of hemoglobin to maintain oxygen transport and to the function and formation of other physiologically important heme and non-heme compounds.

Ferric carboxymaltose (procedure code J1439) may be indicated for, but is not limited to, treatment of iron deficiency anemia for adult clients with:

- Intolerance or unsatisfactory response to oral iron.
- Non-dialysis-dependent chronic kidney disease.

Iron Dextran injection (procedure code J1750) may be indicated for, but is not limited to treatment of Iron deficiency anemia when oral administration is unsatisfactory or impossible.

Iron Sucrose injection (procedure code J1756) may be indicated for, but is not limited to treatment of iron deficiency anemia for the following conditions:

- Non-dialysis-dependent chronic kidney disease (NDD-CKD) for clients who are receiving erythropoietin.
- NDD-CKD for clients who are not receiving erythropoietin.

- Hemodialysis-dependent chronic kidney disease (HDD-CKD) for clients who are receiving erythropoietin.
- Peritoneal dialysis-dependent chronic kidney disease (PDD-CKD) clients who are receiving erythropoietin.

Sodium Ferric Gluconate Complex injection (procedure code J2916) may be indicated for, but is not limited to treatment of Iron deficiency anemia in clients who are six years of age or older who are undergoing long term hemodialysis treatments and who are receiving supplemental epoetin therapy.

Ferumoxytol injection (procedure codes Q0138 and Q0139) may be indicated for, but is not limited to treatment of Iron deficiency anemia in adults who have chronic kidney disease (CKD).

Note: *Report procedure code Q0138 for non-end stage renal disease (ESRD) and Q0139 for ESRD injections.*

Authorization is not required for iron injections. Retrospective review may be performed to ensure documentation supports the medical necessity for the service being billed.

7.45 Joint Injections and Trigger Point Injections

The following procedure codes must be used to submit claims for injections into joints:

Procedure Codes for Joint Injections						
20600	20604	20605	20606	20610	20611	20612

The following procedure codes must be used to submit claims for trigger point injections:

Procedure Codes for Trigger Point Injections				
20526	20550	20551	20552	20553

These procedures are valid only in the treatment of acute problems. Procedures billed for reimbursement with chronic diagnosis codes are denied. The provider must use the AT modifier to indicate an acute condition.

Modifier	Use
AT	For acute conditions

The cost of the injection does not include the drugs used. The drug can be reimbursed separately. Multiple joint injections may be reimbursed when billed with the same date of service if the claim indicates the specific site of each injection. The first injection or aspiration is reimbursed at the full profile allowance and any subsequent injections are reimbursed at half allowance.

7.46 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.

7.47 Lanadelumab-flyo

Lanadelumab-flyo (procedure code J0593) is a benefit of Texas Medicaid for clients who are 12 years of age or older.

7.48 Leuprolide Acetate (Lupron Depot)

Procedure codes J9217, J1950, J9218, or J9219 may be reimbursed for leuprolide acetate injections with the following limitations:

Procedure Code	Limitation(s)
J1950	Reimbursed once per month
J9219	Reimbursed once per year

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 per month
3-month	22.5 mg	Billed with a quantity of 3 Reimbursed once every three months
4-month	30 mg	Billed with a quantity of 4 Reimbursed once every 4 months
6-month	45 mg	Billed with a quantity of 6 Reimbursed once every 6 months

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

7.49 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.

7.50 Melphalan

Procedure code J9245 is a benefit when billed with one of the following diagnosis codes:

Diagnosis Codes							
C50011	C50012	C50019	C50021	C50022	C50029	C50111	C50112
C50119	C50121	C50122	C50211	C50212	C50219	C50221	C50222
C50311	C50312	C50319	C50321	C50322	C50411	C50412	C50419
C50421	C50422	C50511	C50512	C50519	C50521	C50522	C50611
C50612	C50619	C50621	C50622	C50811	C50812	C50819	C50821
C50822	C50911	C50912	C50919	C50921	C50922	C50929	C561
C562	C569	C6200	C6201	C6202	C6210	C6211	C6212
C6290	C6291	C6292	C9000	C9001			

7.51 Luspatercept-aamt (Reblozyl)

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

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)

Luspatercept-aamt (Reblozyl) must be prescribed by, or in consultation with, a hematologist.

7.51.1 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.

7.52 Mepsevii (Vestronidase alfa-vjbk)

Vestronidase alfa-vjbk (Mepsevii) (procedure code J3397) is a benefit of Texas Medicaid for 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 diagnosis code 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 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 3.1, "Prior Authorization Requests" in this handbook for additional prior authorization information.

7.53 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) requires prior authorization, and must be prescribed by, or in consultation with, an oncologist or hematologist. Mogamulizumab-kpkc (Poteligeo) (procedure code J9204) may be approved for a duration of every 12 months.

7.53.1 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						

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 3.1, "Prior Authorization Requests" in this handbook for additional prior authorization information.

7.54 Monoclonal Antibodies

7.54.1 Omalizumab

Omalizumab (procedure code J2357) is an injectable drug that is FDA-approved for the treatment of clients who are 6 years of age and older with moderate to severe asthma (as defined by the National Heart, Lung, and Blood Institute's Guidelines for the Diagnosis and management of Asthma). Omalizumab is also FDA-approved for the treatment of clients who are 12 years of age or older and have chronic idiopathic urticaria (CIU) who remain symptomatic despite H1 antihistamine treatment.

Omalizumab may be a benefit of Texas Medicaid when medically necessary with prior authorization. Clients who are younger than the FDA approved age will be considered on a case-by-case basis by the TMHP medical director.

Providers may not bill for an office visit if the only reason for the visit is an omalizumab injection.

7.54.2 Benralizumab

Benralizumab (procedure code J0517) is a benefit of Texas Medicaid for clients who are 12 years of age and older with prior authorization.

Benralizumab is an injectable drug that is FDA-approved and indicated for the treatment of clients who are 12 years of age and older and have severe asthma with an eosinophilic phenotype.

Treatment of benralizumab may not be used concurrently with omalizumab or any other interleukin-5 antagonist.

Procedure codes J0517, J2182, J2357, 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 benralizumab injection.

7.54.3 Mepolizumab

Mepolizumab (procedure code J2182) is a benefit of Texas Medicaid when medically necessary with prior authorization.

Mepolizumab is an injectable drug that is approved by the FDA and indicated for the following treatments:

- 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
- 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

Clients who are younger than the FDA-approved age will be considered on a case-by-case basis by the TMHP medical director.

Treatment with mepolizumab may not occur concurrently with omalizumab or any other interleukin-5 antagonist.

Providers may not bill for an office visit if the only reason for the visit is a mepolizumab injection.

7.54.4 Reslizumab

Reslizumab (procedure code J2786) is a benefit of Texas Medicaid when medically necessary with prior authorization.

Reslizumab is an injectable drug that is FDA-approved and indicated for the treatment of clients who are 18 years of age and 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. Clients who are younger than the FDA-approved age will be considered on a case-by-case basis by the TMHP medical director.

Treatment of reslizumab may not be used concurrently with omalizumab or any other interleukin-5 antagonist.

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

Providers may not bill for an office visit if the only reason for the visit is a reslizumab injection.

7.54.5 Prior Authorization for Omalizumab, Benralizumab, Mepolizumab, and Reslizumab

When requesting prior authorization, the exact dosage must be included with the request using omalizumab (procedure code J2357), benralizumab (J0517), mepolizumab (procedure code J2182), or reslizumab (procedure code J2786). Prior authorization for omalizumab will be considered for clients who are 6 years of age or older with moderate to severe asthma and for clients who are 12 years of age or older with CIU. Prior authorization for reslizumab may be approved for clients who are 18 years of age or older with severe asthma. Prior authorization for benralizumab will be considered for clients who are 12 years of age and older with severe asthma with eosinophilic phenotype.

Prior authorization for mepolizumab will be considered for the following:

- Clients who are 6 years of age or older and have severe asthma with an eosinophilic phenotype (as defined by the National Heart, Lung, and Blood Institute's Guidelines for the Diagnosis and Management of Asthma)
- Adult clients with eosinophilic granulomatosis with polyangiitis
- Clients who are 12 years of age or older with hypereosinophilic symptoms (HES) for 6 months or longer without identifiable non-hematologic secondary cause

Prior authorization approvals for omalizumab, benralizumab, mepolizumab, or reslizumab are for intervals of six months at a time. Clients must be compliant with their omalizumab, benralizumab, mepolizumab, or reslizumab regimen in order to qualify for additional prior authorizations. The provider must submit a statement documenting compliance with the requests for each renewal.

Refer to: Subsection 3.1, "Prior Authorization Requests" in this handbook for additional prior authorization information.

7.54.6 Prior Authorization Criteria for Chronic Idiopathic Urticaria

Prior authorization for omalizumab will be considered for clients who are 12 years of age or older with CIU. Documentation supporting medical necessity for treatment of CIU with omalizumab must be submitted with the request and include all of the following:

- Documented failure of, or contraindication to, antihistamine and leukotriene inhibitor therapies.
- Evidence of an evaluation that excludes other medical diagnoses associated with chronic urticaria.

7.54.7 Prior Authorization Criteria for Asthma — Moderate to Severe (Omalizumab) and Severe (Benralizumab, Mepolizumab, and Reslizumab)

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, benralizumab, mepolizumab, or reslizumab must be submitted with the request and must indicate the following:

- Symptoms are inadequately controlled with use of one of the following combination therapies:
  - 12 months of high-dose inhaled corticosteroid (ICS) given in combination with a minimum of 3 months of controller medication (either a long-acting beta2-agonist [LABA], leukotriene receptor antagonist [LTRA], or theophylline), unless the individual is intolerant of, or has a medical contraindication to these agents; or
  - 6 months of ICS with daily oral glucocorticoids given in combination with a minimum of 3 months of controller medication (a LABA, 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 omalizumab, benralizumab, mepolizumab, or reslizumab, 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.*
- Pulmonary function tests must have been performed within a three-month period and be documented for all clients.

  Note: *Exceptions may be considered with documentation of medical reasons explaining why pulmonary function tests cannot be performed.*
- Client is not currently smoking.

7.54.7.1 Eosinophilic Granulomatosis with Polyangiitis

Prior authorization for mepolizumab will be considered for adult clients who are 18 years and older with eosinophilic granulomatosis with polyangiitis (EGPA).

Documentation supporting medical necessity for treatment of EGPA with mepolizumab must be submitted with the request and meet all of 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

- Refractory disease or has had a history of EGPA relapse within the past 2 years from the requested date of service.
- Attestation from prescriber that client is on a stable dose of corticosteroids.

7.54.7.2 Hypereosinophilic Syndrome (HES)

Prior authorization for mepolizumab will be considered for clients who are 12 years of age and older with hypereosinophilic syndrome for 6 months or longer without non-hematologic secondary cause.

Documents supporting medical necessity for treatment of HES in clients who are 12 years of age or older with mepolizumab 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 2 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 Mepolizumab therapy
- Prescriber's attestation that client has been on a stable dose of HES therapy which includes, but not limited to corticosteroids, immunosuppressive and cytotoxic therapy

7.54.7.3 Mepolizumab

The following additional documentation for treatment with mepolizumab must also be submitted:

- One of the following blood eosinophil counts in the absence of other potential causes of eosinophilia, including hypereosinophilic syndromes, neoplastic disease, and known or suspected parasitic infection:
  - Greater than or equal to 150 cells/microliter at initiation of therapy; or
  - Greater than or equal to 300 cells/microliter within 12 months prior to initiation of therapy

  Note: *1 microliter (ul) is equal to 1 cubic millimeter (mm3)*

7.54.7.4 Omalizumab

The following additional documentation for treatment with omalizumab also must be submitted:

- Positive skin test or RAST to a perennial (not seasonal) aeroallergen within the past 36 months
- Total IgE level greater than 30 IU/ml but less than 1300 IU/ml within the past 12 months

7.54.7.5 Benralizumab

The following additional documentation for treatment with benralizumab must also be submitted with the initial prior authorization request:

- Documented diagnosis of severe eosinophilic asthma
- Blood eosinophil count greater than or equal to 150 cells/microliter before the initiation of therapy, in the absence of other potential causes of eosinophilia including hypereosinophilic syndromes, neoplastic disease, and known or suspected parasitic infection

  Note: *1 microliter (ul) is equal to 1 cubic millimeter (mm3)*

7.54.7.6 Reslizumab

The following additional documentation for treatment with reslizumab must also be submitted:

- Has an eosinophilic phenotype as determined by blood eosinophils of 400 cells/microliter or higher prior to initiation of therapy (within 3-4 weeks of dosing).

  Note: *1 microliter 9ul) is equal to 1 cubic millimeter (mm3).*

- When requesting prior authorization, the exact dosage must be included with the request.

7.54.8 Requirements for Continuation of Therapy

For continuation of therapy with omalizumab, benralizumab, mepolizumab, or reslizumab after 6 continuous months, the requesting provider must submit the following documentation of the client's compliance and satisfactory clinical response to omalizumab, benralizumab, mepolizumab, or reslizumab:

- 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
  - 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, benralizumab, mepolizumab, or reslizumab.

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.

7.55 Moxetumomab Pasudotox-tdfk (Lumoxiti)

Moxetumomab pasudotox-tdfk (Lumoxiti) (procedure code J9313) is a benefit of Texas Medicaid when indicated for the treatment of relapsed or refractory hairy cell leukemia in adults who have received at least two prior systemic therapies, including treatment with a purine nucleoside analog (PNA).

Moxetumomab pasudotox-tdfk (Lumoxiti) must be prescribed by, or in consultation with, an oncologist or hematologist.

Moxetumomab pasudotox-tdfk is not a benefit for clients who have renal impairment with CrCl < 29 ml/min.

7.55.1 Prior Authorization Requirements

Prior authorization is required for moxetumomab pasudotox-tdfk (Lumoxiti) (procedure code J9313). Prior authorization may be granted for a duration of 6 months (6 cycles).

Prior authorization approval for moxetumomab pasudotox-tdfk (Lumoxiti) infusion will be considered if all the following criteria are met:

- The client is 18 years of age or older.
- The client has a confirmed diagnosis of hairy cell leukemia (diagnosis codes C9140 and C9142).

- The client has relapsed or refractory disease.
- The client has received at least two prior systemic therapies, including treatment with a PNA.
- The client does not have severe renal impairment, defined as creatinine clearance (CrCl) or 29 ml/min or less.

Refer to: Subsection 3.1, "Prior Authorization Requests" in this handbook for additional prior authorization information.

7.56 Natalizumab

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

Diagnosis Codes							
G35	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						

7.57 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.

Onasemnogene abeparvovec-xioi (Zolgensma) must be prescribed by, or in consultation with, a board-certified neurologist or pediatric neurologist who is familiar with the diagnosis and management of spinal muscular atrophy. The consultation must include the neurologist's name, credentials, and contact information.

7.57.1 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.

7.57.2 * 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)
  - 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 Type I SMA (diagnosis code G120) based on gene mutation analysis with biallelic SMN1 mutation (deletion or point mutation) and 3 or less copies of SMN2.
- [Revised] 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:
  - [Revised] Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorder (CHOP-INTEND) score
  - [Revised] Bayley scale of infant and toddler development screening test
  - [Revised] 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.
- Physician attestation supports that the client has not received prior onasemnogene abeparvovec-xioi (Zolgensma) therapy.

[Revised] 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:

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

7.58 Panhematin

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

7.59 Patisiran (Onpattro)

Patisiran (Onpattro) is a benefit of Texas Medicaid with prior authorization for the treatment of the polyneuropathy of hereditary transthyretin-mediated (hATTR) amyloidosis in adults.

Prior authorization requests for patisiran (Onpattro) (procedure code J0222) 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, 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
  - Clinical signs and symptoms of the disease (e.g., peripheral/autonomic neuropathy, motor disability)
- The client will not receive patisiran (Onpattro) therapy in combination with other polyneuropathy hATTR amyloidosis therapies (e.g., inotersen or tafamidis meglumine).
- The client has not had a liver transplant.

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

- The client has previously received treatment with patisiran (Onpattro) without an adverse reaction.
- The client has a positive clinical response to patisiran (Onpattro) (e.g., improved neurologic impairment, improved motor function, 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 3.1, "Prior Authorization Requests" in this handbook for additional prior authorization information.

7.60 Plazomicin

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

7.61 Porfimer (Photofrin)

Porfimer (procedure code J9600) is a benefit of Texas Medicaid and is limited to the following diagnosis codes:

Diagnosis Codes						
C153	C154	C155	C158	C159	C787	C7889

7.62 Ravulizumab-cwvz (Ultomiris)

Ravulizumab-cwvz (procedure code J1303) is a benefit of Texas Medicaid and is limited to diagnosis codes D588, D593, D594, D595, and D598.

Procedure code J1303 is restricted to clients who are 18 years of age or older when billed with diagnosis code D595.

7.63 Risperidone (Perseris)

Risperidone (procedure code J2798) is a benefit of Texas Medicaid for clients who are 18 years of age or older.

7.64 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.

7.65 Romosozumab

Romosozumab (procedure code J3111) is a benefit of Texas Medicaid for clients who are 18 years of age or older.

7.66 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
G43801	G43809	G43811	G43819	G43821	G43829	G43831	G43839
G43901	G43909	G43911	G43919	G43A0	G43A1	G43B0	G43B1
G43C0	G43C1	G43D0	G43D1				

7.67 Tagraxofusp-erzs (Elzonris)

Tagraxofusp-erzs (Elzonris) (procedure code J9269) is a CD 123-directed cytotoxin indicated for the treatment of blastic plasmacytoid dendritic cell neoplasm (BPDCN) in adults and pediatric clients who are 2 years of age and older.

Tagraxofusp-erzs (Elzonris) (procedure code J9269) is a benefit of Texas Medicaid with prior authorization.

Tagraxofusp-erzs (Elzonris) must be prescribed by, or in consultation with, a hematologist or oncologist.

7.67.1 Prior Authorization Requirements

Prior authorization is required for tagraxofusp-erzs (Elzonris) (procedure code J9269) 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:

- Client has a diagnosis of blastic plasmacytoid dendritic cell neoplasm (diagnosis code C864) excluding, acute promyelocytic leukemia (APL, FAB, M3)
- Client is 2 years of age or older
- 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
- For renewal or continuation therapy, the client must meet all of the following criteria:

- Client continues to meet initial approval criteria
- Client has previously received treatment with tagraxofusp-erzs (Elzonris) with absence of drug toxicity (i.e. capillary leak syndrome, severe hepatotoxicity, and nephrotoxicity)
- Client has a positive clinical response demonstrated by disease stabilization

Refer to: Subsection 3.1, "Prior Authorization Requests" in this handbook for additional prior authorization information.

7.68 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) and must be prescribed by, or in consultation with, an ophthalmologist or endocrinologist.

7.68.1 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 active TED.
- The client has active TED with a clinical activity score (CAS) of 4 or greater.
- 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.

7.68.2 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).

7.69 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				

7.70 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.

7.71 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.

7.72 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

7.73 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.

7.74 Vitamin B12 (Cyanocobalamin) Injections

Vitamin B12 injections 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.

Vitamin B12 injections may be considered for the following indications:

- Dementia secondary to vitamin B12 deficiency
- Resection of the small intestine
- Schilling test (vitamin B12 absorption test)

Procedure code J3420 must be used when billing for Vitamin B12 (cyanocobalamin) injections. Vitamin B12 (cyanocobalamin) injections are limited to the following diagnosis codes:

Diagnosis Codes							
B700	D510	D511	D512	D513	D518	D520	D521
D528	D529	D531	D649	E538	E710	E71110	E71111
E71118	E71120	E71121	E71128	E7119	E712	E7210	E7211
E7212	E7219	E723	E7251	E7259	E7281	E7289	G621
G63	H4611	H4612	H4613	H463	K900	K901	K902

Diagnosis Codes							
K903	K9041	K9049	K9089	K909	K911	K912	Z903
Z9221	Z980						

Claims that are denied for indications or other diagnosis codes may be considered on appeal with documentation of medical necessity. For the list of diagnosis codes above, documentation in the medical record must include rationale as to why the client was unable to be treated with oral therapy.

7.75 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.

7.75.1 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.

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 10.5.1, "Pharmacy Delivery Method for Clinician-Administered Drugs" in this handbook for additional infor- mation on the "white bagging" delivery method.

Subsection 3.1, "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.

7.75.2 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.

8 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.

8.1 JW Modifier Claims Filing Instructions

Providers must not use the JW modifier for medications manufactured in a multi-dose vial format.

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 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 12, "Pharmacy Prior Authorization" in this handbook.

9.1 Formulary Search

The VDP Formulary 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 PDL drug class, or HCPCS description (for products).

Detailed filters allow searches as follows:

- By program:
  - Medicaid
  - CHIP
  - CSHCN Services Program
  - 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 Formulary Search on the VDP website for more information.

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.

9.2 Vitamin and Mineral Products

Pharmacies enrolled 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 website at *https://www.txvendordrug.com/formulary/formulary-search*. 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.

9.3 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 website at *https://www.txvendordrug.com/formulary/formulary-search*. 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.

9.4 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 website at *https://www.txvendordrug.com/formulary/formulary-search*. Users can select the "LARC" check-box for a list of all drugs.

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.

9.4.1 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.

9.4.2 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.

9.4.3 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.

9.4.4 Manufacturer Information

9.4.4.1 Bayer (Kyleena, Mirena, and Skyla)

9.4.4.1.1 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

9.4.4.1.2 Obtaining Products

Providers use Bayer's Specialty Pharmacy Prescription Request Form. This form is available on the VDP website at txvendordrug.com/formulary/formulary/long-acting-reversible-contraception-products.

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.

9.4.4.1.3 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 txvendordrug.com/formulary/formulary/long-acting-reversible-contraception-products.

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.

9.4.4.2 Merck (Nexplanon)

9.4.4.2.1 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

9.4.4.2.2 Obtaining Products

Providers use Merck's Nexplanon Direct Service Request Form. Request the form from Merck Customer Support Center for Nexplanon (CSCN) at 1-844-639-4321.

Complete the Merck's Nexplanon 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.

9.4.4.2.3 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 Merck Abandoned Unit Program Return Form. This form is available on the VDP website at txvendordrug.com/formulary/formulary/long-acting-reversible-contraception-products.

The Merck 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 TeleRx, Merck's third-party processor.
- Confirm the specialty pharmacy return identification number matches the ID number listed in the return mailing label provided by TeleRx.
- Package the unit in the box in which the Nexplanon was originally shipped or other appropriately sized shipping box/envelope.
- Mail the unit along with the Merck Abandoned Unit Program for Nexplanon Return Form to Pharma Returns. A pre?paid shipping label and address will be provided by TeleRx.

Only LARC products obtained through a specialty pharmacy can be returned through this program.

9.4.4.3 Cooper Surgical (Paragard)

9.4.4.3.1 Specialty Pharmacy Participation

Paragard is available from Biologics by McKesson Specialty Pharmacy, or City Drugs Specialty Pharmacy, both of which ships statewide:

Biologics by McKesson Specialty Pharmacy
Cary, NC 27513
1-888-275-8596
NPI 1487640314

City Drugs
New York, NY 10028
Phone: 1-855-988-4500
NPI 1972880623

9.4.4.3.2 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.

- 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.

9.4.4.3.3 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.

9.4.4.3.4 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.

9.4.4.3.5 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.

9.4.4.4 Makena

9.4.4.4.1 Pharmacy Benefit

Makena (hydroxyprogesterone caproate injection) requires clinical prior authorization for clients enrolled in traditional Medicaid. Providers should complete the Makena Prior Authorization Request (HHS Form 1345) and submit to the Texas Prior Authorization Call Center.

Health Plans may require prior authorization for Makena. Providers should refer to the appropriate health plan for specific requirements and forms.

9.4.4.4.2 Medical Benefit

Makena and the compounded version of 17P are available as a Medicaid medical benefit. For additional information about the medical benefit, providers can visit the TMHP website at www.tmhp.com or call the TMHP Contact Center at 1-800-925-9126.

9.5 Palivizumab (Synagis)

Palivizumab is available to physicians for administration to clients in Medicaid and the CSHCN Services Program through VDP. The 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.

9.5.1 Schedule and Forms

Refer to: The Synagis page on the VDP website for more information about the current season, including forms and schedule.

Prior authorization request forms are reviewed annually. Providers must use the most current version of the Medicaid Synagis Prior Authorization Request (HHS Form 1033) to submit prior authorization requests. Forms received outside the RSV season schedule will not be processed.

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 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.

10.1 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.

10.2 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.

10.3 Prescription Monitoring of 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.

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.

10.4 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 Formulary 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.*

10.5 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.

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.

10.5.1 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.*

10.6 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.

10.6.1 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).

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.

10.6.2 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.

10.6.3 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.

10.6.4 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.

11 Patient Information

11.1 Medication Synchronization

11.1.1 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.

11.1.2 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.

11.1.3 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.

11.1.4 Traditional Medicaid Claims Processing

A synchronized claim will count as one of the three prescriptions Medicaid will pay if a client is limited.

11.1.5 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 Pharmacy MCO Assistance Chart.

11.2 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

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)

11.3 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.

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

11.4 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 2.7.1.1, "Pharmacies (CCP)" in the *Children's Services Handbook* (*Vol. 2, Provider Handbooks*) for more information about pharmacy enrollment in CCP.

11.5 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.

11.6 Free Delivery of Medicaid Prescriptions

Many Medicaid pharmacies offer free delivery of prescriptions to clients enrolled in Medicaid.

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 VDP-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.

12 Pharmacy Prior Authorization

Some Medicaid drugs are subject to one or both types of prior authorization, clinical and non-preferred.

12.1 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 certain 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.

Refer to: The Clinical Prior Authorization Assistance Chart on the VDP website. It identifies the prior authorization each health plans uses and how those authorizations relate to the authorizations used for traditional Medicaid claim processing. The chart is updated quarterly.

Subsection 9.5, "Palivizumab (Synagis)" in this section for information about Synagis prior authorizations.

12.2 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.

12.3 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 7:30 a.m. and 6:30 p.m., central) or online through PAXpress. Online submissions are only available for non-preferred prior authorization requests.

Refer to: The Account Registration Instructions on the PAXpress website.

The VDP Prior Authorization Program Quick Reference Guide for Prescribers on the PAXpress website.

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.*

12.4 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.

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

12.5 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.