



# Texas Medicaid Provider Procedures Manual

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Volume  
2

## Provider Handbooks

### Outpatient Drug Services Handbook

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

# OUTPATIENT DRUG SERVICES HANDBOOK

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## 1 General Information

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

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

**Referto:** “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).*

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

### 1.2 Pharmacy Enrollment

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

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

Pharmacy providers must enroll with HHSC before providing outpatient prescription services and prior to participating in any Medicaid managed care network. To participate in the Medicaid or CHIP managed care networks the pharmacy must contact the health plan.

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

**Referto:** The [VDP Pharmacy Provider Procedure Manual](#) on the VDP website.

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

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

### 1.3 Program Contact Information

| Vendor Drug Program   | Contact  |
|---|--|
| Pharmacy Benefits Access: for questions about outpatient drug and billing (the 800 number is for pharmacy use only and can be used to reach any area within VDP). | 1-800-435-4165   |
| Program Policy and Management   | <a href="mailto:vdp-operations@hhsc.state.tx.us">vdp-operations@hhsc.state.tx.us</a> |
| Drug formulary (Texas listing of national drug codes)   | <a href="mailto:vdp-formulary@hhsc.state.tx.us">vdp-formulary@hhsc.state.tx.us</a>   |
| Texas Pharmacy Prior Authorization Center   | 1-877-728-3927   |
| Texas Pharmacy Third Party Call Center  | 1-866-389-5594   |
| CAD information   | <a href="mailto:vdp-cad@hhsc.state.tx.us">vdp-cad@hhsc.state.tx.us</a>               |
| Texas Drug Utilization Review Board   | <a href="mailto:vdp-advisory@hhsc.state.tx.us">vdp-advisory@hhsc.state.tx.us</a>     |

### 1.4 Education

HHSC and TMHP provide several provider education and training opportunities.

#### 1.4.1 Texas Health Steps Quick Course

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

- [A Prescriber’s Guide to Texas Medicaid Outpatient Pharmacy Prior Authorization](#)

#### 1.4.2 TMHP Learning Management System

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

- [TMHP LMS](#)
- [LMS Registration and Navigation Job Aid](#)

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

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

## 2 Clinician-Administered Drugs

### 2.1 Services, Benefits, Limitations, and Prior Authorization

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

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

**Referto:** Subsection 8, "Pharmacy Benefit" in this handbook for more information.

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

#### 2.1.1 Clinician-administered Drug Search

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

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

**Referto:** The VDP website [CAD Search](#) for more information.

#### 2.1.2 Prior Authorization Requests

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

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

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

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.

### 2.1.3 Electronic Signatures in Prior Authorizations

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

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

## 3 Reimbursement

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

- If the drug or biological is considered a new drug or biological (that is, approved for marketing by the Food and Drug Administration within 12 months of implementation as a benefit of 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.*

**Referto:** Subsection 7.1, “JW Modifier Claims Filing Instructions” in this handbook for further instructions about the JW modifier.

## 4 Injectable Medications as a Pharmacy Benefit

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

**Referto:** Subsection 8, “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.

**Referto:** Subsection 9.5.1, “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 | <ul style="list-style-type: none"> <li>• No acceptable oral equivalent is available.</li> <li>• Injectable medication is the standard treatment of choice.</li> <li>• The oral route is contraindicated.</li> <li>• 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.</li> <li>• The client has demonstrated noncompliance with orally prescribed medication (must be documented on the claim and in the medical record).</li> <li>• Previously attempted oral medication regimens have proven ineffective (must be supported by documentation in the medical record).</li> <li>• Situation is emergent.</li> </ul> |

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

## 5 National Drug Code (NDC)

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

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

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

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

### 5.1 Calculating Billable HCPCS and NDC Units

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



### 5.1.1 Single-Dose Vials Calculation Examples

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

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

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

### 5.1.2 Multi-Dose Vials Calculation Examples

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

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 |

| <b>Multi-Dose Calculation Examples for Dexamethasone</b>               |                    |
|--|--------------------|
| HCPCS CODE BILLING UNIT(s) = Dose divided by units found in HCPCS code | 8mg/1mg = 8        |
| NDC Information on Vial/Box  | 20mg/5ml = 4mg/1ml |
| NDC BILLING UNIT(s) = Dose divided by NDC unit from vial/box           | 8/4 = 2            |
| Quantity Information Required on Claim (HCPCS and NDC)                 | 8 and 2 ML         |

### 5.1.3 Single and Multi-Use Vials

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

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

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

### 5.1.4 Nonspecific, Unlisted, or Miscellaneous Procedure Codes

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

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

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

The claim will be denied when:

- The information is not sufficient to determine medical necessity.
- 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  
12365-A Riata Trace Parkway  
Austin, TX 78727-6418  
Fax: 1-512-514-4213

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

## 6 Outpatient Drugs—Benefits and Limitations

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

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

### 6.1 Abatacept (Orencia)

Abatacept (Orencia) 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 with the indications below.

Abatacept (Orencia) is indicated for the following:

- Moderate to severe rheumatoid arthritis in adult clients. Concomitant use of abatacept with other immunosuppressives [e.g., biologic disease modifying antirheumatic drugs (bDMARDs), Janus kinase (JAK) inhibitors] is not recommended. Concomitant use with a Tumor necrosis factor (TNF) antagonist can increase the risk of infections and serious infections.

- Moderate to severe juvenile arthritis in adult and pediatric clients who are 2 years of age or older (clients who are 2 years of age or older may receive subcutaneous formulation and clients who are 6 years of age or older may receive intravenous formulation). Abatacept may be used as monotherapy or concomitantly with methotrexate.
- Psoriatic arthritis in adult clients.
- The prophylaxis of acute graft versus host disease (aGVHD), in combination with a calcineurin inhibitor and methotrexate, in adults and pediatric clients who are 2 years of age or older undergoing hematopoietic stem cell transplantation (HSCT) from a matched or 1 allele-mismatched unrelated donor.

### **6.1.1 Prior Authorization for Abatacept (Orencia)**

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

- Dates of treatment
- The number of anticipated doses
- The dosage to be administered
- Diagnosis of adult RA, juvenile idiopathic arthritis (JIA) or adult psoriatic arthritis (PsA)
- Evidence that the drug will be used as prophylaxis of aGVHD

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

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

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

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

- The client is 18 years of age or older.
- Abatacept (Orencia) will not be used in combination with another biologic agent.

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

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

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

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

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

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

## 6.2 Adalimumab

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 |
| 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 |

| Diagnosis Codes |        |        |        |        |        |        |        |
|-----------------|--------|--------|--------|--------|--------|--------|--------|
| 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 |        |        |        |

### 6.3 Ado-trastuzumab entansine (Kadcyla)

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

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

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

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

- Evidence of HER2 positive breast cancer as evidenced by immunochemistry (IHC) test or fluorescent in situ hybridization (FISH) test
- Evidence of metastatic breast cancer
- Evidence demonstrating prior treatment for this diagnosis with trastuzumab and a taxane oncology agent separately or in combination



- Evidence demonstrating receipt of prior therapy for this diagnosis or recurrent disease, including the previous treatment protocol, within six months of completing adjuvant therapy.

## 6.4 Alzheimer's Disease (AD)

Aducanumab-avwa (Aduhelm) (procedure code J0172) and lecanemab-irmb (Leqembi) (procedure code J0174) are benefits of Texas Medicaid for clients with prior authorization. Procedure code J0172 is limited to diagnosis codes G300, G301, G308, or G309.

Aducanumab-avwa (Aduhelm) and lecanemab-irmb (Leqembi) are amyloid beta-directed antibodies indicated to treat Alzheimer's disease (AD) by reducing amyloid-beta plaques.

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

### 6.4.1 Prior Authorization

#### Initial Requests

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

- Client has a confirmed diagnosis of Alzheimer's disease (G300, G301, G308, or G309).
- Prescriber attestation that other forms of dementia except Alzheimer's disease have been ruled out by appropriate lab and/or other diagnostic testing.
- Prescriber's confirmation of amyloid beta-plaques presence.
- Clinical testing must confirm client has mild cognitive impairment caused by Alzheimer's disease or mild stage of Alzheimer's disease.
- Documentation that client has received a baseline brain-magnetic resonance imaging (MRI) prior to initiating treatment (within the past year) to evaluate for pre-existing Amyloid Related Imaging Abnormalities (ARIA).
- The following are the monitoring requirements during the aducanumab-avwa (Aduhelm) treatment period:
  - Prescriber must ensure the client is not currently taking any anti-coagulant (except for aspirin at a prophylactic dose or less) or have a history of clotting disorder.
  - Prescriber must monitor for ARIA during the first eight doses of treatment, particularly during titration.
  - Prescriber attestation to obtain a brain MRI prior to the 5th, 7th, 9th and 12th infusion to check for asymptomatic ARIA.
  - Clients with severe amyloid related imaging abnormalities hemosiderin deposition (ARIA-H) may continue therapy only if radiographic stabilization has been confirmed by a follow-up brain MRI and supported by clinical evaluation.

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

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

**Re-certification/Extension**

For renewal or continuation therapy of aducanumab-avwa (Aduhelm) or lecanemab-irmb (Leqembi), the client must meet the following requirements:

- Client continues to meet all of the initial authorization approval criteria.
- Client has not progressed to moderate or severe dementia caused by Alzheimer’s disease.
- Client experienced positive clinical response to therapy as demonstrated by no increase in amyloid plaque or radiographic stabilization as compared to baseline.
- Documentation of a brain MRI prior to the 5th, 7th, 9th, and 12th infusion to check for ARIA with aducanumab-avwa (Aduhelm) treatment.
- Documentation of brain MRI prior to the 5th, 7th, and 14th infusion to check for ARIA with lecanemab-irmb (Leqembi) treatment.
- Client has not experienced any complications or unacceptable toxicities during aducanumab-avwa (Aduhelm) or lecanemab-irmb (Leqembi) treatment.

**6.5 Afamelanotide Implant (Scenesse)**

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

**6.6 Ajoy (Fremanezumab-vfrm)**

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

**6.7 \* Amisulpride (Barhemsys)**

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

**6.8 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: <ul style="list-style-type: none"> <li>• Oral route contraindicated or an acceptable oral equivalent is not available.</li> <li>• Injectable medication is the accepted treatment of choice. Oral medication regimen has proven ineffective or is not applicable.</li> <li>• The patient has a temperature over 102 degrees and a high level of antibiotic is needed immediately.</li> <li>• 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.</li> </ul> |

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

## 6.9 Antineoplastic (Oncology) Agents

### 6.9.1 Amivantamab-vmjw (Rybervant)

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

### 6.9.2 Cemiplimab-rwlc (Libtayo)

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

### 6.9.3 Daratumumab and Hyaluronidase-fihj (Darzalex Faspro)

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

### 6.9.4 Degarelix (Firmagon)

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

### 6.9.5 Dostarlimab-gxly (Jemperli)

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

### 6.9.6 Enfortumab Vedotin-ejfv (Padcev)

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

### 6.9.7 Hydroxyprogesterone Caproate

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

| Diagnosis Codes |      |      |      |      |      |      |  |
|-----------------|------|------|------|------|------|------|--|
| C541            | N897 | N910 | N911 | N912 | N925 | N938 |  |

### 6.9.8 Isatuximab-irfc (Sarclisa)

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

### 6.9.9 Loncastuximab Tesirine-lpyl (Zynlonta)

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

### 6.9.10 Lurbinectedin (Zepzelca)

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

### 6.9.11 Margetuximab-cmkb (Margenza)

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

**6.9.12 Melphalan (Evomela)**

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

**6.9.13 Mitomycin for Pyelocalyceal Solution (Jelmyto)**

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

**6.9.14 Naxitamab-gqgk (Danyelza)**

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

**6.9.15 Polatuzumab vedotin (Polivy)**

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

**6.9.16 Sacituzumab govitecan-hziy (Trodelvy)**

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

**6.9.17 Tafasitamab-cxix (Monjuvi)**

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

**6.9.18 Tisotumab Vedotin-tftv (Tivdak)**

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

**6.10 \* Antisense Oligonucleotides (eteplirsen, golodirsen, and nusinersen)**

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

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

**6.10.1 \* Prior Authorization Requirements**

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

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

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

The dispensing DME pharmacy may not request prior authorization.

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

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

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

**Note:** For additional information on white bag delivery, providers may refer to Subsection 9.5.1, “Pharmacy Delivery Method for Clinician-Administered Drugs” in this handbook.

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

**Referto:** Subsection 2.1.2, “Prior Authorization Requests” in this handbook for additional prior authorization information.

#### **6.10.1.1 Initial Requests (for all Antisense Oligonucleotides)**

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

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

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

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

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

- Genetic testing must confirm that the client’s Duchenne muscular dystrophy (DMD) gene is amenable to exon 45 skipping.
- Serum cystatin C, urine dipstick, and urine protein-to-creatinine ratio should be measured prior to initiating Amondys 45.

- Monitor baseline renal function (i.e. Glomerulus Filtration Rate, GFR) with therapy initiation and continuation.
- Current client weight, including the date the weight was obtained; the weight must be dated no more than 30 days before the request date.

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

- Baseline 6MWT (6-minute walk test)
- Brooke Upper Extremity Scale
- North Star Ambulatory Assessment

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

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

- Genetic testing must confirm that the client's DMD gene is amenable to exon 51 skipping.
- 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
- 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 (HF MSE).
- The Upper Limb Module (UML).
- Baseline 6MWT.
- Children’s Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND).

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

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

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

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

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

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

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

#### **6.10.1.2 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

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

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

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

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

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

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

### **6.10.1.3 Exclusions**

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

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

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

**6.11 \* Aripiprazole (Abilify Asimtufii)**

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

**6.12 Aripiprazole Lauroxil, (Aristada Initio)**

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

**6.13 Asparagine Specific Enzymes**

**6.13.1 Calaspargase Pegol-Mknl (Asparlas)**

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

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

**6.13.2 Pegaspargase (Oncaspar)**

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

**6.14 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  |       |       |       |       |

**6.15 \* Beremagene geperpavec-svdt (Vyjuvek)**

[Revised] Beremagene geperpavec-svdt (Vyjuvek) is a herpes-simplex virus type 1 (HSV-1) vector-based gene therapy indicated to treat wounds in patients who are 6 months of age or older with dystrophic epidermolysis bullosa (DEB) with mutation in the collagen type VII alpha 1 chain (COL7A1) gene.

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

**6.15.1 \* Prior Authorization Requirements**

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

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

- [Revised] The client is at least 6 months of age or older.
- [Revised] The client has a confirmed diagnosis of DEB (diagnosis code Q812).
- [Revised] Genetic test confirming client has a mutation in the collagen type VII alpha 1 chain (COL7A1) gene.

- [Revised] The client does not have current evidence or history of squamous cell carcinoma or active infection in the area requiring beremagene geperpavec-svdt (Vyjuvek) application.
- [Revised] Female clients who are of childbearing age have a confirmed negative pregnancy status as treatment with beremagene geperpavec-svdt (Vyjuvek) may be potentially hazardous to a fetus.

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

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

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

**Referto:** [Revised] Subsection 2.1.2, "Prior Authorization Requests" in this handbook for additional prior authorization information.

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

## 6.16 Betibeglogene Autotemcel (Zynteglo)

Betibeglogene autotemcel (Zynteglo) (procedure code J3590) is a benefit of Texas Medicaid for clients who are 4 years of age or older with prior authorization.

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

Betibeglogene autotemcel (Zynteglo) (procedure code J3590) is limited to one transfusion treatment per lifetime and may be infused as a single infusion in one or more infusion bags.

### 6.16.1 Prior Authorization Requirements

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

- The client is 4 years of age or older.
- The client has a documented diagnosis of  $\beta$ -thalassemia (diagnosis code D561) and other forms of thalassemia have been ruled out.
- The client is RBC transfusion dependent and has documented history of receiving RBC transfusions of at least 100 ml per kilogram per year (pRBC/kg/yr) or at least 8 or more transfusions of regular RBCs per year for two years.
- The client has not had a prior hematopoietic stem cell transplant (HSCT) and is unable to find a matched related donor.
- The client is stable and eligible for HSCT, according to the following criteria:
  - No advanced liver disease

- No human immunodeficiency virus (HIV) positive diagnosis
- No hepatitis B virus (HBV) and hepatitis C virus (HCV)
- No prior or current malignancies
- No bleeding disorders
- Normal iron levels in the heart
- Normal levels of white blood cells
- Normal platelet counts
- The prescriber attests to avoid the use of anti-retroviral medications or hydroxyurea for one month prior to mobilization and until all cycles of apheresis are completed
- The prescriber attests to discontinue iron chelators at least seven days prior to initiation of myeloablative conditioning and the use of myelosuppressive iron chelators should be avoided for 6 months after betibeglogene autotemcel (Zynteglo) infusion

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

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

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

### 6.17 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  | G3781 | G3789 | G379  | G43701 | G43709 | G43711 |
| G43719          | G800  | G801  | G802  | G803  | G804   | G808   | G809   |
| G8110           | G8111 | G8112 | G8113 | G8114 | G8220  | G8221  | G8222  |

| Diagnosis Codes |        |        |        |        |        |        |        |
|-----------------|--------|--------|--------|--------|--------|--------|--------|
| G8250           | G8251  | G8252  | G8253  | G8254  | G830   | G8310  | G8311  |
| G8312           | G8313  | G8314  | G8320  | G8321  | G8322  | G8323  | G8324  |
| G8330           | G8331  | G8332  | G8333  | G8334  | G834   | H4901  | H4902  |
| H4903           | H4911  | H4912  | H4913  | H4921  | H4922  | H4923  | H4931  |
| H4932           | H4933  | H4941  | H4942  | H4943  | H499   | H5000  | H50011 |
| H50012          | H50021 | H50022 | H50031 | H50032 | H50041 | H50042 | H5005  |
| H5006           | H5007  | H5008  | H5010  | H50111 | H50112 | H50121 | H50122 |
| H50131          | H50132 | H50141 | H50142 | H5015  | H5016  | H5017  | H5018  |
| H5021           | H5022  | H5030  | H50311 | H50312 | H5032  | H50331 | H50332 |
| H5034           | H5040  | H50411 | H50412 | H5042  | H5043  | H5050  | H5051  |
| H5052           | H5053  | H5054  | H5055  | H5060  | H50611 | H50612 | H50621 |
| H50622          | H50629 | H50631 | H50632 | H50639 | H50641 | H50642 | H50649 |
| H50651          | H50652 | H50659 | H50661 | H50662 | H50669 | H50671 | H50672 |
| H50679          | H50681 | H50682 | H50689 | H5069  | H50811 | H50812 | H5089  |
| H510            | H5111  | H5112  | H5121  | H5122  | H5123  | H518   | H519   |
| I69031          | I69032 | I69033 | I69034 | I69041 | I69042 | I69043 | I69044 |
| I69051          | I69052 | I69053 | I69054 | I69061 | I69062 | I69063 | I69064 |
| I69065          | I69098 | I69131 | I69132 | I69133 | I69134 | I69141 | I69142 |
| I69143          | I69144 | I69151 | I69152 | I69153 | I69154 | I69161 | I69162 |
| I69163          | I69164 | I69165 | I69198 | I69231 | I69232 | I69233 | I69234 |
| I69241          | I69242 | I69243 | I69244 | I69251 | I69252 | I69253 | I69254 |
| I69261          | I69262 | I69263 | I69264 | I69265 | I69298 | I69331 | I69332 |
| I69333          | I69334 | I69341 | I69342 | I69343 | I69344 | I69351 | I69352 |
| I69353          | I69354 | I69361 | I69362 | I69363 | I69364 | I69365 | I69398 |
| I69831          | I69832 | I69833 | I69834 | I69841 | I69842 | I69843 | I69844 |
| I69851          | I69852 | I69853 | I69854 | I69861 | I69862 | I69863 | I69864 |
| I69865          | I69898 | J385   | K117   | K220   | K600   | K601   | K602   |
| M436            | M62838 | M722   | N318   | N319   | 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   |
| G370                      | G371   | G372   | G374   | G375   | G3781  | G3789  | G379   |
| G800                      | G801   | G802   | G804   | G808   | G809   | G8110  | G8111  |
| G8112                     | G8113  | G8114  | G8253  | G8254  | G830   | G8320  | G8321  |
| G8322                     | G8323  | G8324  | I69059 | I69259 | I69359 | I69859 | I69959 |
| I69051                    | I69052 | I69151 | I69152 | I69251 | I69252 | I69351 | I69352 |
| I69851                    | I69852 | I69951 | I69952 | I69053 | I69054 | I69153 | I69154 |
| I69253                    | I69254 | I69353 | I69354 | I69853 | I69854 | I69953 | I69954 |

| Diagnosis Codes for J0586 |        |        |        |        |        |        |        |
|---------------------------|--------|--------|--------|--------|--------|--------|--------|
| 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.<br><i>Example:</i> A provider that administers 400 units of medication would submit a claim for a quantity of 400. |

| Procedure Codes | Quantity Limitations of Medication | Billing Units   |
|-----------------|------------------------------------|---|
| J0586           | 1,500 units                        | One billing unit is equal to 5 units of medication.<br><i>Example:</i> 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.<br><i>Example:</i> 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.<br><i>Example:</i> 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.

## 6.18 Brexanolone (Zulresso)

Brexanolone (Zulresso) (procedure code J1632) is a benefit for female clients who are 15 years of age or older, and is indicated for the treatment of postpartum depression in adults.

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.

### 6.18.1 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).



### 6.18.2 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.

*Referto:* Subsection 2.1.2, “Prior Authorization Requests” in this handbook for additional prior authorization information.

### 6.19 Brolucizumab-DBLL (Beovu)

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

### 6.20 Bupivacaine

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

### 6.21 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) 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.

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

## 6.22 Cabotegravir and Rilpivirine (Cabenuva)

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

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

## 6.23 Caffeine Citrate (Cafcit)

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

## 6.24 Calcitonin Gene Related Peptide (CGRP) agents

### 6.24.1 Eptinezumab-JJMR (Vyepiti)

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

### 6.24.2 Fremanezumab-vfrm (Ajovy)

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

## 6.25 \* Cantharidin

[Revised] Cantharidin (procedure code C9164) is a benefit of Texas Medicaid for clients who are 2 years of age or older and is restricted to diagnosis code B081.

## 6.26 Cefiderocol (Fetroja)

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

## 6.27 Chelating Agents

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

### 6.27.1 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 |
| T56821A         | T56821D | T56821S | T56822A | T56822D | T56822S | T56823A | T56823D |
| T56823S         | T56824A | T56824D | T56824S | T56891A | T56891D | T56891S | T56892A |
| T56892D         | T56892S | T56893A | T56893D | T56893S | T56894A | T56894D | T56894S |
| T5691XA         | T5691XD | T5691XS | T5692XA | T5692XD | T5692XS | T5693XA | T5693XD |
| T5693XS         | T5694XA | T5694XD | T5694XS | T570X1A | T570X1D | T570X1S | T570X2A |
| T570X2D         | T570X2S | T570X3A | T570X3D | T570X3S | T570X4A | T570X4D | T570X4S |

### 6.27.2 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 | T56821A | T56821D | T56821S | T56822A |
| T56822D         | T56822S | T56823A | T56823D | T56823S | T56824A | T56824D | T56824S |
| T56891A         | T56891D | T56891S | T56892A | T56892D | T56892S | T56893A | T56893D |
| T56893S         | T56894A | T56894D | T56894S | T5691XA | T5691XD | T5691XS | T5692XA |
| T5692XD         | T5692XS | T5693XA | T5693XD | T5693XS | T5694XA | T5694XD | T5694XS |

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

| Diagnosis Codes |         |         |         |  |  |  |
|-----------------|---------|---------|---------|--|--|--|
| T5693XS         | T5694XA | T5694XD | T5694XS |  |  |  |

## 6.28 Chimeric Antigen Receptor (CAR) T-Cell Therapy

Axicabtagene ciloleucel (Yescarta) (procedure code Q2041), Brexucabtagene autoleucel (Tecartus) (procedure code Q2053), Ciltacabtagene autoleucel (Carvykti) (procedure code Q2056), Idecabtagene vicleucel (ABECMA) (procedure code Q2055), Lisocabtagene maraleucel (Breyanzi) (procedure code Q2054), 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 Q2041, Q2042, Q2053, Q2054, Q2055, and Q2056 are limited to once per lifetime, any provider.

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

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

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

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

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

Lisocabtagene maraleucel (Breyanzi) is a CD-19 directed genetically modified autologous T-cell immunotherapy indicated to treat adult clients with large B-cell lymphoma, including diffuse large B-cell lymphoma (DLBCL) not otherwise specified (including DLBCL arising from indolent lymphoma), high-grade B-cell lymphoma, primary mediastinal large B-cell lymphoma, and follicular lymphoma grade 3B who have:

- Refractory disease to first-line chemoimmunotherapy or relapse within 12 months of first-line chemoimmunotherapy.
- Refractory disease to first-line chemoimmunotherapy or relapse after first-line chemoimmunotherapy and are not eligible for hematopoietic stem cell transplant (HSCT) due to comorbidities or age.
- Relapsed or refractory disease after two or more lines of systemic therapy.

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

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

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.

### **6.28.1 Prior Authorization Criteria for Axicabtagene Ciloleucel (Yescarta)**

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

- The client is 18 years of age or older.
- The client has one of the following:
  - Relapsed or refractory disease, defined as progression after two or more lines of systemic therapy (which may or may not include therapy supported by autologous stem cell transplant)
  - Large B-cell lymphoma that is refractory to first-line chemoimmunotherapy or that relapses within 12 months of first-line chemoimmunotherapy
- The client does not have primary central nervous system lymphoma/disease.
- The client does not have an active infection or inflammatory disorder.
- The client has not received prior CD-19 directed CAR-T therapy.
- The client must have a histologically confirmed diagnosis of one of the following types of aggressive non-Hodgkin's lymphoma (diagnosis codes C8330, C8331, C8332, C8333, C8334, C8335, C8336, C8337, C8338, C8339, C8510, and C8520).

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

- The client is 18 years of age or older.

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

| Diagnosis Codes |       |       |       |       |       |       |       |
|-----------------|-------|-------|-------|-------|-------|-------|-------|
| C8200           | C8201 | C8202 | C8203 | C8204 | C8205 | C8206 | C8207 |
| C8208           | C8209 | C8210 | C8211 | C8212 | C8213 | C8214 | C8215 |
| C8216           | C8217 | C8218 | C8219 | C8220 | C8221 | C8222 | C8223 |
| C8224           | C8225 | C8226 | C8227 | C8228 | C8229 | C8230 | C8231 |
| C8232           | C8233 | C8234 | C8235 | C8236 | C8237 | C8238 | C8239 |
| C8240           | C8241 | C8242 | C8243 | C8244 | C8245 | C8246 | C8247 |
| C8248           | C8249 | C8250 | C8251 | C8252 | C8253 | C8254 | C8255 |
| C8256           | C8257 | C8258 | C8259 | C8260 | 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 |       |       |       |       |       |       |

**6.28.2 Prior Authorization Criteria for Brexucabtagene Autoleucel (Tecartus)**

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

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

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

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

**6.28.3 Prior Authorization Criteria for Ciltacabtagene Autoleucel (Carvykti)**

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

- The client is 18 years of age or older.
- The client has histologically confirmed diagnosis of relapse or refractory multiple myeloma (diagnosis codes C9000 and C9002).
- The client has relapsed or refractory disease and has received four or more lines of the following systemic therapies before treatment with ciltacabtagene autoleucl (Carvykti), which must include:
  - A proteasome inhibitor
  - An immunomodulatory agent
  - An Anti-CD38 monoclonal antibody
- The client does not have primary central nervous system lymphoma/disease.
- The client does not have an active infection or inflammatory disorder.
- The client has not received prior CAR-T therapy.
- Ciltacabtagene autoleucl (Carvykti) (procedure code Q2056) is limited to once per lifetime.

#### **6.28.4 Prior Authorization Criteria for Idecabtagene Vicleucl (ABECMA)**

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

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

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

#### **6.28.5 Prior Authorization Criteria for Lisocabtagene Maraleucl (Breyanzi)**

Prior authorization approval of lisocabtagene maraleucl (Breyanzi) (procedure code Q2054) infusion therapy will be considered when all of the following criteria are met:

- The client has a histologically confirmed diagnosis of large B-cell lymphoma, including diffuse large B-cell lymphoma not otherwise specified (including DLBCL arising from indolent lymphoma), high-grade B-cell lymphoma, primary mediastinal large B-cell lymphoma, or follicular lymphoma grade 3B with one of the following:
  - Refractory disease to first-line chemoimmunotherapy or relapse within 12 months of first line chemoimmunotherapy; or
  - Refractory disease to first-line chemoimmunotherapy or relapse after first line chemoimmunotherapy, and are not eligible for hematopoietic stem cell transplant (HSCT) due to comorbidities or age; or
  - Relapsed or refractory disease after two or more lines of systemic therapy.



- The client is 18 years of age or older.
- The client does not have primary central nervous system lymphoma/disease.
- The client does not have an active infection or inflammatory disorder.
- The client has not received prior CD-19 directed CAR-T therapy.
- The client has one of the following lymphoma diagnosis codes:

| Diagnosis Codes |       |       |       |       |       |       |
|-----------------|-------|-------|-------|-------|-------|-------|
| C8240           | C8241 | C8242 | C8243 | C8244 | C8245 | C8246 |
| C8247           | C8248 | C8249 | C8250 | C8330 | C8331 | C8332 |
| C8333           | C8334 | C8335 | C8336 | C8337 | C8338 | C8339 |
| C8390           | C8391 | C8392 | C8393 | C8394 | C8395 | C8396 |
| C8397           | C8398 | C8399 | C8510 | C8511 | C8512 | C8513 |
| C8514           | C8515 | C8516 | C8517 | C8518 | C8519 | C8520 |
| C8521           | C8522 | C8523 | C8524 | C8525 | C8526 | C8527 |
| C8528           | C8529 | C8580 | C8581 | C8582 | C8583 | C8584 |
| C8585           | C8586 | C8587 | C8588 | C8589 |       |       |

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

**6.28.6 Prior Authorization Criteria for Tisagenlecleucel (Kymriah)**

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

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

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

- The client has a confirmed diagnosis of relapsed or refractory large B-cell lymphoma (diagnosis codes C8330, C8331, C8332, C8333, C8334, C8335, C8336, C8337, C8338, 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 defined as progression after two or more lines of systemic therapy (which may or may not include therapy supported by autologous stem cell transplant).
- The client does not have primary central nervous system lymphoma
- The client has not received prior CD-19 directed CAR-T therapy

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

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

| Diagnosis Codes |       |       |       |       |       |       |       |
|-----------------|-------|-------|-------|-------|-------|-------|-------|
| C8200           | C8201 | C8202 | C8203 | C8204 | C8205 | C8206 | C8207 |
| C8208           | C8209 | C8210 | C8211 | C8212 | C8213 | C8214 | C8215 |
| C8216           | C8217 | C8218 | C8219 | C8220 | C8221 | C8222 | C8223 |
| C8224           | C8225 | C8226 | C8227 | C8228 | C8229 | C8230 | C8231 |
| C8232           | C8233 | C8234 | C8235 | C8236 | C8237 | C8238 | C8239 |
| C8240           | C8241 | C8242 | C8243 | C8244 | C8245 | C8246 | C8247 |
| C8248           | C8249 | C8250 | C8251 | C8252 | C8253 | C8254 | C8255 |
| C8256           | C8257 | C8258 | C8259 | C8260 | 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 |       |       |       |       |       |       |

**Referto:** Subsection 2.1.2, “Prior Authorization Requests” in this handbook for additional prior authorization information.

## 6.29 Ciltacabtagene Autoleucl

Ciltacabtagene autoleucl (procedure code Q2056) is a benefit of Texas Medicaid for clients who are 18 years of age or older.

## 6.30 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.

### 6.30.1 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.

**Referto:** Subsection 2.1.2, “Prior Authorization Requests” in this handbook for additional prior authorization information.

### 6.31 Coagulation Factor IX (Ixinity)

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

### 6.32 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), pegfilgrastim (procedure code J2506), and eflapegrastim-xnst (procedure code J1449) are granulocyte colony stimulating factors (G-CSFs). The biosimilars filgastrim, pegfilgrastim (Fulphila) (procedure code Q5108), (Nivestym) (procedure code Q5110), pegfilgrastim-cbqv (Udenyca) (procedure code Q5111), pegfilgrastim-bmez (Ziextenzo) (procedure code Q5120), pegfilgrastim (Nyvepria) (procedure code Q5122), filgrastim (Releuko) (procedure code Q5125), pegfilgrastim-fpgk (Stimufend) (procedure code Q5127), and pegfilgrastim-pbbk, (Fylnetra) (procedure code Q5130) are G-CSFs. G-CSFs 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 J2506 will be denied if billed on the same date of service as procedure code J1442.

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

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

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 |

| Diagnosis Codes |        |        |        |        |        |        |        |
|-----------------|--------|--------|--------|--------|--------|--------|--------|
| 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   | C563   | C5701  | C5702  | C5711  | C5712  |
| C5721           | C5722  | C573   | C574   | C577   | C578   | C579   | C58    |
| C600            | 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   |

| Diagnosis Codes |        |        |        |        |        |        |        |
|-----------------|--------|--------|--------|--------|--------|--------|--------|
| 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  | C7963  | 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  | 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  |

| Diagnosis Codes |        |         |         |         |         |         |         |
|-----------------|--------|---------|---------|---------|---------|---------|---------|
| C8449           | C8461  | C8462   | C8463   | C8464   | C8465   | C8466   | C8467   |
| C8468           | C8469  | C8471   | C8472   | C8473   | C8474   | C8475   | C8476   |
| C8477           | C8478  | C8479   | C847A   | C8491   | C8492   | C8493   | C8494   |
| 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  | 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 |

| Diagnosis Codes |         |         |         |         |         |       |       |
|-----------------|---------|---------|---------|---------|---------|-------|-------|
| T451X3A         | T451X3D | T451X3S | T451X4A | T451X4D | T451X4S | T8601 | T8602 |
| T8603           | T8609   | Z5111   | Z5112   | Z5189   | Z9481   | Z9484 |       |

### 6.33 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).

#### 6.33.1 Prior Authorization

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

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

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

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

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

**Referto:** Subsection 2.1.2, “Prior Authorization Requests” in this handbook for additional prior authorization information.

### 6.34 \* Delandistrogene moxeparvec-rokl (Elevidys)

[Revised] Delandistrogene moxeparvec-rokl (Elevidys) is an adeno-associated virus vector-based gene therapy indicated for the treatment of ambulatory pediatric clients who are 4 through 5 years of age with Duchenne muscular dystrophy (DMD) with a confirmed mutation in the DMD gene.

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

#### 6.34.1 \* Prior Authorization Requirements

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

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

- [Revised] The client is 4 through 5 years of age.

- [Revised] The client has a confirmed mutation in the DMD gene between exons 18 to 58 (diagnosis code G7101).
- [Revised] The client does not have any deletion in exon 8 or exon 9 in the DMD gene.
- [Revised] Documentation that client is ambulatory and not wheelchair bound (able to walk with or without assistance).
- [Revised] The client is not on concomitant DMD antisense oligonucleotide therapy (e.g., golodirsen, casimersen, viltolarsen, eteplirsen, etc.).
- [Revised] Documentation of client’s baseline testing for presence of anti-AAVrh74 total binding antibody titers of <1:400.
- [Revised] The client has no current infection. If there are signs of infection prior to infusion, treatment with delandistrogene moxeparvovec-rokl (Elevidys) should be postponed until the infection clears.
- [Revised] Due to the possibility of acute serious liver injury, client’s liver function must be monitored prior and post delandistrogene moxeparvovec-rokl (Elevidys) therapy.
- [Revised] Documentation of client’s platelet count and troponin-I level should be obtained prior to infusion.
- [Revised] The client does not have a history of previously receiving treatment with delandistrogene moxeparvovec-rokl (Elevidys) infusion.

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

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

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

**Referto:** [Revised] Subsection 2.1.2, “Prior Authorization Requests” in this handbook for additional prior authorization information.

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

### 6.35 \* **Dexmedetomidine**

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

### 6.36 **Dimethyl sulfoxide**

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



### 6.37 Eculizumab (Soliris)

Eculizumab (Soliris) (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           |      |      |      |      |      |      |       |

### 6.38 Edaravone (Radicava)

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

### 6.39 \* Efgartigimod

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

### 6.40 Elivaldogene Autotemcel (Skysona)

Elivaldogene autotemcel (Skysona) (procedure code J3590) is a benefit of Texas Medicaid for male clients who are 4 through 17 years of age with prior authorization.

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

Elivaldogene autotemcel (Skysona) (procedure code J3590) is limited to one transfusion treatment per lifetime.

#### 6.40.1 Prior Authorization Requirements

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

- The client is male who is 4 through 17 years of age.
- The client has a documented diagnosis of CALD (diagnosis code E71511, E71520, E71521, E71528, or E71529).
- The client has a variant in the ABCD1 gene as evident by a genetic test.
- The client’s CALD is caused by the presence of a variant of the ABCD1 gene causing elevated very long chain fatty acid (VLCFA) and not secondary to head trauma.
- The client has early, active CALD as defined by all the following:
  - The client is asymptomatic or mildly symptomatic with neurologic function score (NFS) of less than or equal to 1.
  - The client has gadolinium enhancement on brain magnetic resonance imaging (MRI).
  - The client has a Loes score ranging from 0.5 to 9.
- The client has not had a hematopoietic stem cell transplant (HSCT), is eligible for HSCT, and is unable to find a matched related donor.
- The client’s screening result is negative for hepatitis B virus (HBV), hepatitis C virus (HCV), human immunodeficiency virus (HIV)-1 and HIV-2, and Human T-lymphotropic virus type I (HTLV-I) and type II (HTLV-II) prior to the collection of cells for manufacturing.

- The prescriber must attest to monitor the client closely for evidence of life-threatening hematological malignancy through complete blood counts (CBC) at least every six months and through assessment for possible clonal expansion at least twice in the first year and annually thereafter.
- The prescriber must attest to monitor the client for signs of bleeding and infections after the treatment with elivaldogene autotemcel (Skysona) as life-threatening bacterial or viral infections may occur as well as thrombocytopenia and prolonged cytopenia.
- The client must avoid taking anti-retroviral medications for at least one month prior to initiating medication for stem cell mobilization and for the expected duration for elimination of the medications, and until all cycles of apheresis are complete.

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

### 6.41 \* Elranatamab-bcmm

[Revised] Elranatamab-bcmm (procedure code C9165) is a benefit of Texas Medicaid for clients who are 18 years of age or older.

### 6.42 Emapalumab-lzsg (Gamifant)

Emapalumab-lzsg (Gamifant) is an interferon gamma (IFN $\gamma$ ) 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.

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

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

#### 6.42.1 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  $\geq 101.3$  °F
    - Splenomegaly
    - Cytopenia defined by at least 2 of the following: Hemoglobin  $< 9$  g/dl; OR platelet count  $< 100 \times 10^9/L$ ; OR neutrophils  $< 1 \times 10^9/L$  OR Fasting triglycerides  $> 265$  mg/dl OR fibrinogen  $\leq 1.5$  g/L
    - Hemophagocytosis in the liver, bone marrow, spleen or lymph node
    - Low or absent natural killer (NK) cell activity
    - Serum ferritin concentration  $\geq 500$  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.

**Referto:** Subsection 2.1.2, “Prior Authorization Requests” in this handbook for additional prior authorization information.

### 6.43 \* Enzyme Replacement Therapy (ERT)

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

The following ERT therapies are benefits of Texas Medicaid:

- Agalsidase beta (Fabrazyme) is indicated in clients who are 2 years of age or older with Fabry disease and may be reimbursed with diagnosis code E7521.
- Alglucosidase alfa (Lumizyme) is indicated for clients with Pompe disease (GAA deficiency) and may be reimbursed with diagnosis code E7402.
- Avalglucosidase alfa-ngpt (Nexviazyme) is indicated for clients who are 1 year of age or older with late onset Pompe disease (lysosomal acid alpha-glucosidase [GAA] deficiency) and may be reimbursed with diagnosis code E7402.
- Cerliponase alfa (Brineura) is indicated to slow the loss of ambulation in symptomatic pediatric clients who are 3 years of age or older with late infantile neuronal ceroid lipofuscinosis type 2 (CLN2) and may be reimbursed with diagnosis code E754.
- Elosulfase alfa (Vimizim) is a hydrolytic lysosomal glycosaminoglycan- (GAG) specific enzyme indicated for clients who are 5 years of age or older with mucopolysaccharidosis type IVA and may be reimbursed with diagnosis code E76210.
- Galsulfase (Naglazyme) is a hydrolytic lysosomal glycosaminoglycan- (GAG) specific enzyme indicated for clients with mucopolysaccharidosis VI (MPS VI; Maroteaux-Lamy syndrome) and may be reimbursed with diagnosis code E7629.
- Idursulfase (Elaprase) is a hydrolytic lysosomal glycosaminoglycan- (GAG) specific enzyme indicated for clients with Hunter syndrome (mucopolysaccharidosis II [MPS II]) and may be reimbursed with diagnosis code E761.
- Imiglucerase (Cerezyme) is indicated for long-term ERT for clients who are 2 years of age or older with a confirmed diagnosis of Type 1 Gaucher disease (diagnosis code E7522) that results in one or more of the following conditions:
  - Anemia (low red blood cell count)
  - Thrombocytopenia (low blood platelet count)

- Bone disease
- Hepatomegaly or splenomegaly (enlarged liver or spleen)
- Laronidase (Aldurazyme) is indicated in clients with Hurler and Hurler-Scheie forms of mucopolysaccharidosis I (MPS I) and clients with the Scheie form who have moderate to severe symptoms and may be reimbursed with diagnosis codes E7601, E7602, and E7603.
- Olipudase alfa-rpcp (Xenpozyme) is indicated for the treatment of non-central nervous system manifestations of acid sphingomyelinase deficiency (ASMD) in adult and pediatric patients with diagnosis codes E75241 and E75244. The following requirements must be met:
  - Pregnancy status of female clients of reproductive potential must be verified prior to initiating treatment.
  - Client’s baseline transaminase level must be obtained.
  - Assessment of alanine transaminase (ALT) and aspartate aminotransferase (AST) must be conducted within one month prior to initiation of Olipudase alfa-rpcp, within 72 hours prior to any infusion during dose escalation, or prior to the next scheduled Olipudase alfarpcp infusion upon resuming treatment following a missed dose.
- [Revised] Pegunigalsidase alfa-iwxj (Elfabrio) is indicated for the treatment of adult clients with confirmed Fabry disease with diagnosis code E7521.
- Protein C concentrate, human (Ceprotin) is indicated in pediatric and adult clients with severe congenital protein C deficiency for the prevention and treatment of venous thrombosis and purpura fulminans and may be reimbursed with diagnosis cod D6859.
- Sebelipase alfa (Kanuma) is indicated for the treatment of pediatric and adult clients with a diagnosis of lysosomal acid lipase (LAL) deficiency and may be reimbursed with diagnosis code E755.
- Taliglucerase alfa (Elelyso) is indicated for long-term ERT for adult clients with Type 1 Gaucher disease and may be reimbursed with diagnosis code E7522.
- Velaglucerase alfa (VPRIV) is indicated for long-term ERT for clients with Type 1 Gaucher disease and may be reimbursed with diagnosis code E7522.
- [Revised] Velmanase alfa-tycv (Lamzedo) is indicated to treat non-central nervous system manifestation of alpha-mannosidosis in adult and pediatric clients with diagnosis code E771. The following requirement must be met:
  - [Revised] Pregnancy status of female clients of reproductive potential must be verified prior to initiating treatment.

**6.43.1 \* Reimbursement for ERT**

The following procedure codes may be reimbursed for ERT services:

| [Revised] Procedure Codes |       |       |       |       |       |       |       |       |       |
|---------------------------|-------|-------|-------|-------|-------|-------|-------|-------|-------|
| J0180                     | J0217 | J0218 | J0219 | J0221 | J0567 | J1322 | J1458 | J1743 | J1786 |
| J1931                     | J2508 | J2724 | J2840 | J3060 | J3385 |       |       |       |       |

Procedure code J0219 is restricted to clients who are 1 year of age or older.

**6.43.2 Prior Authorization**

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

- A request for the specific enzyme replacement therapy.

- Laboratory evidence of the enzyme deficiency, (i.e., below the laboratory-defined cut-off value as determined by the laboratory).

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

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

#### **6.44 \* Epcoritamab-bysp (Epkinly)**

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

#### **6.45 Eravacycline (Xerava)**

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

#### **6.46 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) 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.

##### **6.46.1 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.

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

## 6.47 Esmolol Hydrochloride

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

## 6.48 Etranacogene Dezaparvovec-drlb (Hemgenix)

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

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

### 6.48.1 Prior Authorization Requirements

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

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

- The client is 18 years of age or older.
- The client has a confirmed diagnosis of Hemophilia B (Hereditary factor IX deficiency) (diagnosis code D67) and all other bleeding disorders not related to Hemophilia B have been ruled out.
- The client must meet one of the following criteria:
  - Is currently using Factor IX prophylaxis therapy, or
  - Has current or historical life-threatening hemorrhage, or

- Has a history of repeated, serious spontaneous bleeding episodes.
- A Factor IX inhibitor titer testing must be performed, and client must have a baseline anti-AAV5 antibody titer of  $\leq 1:678$ .
- The client must be tested for Factor IX inhibitor presence and testing result must be negative.
  - If testing yields a positive result, a second Factor IX inhibitor titer test should be performed within two weeks.
  - Etranacogene dezaparvovec-drlb (Hemgenix) should not be administered if the results for the initial and second test for human Factor IX inhibitor are positive.
- Baseline liver condition and function assessment must be assessed prior to etranacogene dezaparvovec-drlb (Hemgenix) infusion.
  - Documentation includes, but is not limited to alanine aminotransferase (ALT), aspartate aminotransferase (AST), alkaline phosphatase (ALP), and total bilirubin
  - Documentation of hepatic ultrasound and elastography must be provided.
- The client does not have a history of previously receiving treatment with etranacogene dezaparvovec-drlb (Hemgenix) infusion.

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

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

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

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

### **6.49 Evinacumab-dgnb (Evkeeza)**

Evinacumab-dgnb (procedure code J1305) is a benefit of Texas Medicaid for clients who are 5 years of age or older.

### **6.50 Fam-trastuzumab Deruxtecan-nxki**

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

### **6.51 Fecal Microbiota**

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

### **6.52 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.

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

### 6.53 Furosemide (Furoscix)

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

### 6.54 Givosiran (Givlaari)

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

### 6.55 \* Glofitamab-gxbm

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

### 6.56 Granisetron Hydrochloride

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

### 6.57 Hematopoietic Injections

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

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

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

**Referto:** Subsection 6.2.7.1, “Hematopoietic Injections” in the *Clinics and Other Outpatient Facility Services Handbook (Vol. 2, Provider Handbooks)* for information about outpatient facility criteria.

#### 6.57.1 Darbepoetin Alfa

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

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

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

| Diagnosis Codes |       |       |      |      |       |      |      |
|-----------------|-------|-------|------|------|-------|------|------|
| C9000           | C9001 | C9002 | D460 | D461 | D4621 | D46A | D46B |



| Diagnosis Codes |       |      |       |      |       |       |       |
|-----------------|-------|------|-------|------|-------|-------|-------|
| D611            | D612  | D613 | D6189 | D619 | D630  | D631  | D644  |
| D6481           | D6489 | D649 | N181  | N182 | N1830 | N1831 | N1832 |
| N184            | N185  | N186 | N189  | N19  | Z5111 | Z5112 |       |

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

### 6.57.2 Epoetin Alfa (EPO)

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

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

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

| Diagnosis Codes |       |       |       |       |      |       |       |
|-----------------|-------|-------|-------|-------|------|-------|-------|
| B20             | C9000 | C9001 | C9002 | D460  | D461 | D4621 | D4622 |
| D464            | D469  | D46A  | D46B  | D46C  | D46Z | D471  | D479  |
| D47Z9           | D611  | D612  | D613  | D6189 | D619 | D630  | D631  |
| D644            | D6481 | D6489 | D649  | 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).

### 6.57.3 Methoxy Polyethylene Glycol-Epoetin Beta (Mircera)

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

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

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

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

| Diagnosis Codes |       |       |      |       |      |      |      |
|-----------------|-------|-------|------|-------|------|------|------|
| D631            | 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).

## 6.58 Hemophilia Drugs

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

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

### 6.58.2 Coagulation factor Xa (Recombinant), Inactivated-zhzo (Andexxa)

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

### 6.58.3 Factor VIIa (Antihemophilic factor, Recombinant)-JNCW (Sevenfact)

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

## 6.59 Hereditary Angioedema (HAE) agents

### 6.59.1 C1 Esterase Inhibitor (Human) (Berinert)

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

### 6.59.2 C1 Esterase Inhibitor (Human) (Cinryze)

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

### 6.59.3 C1 Esterase Inhibitor (Human) (Haegarda)

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

### 6.59.4 C1 Esterase Inhibitor (Recombinant) (Ruconest)

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

### 6.59.5 Ecallantide (Kalbitor)

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

### 6.59.6 Icatibant (Firazyr)

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

### 6.59.7 Lanadelumab-flyo (Takhzyro)

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

## 6.60 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.

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

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

## 6.61 Imipenem, Cilastatin, and Relebactam (Recarbrio)

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

### 6.62 Immune Globulin

Immune globulins may be indicated for treatment of certain immune disorders and states of immunodeficiency. Age and diagnosis restrictions for the procedure codes listed below may vary according to the FDA approved indications. The following immune globulin procedure codes are benefits of Texas Medicaid:

| Procedure Codes |       |       |       |       |       |       |       |       |       |
|-----------------|-------|-------|-------|-------|-------|-------|-------|-------|-------|
| 90284           | 90291 | J1554 | J0850 | J1459 | J1460 | J1551 | J1555 | J1556 | J1557 |
| J1558           | J1559 | J1561 | J1566 | J1568 | J1569 | J1572 | J1575 | J1576 | 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.*

### 6.63 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 | J0717 | J1595 | J1602 | J7501 | J7516 | J7519 |
| 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):<br>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:<br>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:<br>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:<br>For the prophylaxis of organ rejection in adults receiving a kidney transplant, to be used in combination with basiliximab injection, mycophenolate mofetil, and corticosteroids.   |
| J0717          | Psoriatic arthritis, Ulcerative colitis, Ankylosing spondylitis, Crohn’s disease  |
| J1595          | Multiple sclerosis (MS):<br>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. |
| J1602          | Psoriatic arthritis, Rheumatoid arthritis, Ankylosing spondylitis   |

| Procedure Code | Conditions   |
|----------------|--|
| J7501          | Renal homotransplantations:<br>Adjunct for the prevention of rejection in renal homotransplantation.<br>Rheumatoid arthritis:<br>Azathioprine is indicated only in adult patients meeting the criteria for classic or definite rheumatoid arthritis as specified by the American Rheumatism Association. |
| J7516, J7519   | Allogeneic transplants:<br>For prophylaxis of organ rejection in kidney, liver, and heart allogeneic transplants.  |
| J7525          | Organ rejection prophylaxis:<br>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.

### 6.64 Inclisiran (Leqvio)

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

### 6.65 Inebilizumab-cdon (Uplizna)

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

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

#### 6.65.1 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.

**6.66 \* Infliximab (Remicade), Inflectra, Renflexis**

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

| <b>[Revised] Diagnosis Codes</b> |              |        |        |        |        |        |        |
|----------------------------------|--------------|--------|--------|--------|--------|--------|--------|
| 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  |
| <b>M057A</b>                     | M05811       | M05812 | M05821 | M05822 | M05831 | M05832 | M05841 |
| M05842                           | M05851       | M05852 | M05861 | M05862 | M05871 | M05872 | M0589  |
| <b>M058A</b>                     | M06011       | M06012 | M06021 | M06022 | M06031 | M06032 | M06041 |
| M06042                           | M06051       | M06052 | M06061 | M06062 | M06071 | M06072 | M0608  |
| M0609                            | <b>M060A</b> | M06811 | M06812 | M06819 | M06821 | M06822 | M06829 |
| M06831                           | M06832       | M06839 | M06841 | M06842 | M06849 | M06851 | M06852 |
| M06859                           | M06861       | M06862 | M06869 | M06871 | M06872 | M06879 | M0688  |
| M0689                            | <b>M068A</b> | 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 |

| [Revised] Diagnosis Codes |        |        |        |        |        |        |        |
|---------------------------|--------|--------|--------|--------|--------|--------|--------|
| M0888                     | M0889  | M08931 | M08932 | M08941 | M08942 | M08951 | M08952 |
| M08961                    | M08962 | M08971 | M08972 | M0898  | M450   | M451   | M452   |
| M453                      | M454   | M455   | M456   | M457   | M458   | M45A0  | M45A1  |
| M45A2                     | M45A3  | M45A4  | M45A5  | M45A6  | M45A7  | M45A8  | M45AB  |

### 6.67 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.

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).

#### 6.67.1 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

**Referto:** Subsection 2.1.2, “Prior Authorization Requests” in this handbook for additional prior authorization information.

#### 6.67.2 Documentation Requirements

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

#### 6.67.3 Exclusions

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

### 6.68 Insulin

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

## 6.69 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:

| Procedure Codes |       |       |       |       |       |       |  |
|-----------------|-------|-------|-------|-------|-------|-------|--|
| J1826           | J1830 | J9214 | J9216 | S0145 | Q3027 | Q3028 |  |

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

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

- Chronic granulomatous disease
- Malignant osteoporosis

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.*

## 6.70 Invega Hafyera

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

## 6.71 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 derisomaltose (procedure code J1437) 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.

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

- Adult and pediatric clients who are 1 year of age and older that have either intolerance or unsatisfactory response to oral iron.
- Adult clients who have 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 code Q0138) 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).

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

## 6.72 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.

**6.73 Labetalol Hydrochloride**

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

**6.74 Lactated Ringer’s**

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

**6.75 Lefamulin (Xenleta)**

Lefamulin (procedure code J0691) is a benefit of Texas Medicaid for clients who are 18 years of age or older.

**6.76 Lenacapavir (Sunlenca)**

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

**6.77 Leuprolide Acetate (Lupron Depot)**

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

| Procedure Code | Limitation(s)             |
|----------------|---------------------------|
| J1950          | Reimbursed once per month |

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

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

**6.78 Lumasiran (Oxlumo)**

Lumasiran (procedure code J0224) is a benefit of Texas Medicaid for clients when billed with diagnosis code E7253.

## 6.79 Lupus Treatment Agents

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

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

Belimumab (Benlysta) is indicated to treat the following:

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

### 6.79.1 Initial Requests

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

- The client is 18 years of age or older.
- The client has a confirmed diagnosis of systemic lupus erythematosus (M3210, M3211, M3212, M3213, M3214, M3215, M3219, M328, M329).
- The client does not have active lupus nephritis or severe active central nervous lupus.
- The client is currently receiving at least one stable standard-of-care treatment for active systemic lupus erythematosus.
- The client is not receiving anifrolumab-fina (Saphnelo) in combination with a biologic agent.

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

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

### 6.79.2 Recertification or Extension

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

- The client continues to meet the initial authorization approval criteria.

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

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

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

## 6.80 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)

### 6.80.1 Prior Authorization for Luspatercept-aamt (Reblozyl)

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

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

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

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

- Client who has anemia with beta thalassemia requiring regular RBC transfusions:
  - The client had a positive response/hematological improvement demonstrated by a reduction in RBC transfusion as indicated by the prescribing physician.

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

### 6.81 Medroxyprogesterone Acetate (Depo Provera)

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

### 6.82 Meloxicam (Anjeso)

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

### 6.83 Mepsevii (Vestronidase alfa-vj bk)

Vestronidase alfa-vj bk (Mepsevii) (procedure code J3397) is a benefit of Texas Medicaid for pediatric and adult clients with prior authorization. Vestronidase alfa-vj bk (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-vj bk 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.).

*Referto:* Subsection 2.1.2, “Prior Authorization Requests” in this handbook for additional prior authorization information.

### 6.84 Mirvetuximab Soravtansine-gynx (Elahere)

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

## 6.85 Mogamulizumab-kpkc (Poteligeo)

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

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

### 6.85.1 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

**Referto:** Subsection 2.1.2, “Prior Authorization Requests” in this handbook for additional prior authorization information.

## 6.86 Monoclonal Antibodies

### 6.86.1 Omalizumab

Omalizumab may be a benefit of Texas Medicaid when medically necessary with prior authorization.

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

- 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).

- Clients who are 12 years of age or older and have chronic idiopathic urticaria (CIU) who remain symptomatic despite H1 antihistamine treatment.
- Add-on maintenance treatment of nasal polyps in adult clients who are 18 years of age and older with inadequate response to nasal corticosteroids.

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

### **6.86.2 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.

### **6.86.3 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
- Add-on maintenance treatment of chronic rhinosinusitis with nasal polyps (CRSwNP) in adult clients who are 18 years of age or older with inadequate response to nasal corticosteroids.

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

### **6.86.4 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.

### **6.86.5 Tezepelumab-ekko (Tezspire)**

Tezepelumab-ekko (procedure code J2356) is a benefit of Texas Medicaid when medically necessary with prior authorization.

Tezepelumab-ekko is an injection drug that is FDA-approved and indicated as an add-on maintenance treatment of adult and pediatric clients who are 12 years of age and older with severe asthma.

### **6.86.6 Prior Authorization for Omalizumab, Benralizumab, Mepolizumab, Reslizumab, and Tezepelumab-ekko**

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

- Moderate to severe asthma
  - Client is 6 years of age or older.

- Client has a diagnosis of moderate to severe asthma (as defined by the National Heart, Lung, and Blood Institute's Guidelines for the Diagnosis and management of Asthma) (diagnosis codes J4540 and J4550).
- Client has a positive skin test or radioabsorbent assay test (RAST) to a perennial (not seasonal) aeroallergen within the past 36 months.
- Client has a total IgE level greater than 30 IU/ml but less than 1300 IU/ml within the past 12 months.
- Chronic Idiopathic Urticaria (CIU)
  - Client is 12 years of age or older
  - Client has a diagnosis of CIU with symptoms despite H1 antihistamine treatment (diagnosis code L501).
  - Documentation supporting medical necessity for the treatment of CIU with omalizumab must be submitted with request and include the following:
    - Documented failure of, or contraindication to, antihistamine
    - Evidence of an evaluation that excludes other medical diagnosis associated with chronic urticaria
- Add-on maintenance treatment of nasal polyps
  - Client is 18 years of age or older
  - Client has a diagnosis of nasal polyps (diagnosis codes J330, J331, J338, J339) with inadequate response to nasal corticosteroids
  - Documentation supporting medical necessity for maintenance treatment of nasal polyps with omalizumab must be submitted with the request and include the following:
    - Client has bilateral nasal polyposis confirmed by physical examination or nasal endoscopy
    - Documented failure of, or contraindication to, prior corticosteroids as monotherapy
    - Documented inadequate response to prior corticosteroid treatments

Prior authorization for benralizumab (Fasenra) will be considered for clients who are 12 years of age or older with severe asthma with eosinophilic phenotype (as defined by the National Heart, Lung, and Blood Institute's Guidelines for the Diagnosis and management of Asthma) (diagnosis codes J4550, J4551, J4552).

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

- Severe asthma with eosinophilic phenotype
  - Client is 6 years of age or older

Client has a diagnosis of severe asthma with eosinophilic phenotype (as defined by the National Heart, Lung, and Blood Institute's Guidelines for the Diagnosis and management of Asthma) (diagnosis codes J4550, J4551, J4552)

- Eosinophilic granulomatosis with polyangiitis (EGPA)
  - Client is 18 years of age or older
  - Confirmed diagnosis of eosinophilic granulomatosis with polyangiitis (diagnosis code M301)
  - Documentation supporting medical necessity for treatment of EGPA with mepolizumab must be submitted with the request and meet the following:
    - Diagnosis of EGPA



- Medical history of asthma
- Presence of at least 2 of the following EGPA characteristics below:
  - Histopathological findings of eosinophilic vascularitis, perivascularitis eosinophilic infiltration or eosinophil-rich granulomatous inflammation
  - Neuropathy
  - Pulmonary infiltrates, non-fixed; Sino-nasal abnormality
  - Cardiomyopathy
  - Glomerulonephritis
  - Alveolar hemorrhage
  - Palpable purpura
  - Anti-neutrophils cytoplasmic antibody
- Client use of an oral glucocorticoid and/or cyclophosphamide, azathioprine, methotrexate, or leflunomide
- Refractory disease or has had a history of EGPA relapse
- Hypereosinophilic Symptoms (HES)
  - Client is 12 years of age or older
  - Client has a diagnosis of hypereosinophilic symptoms (HES) for 6 months or longer without identifiable non-hematologic secondary cause (diagnosis codes D72110, D72111, D72118, and D72119)
  - 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 of Mepolizumab therapy
    - Prescriber's attestation that client has been on a stable dose of HES therapy which includes, but no limited to corticosteroids, immunosuppressive and cytotoxic therapy
- Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)
  - Prior authorization for mepolizumab (Nucala) will be considered for clients as an add-on maintenance treatment of chronic rhinosinusitis with nasal polyps when all the following are met:
    - Client is 18 years of age or older
    - Confirmed diagnosis of chronic rhinosinusitis with nasal polyps (diagnosis codes J330, J331, J338, J339)
    - Evidence of inadequate response to nasal corticosteroid

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

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

- Add-on maintenance for severe asthma
  - Client is 12 years of age and older
  - Client has a diagnosis of severe asthma (as defined by the National Heart, Lung, and Blood Institute’s Guidelines for the Diagnosis and management of Asthma) (diagnosis codes J4550 and J4551).
  - Tezepelumab-ekko is being used as an add-on maintenance therapy. Tezepelumab-ekko is not to be used as a single or primary therapy.
  - Client is currently on the following as a regular treatment for severe asthma and compliant on the therapy:
    - Medium or high-dose inhaled corticosteroid therapy, and
    - An additional asthma controller
  - Tezepelumab-ekko should not be used for relief of acute bronchospasm or status asthmaticus.
  - Tezepelumab-ekko may not be used in combination with anti-IgE, anti-IL4 or anti-IL5 monoclonal antibody agents (i.e., benralizumab, omalizumab, mepolizumab, reslizumab, dupilumab, etc.)
  - Tezepelumab-ekko should not be administered concurrently with live attenuated vaccination.

A client with preexisting helminth infections should be treated prior to receiving omalizumab, benralizumab, mepolizumab, reslizumab, or tezepelumab-ekko therapy.

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

**Referto:** Subsection 2.1.2, “Prior Authorization Requests” in this handbook for additional prior authorization information.

### **6.86.7 Prior Authorization Criteria for Asthma — Moderate to Severe (Omalizumab) and Severe (Benralizumab, Mepolizumab, Reslizumab, and Tezepelumab-ekko)**

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, reslizumab, or tezepelumab-ekko must be submitted with the request and must indicate the following:

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

**Note:** *Exceptions to the criteria above will be considered on a case-by-case basis, which will require a letter from the prescribing provider stating the medical necessity for 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.*

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

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

Tezepelumab-ekko may not be used in combination with anti-IgE, anti-IL4 or anti-IL5 monoclonal antibody agents (i.e., benralizumab, omalizumab, mepolizumab, reslizumab, dupilumab, etc.)

### **6.86.8 Requirements for Continuation of Therapy for Omalizumab, Benralizumab, Mepolizumab, Reslizumab, or Tezepelumab-ekko**

For continuation of therapy with omalizumab, benralizumab, mepolizumab, reslizumab, or tezepelumab-ekko 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, reslizumab, or tezepelumab-ekko:

- 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 waking, 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, reslizumab, or tezepelumab-ekko.

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

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

### **6.86.9 Reimbursement**

Procedure codes J0517, J2182, J2356, 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 omalizumab, benralizumab, mepolizumab, reslizumab, or tezepelumab-ekko injection.

### 6.86.10 Mosunetuzumab-axgb

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

### 6.87 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 is not a benefit for clients who have renal impairment with CrCl < 29 ml/min.

#### 6.87.1 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.

**Referto:** Subsection 2.1.2, “Prior Authorization Requests” in this handbook for additional prior authorization information.

### 6.88 \* Nadofaragene Firadenovec-vncg (Adstiladrin)

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

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

#### 6.88.1 \* Prior Authorization Requirements

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

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

- [Revised] The client is 18 years of age or older.
- [Revised] The client has a confirmed diagnosis of non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) with or without papillary tumors.
- [Revised] The client’s disease is high-risk and BCG unresponsive as defined as persistent disease following adequate BCG therapy, disease recurrence after an initial tumor-free state following adequate BCG therapy, or T1 disease following a single induction course of BCG.
- [Revised] The client does not have any metastatic urothelial carcinoma.

- [Revised] The client does not have a hypersensitivity to interferon alfa.
- [Revised] The client is not immunocompromised or immunodeficient.

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

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

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

**Referto:** [Revised] Subsection 2.1.2, “Prior Authorization Requests” in this handbook for additional prior authorization information.

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

### 6.89 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 |        |        |        |        |        |        |

### 6.90 Nitroglycerin

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

### 6.91 Nivolumab and Relatlimab-rmbw

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

### 6.92 Onasemnogene abeparvovec-xioi (Zolgensma)

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

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

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

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

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

### 6.92.1 Prior Authorization Requirements

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

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

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

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

### 6.92.2 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 SMA (diagnosis code G120) based on gene mutation analysis with biallelic SMN1 mutation (deletion or point mutation).
- The administration of onasemnogene abeparvovec-xioi (Zolgensma) may cause serious liver injury or failure. Providers must also complete the following to administer the drug:
  - Examine the client's liver function by clinical examination and laboratory testing (e.g., hepatic aminotransferases [aspartate aminotransferase (AST) and alanine aminotransferase (ALT)], total bilirubin, and prothrombin time) before infusion of onasemnogene abeparvovec-xioi (Zolgensma).
  - Administer a systemic corticosteroid before and after the administration of the drug.
  - Continue to monitor the client's liver function at least 3 months after the infusion of the drug.
- Evaluation of motor skill and function must be documented using a standardized test. However, it is not a prerequisite of therapy and should not delay treatment. Standardized testing tools that may be used to evaluate motor skill/function include, but are not limited to:
  - Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorder (CHOP-INTEND) score

- Bayley scale of infant and toddler development screening test
- WHO Multicenter Growth Reference Study (WHO MGRS)
- Baseline documentation supports an AAV9 antibody titer of 1:50 or lower, as determined by enzyme-linked immunosorbent assay (ELISA) binding immunoassay.
- Physician attestation supports that the client has not received prior onasemnogene abeparvovec-xioi (Zolgensma) therapy.

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

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

### 6.93 Panhematin

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

### 6.94 Pegcetacoplan

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

### 6.95 Polyneuropathy of Hereditary Transthyretin-mediated (hATTR) Amyloidosis

Onpattro (Patisiran) and Amvuttra (Vutrisiran) are benefits 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 (procedure code J0222) and vutrisiran (procedure code J0225) must be submitted with a Special Medical Prior Authorization (SMPA) Request Form and may be approved for 12 months per prior authorization request.

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

- The client is 18 years of age or older.
- The client has a diagnosis of hATTR amyloidosis (diagnosis code E851), supported by the following:
  - Transthyretin (TTR) mutation proven by genetic testing
  - 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 tafamidis meglumine or vutrisiran).
- The client has not had a liver transplant.

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

- The client is 18 years of age or older
- The client has a diagnosis of hATTR amyloidosis (diagnosis code E851), supported by the following:
  - Transthyretin (TTR) mutation proven by genetic testing

- Clinical signs and symptoms of the disease (e.g., peripheral or autonomic neuropathy, motor disability)
- The client will not receive vutrisiran (Amvuttra) therapy in combination with other therapies for polyneuropathy caused by hATTR amyloidosis (e.g., inotersen, patisiran, or tafamidis meglumine).
- The client will receive vitamin A supplementation at the recommended daily allowance while on vutrisiran (Amvuttra) therapy.
- The client has not had a liver transplant.

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

- The client has previously received treatment with patisiran (Onpattro) or vutrisiran (Amvuttra) without an adverse reaction.
- The client has a positive clinical response to patisiran (Onpattro) or vutrisiran (Amvuttra) (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.

*Referto:* Subsection 2.1.2, “Prior Authorization Requests” in this handbook for additional prior authorization information.

### 6.96 Plasminogen Human-tvmh (Ryplazim)

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

### 6.97 Plazomicin

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

### 6.98 Ravulizumab-cwvz (Ultomiris)

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

| Diagnosis Codes |       |       |       |      |      |      |       |
|-----------------|-------|-------|-------|------|------|------|-------|
| D588            | D5930 | D5932 | D5939 | D594 | D595 | D598 | G7000 |
| G7001           |       |       |       |      |      |      |       |

### 6.99 Remimazolam

Remimazolam (procedure code J2249) is a benefit of Texas Medicaid for clients who are 18 years of age or older.

### 6.100 Retifanlimab-dlwr (Zynyz)

Retifanlimab-dlwr (procedure code J9345) is a benefit of Texas Medicaid for clients who are 18 years of age or older.



**6.101 Rilonecept (Arcalyst)**

Rilonecept (procedure code J2793) is a benefit of Texas Medicaid for clients who are 12 years of age or older.

**6.102 \* Risperidone**

[Revised] Risperidone (Perseris) (procedure code J2798) and (Uzedy) (procedure code J2799) are benefits of Texas Medicaid for clients who are 18 years of age or older.

**6.103 Rituximab-Abbs, (Truxima)**

Rituximab-abbs (Truxima) (procedure code Q5115) is a benefit of Texas Medicaid for clients who are 18 years of age or older.

**6.104 Romosozumab**

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

**6.105 \* Ronzanolixizum-noli (Rystiggo)**

[Revised] Ronzanolixizum-noli (procedure code J9333) is a benefit of Texas Medicaid for clients who are 18 years of age or older and is restricted to diagnosis codes G7000 and G7001.

**6.106 Sirolimus Protein-bound Particles (Fyarro)**

Sirolimus protein-bound particles (Fyarro) (procedure code J9331) is a benefit of Texas Medicaid for clients who are 18 years of age or older.

**6.107 Spesolimab-sbzo (Spevigo)**

Spesolimab-sbzo (Spevigo) (procedure code J1747) is a benefit of Texas Medicaid for clients who are 18 years of age or older and restricted to diagnosis code L401.

**6.108 Sutimlimab-jome (Enjaymo)**

Sutimlimab-jome (Enjaymo) (procedure code J1302) is a benefit of Texas Medicaid for clients who are 18 years of age or older.

**6.109 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  |        |        |        |        |

### 6.110 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.

### 6.111 \* Talquetamab-tgvs (Talvey)

[Revised] Talquetamab-tgvs (procedure code C9163) is a benefit of Texas Medicaid for clients who are 18 years of age or older.

#### 6.111.1 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

**Referto:** Subsection 2.1.2, “Prior Authorization Requests” in this handbook for additional prior authorization information.

### 6.112 Tebentafusp-tebn (Kimmtrak)

Tebentafusp-tebn (Kimmtrak) (procedure code J9274) is a benefit of Texas Medicaid for clients who are 18 years of age or older.

### 6.113 Teclistamab-cqyv (Tecvayli)

Teclistamab-cqyv (Tecvayli) (procedure code J9380) is a benefit of Texas Medicaid for clients who are 18 years of age or older.

### 6.114 Teplizumab-mzwv (Tzielid)

Teplizumab-mzwv (Tzielid) is indicated to delay the onset of Stage 3 type 1 diabetes (T1D) in adult and pediatric clients who are 8 years of age or older with Stage 2 T1D.

Teplizumab-mzwv (Tzielid) (procedure code J9381) is a benefit of Texas Medicaid with prior authorization.

Teplizumab-mzwv (Tzielid) therapy may be approved for the 14-day treatment duration if all the following criteria are met:

- The client is 8 years of age or older.
- The client is given teplizumab-mzwv (Tzielid) to delay the onset of Stage 3 T1D. The use of teplizumab-mzwv (Tzielid) is not approved in type 2 diabetes or any other stages of type 1 diabetes other than Stage 2 T1D.
- The client has a diagnosis of Stage 2 T1D confirmed by the following:
  - Documentation of at least two positive pancreatic islet autoantibodies:
    - Islet cell autoantibody (ICA)
    - Insulinoma-associated antigen 2 autoantibody (IA-2A)
    - Insulin autoantibody (IAA)
    - Zinc transporter 8 autoantibody (ZnT8A)
    - Glutamic acid decarboxylase 65 (GAD) autoantibodies
  - Documentation of dysglycemia without overt hyperglycemia using oral glucose tolerance test (OGTT), or another appropriate test for dysglycemia may be used if OGTT is not available.
- The clinical history does not suggest that the client has type 2 diabetes.
- The prescriber must obtain and assess a complete blood count and liver enzyme tests prior to the initiation of treatment with teplizumab-mzwv (Tzielid) because the use of teplizumab-mzwv (Tzielid) is not recommended in clients with certain lab abnormalities.
- The prescriber must assess client's history of chronic infection and monitor for any signs of active serious infection while on teplizumab-mzwv (Tzielid). If a serious infection develops, teplizumab-mzwv (Tzielid) therapy should be discontinued.

### 6.115 Teprotumumab-trbw (Tepezza)

Teprotumumab-trbw (Tepezza) (procedure code J3241) is a benefit of Texas Medicaid and prior authorization is required. Teprotumumab-trbw (Tepezza) is indicated for the treatment of thyroid eye disease (TED) regardless of TED activity or duration.

#### 6.115.1 Prior Authorization Requirements

Prior authorization requests for procedure code J3241 must be submitted with a Special Medical Prior Authorization (SMPA) Request Form.

The client must meet all of the following requirements for approval of Teprotumumab-trbw (Tepezza):

- The client has a diagnosis of Graves' disease associated with TED.
- The client is euthyroid, or the client has either mild hypothyroidism or mild hyperthyroidism.
- The client has no history of prior surgical intervention for TED and does not plan to have surgical treatment while on Teprotumumab-trbw (Tepezza).
- The client may not exceed the course of eight total infusions per lifetime.

**6.115.2 Exclusions**

Teprotumumab-trbw (Tepezza) should not be used in pregnancy as it may potentially lead to fetal loss. Females of reproductive potential should use effective contraception prior to initiation, during treatment with Teprotumumab-trbw (Tepezza) and for 6 months after the last dose of Teprotumumab-trbw (Tepezza).

**6.116 Thyrotropin alpha for injection (Thyrogen)**

Thyrotropin alpha for injection (Thyrogen) (procedure code J3240) is a benefit of Texas Medicaid and is limited to the following diagnosis codes:

| Diagnosis Codes |       |       |        |      |      |      |      |
|-----------------|-------|-------|--------|------|------|------|------|
| C323            | C73   | D020  | D093   | D098 | D380 | D440 | D442 |
| D449            | D497  | E010  | E011   | E012 | E040 | E042 | E048 |
| E049            | E0500 | E0520 | Z85850 |      |      |      |      |

**6.117 Tildrakizumab (Ilumya)**

Tildrakizumab (procedure code J3245) is a benefit of Texas Medicaid for clients who are 18 years of age or older, and is limited to diagnosis code L400.

**6.118 Tisotumab Vedotin-tftv**

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

**6.119 Trastuzumab**

Procedure code J9355 is a benefit of Texas Medicaid. Reimbursement for this drug is considered when it is used as a single agent for the treatment of clients who have metastatic breast cancer whose tumors overexpress the Her-2 protein and who have received one or more chemotherapy regimens for their metastatic disease. Trastuzumab may also be reimbursed when:

- Used in combination with paclitaxel for the treatment of clients who have metastatic breast cancer whose tumors overexpress the Her-2 protein and who have not received chemotherapy for their metastatic disease.
- Used as part of a treatment regimen containing doxorubicin, cyclophosphamide, and paclitaxel for the adjuvant treatment of clients who have Her-2-overexpressing, node-positive breast cancer.

Trastuzumab is a benefit for clients whose tumors have Her-2 protein overexpression.

When billing for the test used to determine whether a client overexpresses the Her-2 protein, use procedure code 83950. Diagnosis of overexpression of the Her-2 protein must be made before Texas Medicaid will consider reimbursement for trastuzumab. This test may be reimbursed only once in a client’s lifetime to the same provider. An additional test by the same provider requires documentation to support the medical necessity.

**6.120 Tremelimumab-actl (Imjudo)**

Tremelimumab-actl (Imjudo) (procedure code J9347) is a benefit of Texas Medicaid for clients who are 18 years of age or older.

### 6.121 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 |

### 6.122 Trilaciclib (Cosela)

Trilaciclib (procedure code J1448) is a benefit of Texas Medicaid for clients who are 18 years of age or older.

### 6.123 Ublituximab-xiiy (Briumvi)

Ublituximab-xiiy (Briumvi) (procedure code J2329) is a benefit of Texas Medicaid for clients who are 18 years of age or older.

### 6.124 \* Valoctocogene Roxaparvovec-rvox (Roctavian)

[Revised] Valoctocogene roxaparvovec-rvox (Roctavian) is an adeno-associated virus vector-based gene therapy indicated to treat adult clients with severe hemophilia A (congenital Factor VIII deficiency with factor VIII activity < 1 IU/dL) without pre-existing antibodies to adeno-associated virus serotype 5 (AAV5) detected by an FDA-approved test.

[Revised] Valoctocogene roxaparvovec-rvox (Roctavian) (procedure code J1412) is a benefit of Texas Medicaid with prior authorization and restricted to diagnosis code D66. Procedure code J1412 is limited to once per lifetime.

#### 6.124.1 \* Prior Authorization Requirements

[Revised] Prior authorization is required for valoctocogene roxaparvovec-rvox (Roctavian) therapy and must be submitted with a Special Medical Prior Authorization Form.

[Revised] Valoctocogene roxaparvovec-rvox (Roctavian) is a one-time infusion therapy indicated for the treatment of a client who meets the following criteria:

- [Revised] The client is 18 years of age or older.
- [Revised] The client has a confirmed diagnosis of severe Hemophilia A (congenital Factor VIII deficiency) as defined by:
  - [Revised] Factor VIII activity level < 1 IU/dL (in the absence of exogenous Factor VIII).
- [Revised] Evidence of other bleeding disorders not related to Hemophilia A has been ruled out.
- [Revised] The client has no history of Factor VIII inhibitors and a negative screening test prior to treatment.
- [Revised] The client’s baseline test (as determined by an FDA-approved test) is negative for pre-existing antibodies to adeno-associated virus serotype 5 (AAV5).
- [Revised] The client’s baseline liver function assessment must be assessed prior to valoctocogene roxaparvovec-rvox (Roctavian) infusion and include the following documentation, but not limited to:
  - [Revised] Alanine aminotransferase (ALT), aspartate aminotransferase (AST), alkaline phosphatase (ALP), and total bilirubin.
  - [Revised] Hepatic ultrasound and elastography or laboratory assessments for liver fibrosis must be provided.

- [Revised] The prescriber attests to counseling clients regarding consuming alcohol post-administration of valoctocogene roxaparvec-rvox (Roctavian).
- [Revised] The client does not have any active infections, either acute or chronic.
- [Revised] The client does not have stage 3 or 4 liver fibrosis or cirrhosis.
- [Revised] The client does not have a known hypersensitivity to mannitol.
- [Revised] The client does not have a history of previously receiving treatment with valoctocogene roxaparvec-rvox (Roctavian) infusion.

[Revised] Monitoring parameters after valoctocogene roxaparvec-rvox (Roctavian) infusion include the following:

- [Revised] Monitor hepatic function and liver enzymes. Alanine aminotransferase (ALT) should be monitored weekly for at least 26 weeks post-infusion as there are risks of hepatotoxicity. Monitor for and manage adverse reaction from corticosteroid use.
- [Revised] Monitor for elevated Factor VIII activity as thromboembolic events may occur with elevated factor VIII activity above the upper limit of normal (ULN).
- [Revised] Monitor for hepatocellular malignancy in patients with risk factors for hepatocellular carcinoma (e.g., hepatitis B or C, non-alcoholic fatty liver disease, chronic alcohol consumption, non-alcoholic steatohepatitis, advanced age). Perform regular (annually) liver ultrasound and alpha-fetoprotein testing following administration.

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

**Referto:** [Revised] Subsection 2.1.2, "Prior Authorization Requests" in this handbook for additional prior authorization information.

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

### 6.125 Valrubicin sterile solution for intravesical instillation (Valstar)

Procedure code J9357 valrubicin sterile solution for intravesical instillation (Valstar), is a benefit for clients with the diagnosis of bladder cancer in situ who have been treated unsuccessfully with BCG therapy and have an unacceptable morbidity or mortality risk if immediate cystectomy should be performed. Documentation of diagnosis and treatment must be submitted with the claim.

### 6.126 Vasopressin

Vasopressin (procedure codes J2598 and J2599) is a benefit of Texas Medicaid for clients who are 18 years of age or older.

### 6.127 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   |
| K903            | K9041  | K9049  | K90821 | K90822 | K90829 | K9083  | 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.

### 6.128 Voretigene neparvovec-rzyl (Luxturna)

Voretigene neparvovec-rzyl (Luxturna) is an adeno-associated virus vector-based gene therapy indicated for the treatment of patients with confirmed biallelic RPE65 mutation-associated retinal dystrophy, who have viable retinal cells in each eye as determined by the treating physician.

Luxturna (procedure code J3398) is a benefit of Texas Medicaid for clients who are 1 year through 65 years of age with prior authorization.

Voretigene neparvovec-rzyl (Luxturna) must be prescribed and administered by a retinal surgeon at an ocular gene therapy treatment center with experience performing intraocular surgery.

#### 6.128.1 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.

**Referto:** Subsection 9.5.1, “Pharmacy Delivery Method for Clinician-Administered Drugs” in this handbook for additional information on the “white bagging” delivery method.

Subsection 2.1.2, “Prior Authorization Requests” in this handbook for additional prior authorization information.

Prior authorization request for Luxturna injections will be considered when all of the following criteria are met:

- Client is 1 year of age through 65 years of age
- A documented diagnosis of a confirmed biallelic RPE65 mutation-associated retinal dystrophy (e.g., Leber’s congenital amaurosis subtype 2, retinitis pigmentosa, or early onset severe retinal dystrophy)
- Genetic testing documenting biallelic mutations of the RPE65 gene
- Systemic corticosteroids equivalent to prednisone 1 mg/kg/day are administered for a total of 7 days, starting 3 days before administration of voretigene neparvovec-rzyl to each eye and followed by a tapering dose
- Client has viable retinal cells in each eye as determined by the treating physician and assessed in the previous 6 months. Verification of viable retinal cells must be documented and evident by one of the following:
  - An area of retina within the posterior pole of greater than 100 µm thickness shown on optical coherence tomography (OCT)
  - Greater than or equal to 3 disc areas of retina without atrophy or pigmentary degeneration within the posterior pole
    - Remaining visual field within 30 degrees of fixation as measured by a III4e isopter or equivalent
  - Prescribed and administered by retinal surgeon at an ocular gene therapy treatment center with experience performing intraocular surgery
  - Patient has not previously received RPE65 gene therapy in intended eye
  - Injection of the second eye must be administered at least 6 days after the first eye
  - Have not had intraocular surgery within 6 months in either eye indicated for treatment

Benefit not to exceed more than 1 injection per eye per lifetime.

Authorization is valid for a period of 6 months from approval.

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

### **6.128.2 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.

## **7 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.

**Referto:** “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.

## 7.1 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.

## 8 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 11, “Pharmacy Prior Authorization” in this handbook.

### 8.1 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

*Referto:* The [Formulary Search](#) on the VDP website for more information.

### 8.1.1 Epocrates

The Texas Medicaid formulary and Preferred Drug List are available on the Epocrates drug information system. Epocrates ([epocrates.com](http://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.

## 8.2 Drug Shortages

HHSC encourages prescribing providers to notify HHSC about potential drug shortages impacting prescribing choice and pharmacy claim processing using the [Drug Shortage Notification](#) (HHS Form 1315).

Significant drug shortages affecting multiple pharmacies and distributors can have a continuing adverse impact on people enrolled in Medicaid if not resolved promptly. The process ensures notification of alternatives to the shorted drug, the timeline of the shortage, and the drug’s availability for use.

## 8.3 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 [www.txvendordrug.com/formulary/formulary-search](http://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.

## 8.4 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 [www.txvendordrug.com/formulary/formulary-search](http://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.

#### **8.4.1 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.

#### **8.4.2 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.

#### **8.4.3 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.

#### **8.4.4 Manufacturer Information**

##### **8.4.4.1 Bayer (Kyleena, Mirena, and Skyla)**

###### **8.4.4.1.1 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

###### **8.4.4.1.2 Obtaining Products**

Providers use Bayer's Specialty Pharmacy Prescription Request Form. This form is available on the VDP website at [www.txvendordrug.com/resources/downloads](http://www.txvendordrug.com/resources/downloads).

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.

#### 8.4.4.1.3 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 [www.txvendordrug.com/resources/downloads](http://www.txvendordrug.com/resources/downloads).

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.

#### 8.4.4.2 Organon (Nexplanon)

##### 8.4.4.2.1 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

##### 8.4.4.2.2 Obtaining Products

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

Complete the CSCN Direct Service Request Form as follows:

- At the top of the first page of the form, check the “Prescription Order” box and select a specialty pharmacy.
- Complete the patient and prescriber information including the patient’s pharmacy drug benefit and medical insurance information. Include copies of the patient’s insurance card and prescription drug card.
- Have the patient read and sign the “Patient Authorization” section.
- Ensure the physician signs both the Dispense as Written and prescriber signature lines, and the appropriate diagnosis code is selected.
- Fax the completed form to the CSCN at 1-844-232-2618.
- The CSCN will forward the prescription to the specialty pharmacy you selected after confirming the benefits of the patient.

#### 8.4.4.2.3 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 Organon Abandoned Unit Program Return Form. This form is available on the VDP website at [www.txvendordrug.com/resources/downloads](http://www.txvendordrug.com/resources/downloads).

The Organon Abandoned Unit Program Return Form may be submitted by mail or fax as follows:

- Fax the form to the specialty pharmacy for verification.
- Wait to receive the return identification number from the specialty pharmacy and return mailing label and instructions, which will be provided by C3i, Organon’s third-party processor.
- Confirm the specialty pharmacy return identification number matches the ID number listed in the return mailing label provided by C3i.
- Package the unit in the box in which the Nexplanon was originally shipped or other appropriately sized shipping box or envelope.
- Mail the unit along with the Organon Abandoned Unit Program for Nexplanon Return Form to Cardinal Health 3PL. A pre-paid shipping label and address will be provided by C3i.

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

#### 8.4.4.3 Cooper Surgical (Paragard)

##### 8.4.4.3.1 Specialty Pharmacy Participation

Paragard is available from the following specialty pharmacy, which ships statewide:

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

##### 8.4.4.3.2 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.

#### 8.4.4.3.3 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.

#### 8.4.4.3.4 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.

#### 8.4.4.3.5 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.

## 8.5 Mosquito Repellent Benefit

HHSC covers mosquito repellent year-round for the prevention of the Zika virus.

A list of products is available through the [Formulary Product search](#). Users can search by product name, the 11-digit National Drug Code (NDC), or click the “mosquito repellent” checkbox to view all products.

Clients that are eligible for the benefit include the following demographics:

- Females who are 10 through 55 years of age
- Pregnant females of any age
- Males who are 14 years of age and older

HHSC requires a prescription for all clients. For more information refer to the VDP Formulary Product Search website at [www.txvendordrug.com/formulary/formulary-search](http://www.txvendordrug.com/formulary/formulary-search).

## 8.6 Palivizumab (Synagis)

Palivizumab is available to physicians for administration to clients in Medicaid and the CSHCN Services Program through VDP. This enables physicians to have palivizumab shipped directly to their office from a network pharmacy, and not purchase the drug.

Physicians who obtain palivizumab through VDP may not submit claims to TMHP for the drug. The administering provider may submit a claim to TMHP for an injection administration fee and any medically necessary office-based evaluation and management service provided at time of injection.

### 8.6.1 Schedule

The following sections provide information about the forms used for prior authorization requests.

*Referto:* The [Synagis](#) page on the VDP website for the current season's schedule.

### 8.6.2 Forms

*Note:* Palivizumab is also available for clients enrolled in the Children with Special Health Care Needs (CSHCN) Services Program. Providers can refer to the CSHCN Services Program Provider Manual for details.

#### 8.6.2.1 Managed Care

Medicaid managed care and CHIP require the Texas Standard Prior Authorization Form for Prescription Drug Benefits (Texas Department of Insurance Form NORFR002). Prescribing providers should contact the MCO for prior authorization requirements and forms. MCOs may require additional information in addition to the MCO-specific addendum form. The MCO's form will reflect the appropriate MCO contact information and reconsideration request process.

#### 8.6.2.2 Traditional Medicaid

The prescribing provider must send the Standard Prior Authorization Request (TDI NOFR002), the [Synagis Standard Prior Authorization Addendum](#) (HHS 1321), the prescription for Synagis, and any supporting information to the Medicaid-enrolled pharmacy. Pharmacy staff will submit the form to the Texas Prior Authorization Call Center.

## 8.7 Vitamin and Mineral Products

HHSC-enrolled pharmacies with VDP can dispense vitamin and mineral products to clients who are 20 years of age and younger and enrolled in traditional Medicaid. These products are also available to clients enrolled in Medicaid managed care, if the dispensing pharmacy is contracted with the client's health plan.

To expedite pharmacy claim processing for vitamin and mineral products, prescribing providers are encouraged to include the diagnosis on the prescription.

The list of products that can be dispensed at a pharmacy and information about the provision of these products to clients enrolled in fee-for-service can be found on the VDP Product Search website at [www.txvendordrug.com/formulary/formulary-search](http://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 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.

**Referto:** “Section 1: Provider Enrollment and Responsibilities” (*Vol. 1, General Information*) for more information.

### 9.1 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.

**Referto:** The [VDP Pharmacy Provider Procedure Manual](#) on the VDP website.

### 9.2 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.

**Referto:** 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.

### 9.3 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.

**Referto:** The [Texas Prescription Monitoring Program](#) page of TSBP website.

### 9.4 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.

**Referto:** 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.*

### 9.5 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.

**Referto:** Subsection 6.3.4, “National Drug Code (NDC)” in “Section 6: Claims Filing” (*Vol. 1, General Information*) for additional information on claim filing using NDC.

The VDP website [CAD Search](#) for more information.

### 9.5.1 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.*

## 9.6 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.

### 9.6.1 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.

### **9.6.2 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 naïve” 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 naïve, 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 naïve. 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.

### **9.6.3 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.

### **9.6.4 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.

## **10 Patient Information**

### **10.1 Medicaid Drug Benefits**

Clients enrolled in traditional Medicaid are limited to three prescriptions per month with the following exceptions:

- Clients enrolled in waiver programs such as Community Living Assistance (CLASS) and Community-Based Alternatives (CBA)
- Texas Health Steps (THSteps)-eligible clients (clients who are 20 years of age and younger)
- Clients in skilled nursing facilities

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)

## 10.2 Cost Avoidance Coordination of Benefits

Cost avoidance coordination of benefits for pharmacy claims ensures compliance with CMS regulations. Under federal rules, Medicaid agencies must be the payer of last resort. The cost avoidance model checks for other known insurance at point of sale, preventing Medicaid from paying a claim until the pharmacy attempts to obtain payment from the client's primary third party insurance.

## 10.3 Medicaid Children's Services Comprehensive Care Program

Medically-necessary drugs and supplies that are not covered by the VDP may be available to children and adolescents (birth through 20 years of age) through the Medicaid Comprehensive Care Program (CCP). Drugs and supplies not covered could include, as examples, some over-the-counter drugs, nutritional products, diapers, and disposable or expendable medical supplies.

The Prior Authorization fax number is 1-512-514-4212.

**Referto:** Subsection 2.8.1.1, "Pharmacies (CCP)" in the *Children's Services Handbook (Vol. 2, Provider Handbooks)* for more information about pharmacy enrollment in CCP.

## 10.4 Pharmacy Lock-In

Clients enrolled in traditional Medicaid can be "locked-in" to a specific primary care pharmacy. Those clients will have "Lock-in" identified on the face of their Your Texas Benefits Medicaid card. Clients who are not "locked-in" to a specific pharmacy may obtain their drugs or supplies from any enrolled Medicaid pharmacy.

**Referto:** 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.

## 10.5 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 HHSC-enrolled pharmacies have certified their delivery services meet the minimum conditions for the payment of the delivery fee. These certified delivery pharmacies are reimbursed a delivery fee that is included in the medication dispensing formula.

- Refer clients enrolled in Medicaid managed care to their respective health plan. Each health plan develops its own participating pharmacy network for the delivery service.

Deliveries are made to client's home and not institutions, such as nursing homes. Delivery service is not applicable for mail-order prescriptions and not available for over-the-counter drugs.

## 10.6 Medication Synchronization

### 10.6.1 Overview

Medication Synchronization establishes processes for early refills in order to align the filling or refilling of multiple medications for a client with chronic illnesses.

The Texas Insurance Code §1369(j) allows a client enrolled in Medicaid, their prescribing physician, or the dispensing pharmacist to initiate the medication synchronization request. This process allows for clients to pick up all their medication on a single day each month versus requiring clients to make multiple pharmacy visits to obtain different prescription medications with different refill dates.

### 10.6.2 Eligible Medications

A drug is eligible for medication synchronization if it meets the following conditions:

- It is listed on the Medicaid, CHIP, KHC or CSHCN formulary.
- It is used for treatment and management of chronic illnesses.
- It is a formulation or dosage form that can be effectively dispensed in a medication synchronization protocol.
- It must meet all prior authorization criteria applicable to the medication on the date the synchronization request is made. This includes clinical prior authorizations, non-preferred prior authorizations, and drug utilization review edits.
- The original prescription must have refills.

**Exception:** *The prescription could be new but the drug is categorized with the same Generic Code Number (GCN) class, and if the pharmacy uses the override code, the claim will pay. Having available refills is not required.*

A claim cannot be synchronized if it is a Schedule II controlled substance or a Schedule III controlled substance containing hydrocodone.

### 10.6.3 Chronic Illness

Medications eligible for synchronization must be used to treat chronic illnesses. A chronic illness is defined as an illness or physical condition that is:

- Reasonably expected to continue for an uninterrupted period of at least three months, and
- Controlled, but not cured by medical treatment. This includes drugs used to treat mental health conditions and substance use.

### 10.6.4 Traditional Medicaid Claims Processing

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

### 10.6.5 Medicaid Managed Care and CHIP Claims Processing

Each health plan has an HHSC-approved process for medication synchronization for clients eligible for Medicaid or CHIP. In CHIP, cost sharing or co-payment amounts will be prorated. Dispensing fees will not be prorated.

Pharmacy staff should contact the client’s health plan for medication synchronization requirements using the contact information on the [www.txvendordrug.com/sites/default/files/docs/mco-resource-information.pdf](http://www.txvendordrug.com/sites/default/files/docs/mco-resource-information.pdf).

## 11 Pharmacy Prior Authorization

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

### 11.1 Clinical Prior Authorization

Clinical prior authorizations utilize evidence-based clinical criteria and nationally recognized peer-reviewed information. These prior authorizations may apply to an individual drug or a drug class on the formulary, including some preferred and non-preferred drugs. There are specific clinical prior authorizations that all health plans are required to perform. Usage of all other clinical prior authorizations will vary between health plans and at the discretion of each health plan.

Some clinical prior authorizations require prescribing providers to submit forms for clients enrolled in traditional Medicaid. Refer to each form’s instruction page linked below for submission requirements and instructions. Prescribing providers must submit each form below with the [Texas Department of Insurance Standard Prior Authorization Request](#) and submit by fax to the Texas Prior Authorization Call Center at 866-469-8590.

Health plans may require prior authorization for these drugs. Providers should contact the appropriate health plan for specific requirements and forms.

| Drug Name   | Number        |
|---|---------------|
| <a href="#">Cystic Fibrosis Agents (Kalydeco, Orkambi, and Symdeko)</a>   | HHS Form 1338 |
| <a href="#">Emflaza</a>   | HHS Form 1347 |
| <a href="#">Increlex</a>  | HHS Form 1357 |
| <a href="#">Proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitors</a>                                      | HHS Form 1355 |
| <a href="#">Phosphate Binders</a>   | HHS Form 1348 |
| <a href="#">Synagis</a>   | HHS Form 1321 |
| Refer to: Subsection 8.6, “Palivizumab (Synagis)” in this section for information about Synagis prior authorizations. |               |
| <a href="#">Xyrem</a>   | HHS Form 1356 |

**Referto:** The Clinical Prior Authorization Assistance Chart is available on the VDP website [www.txvendordrug.com/sites/default/files/docs/cpa-assistance-chart.pdf](http://www.txvendordrug.com/sites/default/files/docs/cpa-assistance-chart.pdf). It identifies each health plan’s prior authorization and how those authorizations relate to the authorizations used for traditional Medicaid claim processing. The chart is updated quarterly.

### 11.2 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.

**Referto:** Medicaid health plans are required to adhere to the Texas Medicaid Preferred Drug List.

**Note:** CHIP does not have a PDL.

**Referto:** The [PDL Prior Authorization Criteria Guide](#) that explains the criteria that are used to evaluate the PDL prior authorization requests.

### 11.3 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.

**Referto:** 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.*

### 11.4 Prior Authorization Reconsideration

The prescribing provider may request reconsideration if the prior authorization request is denied.

#### 11.4.1 Managed Care

Prescribing providers should refer to the Prescriber MCO Assistance Chart and contact the prior authorization call center for the MCO's reconsideration or appeal processes.

#### 11.4.2 Fee-for-service Medicaid

The Texas Prior Authorization Call Center will notify prescribing providers of their right to request a reconsideration of the decision rendered. Providers should complete the [Texas Medicaid Prior Authorization Reconsideration Request](#) (HHS Form 1322) and submit it to the Texas Prior Authorization Call Center. Refer to the form's instruction page for requirements and submission instructions. Providers may also include supporting documentation with their form submission, including:

- Medication documentation, such as the patient's medical records or lab results supporting the medical reason for the treatment
- Peer-reviewed literature supporting the safety, efficacy, and rationale for using the medication outside the current Medicaid criteria, if applicable

The Texas Prior Authorization Call Center will mail a copy of the reconsideration determinations to the requesting provider and client. The client's letter will include the HHSC prior authorization appeal process if the reconsideration request is denied.

### 11.5 72-Hour Emergency Supply

Federal and Texas law allows for a 72-hour emergency supply of a prescribed drug to be provided when a medication is needed without delay and prior authorization is not available. This rule applies to non-preferred drugs on the PDL and any drug that is affected by a clinical prior authorization.

Drugs not on the PDL may also be subject to clinical prior authorization.



## 12 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.