



# Texas Medicaid Provider Procedures Manual

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2

## Provider Handbooks

### Clinician-Administered Drugs Handbook

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

# CLINICIAN-ADMINISTERED DRUGS HANDBOOK

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## 1 General Information

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

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

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

## 2 Enrollment

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

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

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

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

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

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

**Refer to:** “Appendix B: Vendor Drug Program” (Vol. 1, General Information) for information.

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

### 3.1 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.

## 4 Reimbursement

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

- If the drug or biological is considered a new drug or biological (that is, approved for marketing by the Food and Drug Administration within 12 months of implementation as a benefit of Texas Medicaid), it may be reimbursed at an amount equal to 89.5 percent of average wholesale price (AWP).
- If the drug or biological does not meet the definition of a new drug or biological, it may be reimbursed at an amount equal to 85 percent of AWP.
- Vaccines may be reimbursed at an amount equal to 89.5 percent of AWP.
- Infusion drugs furnished through an item of implanted durable medical equipment may be reimbursed at an amount equal to 89.5 percent of AWP.
- Drugs, other than vaccines and infusion drugs, may be reimbursed at an amount equal to 106 percent of the average sales price (ASP).

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

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

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

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

## 5 Injectable Medications as a Pharmacy Benefit

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

**Referto:** “Appendix B: Vendor Drug Program” (*Vol. 1, General Information*) 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 B.3.5.1, “Pharmacy Delivery Method for Clinician-Administered Drugs” in “Appendix B: Vendor Drug Program” (*Vol. 1, General Information*) 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.

## 6 National Drug Code (NDC)

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

**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.

### 6.1 Calculating Billable HCPCS and NDC Units

All drug claims must include HCPCS billing units as well as NDC billing units. HCPCS billing units are calculated by dividing the amount administered by the units found in the procedure code description. The calculated HCPCS billing unit is also needed to determine the correct NDC billing unit. NDC billing units are calculated by multiplying the HCPCS billing unit by the conversion factor. The conversion factor is calculated by dividing the HCPCS unit (found in the code description) by the NDC unit (found on the box or packaging). See calculation examples in the following sections. The NDC billing unit also requires a unit of measurement. For example, if the NDC is for a liquid medication the submitted units

must be in milliliters (ML). If the NDC is for a powder form then the submitted units are Unit (UN). Other allowable NDC units are GR for gram, F2 for international unit, and ME for milligram. For all claims, the HCPCS and NDC billing units are required, along with the specific NDC and HCPCS procedure code. Claims submitted with incorrect unit calculations may cause delayed or incorrect payment.

### 6.1.1 Single-Dose Vials Calculation Examples

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

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

|  | Zofran                  | Avastin                   | Rocephin                    |
|--|-------------------------|---------------------------|-----------------------------|
| <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 &amp; NDC)</b>  | 4 and 2 ML              | 0.8 and 0.32 ML           | 4 and 2 UN                  |

### 6.1.2 Multi-Dose Vials Calculation Examples

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

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



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

### 6.1.3 Single and Multi-Use Vials

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

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

Texas Medicaid does not pay for any drug wastage from single-use or multi-use vials.

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

### 6.1.4 \* Nonspecific, Unlisted or Miscellaneous Procedure Codes

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

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

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

The claim will be denied when:

- The information is not sufficient to determine medical necessity.
- The pricing information is insufficient for pricing the claim.
- There is a more appropriate billing procedure code for the drug or biological.
- The NDC and HCPCs (if applicable) codes are missing.

Providers are responsible for administering drugs based on the U.S. Food and Drug Administration (FDA)-approved guidelines. In the absence of FDA indications, a drug needs to meet the following criteria:

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

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

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

Texas Medicaid & Healthcare Partnership  
 Special Medical Prior Authorization Department  
 12357-B Riata Trace Parkway, Suite 100  
 Austin, TX 78727  
 Fax: 1-512-514-4213

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

| <b>[Revised] Injectable Medication (* indicates more information after table)</b> | <b>[Revised] Procedure Code(s)</b> | <b>[Revised] Reimbursable Place of Service and Other Limitations or Restrictions</b>                                |
|---|------------------------------------|---|
| Abatacept (Orencia)*  | J0129                              | Place of Service: Office, Outpatient Hospital<br>Prior Authorization Required<br>Diagnosis Restricted               |
| Adalimumab*   | J0135                              | Place of Service: Office, Outpatient Hospital<br>Diagnosis Restricted   |
| Ado-trastuzumab entansine (Kadcyla)*  | J9354                              | Place of Service: Office, Outpatient Hospital<br>See Treatment Criteria after table                                 |
| Alglucosidase Alfa (Myozyme)*   | J0220, J0221                       | Place of Service: Office, Outpatient Hospital<br>Prior Authorization Required<br>See Treatment Criteria after table |
| Amifostine*   | J0207                              | Place of Service: Home, Office, Outpatient Hospital<br>Diagnosis Restricted   |

| <b>[Revised] Injectable Medication (* indicates more information after table)</b> | <b>[Revised] Procedure Code(s)</b> | <b>[Revised] Reimbursable Place of Service and Other Limitations or Restrictions</b>  |
|---|------------------------------------|---|
| Antibiotics & Steroids*   | Multiple                           | Place of Service: Varies, please verify with TMHP<br>Modifier Requirements  |
| Antisense Oligonucleotides (etepirsen and nusinersen)*                            | J1428, J2326                       | Place of Service: Office, Outpatient Hospital<br>Prior Authorization Required<br>See Treatment Criteria after table   |
| Axicabtagene Ciloleuce*l*   | Q2041                              | Place of Service: Office, Outpatient Hospital<br>Prior authorization required   |
| Azacitidine (Vidaza)*   | J9025                              | Place of Service: Office, Outpatient Hospital<br>Diagnosis Restricted   |
| Benralizumab*   | J0517                              | Place of Service: Office, Outpatient Hospital<br>Prior authorization required   |
| Blood Factor Products*  | Codes listed after table*          | Place of Service: Office, Outpatient Hospital<br>Prior Authorization Required for code J7199 only   |
| Botulinum Toxin Type A & Type B*  | J0585, J0586, J0587, J0588         | Place of Service: Office, Outpatient Hospital<br>Diagnosis Restricted   |
| Burosumab-twza (Crysvita)*  | J0584                              | Place of Service: Home, Office, Outpatient Hospital<br>Prior authorization required   |
| Chelating Agents*   | J0470, J0600, J0895                | Place of Service: Office, Outpatient Hospital<br>Diagnosis Restricted   |
| Cladribine (Leustatin)  | J9065                              | Place of Service: Home, Office, Outpatient Hospital<br>Diagnosis Restrictions: C8441, C8442, C8443, C8444, C8445, C8446, C8447, C8448, C8449, C9140, C9141, C9142 |
| Clofarabine*  | J9027                              | Place of Service: Office, Outpatient Hospital<br>Prior Authorization Required   |
| Colony Stimulating Factor (Filgrastim, Pegfilgrastim, and Sargramostim)*          | J1442, J1447, Q5101, J2505, J2820  | Place of Service: Office, Outpatient Hospital<br>Diagnosis Restricted   |
| Denileukin diftitox (Ontak)*  | J9160                              | Place of Service: Office, Outpatient Hospital<br>See Treatment Criteria after table   |
| Dimethyl sulfoxide  | J1212                              | Place of Service: Office, Outpatient Hospital<br>Diagnosis Restrictions: N3010, N3011   |

| <b>[Revised] Injectable Medication (* indicates more information after table)</b> | <b>[Revised] Procedure Code(s)</b>       | <b>[Revised] Reimbursable Place of Service and Other Limitations or Restrictions</b>   |
|---|--|--|
| Eculizumab  | J1300                                    | Place of Service: Office, Outpatient Hospital<br>Diagnosis Restrictions: D588, D591, D593, D594, D595, D596, D598  |
| Edaravone (Radicava)*   | <b>J1301</b>                             | Place of Service: Office, Outpatient Hospital<br>Prior Authorization Required  |
| Etelcalcetide   | J0606                                    | Place of Service: Office, Outpatient Hospital<br>Diagnosis Restrictions: N2581, Z992<br>Restricted to clients who are 18 years of age and older            |
| Fluocinolone Acetonide (Retisert)*  | J7311                                    | Place of Service: Office, Outpatient Hospital<br>Prior Authorization Required  |
| Galsulfase  | J1458                                    | Place of Service: Office, Outpatient Hospital<br>Diagnosis Restrictions: E7601, E7602, E7603, E761, E76210, E76211, E76219, E7622, E7629, E763, E768, E769 |
| Granisetron hydrochloride   | J1626                                    | Place of Service: Home, Office, Outpatient Hospital<br>Diagnosis Restrictions: Z5189, Z510, Z5111, Z5112   |
| Hematopoietic Injections*   | <b>J0881, J0882, J0885, J0887, Q4081</b> | Place of Service: Office, Outpatient Hospital<br>Diagnosis Restricted  |
| <b>Hydroxyprogesterone Caproate</b>   | J1726, J1729                             | <i>The Gynecological, Obstetrics, and Family Planning Title XIX Services Handbook (Vol. 2, Provider Handbooks)</i>   |
| <b>Ibalizumab-uiyk (Trogarzo)*</b>  | <b>J1746</b>                             | <b>Place of Service: Office, Outpatient Hospital<br/>Prior Authorization Required</b>  |
| Ibutilide fumarate  | J1742                                    | Place of Service: Home, Office, Outpatient Hospital<br>Diagnosis Restrictions: I480, I481, I482, I483, I484  |
| Idursulfase (Elaprase)  | J1743                                    | Place of Service: Office, Outpatient Hospital<br>Diagnosis Restrictions: E7601, E7602, E7603, E761, E76210, E76211, E76219, E7622, E7629, E763, E768, E769 |
| Immune Globulin*  | See details after table                  | Place of Service: Home, Office, Outpatient Hospital<br>Exceptions: J1568, J7504, J7511: Office, Outpatient Hospital<br>Diagnosis Restricted                |
| Immunosuppressive Drugs*  | See details after table                  | Place of Service: Home (J0202 only), Office, Outpatient Hospital<br>See Treatment Criteria after table   |

| <b>[Revised] Injectable Medication (* indicates more information after table)</b>  | <b>[Revised] Procedure Code(s)</b>       | <b>[Revised] Reimbursable Place of Service and Other Limitations or Restrictions</b>  |
|--|--|---|
| Infliximab (Remicade)*, Inflectra*, Renflexis*   | J1745, Q5103, Q5104                      | Place of Service: Office, Outpatient Hospital<br>Diagnosis Restricted<br>Procedure codes J1745, Q5103, and Q5104 will not be reimbursed for the same date of service by any provider. |
| Inotuzumab ozogamicin (Besponsa)*  | J9229                                    | Place of Service: Office, Outpatient Hospital<br>Prior Authorization Required   |
| Interferon*  | See details after table                  | Place of Service: Office, Outpatient Hospital<br>See Treatment Criteria after table   |
| Iron Injections*<br>Includes: ferric carboxymaltose, iron dextran, iron sucrose, sodium ferric gluconate complex in sucrose, and ferumoxytol | J1439, J1750, J1756, J2916, Q0138, Q0139 | Place of Service: Home, Office, Outpatient Hospital<br>See Treatment Criteria after table   |
| Joint Injections and Trigger Point Injections*   | See details after table                  | Place of Service: Home, Office, Outpatient Hospital   |
| Lactated Ringer's  | J7121                                    | Place of Service: Office<br>Restricted to clients who are birth through 20 years of age   |
| Leuprolide Acetate (Lupron Depot)*   | J1950, J9217, J9218, J9219               | Place of Service: Office, Outpatient Hospital<br>See reimbursement limitations after table  |
| Medroxyprogesterone Acetate (Depo Provera)   | J1050                                    | <i>The Gynecological, Obstetrics, and Family Planning Title XIX Services Handbook (Vol. 2, Provider Handbooks)</i>  |
| Melphalan*   | J9245                                    | Place of Service: Home, Office, Outpatient Hospital<br>Diagnosis Restricted   |
| Mepolizumab*   | J2182                                    | Place of Service: Office, Outpatient Hospital<br>Prior Authorization Required   |
| Mepsevii (Vestronidase alfa-vjvk)*   | J3397                                    | Place of Service: Office, Outpatient Hospital<br>Prior Authorization Required   |
| Natalizumab*   | J2323                                    | Place of Service: Office, Outpatient Hospital<br>Diagnosis Restricted   |
| Omalizumab*  | J2357                                    | Place of Service: Office, Outpatient Hospital<br>Prior Authorization Required   |
| Porfimer (Photofrin)   | J9600                                    | Place of Service: Home, Office, Outpatient Hospital<br>Diagnosis Restrictions: C153, C154, C155, C158, C159, C787, C7889  |

| <b>[Revised] Injectable Medication (* indicates more information after table)</b> | <b>[Revised] Procedure Code(s)</b> | <b>[Revised] Reimbursable Place of Service and Other Limitations or Restrictions</b>   |
|---|------------------------------------|--|
| Reslizumab*   | J2786                              | Place of Service: Office, Outpatient Hospital<br>Prior Authorization Required  |
| Sumatriptan succinate (Imitrex)*  | J3030                              | Place of Service: Office, Outpatient Hospital<br>Diagnosis Restricted  |
| Thyrotropin alpha for injection (Thyrogen)  | J3240                              | Place of Service: Home, Office, Outpatient Hospital<br>Diagnosis Restrictions: C323, C73, D020, D093, D098, D380, D440, D442, D449, D497, E010, E011, E012, E040, E042, E048, E049, E0500, E0520, Z85850 |
| Tisagenlecleucel (Kymriah)*   | Q2042                              | Place of Service: Office, Outpatient Hospital<br>Prior Authorization Required  |
| Trastuzumab*  | J9355                              | Place of Service: Office, Outpatient Hospital<br>See Treatment Criteria after table  |
| Triamcinolone Acetonide*  | J3304                              | Place of Service: Office, Outpatient Hospital<br>Diagnosis Restricted  |
| Valrubicin sterile solution for intravesical instillation (Valstar)*              | J9357                              | Place of Service: Home, Office, Outpatient Hospital<br>See Treatment Criteria after table  |
| Vitamin B12 (Cyanocobalamin) Injections*  | J3420                              | Place of Service: Home, Office, Outpatient Hospital<br>Diagnosis Restricted  |
| Voretigene Neparvovec-rzyl (Luxturna)   | J3398                              | Place of service: Office, Outpatient Hospital<br>See Treatment Criteria after table  |

## 7 Abatacept (Orencia)

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

### 7.1 Prior Authorization for Abatacept (Orencia)

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

- Dates of treatment
- The number of anticipated doses
- The dosage to be administered

- Diagnosis of adult RA or juvenile idiopathic arthritis (JIA)
  - Note: A diagnosis of adult RA must conform to the American College of Rheumatology (ACR) RA classification that requires the following:*
- Presence of synovitis in at least one joint
- Absence of an alternative diagnosis to explain the synovitis
- A combined score of at least six out of ten on the level of involved joints, abnormality, and symptom duration from the individual scores in four domains:
  - The number and sites of involved joints
  - Serologic abnormality
  - Elevated acute-phase response
  - Symptom duration

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

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

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

- Documentation from the physician stating that there has been at least a 20-percent improvement as defined by the ACR
- The number of anticipated doses
- The dosage to be administered

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

## 8 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 |

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



| Diagnosis Codes |        |        |        |        |
|-----------------|--------|--------|--------|--------|
| M488X5          | M488X6 | M488X7 | M488X8 | M488X9 |

## 9 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.

## 10 Alglucosidase Alfa (Myozyme)

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

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

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

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

## 11 Amifostine

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

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

Amifostine may be reimbursed for the following indications:

- Bone marrow toxicity
- Cisplatin- and cyclophosphamide-induced (prophylaxis)
- Advanced solid tumors
- Head and neck carcinoma
- Malignant lymphoma
- Non-small cell lung cancer
- Myelodysplastic syndromes
- Nephrotoxicity
- Advanced ovarian carcinoma
- Melanoma
- Advanced solid tumors of non-germ cell origin
- Neurotoxicity
- Reduction in the incidence of mucositis in clients receiving radiation therapy, or radiation combined with chemotherapy
- Reduction in the incidence of xerostomia associated with postoperative radiation treatment of head and neck cancer, where the radiation port includes a substantial portion of the parotid glands

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

| Diagnosis Codes |       |      |      |      |      |      |      |
|-----------------|-------|------|------|------|------|------|------|
| A690            | A691  | C000 | C001 | C002 | C003 | C004 | C005 |
| C006            | C008  | C01  | C020 | C021 | C022 | C023 | C024 |
| C028            | C029  | C030 | C031 | C039 | C040 | C041 | C048 |
| C049            | C050  | C051 | C052 | C058 | C059 | C060 | C061 |
| C062            | C0689 | C069 | C07  | C080 | C081 | C089 | C090 |
| C091            | C098  | C099 | C100 | C101 | C102 | C103 | C104 |
| C108            | C109  | C110 | C111 | C112 | C113 | C118 | C119 |
| C12             | C130  | C131 | C132 | C138 | C139 | C140 | C142 |
| C148            | C153  | C154 | C155 | C158 | C159 | C160 | C161 |
| C162            | C163  | C164 | C165 | C166 | C168 | C169 | C170 |
| C171            | C172  | C173 | C178 | C179 | C180 | C181 | C182 |
| C183            | C184  | C185 | C186 | C187 | C188 | C189 | C19  |

| Diagnosis Codes |        |        |        |        |        |        |        |
|-----------------|--------|--------|--------|--------|--------|--------|--------|
| C20             | C210   | C211   | C218   | C220   | C221   | C222   | C223   |
| C227            | C228   | C229   | C23    | C240   | C241   | C248   | C249   |
| C250            | C251   | C252   | C253   | C254   | C257   | C258   | C259   |
| C260            | C261   | C269   | C300   | C301   | C310   | C311   | C312   |
| C313            | C318   | C319   | C320   | C321   | C322   | C323   | C328   |
| C329            | C33    | C3400  | C3401  | C3402  | C3410  | C3411  | C3412  |
| C342            | C3430  | C3431  | C3432  | C3480  | C3481  | C3482  | C3490  |
| C3491           | C3492  | C37    | C380   | C381   | C382   | C383   | C384   |
| C388            | C390   | C399   | C4000  | C4001  | C4002  | C4010  | C4011  |
| C4012           | C4020  | C4021  | C4022  | C4030  | C4031  | C4032  | C4081  |
| C4082           | C410   | C411   | C412   | C413   | C414   | C419   | C430   |
| C4310           | C4311  | C4312  | C4320  | C4321  | C4322  | C4330  | C4331  |
| C4339           | C434   | C4351  | C4352  | C4359  | C4360  | C4361  | C4362  |
| C4370           | C4371  | C4372  | C438   | C439   | C4491  | C4492  | C4499  |
| C460            | C461   | C462   | C463   | C464   | C4650  | C4651  | C4652  |
| C467            | C469   | C478   | C480   | C481   | C482   | C488   | C490   |
| C4910           | C4911  | C4912  | C4920  | C4921  | C4922  | C493   | C494   |
| C495            | C496   | C498   | C499   | C50011 | C50012 | C50019 | C50021 |
| C50022          | C50029 | C50111 | C50112 | C50119 | C50121 | C50122 | C50211 |
| C50212          | C50219 | C50221 | C50222 | C50311 | C50312 | C50319 | C50321 |
| C50322          | C50411 | C50412 | C50419 | C50421 | C50422 | C50511 | C50512 |
| C50519          | C50521 | C50522 | C50611 | C50612 | C50619 | C50621 | C50622 |
| C50811          | C50812 | C50819 | C50821 | C50822 | C50911 | C50912 | C50919 |
| C50921          | C50922 | C50929 | C510   | C511   | C512   | C519   | C52    |
| C530            | C531   | C538   | C539   | C540   | C541   | C542   | C543   |
| C548            | C549   | C55    | C561   | C562   | C569   | C5700  | C5701  |
| C5702           | C5710  | C5711  | C5712  | C5720  | C5721  | C5722  | C573   |
| C574            | C577   | C578   | C579   | C58    | C600   | C601   | C602   |
| C608            | C609   | C61    | C6200  | C6201  | C6202  | C6210  | C6211  |
| C6212           | C6290  | C6291  | C6292  | C6300  | C6301  | C6302  | C6310  |
| C6311           | C6312  | C632   | C637   | C638   | C639   | C641   | C642   |
| C649            | C651   | C652   | C659   | C661   | C662   | C669   | C670   |
| C671            | C672   | C673   | C674   | C675   | C676   | C677   | C678   |
| C679            | C680   | C681   | C688   | C689   | C6900  | C6901  | C6902  |
| C6910           | C6911  | C6912  | C6920  | C6921  | C6922  | C6930  | C6931  |
| C6932           | C6940  | C6941  | C6942  | C6950  | C6951  | C6952  | C6960  |
| C6961           | C6962  | C6980  | C6981  | C6982  | C6990  | C6991  | C6992  |
| C700            | C701   | C709   | C710   | C711   | C712   | C713   | C714   |
| C715            | C716   | C717   | C718   | C719   | C720   | C721   | C7221  |
| C7222           | C7231  | C7232  | C7241  | C7242  | C7250  | C7259  | C729   |

| Diagnosis Codes |       |       |       |       |       |       |       |
|-----------------|-------|-------|-------|-------|-------|-------|-------|
| C73             | C7401 | C7402 | C7411 | C7412 | C7490 | C750  | C751  |
| C752            | C753  | C754  | C755  | C758  | C759  | C760  | C761  |
| C762            | C763  | C7640 | C7641 | C7642 | C7650 | C7651 | C7652 |
| C768            | C770  | C771  | C772  | C773  | C774  | C775  | C778  |
| C779            | C7800 | C7801 | C7802 | C781  | C782  | C7839 | C784  |
| C785            | C786  | C787  | C7889 | C7900 | C7901 | C7902 | C7911 |
| C7919           | C792  | C7931 | C7932 | C7949 | C7951 | C7952 | C7960 |
| C7961           | C7962 | C7970 | C7971 | C7972 | C7981 | C7982 | C7989 |
| C800            | C801  | C802  | C8100 | C8101 | C8102 | C8103 | C8104 |
| C8105           | C8106 | C8107 | C8108 | C8109 | C8110 | C8111 | C8112 |
| C8113           | C8114 | C8115 | C8116 | C8117 | C8118 | C8119 | C8120 |
| C8121           | C8122 | C8123 | C8124 | C8125 | C8126 | C8127 | C8128 |
| C8129           | C8130 | C8131 | C8132 | C8133 | C8134 | C8135 | C8136 |
| C8137           | C8138 | C8139 | C8140 | C8141 | C8142 | C8143 | C8144 |
| C8145           | C8146 | C8147 | C8148 | C8149 | C8170 | C8171 | C8172 |
| C8173           | C8174 | C8175 | C8176 | C8177 | C8178 | C8179 | C8190 |
| C8191           | C8192 | C8193 | C8194 | C8195 | C8196 | C8197 | C8198 |
| C8199           | C8201 | C8202 | C8203 | C8204 | C8205 | C8206 | C8207 |
| C8208           | C8209 | C8211 | C8212 | C8213 | C8214 | C8215 | C8216 |
| C8217           | C8218 | C8219 | C8221 | C8222 | C8223 | C8224 | C8225 |
| C8226           | C8227 | C8228 | C8229 | C8231 | C8232 | C8233 | C8234 |
| C8235           | C8236 | C8237 | C8238 | C8239 | C8241 | C8242 | C8243 |
| C8244           | C8245 | C8246 | C8247 | C8248 | C8249 | C8251 | C8252 |
| C8253           | C8254 | C8255 | C8256 | C8257 | C8258 | C8259 | C8261 |
| C8262           | C8263 | C8264 | C8265 | C8266 | C8267 | C8268 | C8269 |
| C8280           | C8281 | C8282 | C8283 | C8284 | C8285 | C8286 | C8287 |
| C8288           | C8289 | C8290 | C8291 | C8292 | C8293 | C8294 | C8295 |
| C8296           | C8297 | C8298 | C8299 | C8330 | C8331 | C8332 | C8333 |
| C8334           | C8335 | C8336 | C8337 | C8338 | C8339 | C8350 | C8351 |
| C8352           | C8353 | C8354 | C8355 | C8356 | C8357 | C8358 | C8359 |
| C8370           | C8371 | C8372 | C8373 | C8374 | C8375 | C8376 | C8377 |
| C8378           | C8379 | C8380 | C8381 | C8382 | C8383 | C8384 | C8385 |
| C8386           | C8387 | C8388 | C8389 | C8391 | C8392 | C8393 | C8394 |
| C8395           | C8396 | C8397 | C8398 | C8399 | C8400 | C8401 | C8402 |
| C8403           | C8404 | C8405 | C8406 | C8407 | C8408 | C8409 | C8410 |
| C8411           | C8412 | C8413 | C8414 | C8415 | C8416 | C8417 | C8418 |
| C8419           | C8491 | C8492 | C8493 | C8494 | C8495 | C8496 | C8497 |
| C8498           | C8499 | C84A1 | C84A2 | C84A3 | C84A4 | C84A5 | C84A6 |
| C84A7           | C84A8 | C84A9 | C84Z1 | C84Z2 | C84Z3 | C84Z4 | C84Z5 |
| C84Z6           | C84Z7 | C84Z8 | C84Z9 | C8511 | C8512 | C8513 | C8514 |

| Diagnosis Codes |         |         |         |         |         |         |         |
|-----------------|---------|---------|---------|---------|---------|---------|---------|
| C8515           | C8516   | C8517   | C8518   | C8519   | C8521   | C8522   | C8523   |
| C8524           | C8525   | C8526   | C8527   | C8528   | C8529   | C8580   | C8581   |
| C8582           | C8583   | C8584   | C8585   | C8586   | C8587   | C8588   | C8589   |
| C8591           | C8592   | C8593   | C8594   | C8595   | C8596   | C8597   | C8598   |
| C8599           | C860    | C861    | C862    | C863    | C864    | C865    | C866    |
| C880            | C882    | C883    | C888    | C889    | C9000   | C9001   | C9002   |
| C9010           | C9011   | C9012   | C9020   | C9021   | C9022   | C9030   | C9031   |
| C9032           | C9140   | C9141   | C9142   | C960    | C964    | C965    | C966    |
| C969            | C96A    | C96Z    | D030    | D0310   | D0311   | D0312   | D0320   |
| D0321           | D0322   | D0330   | D0339   | D034    | D0351   | D0352   | D0359   |
| D0360           | D0361   | D0362   | D0370   | D0371   | D0372   | D038    | D039    |
| D588            | D589    | D590    | D591    | D592    | D593    | D594    | D595    |
| D596            | D598    | D599    | D6101   | D6109   | D61810  | D61811  | D61818  |
| D6182           | D619    | D62     | D630    | D631    | D638    | D640    | D641    |
| D642            | D643    | D644    | D6481   | D6489   | D649    | G620    | H903    |
| H905            | H933X1  | H933X2  | H933X3  | H933X9  | K117    | N059    | T451X1A |
| T451X1D         | T451X1S | T451X2A | T451X2D | T451X2S | T451X3A | T451X3D | T451X3S |
| T451X4A         | T451X4D | T451X4S | T4591xA | T4591xD | T4591xS | T4592xA | T4592xD |
| T4592xS         | T4593xA | T4593xD | T4593xS | T4594xA | T4594xD | T4594xS | T50905A |
| T50905D         | T50905S | T66xxxA | T66xxxD | T66xxxS | Z510    | Z5111   |         |

## 12 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.

## 13 Antisense Oligonucleotides (eteplirsen and nusinersen)

Antisense oligonucleotides, eteplirsen (Exondys 51) (procedure code J1428) and nusinersen (Spinraza) (procedure code J2326) may be benefits of Texas Medicaid with prior authorization.

Procedure code J1428 is limited to clients who are birth through 19 years of age.

Procedure code J2326 is limited to clients who are birth through 20 years of age.

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.

### 13.1 Prior Authorization Requirements

Prior authorization requests for procedure codes J1428 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 eteplirsen or nusinersen. Physician services include the procedural costs and the associated supplies for the administration of the medication.

For situations in which procedure code J2326 is 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 nusinersen. 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 nusinersen is in place.

**Note:** For additional information on white bag delivery, providers may refer to Subsection B.3.5.1, "Pharmacy Delivery Method for Clinician-Administered Drugs" in "Appendix B: Vendor Drug Program" (Vol. 1, General Information).

The 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.

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

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

Prior authorization requests must 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.

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.

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

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

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

- A diagnosis specific to the requested antisense oligonucleotide
- Genetic testing specific to the requested antisense oligonucleotide
- Client age specific to the requested antisense oligonucleotide
- Documentation of baseline physical function. Testing tools used to measure physical function must be age appropriate for the client being tested.
- A neurologist's consultation dated no more than six months prior to the initially requested authorization start date. The consultation must include the neurologist's name, credentials, contact information, and a recommendation for treatment with the requested antisense oligonucleotide.
- Documentation of the requested antisense oligonucleotide dosage and administration schedule, including the number of injections to be administered during the prior authorization period, the requested units per injection, and the dosage calculation. This information must be submitted in Section C of the SMPA request form under Statement of Medical Necessity.

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

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

- Genetic testing must confirm that the client's DMD gene is amenable to exon 51 skipping.
- Client age (birth through 19 years of age)
- Current client weight, including the date the weight was obtained; the weight must be dated no more than 30 days before the request date.

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

- Brooke Upper Extremity Scale

- Baseline 6-minute walk test (6MWT)
- Pediatric Evaluation of Disability Inventory

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

- Genetic testing must confirm biallelic pathogenic variants in the client's survival motor neuron 1 (SMN1) gene
- Client age (birth through 20 years of age)
- Baseline pulmonary status, including any requirements for invasive or non-invasive ventilation

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

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

### **13.1.2 Recertification/Extension Requests (for all Antisense Oligonucleotides)**

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

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

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

- A diagnosis specific to the requested antisense oligonucleotide
- Client age
- Current documentation of physical function
- Testing tools used to measure physical function must be age appropriate for the client being tested. Providers must use the same testing instrument as used in the initial evaluation. If re-use of the initial testing instrument is not appropriate, for example, due to change in client status or restricted age range of the testing tool, the provider must explain the reason for the change.
- The physical function testing tool results must include one of the following:
  - An increase in physical function from baseline has been observed
  - Baseline physical function has been maintained
- A neurology consultation dated no more than one rolling year of the recertification/extension date that includes the name, credentials, and contact information for the consulting neurologist recommending ongoing treatment with the requested antisense oligonucleotide
- Statement from prescribing clinician that the client has been compliant with the treatment



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

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

The medical necessity documentation for 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.

### 13.1.3 Exclusions

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

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

## 14 Axicabtagene Ciloleucel

Procedure code Q2041 is a benefit of Texas Medicaid for clients who are 18 years of age and older. Prior authorization is required and the following medical criteria must be met:

- The client must have a histologically confirmed diagnosis of one of the following types of aggressive non-Hodgkin's lymphoma:
  - Diffuse large B-cell lymphoma, not otherwise specified
  - High-grade B-cell lymphoma
  - Primary mediastinal large B-cell lymphoma
  - Transformed follicular lymphoma
- The client must have relapsed or refractory disease, defined as progression after two or more lines of systemic therapy (which may or may not include therapy supported by autologous stem cell transplant)
- The client must have received adequate prior therapy including, at a minimum, all of the following:
  - An anthracycline-containing chemotherapy regimen
  - For CD20+ disease, anti-CD20 monoclonal antibody
  - For clients with transformed follicular lymphoma, prior chemotherapy for follicular lymphoma with chemotherapy refractory disease after transformation to DLBCL
- There must be documentation of all of the following clinical findings:
  - Eastern Cooperative Oncology Group performance status of 0 or 1
  - Absolute neutrophil count  $\geq 1000/\mu\text{L}$
  - Absolute lymphocyte count  $> 100/\mu\text{L}$
  - Platelet count  $\geq 75,000/\mu\text{L}$

- The health-care facility has enrolled in the Yescarta Risk Evaluation and Mitigation Strategies and training has been given to the provider on the management of cytokine release syndrome and neurological toxicities
- The treatment has been prescribed by an oncologist or in consultation with an oncologist

Procedure code Q2041 is limited to once per lifetime, any provider.

## 15 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  |       |       |       |       |

## 16 \* Blood Factor Products

The following blood factor products procedure codes are a benefit of Texas Medicaid:

| [Revised] Procedure Codes |       |       |       |       |       |       |       |       |       |
|---------------------------|-------|-------|-------|-------|-------|-------|-------|-------|-------|
| J7170                     | J7175 | J7177 | J7178 | J7179 | J7180 | J7181 | J7182 | J7183 | J7185 |
| J7186                     | J7187 | J7188 | J7189 | J7190 | J7192 | J7193 | J7194 | J7195 | J7197 |
| J7198                     | J7199 | J7200 | J7201 | J7202 | J7203 | J7205 | J7207 | J7209 | J7210 |
| J7211                     |       |       |       |       |       |       |       |       |       |

Procedure code J7199 requires prior authorization and must be submitted to the Special Medical Prior Authorization (SMPA) Procedure code J7199 is the only blood factor product that requires prior authorization. Supporting documentation that must be submitted with electronic or paper requests for prior authorization must include the following:

- The client’s diagnosis
- A clear, concise description of the drug or biological such as the manufacturer’s prescribing information
- A CPT or HCPCS procedure code that is comparable to the drug or biological being requested
- Documentation of the medical necessity of the requested drug or biological
- The rationale for the recommendation of this particular drug or biological
- Documentation of prior treatment or that prior treatment was considered but ruled out in favor of a new drug for this diagnosis
- Documentation that the drug or biological is not investigational or experimental
- The place of service in which the drug or biological is to be administered
- The physician’s intended charge for the drug or biological

Reimbursement is available when the antihemophilic product is administered by or under personal physician supervision. All documentation must include the authorization request form and be maintained in the client's medical record and is subject to retrospective review.

## 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   | G378   | G379   | G43701 | G43709 | G43711 | G43719 |
| G800            | G801   | G802   | G803   | G804   | G808   | G809   | G8110  |
| G8111           | G8112  | G8113  | G8114  | G8220  | G8221  | G8222  | G8250  |
| G8251           | G8252  | G8253  | G8254  | G830   | G8310  | G8311  | G8312  |
| G8313           | G8314  | G8320  | G8321  | G8322  | G8323  | G8324  | G8330  |
| G8331           | G8332  | G8333  | G8334  | G834   | H4901  | H4902  | H4903  |
| H4911           | H4912  | H4913  | H4921  | H4922  | H4923  | H4931  | H4932  |
| H4933           | H4941  | H4942  | H4943  | H499   | H5000  | H50011 | H50012 |
| H50021          | H50022 | H50031 | H50032 | H50041 | H50042 | H5005  | H5006  |
| H5007           | H5008  | H5010  | H50111 | H50112 | H50121 | H50122 | H50131 |
| H50132          | H50141 | H50142 | H5015  | H5016  | H5017  | H5018  | H5021  |
| H5016           | H5017  | H5018  | H5021  | H5022  | H5030  | H50311 | H50312 |
| H5032           | H50331 | H50332 | H5034  | H5040  | H50411 | H50412 | H5042  |
| H5043           | H5050  | H5051  | H5052  | H5053  | H5054  | H5055  | H5060  |
| H50611          | H50612 | H5069  | H50811 | H50812 | H5089  | H510   | H5111  |
| H5112           | H5121  | H5122  | H5123  | H518   | H519   | I69031 | I69032 |
| I69033          | I69034 | I69041 | I69042 | I69043 | I69044 | I69051 | I69052 |
| I69053          | I69054 | I69061 | I69062 | I69063 | I69064 | I69065 | I69098 |
| I69131          | I69132 | I69133 | I69134 | I69141 | I69142 | I69143 | I69144 |

| Diagnosis Codes |        |        |        |        |        |        |        |
|-----------------|--------|--------|--------|--------|--------|--------|--------|
| I69151          | I69152 | I69153 | I69154 | I69161 | I69162 | I69163 | I69164 |
| I69165          | I69198 | I69231 | I69232 | I69233 | I69234 | I69241 | I69242 |
| I69243          | I69244 | I69251 | I69252 | I69253 | I69254 | I69261 | I69262 |
| I69263          | I69264 | I69265 | I69298 | I69331 | I69332 | I69333 | I69334 |
| I69341          | I69342 | I69343 | I69344 | I69351 | I69352 | I69353 | I69354 |
| I69361          | I69362 | I69363 | I69364 | I69365 | I69398 | I69831 | I69832 |
| I69833          | I69834 | I69841 | I69842 | I69843 | I69844 | I69851 | I69852 |
| I69853          | I69854 | I69861 | I69862 | I69863 | I69864 | I69865 | I69898 |
| J385            | K117   | K220   | K600   | K601   | K602   | M436   | M62838 |
| M722            | N318   | N3281  | N3644  | R490   | R498   |        |        |

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

| Diagnosis Codes for J0586 |        |        |        |        |        |        |        |
|---------------------------|--------|--------|--------|--------|--------|--------|--------|
| G114                      | G241   | G243   | G244   | G245   | G248   | G35    | G360   |
| G370                      | G371   | G372   | G374   | G375   | G378   | G379   | G800   |
| G801                      | G802   | G804   | G808   | G809   | G8110  | G8111  | G8112  |
| G8113                     | G8114  | G8253  | G8254  | G830   | G8320  | G8321  | G8322  |
| G8323                     | G8324  | I69059 | I69259 | I69359 | I69859 | I69959 | I69051 |
| I69052                    | I69151 | I69152 | I69251 | I69252 | I69351 | I69352 | I69851 |
| I69852                    | I69951 | I69952 | I69053 | I69054 | I69153 | I69154 | I69253 |
| I69254                    | I69353 | I69354 | I69853 | I69854 | I69953 | I69954 | I69039 |
| I69139                    | I69239 | I69339 | I69839 | I69939 | I69031 | I69032 | I69131 |
| I69132                    | I69231 | I69232 | I69331 | I69332 | I69831 | I69832 | I69931 |
| I69932                    | I69033 | I69034 | I69133 | I69134 | I69233 | I69234 | I69333 |
| I69334                    | I69833 | I69834 | I69933 | I69934 | J385   | M436   | M62838 |
| M722                      |        |        |        |        |        |        |        |

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

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

| Diagnosis Codes for J0588 |        |        |        |        |        |        |        |
|---------------------------|--------|--------|--------|--------|--------|--------|--------|
| G243                      | G245   | G800   | G801   | G802   | G830   | G8110  | G8111  |
| G8112                     | G8113  | G8114  | G8253  | G8254  | G8320  | G8321  | G8322  |
| G8323                     | G8324  | I69059 | I69259 | I69359 | I69859 | I69959 | I69051 |
| I69052                    | I69151 | I69152 | I69251 | I69252 | I69351 | I69352 | I69851 |
| I69852                    | I69951 | I69952 | I69053 | I69054 | I69153 | I69154 | I69253 |
| I69254                    | I69353 | I69354 | I69853 | I69854 | I69953 | I69954 | I69039 |
| I69139                    | I69239 | I69339 | I69839 | I69939 | I69031 | I69032 | I69131 |
| I69132                    | I69231 | I69232 | I69331 | I69332 | I69831 | I69832 | I69931 |
| I69932                    | I69033 | I69034 | I69133 | I69134 | I69233 | I69234 | I69333 |
| I69334                    | I69833 | I69834 | I69933 | I69934 |        |        |        |

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

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

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

Texas Medicaid does not reimburse providers for the amount of the botulinum toxin drugs discarded.

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.       |
| 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.

## 18 \* Burosumab-Twza (Crysvita)

[Revised] Burosumab-Twza (Crysvita) (procedure code J0584) is a benefit of Texas Medicaid for clients who are one year of age or older with prior authorization. Burosumab-Twza (Crysvita) may be approved for a duration of every 12 months per prior authorization request.

[Revised] For initial therapy, the following criteria must be met:

- [Revised] The client is one year of age or older.
- [Revised] The client has a diagnosis of X-linked hypophosphatemia (XLH) (diagnosis code E8330 or E8331) that is supported by one of the following:
  - [Revised] Confirmed phosphate regulating gene with homology to endopeptidases located on the X chromosome (PHEX-gene) mutation
  - [Revised] Serum fibroblast growth factor-23 (FGF23) level >30 pg/ml
- [Revised] The prescriber discontinues any oral phosphate or active vitamin D analog supplementation at least one week prior to starting burosumab-twza (Crysvita) therapy.
- [Revised] The prescriber agrees to measure serum phosphate throughout therapy and withhold medication when serum phosphorus is above 5 mg/dl.

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

- [Revised] The client has previously received treatment with burosumab-twza (Crysvita).
- [Revised] Documentation from physician confirming one of the following:
  - [Revised] The client has achieved normal level of serum phosphate.
  - [Revised] 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).
- [Revised] The physician continues to monitor serum phosphate level.

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

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

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

[Revised] Prior authorization requests for procedure code J0584 must 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:** [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.

[Revised] 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.

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

[Revised] 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 unit.

[Revised] The Special Medical Prior Authorization (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.

[Revised] 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.

## 19 Chelating Agents

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

### 19.1 Dimercaprol

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

| Diagnosis Codes |         |         |         |         |         |         |         |
|-----------------|---------|---------|---------|---------|---------|---------|---------|
| T560X1A         | T560X1D | T560X1S | T560X2A | T560X2D | T560X2S | T560X3A | T560X3D |
| T560X3S         | T560X4A | T560X4D | T560X4S | T561X1A | T561X1D | T561X1S | T561X2A |
| T561X2D         | T561X2S | T561X3A | T561X3D | T561X3S | T561X4A | T561X4D | T561X4S |
| T564X1A         | T564X1D | T564X1S | T564X2A | T564X2D | T564X2S | T564X3A | T564X3D |
| T564X3S         | T564X4A | T564X4D | T564X4S | T565X1A | T565X1D | T565X1S | T565X2A |
| T565X2D         | T565X2S | T565X3A | T565X3D | T565X3S | T565X4A | T565X4D | T565X4S |
| T566X1A         | T566X1D | T566X1S | T566X2A | T566X2D | T566X2S | T566X3A | T566X3D |
| T566X3S         | T566X4A | T566X4D | T566X4S | T56811A | T56811D | T56811S | T56812A |
| T56812D         | T56812S | T56813A | T56813D | T56813S | T56814A | T56814D | T56814S |
| T56891A         | T56891D | T56891S | T56892A | T56892D | T56892S | T56893A | T56893D |
| T56893S         | T56894A | T56894D | T56894S | T5691XA | T5691XD | T5691XS | T5692XA |
| T5692XD         | T5692XS | T5693XA | T5693XD | T5693XS | T5694XA | T5694XD | T5694XS |
| T570X1A         | T570X1D | T570X1S | T570X2A | T570X2D | T570X2S | T570X3A | T570X3D |
| T570X3S         | T570X4A | T570X4D | T570X4S |         |         |         |         |

## 19.2 Edetate calcium disodium

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

| Diagnosis Codes |         |         |         |         |         |         |         |
|-----------------|---------|---------|---------|---------|---------|---------|---------|
| T560X1A         | T560X1D | T560X1S | T560X2A | T560X2D | T560X2S | T560X3A | T560X3D |
| T560X3S         | T560X4A | T560X4D | T560X4S | T564X1A | T564X1D | T564X1S | T564X2A |
| T564X2D         | T564X2S | T564X3A | T564X3D | T564X3S | T564X4A | T564X4D | T564X4S |
| T565X1A         | T565X1D | T565X1S | T565X2A | T565X2D | T565X2S | T565X3A | T565X3D |
| T565X3S         | T565X4A | T565X4D | T565X4S | T566X1A | T566X1D | T566X1S | T566X2A |
| T566X2D         | T566X2S | T566X3A | T566X3D | T566X3S | T566X4A | T566X4D | T566X4S |
| T56811A         | T56811D | T56811S | T56812A | T56812D | T56812S | T56813A | T56813D |
| T56813S         | T56814A | T56814D | T56814S | T56891A | T56891D | T56891S | T56892A |
| T56892D         | T56892S | T56893A | T56893D | T56893S | T56894A | T56894D | T56894S |
| T5691XA         | T5691XD | T5691XS | T5692XA | T5692XD | T5692XS | T5693XA | T5693XD |
| T5693XS         | T5694XA | T5694XD | T5694XS |         |         |         |         |

## 19.3 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           | D571    | D5720   | D57211  | D57212  | D57219  | D5740   | D57411  |
| D57412          | D57419  | D5780   | D57811  | D57812  | D57819  | E83111  | E83118  |
| N181            | N182    | N183    | N184    | N185    | N186    | N189    | N19     |
| T454X1A         | T454X1D | T454X1S | T454X2A | T454X2D | T454X2S | T454X3A | T454X3D |
| T454X3S         | T454X4A | T454X4D | T454X4S | T470X1A | T470X1D | T470X1S | T470X2A |
| T470X2D         | T470X2S | T470X3A | T470X3D | T470X3S | T470X4A | T470X4D | T470X4S |
| T471X1A         | T471X1D | T471X1S | T471X2A | T471X2D | T471X2S | T471X3A | T471X3D |
| T471X3S         | T471X4A | T471X4D | T471X4S | T564X1A | T564X1D | T564X1S | T564X2A |
| T564X2D         | T564X2S | T564X3A | T564X3D | T564X3S | T564X4A | T564X4D | T564X4S |
| T565X1A         | T565X1D | T565X1S | T565X2A | T565X2D | T565X2S | T565X3A | T565X3D |
| T565X3S         | T565X4A | T565X4D | T565X4S | T566X1A | T566X1D | T566X1S | T566X2A |
| T566X2D         | T566X2S | T566X3A | T566X3D | T566X3S | T566X4A | T566X4D | T566X4S |
| T56811A         | T56811D | T56811S | T56812A | T56812D | T56812S | T56813A | T56813D |
| T56813S         | T56814A | T56814D | T56814S | T56891A | T56891D | T56891S | T56892A |
| T56892D         | T56892S | T56893A | T56893D | T56893S | T56894A | T56894D | T56894S |
| T5691XA         | T5691XD | T5691XS | T5692XA | T5692XD | T5692XS | T5693XA | T5693XD |
| T5693XS         | T5694XA | T5694XD | T5694XS |         |         |         |         |



## 20 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.

### 20.1 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.

## 21 Colony Stimulating Factors (Filgrastim, Pegfilgrastim, and Sargramostim)

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

Filgrastim (procedure codes J1442, J1447, and Q5101) and pegfilgrastim (procedure code J2505) are granulocyte colony stimulating factors (G-CSFs). Sargramostim (procedure code J2820) is a granulocyte-macrophage colony stimulating factor (GM-CSF). GM-CSF and G-CSF stimulate neutrophil production after autologous bone marrow transplant and significantly reduce the duration and impact of neutropenia. To submit claims for reimbursement of colony stimulating factors, providers must submit the most appropriate procedure code with the number of units administered.

Procedure code J2505 is not reimbursed when submitted with the same date of service as procedure code J1442.

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 |

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

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

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

| Diagnosis Codes |         |         |         |         |         |         |         |
|-----------------|---------|---------|---------|---------|---------|---------|---------|
| D6109           | D611    | D612    | D613    | D6189   | D700    | D701    | D702    |
| D703            | D704    | D8940   | D8941   | D8942   | D8943   | D8949   | P615    |
| T451X1A         | T451X1D | T451X1S | T451X2A | T451X2D | T451X2S | T451X3A | T451X3D |
| T451X3S         | T451X4A | T451X4D | T451X4S | T8601   | T8602   | T8603   | T8609   |
| Z5111           | Z5112   | Z5189   | Z9481   | Z9484   |         |         |         |

## 22 Denileukin diftitox (Ontak)

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

## 23 \* Edaravone (Radicava)

[Revised] 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).

## 24 Fluocinolone Acetonide (Retisert)

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

## 25 \* Hematopoietic Injections

[Revised] Hematopoietic agents erythropoietin alfa, epoetin alfa (EPO), epoetin beta (Mircera), and darbepoetin alfa are benefits of Texas Medicaid and reimbursed using procedure codes J0881, J0882, J0885, and J0887 and an appropriate diagnosis code.

[Revised] 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, epoetin beta, and darbepoetin alfa. These records are subject to retrospective review to determine appropriate utilization and reimbursement for this service.

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

[Revised] EPO, epoetin beta (Mircera), and darbepoetin alfa injections are limited to specific diagnosis codes as indicated in this section.

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

## 25.1 Darbepoetin Alfa

Darbepoetin alfa (procedure codes J0881 and J0882) is an erythropoiesis-stimulating protein closely related to erythropoietin. Darbepoetin stimulates erythropoiesis by the same mechanism as EPO. Darbepoetin alfa has approximately a three-fold longer half-life than EPO, resulting in a sustained 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 |
| D611            | D612  | D613  | D6189 | D619  | D630  | D631 | D644 |
| D6481           | D6489 | D649  | N181  | N182  | N183  | N184 | N185 |
| N186            | N189  | N19   | Z5111 | Z5112 |       |      |      |

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

| Diagnosis Codes |      |      |      |      |      |      |      |
|-----------------|------|------|------|------|------|------|------|
| D631            | N181 | N182 | N183 | N184 | N185 | N186 | N189 |
| N19             |      |      |      |      |      |      |      |

Darbepoetin is limited to 100 units per day (100 mcg). Darbepoetin should be administered as follows:

- Once a week if the client was receiving EPO two to three times weekly
- Once every two weeks if the client was receiving EPO once a week

## 25.2 Epoetin Alfa (EPO)

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

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

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

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

| Diagnosis Codes |       |       |      |      |      |      |      |
|-----------------|-------|-------|------|------|------|------|------|
| D644            | D6481 | D6489 | D649 | N181 | N182 | N183 | 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).

### 25.3 \* Epoetin Beta (Mircera)

[Revised] Epoetin beta (Mircera) (procedure code J0887) is limited to diagnosis codes D631 and N186.

[Revised] 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.

[Revised] Epoetin beta (Mircera) is limited to one injection every 2 calendar weeks, any provider (Sunday through Saturday).

### 26 \* Ibalizumab-uiyk (Trogarzo)

[Revised] 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.

[Revised] For initial therapy, the following criteria must be met:

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

[Revised] Physician uses ibalizumab-uiyk (Trogarzo) concomitantly with another antiretroviral medication to which the client's virus is susceptible.

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

- [Revised] The client has previously received treatment with ibalizumab-uiyk (Trogarzo).
- [Revised] Documentation from the physician confirming that the client has achieved a clinical viral response defined as one of the following:

- [Revised] Decrease in viral load
- [Revised] Sustained viral load reduction
- [Revised] The physician continues ibalizumab-uiyk (Trogarzo) therapy with another antiretroviral.

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

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

[Revised] Prior authorization requests for procedure code J1746 must 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:** [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.

[Revised] 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.

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

[Revised] 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 unit.

[Revised] The Special Medical Prior Authorization (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.

[Revised] 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.

## 27 Immune Globulin

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

| Procedure Codes |       |       |       |       |       |       |       |       |       |
|-----------------|-------|-------|-------|-------|-------|-------|-------|-------|-------|
| 90284           | 90291 | J0850 | J1459 | J1460 | J1555 | J1556 | J1557 | J1559 | J1560 |
| J1561           | J1566 | J1568 | J1569 | J1572 | J1575 | J1599 | J1670 | J7288 | 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.



## 28 Immunosuppressive Drugs

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

The following procedure codes are benefits of Texas Medicaid:

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

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

| Procedure Code | Conditions   |
|----------------|--|
| J0202          | Multiple sclerosis (MS):<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.  |
| J0490          | Systemic lupus erythematosus (SLE):<br>For use in clients with moderate to severe SLE when other forms of treatment have failed to control moderate to severe symptoms   |
| J0717          | Psoriatic arthritis, Ulcerative colitis, Ankylosing spondylitis, Crohn's disease   |
| J1595          | Multiple sclerosis (MS):<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  |
| 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          | 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.

## 29 Infliximab (Remicade), Inflectra\*, Renflexis\*

Procedure code J1745, Q5103, and Q5104 are benefits of Texas Medicaid 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 | K5150  | K51511 | K51512 | K51513 | K51514 |
| K51518          | K5180  | K51811 | K51812 | K51813 | K51814 | K51818 | K5190  |
| K51911          | K51912 | K51913 | K51914 | K51918 | K603   | K632   | L400   |
| L401            | L402   | L403   | L404   | L4050  | L4051  | L4052  | L4053  |
| L4054           | L4059  | L408   | M05011 | M05012 | M05021 | M05022 | M05031 |
| M05032          | M05041 | M05042 | M05051 | M05052 | M05061 | M05062 | M05071 |
| M05072          | M0509  | M05411 | M05412 | M05421 | M05422 | M05431 | M05432 |
| M05441          | M05442 | M05451 | M05452 | M05461 | M05462 | M05471 | M05472 |
| M0549           | M05511 | M05512 | M05521 | M05522 | M05531 | M05532 | M05541 |
| M05542          | M05551 | M05552 | M05561 | M05562 | M05571 | M05572 | M0559  |
| M05611          | M05612 | M05621 | M05622 | M05631 | M05632 | M05641 | M05642 |
| M05651          | M05652 | M05661 | M05662 | M05671 | M05672 | M0569  | M05711 |
| M05712          | M05721 | M05722 | M05731 | M05732 | M05741 | M05742 | M05751 |
| M05752          | M05761 | M05762 | M05769 | M05771 | M05772 | M05779 | M0579  |
| M05811          | M05812 | M05821 | M05822 | M05831 | M05832 | M05841 | M05842 |
| M05851          | M05852 | M05861 | M05862 | M05871 | M05872 | M0589  | M06011 |
| M06012          | M06021 | M06022 | M06031 | M06032 | M06041 | M06042 | M06051 |
| M06052          | M06061 | M06062 | M06071 | M06072 | M0608  | M0609  | M06811 |
| M06812          | M06819 | M06821 | M06822 | M06829 | M06831 | M06832 | M06839 |
| M06841          | M06842 | M06849 | M06851 | M06852 | M06859 | M06861 | M06862 |
| M06869          | M06871 | M06872 | M06879 | M0688  | M0689  | M069   | M08011 |
| M08012          | M08021 | M08022 | M08031 | M08032 | M08041 | M08042 | M08051 |
| M08052          | M08061 | M08062 | M08071 | M08072 | M0809  | M08811 | M08812 |
| M08821          | M08822 | M08831 | M08832 | M08841 | M08842 | M08851 | M08852 |
| M08861          | M08862 | M08871 | M08872 | M0888  | M0889  | M08931 | M08932 |
| M08941          | M08942 | M08951 | M08952 | M08961 | M08962 | M08971 | M08972 |

| Diagnosis Codes |      |      |      |      |      |      |      |
|-----------------|------|------|------|------|------|------|------|
| M0898           | M450 | M451 | M452 | M453 | M454 | M455 | M456 |
| M457            | M458 |      |      |      |      |      |      |

### 30 \* Inotuzumab ozogamicin (Besponsa)

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

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

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

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

#### 30.1 \* Prior Authorization Requirements for Inotuzumab ozogamicin (Besponsa)

Prior authorization approval for Besponsa intravenous injection 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

[Revised] Prior authorization requests for procedure code J9229 must 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.

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 unit.

A Special Medical Prior Authorization (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 Special Medical Prior Authorization (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, 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.

### 30.2 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.

### 30.3 Exclusions

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

## 31 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 | J9212 | J9214 | J9216 | S0145 | Q3027 | Q3028 |

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

| Procedure Code                 | Condition(s)   |
|--------------------------------|--|
| J1826, J1830, Q3027, and Q3028 | Relapsing forms of multiple sclerosis  |
| J9212                          | Chronic hepatitis C virus  |
| J9214                          | Acute leukemias<br>AIDs-related Kaposi sarcoma Basal- and squamous-cell cancer Behcet syndrome<br>Bladder tumors (local use for superficial tumors) Carcinoid tumor<br>Chronic granulocytic leukemia Chronic hepatitis B virus Chronic hepatitis C virus<br>Chronic myelogenous leukemia Condylomata acuminata Cutaneous T-cell lymphoma Cytolomegavirus<br>Essential thrombocytopenia Essential thrombocytosis Follicular lymphoma<br>Hairy cell leukemia Herpes simplex Hodgkin's disease<br>Hypereosinophilic syndrome Melanoma<br>Multiple myeloma Mycosis fungoides<br>Non-Hodgkin's lymphoma Ovarian and cervical carcinoma Papilloma viruses Polycythemia vera<br>Renal cell carcinoma Rhino viruses Varicella zoster |
| J9216                          | Chronic granulomatous disease<br>Malignant osteoporosis  |

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

## 32 Iron Injections

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

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

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

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

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

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

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

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

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

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

## 33 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.

### 34 Leuprolide Acetate (Lupron Depot)

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

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

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

| Frequency | Dosage  | Limitations   |
|-----------|---------|---|
| Monthly   | 7.5 mg  | Billed with a quantity of 1<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.**

### 35 Melphalan

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

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

## 36 \* Mepsevii (Vestronidase alfa-vjvk)

[Revised] Vestronidase alfa-vjvk (Mepsevii) (procedure code J3397) is a benefit of Texas Medicaid for pediatric and adult clients with prior authorization. Vestronidase alfa-vjvk (Mepsevii) may be approved for a duration of every 12 months per prior authorization request.

[Revised] For initial therapy, the following criteria must be met:

- [Revised] 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.)
- [Revised] 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:
  - [Revised] Beta-glucuronidase enzyme deficiency in peripheral blood based on leukocytes or cultured fibroblasts
  - [Revised] Mutation in the glucuronidase beta (GUSB) gene, confirmed by molecular genetic testing

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

- [Revised] Client has previously received treatment with vestronidase alfa-vjvk without an adverse reaction.
- [Revised] 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.).

[Revised] Prior authorization requests for procedure code J3397 must 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:** [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.

[Revised] 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.

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

[Revised] 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 unit.

[Revised] The Special Medical Prior Authorization (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.

[Revised] 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.

## 37 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 |        |        |        |        |        |        |

## 38 Monoclonal Antibodies—Asthma and Chronic Idiopathic Urticaria

### 38.1 Omalizumab

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

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

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

### 38.2 \* Benralizumab

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

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

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

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

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

### 38.3 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 for the treatment of clients who are 12 years of age or older and have severe asthma (as defined by the National Heart, Lung, and Blood Institute's Guidelines for the Diagnosis and Management of Asthma) with an eosinophilic phenotype. Clients who are younger than the FDA-approved age will be considered on a case-by-case basis by the TMHP medical director.

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

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



### 38.4 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.

Reslizumab may only be initiated after a six-month trial of omalizumab therapy that has resulted in inadequate response. Criteria is detailed below in the mepolizumab section.

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

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

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

### 38.5 \* Prior Authorization for Omalizumab, Benralizumab, Mepolizumab, and Reslizumab

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

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

Benralizumab, mepolizumab, or reslizumab may only be initiated after a six-month trial of omalizumab therapy that has resulted in inadequate response.

### 38.6 Prior Authorization Criteria for Chronic Idiopathic Urticaria

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

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

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

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

Documentation supporting medical necessity for treatment of asthma with omalizumab, benralizumab, mepolizumab, or reslizumab must be submitted with the request and must indicate the following:

- Symptoms are inadequately controlled with use of one of the following combination therapies:
  - 12 months of high-dose inhaled corticosteroid (ICS) given in combination with a minimum of 3 months of controller medication (either a long-acting beta2-agonist [LABA], leukotriene receptor antagonist [LTRA], or theophylline), unless the individual is intolerant of, or has a medical contraindication to these agents; or
  - 6 months of ICS with daily oral glucocorticoids given in combination with a minimum of 3 months of controller medication (a LABA, LTRA, or theophylline), unless the individual is intolerant of, or has a medical contraindication to these agents.

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

- Pulmonary function tests must have been performed within a three-month period and be documented for all clients.

*Note: Exceptions may be considered with documentation of medical reasons explaining why pulmonary function tests cannot be performed.*

- Client is not currently smoking.

### **38.7.1 Mepolizumab**

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

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

*Note: 1 microliter (ul) is equal to 1 cubic millimeter (mm<sup>3</sup>)*

- Prior authorization for an initial request for mepolizumab will be considered when the client has had an inadequate response after being compliant for 6 months of treatment with omalizumab and meets the criteria for mepolizumab. Failure to respond to omalizumab must be documented in a letter, signed and dated by the prescribing provider, and submitted with the request.

*Note: Exceptions may be considered for clients who meet the criteria for treatment with mepolizumab but do not meet the criteria for omalizumab. Supporting documentation, such as an IgE level that falls outside of the required range or a negative skin test/RAST to a perennial aeroallergen, must be submitted along with the documentation for treatment with mepolizumab, as described above.*

### **38.7.2 Omalizumab**

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

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

### 38.7.3 Benralizumab

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

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

*Note: 1 microliter (ul) is equal to 1 cubic millimeter (mm<sup>3</sup>)*

Prior authorization for an initial request for benralizumab will be considered when the client meets the criteria for benralizumab, and has had an inadequate response after being compliant with 6 months of omalizumab treatment. Failure to respond to omalizumab must be documented in a letter, signed and dated by the prescribing provider, and submitted with the prior authorization request.

*Note: Exceptions may be considered for clients who meet the requirements for treatment with benralizumab but who do not meet the criteria for omalizumab. Supporting documentation (IgE level falls outside of required range and/or negative skin test/RAST to a perennial aeroallergen) must be submitted along with the other required documentation for treatment with benralizumab.*

### 38.7.4 Reslizumab

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

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

*Note: 1 microliter 9ul) is equal to 1 cubic millimeter (mm<sup>3</sup>).*

- Prior authorization for an initial request for reslizumab will be considered when the client has had an inadequate response after being compliant for 6 months of treatment with omalizumab and meets the criteria for reslizumab. Failure to respond to omalizumab must be documented in a letter, signed and dated by the prescribing provider and submitted with the request.

*Note: Exceptions may be considered for clients who meet the requirements for treatment with reslizumab but who do not meet the criteria for omalizumab. Supporting documentation (IgE level falls outside of required range and/ or negative skin test/RAST to a perennial aeroallergen) must be submitted along with the documentation for treatment with reslizumab as described above.*

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

## 38.8 Requirements for Continuation of Therapy

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

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

- Chest tightness or heaviness
- Coughing or clearing throat
- Difficulty taking deep breath or difficulty breathing out
- Shortness of breath
- Sleep disturbance, night 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, or reslizumab.

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

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

### 39 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  |        |        |        |        |

### 40 \* Tisagenlecleucel (Kymriah)

[Revised] Procedure code Q2042 is a benefit of Texas Medicaid with prior authorization when all of the following criteria are met:

- The client has a diagnosis of precursor B-cell acute lymphoblastic leukemia (ALL) that is refractory or in second or later relapse.
- Client is younger than 26 years of age.
- The client does not have an active infection or inflammatory disorder.
- The health-care facility has enrolled in the Kymriah Risk Evaluation and Mitigation Strategies (REMS) and training has been given to the provider on the management of cytokine release syndrome (CRS) and neurological toxicities.
- The treatment has been prescribed by an oncologist or in consultation with an oncologist.

## 41 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.

## 42 \* Triamcinolone Acetonide

[Revised] 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 |

[Revised] Procedure code J3304 is limited to one per 12 weeks, any provider.

## 43 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.

## 44 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  | 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.

## 45 \* 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.

[Revised] 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.

### 45.1 \* 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.

[Revised] 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 B.3.5.1, “Pharmacy Delivery Method for Clinician-Administered Drugs” in “Appendix B: Vendor Drug Program” (*Vol. 1, General Information*) for additional information on the “white bagging” delivery method.

Prior authorization requests must 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.

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 unit.

To complete the prior authorization process electronically, the provider must complete the prior authorization requirements through any approved electronic methods.

A Special Medical Prior Authorization (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 Special Medical Prior Authorization (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 dosage calculation must be submitted in Section C of the Special Medical Prior Authorization (SMPA) Request Form under Statement of Medical Necessity.

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  $\mu\text{m}$  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.

## 45.2 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.

## 46 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.