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Provider Procedures Manual
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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.*

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

2 Enrollment

Refer to: 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.

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

4 Reimbursement

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

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

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

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

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

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

5 Injectable Medications as a Pharmacy Benefit

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

Refer to: "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.

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

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

6 National Drug Code (NDC)

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

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

6.1 Calculating Billable HCPCS and NDC Units

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

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

6.1.1 Single-Dose Vials Calculation Examples

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

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

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

6.1.2 Multi-Dose Vials Calculation Examples

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

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

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

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

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

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

[Revised] Injectable Medication (* indicates more information after table)	[Revised] Procedure Code(s)	[Revised] Reimbursable Place of Service and Other Limitations or Restrictions
Infliximab (Remicade)*, Inflectra*, Renflexis*	J1745, Q5103, Q5104	Place of Service: Office, Outpatient Hospital Diagnosis Restricted 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 Prior Authorization Required
Interferon*	See details after table	Place of Service: Office, Outpatient Hospital See Treatment Criteria after table
Iron Injections* Includes: ferric carboxy-maltose, 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 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 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 See reimbursement limitations after table
Medroxyprogesterone Acetate (Depo Provera)	J1050	The *Gynecological, Obstetrics, and Family Planning Title XIX Services Handbook* (*Vol. 2, Provider Handbooks*)
Melphalan*	J9245	Place of Service: Home, Office, Outpatient Hospital Diagnosis Restricted
Mepolizumab*	J2182	Place of Service: Office, Outpatient Hospital Prior Authorization Required
Mepsevii (Vestronidase alfa-vjbk)*	J3397	Place of Service: Office, Outpatient Hospital Prior Authorization Required
Natalizumab*	J2323	Place of Service: Office, Outpatient Hospital Diagnosis Restricted
Omalizumab*	J2357	Place of Service: Office, Outpatient Hospital Prior Authorization Required
Patisiran (Onpattro)*	C9036	Place of Service: Home, Office, Outpatient Hospital Prior Authorization Required

[Revised] Injectable Medication (* indicates more information after table)	[Revised] Procedure Code(s)	[Revised] Reimbursable Place of Service and Other Limitations or Restrictions
Porfimer (Photofrin)	J9600	Place of Service: Home, Office, Outpatient Hospital Diagnosis Restrictions: C153, C154, C155, C158, C159, C787, C7889
Reslizumab*	J2786	Place of Service: Office, Outpatient Hospital Prior Authorization Required
Sumatriptan succinate (Imitrex)*	J3030	Place of Service: Office, Outpatient Hospital Diagnosis Restricted
Thyrotropin alpha for injection (Thyrogen)	J3240	Place of Service: Home, Office, Outpatient Hospital 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 Prior Authorization Required
Trastuzumab*	J9355	Place of Service: Office, Outpatient Hospital See Treatment Criteria after table
Triamcinolone Acetonide*	J3304	Place of Service: Office, Outpatient Hospital Diagnosis Restricted
Valrubicin sterile solution for intravesical instillation (Valstar)*	J9357	Place of Service: Home, Office, Outpatient Hospital See Treatment Criteria after table
Vitamin B12 (Cyanoco-balamin) Injections*	J3420	Place of Service: Home, Office, Outpatient Hospital Diagnosis Restricted
Voretigene Nepar-vovec-rzyl (Luxturna)	J3398	Place of service: Office, Outpatient Hospital 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
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

Diagnosis Codes							
M08931	M08932	M08939	M08941	M08942	M08949	M08951	M08952
M08959	M08961	M08962	M08969	M08971	M08972	M0898	M13871
M13872	M13879	M450	M451	M452	M453	M454	M455
M456	M457	M458	M459	M488X1	M488X2	M488X3	M488X4
M488X5	M488X6	M488X7	M488X8	M488X9			

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. Aglucosidase alfa may be a benefit of Texas Medicaid for clients of any age who are diagnosed with glycogen storage disease Type II (GSD Type II, also known as Pompe disease), using procedure codes J0220 and J0221. The most appropriate diagnosis code must be indicated on the prior authorization request and on the claim.

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

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

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

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

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

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

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

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

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 (HFMSE).
- 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 ≥ 1000/uL
  - Absolute lymphocyte count > 100/uL
  - Platelet count ≥ 75,000/uL

- 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:

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

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

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

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

- Support for the medical necessity of the botulinum toxin injection:
- A covered diagnosis
- Dosage and frequency of the injections
- Support of the clinical effectiveness of the injections

- Specific site(s) injected

All documentation is subject to retrospective review.

18 Burosumab-Twza (Crysvita)

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.

For initial therapy, the following criteria must be met:

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

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

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

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

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

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

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.

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

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.

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.

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

Diagnosis Codes							
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
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

Diagnosis Codes							
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
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

Diagnosis Codes							
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
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

Diagnosis Codes							
C84Z6	C84Z7	C84Z8	C84Z9	C8511	C8512	C8513	C8514
C8515	C8516	C8517	C8518	C8519	C8521	C8522	C8523
C8524	C8525	C8526	C8527	C8528	C8529	C8581	C8582
C8583	C8584	C8585	C8586	C8587	C8588	C8589	C8591
C8592	C8593	C8594	C8595	C8596	C8597	C8598	C8599
C860	C861	C862	C863	C864	C865	C866	C880
C882	C883	C884	C888	C9000	C9001	C9002	C9010
C9011	C9012	C9020	C9021	C9022	C9030	C9031	C9032
C9100	C9101	C9102	C9110	C9111	C9112	C9130	C9131
C9132	C9140	C9141	C9142	C9150	C9151	C9152	C9160
C9161	C9162	C91A0	C91A1	C91A2	C91Z0	C91Z1	C91Z2
C9200	C9201	C9202	C9210	C9211	C9212	C9220	C9221
C9222	C9230	C9231	C9232	C9240	C9241	C9242	C9250
C9251	C9252	C9260	C9261	C9262	C9290	C9291	C92Z0
C92Z1	C92Z2	C9292	C92A0	C92A1	C92A2	C9300	C9301
C9302	C9310	C9311	C9312	C9330	C9331	C9332	C93Z0
C93Z1	C93Z2	C9400	C9401	C9402	C9420	C9421	C9422
C9430	C9431	C9432	C9440	C9441	C9442	C946	C9480
C9481	C9482	C9500	C9501	C9502	C9510	C9511	C9512
C9590	C9591	C9592	C960	C9620	C9621	C9622	C9629
C964	C965	C966	C96A	C96Z	D0001	D0002	D0003
D0004	D0005	D0006	D0007	D0008	D001	D002	D010
D011	D012	D013	D0149	D015	D017	D020	D021
D0221	D0222	D023	D030	D03111	D03112	D03121	D03122
D0321	D0322	D0339	D034	D0351	D0352	D0359	D0361
D0362	D0371	D0372	D038	D039	D040	D04111	D04112
D04121	D04122	D0421	D0422	D0439	D044	D045	D0461
D0462	D0471	D0472	D048	D0501	D0502	D0511	D0512
D0581	D0582	D060	D061	D067	D070	D071	D072
D0739	D074	D075	D0761	D0769	D090	D0919	D0921
D0922	D093	D098	D45	D4701	D4702	D4709	D49511
D49512	D49519	D4959	D4981	D4989	D600	D601	D608
D6109	D611	D612	D613	D6189	D700	D701	D702
D703	D704	D8940	D8941	D8942	D8943	D8949	P615
T451X1A	T451X1D	T451X1S	T451X2A	T451X2D	T451X2S	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)

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

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.

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.

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

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

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 erythopoietic effect and less frequent dosing. Darbepoetin alfa is indicated for:

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

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

Diagnosis Codes							
C9000	C9001	C9002	D460	D461	D4621	D46A	D46B
D611	D612	D613	D6189	D619	D630	D631	D644
D6481	D6489	D649	N181	N182	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
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).

26 Epoetin Beta (Mircera)

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

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.

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

27 Ibalizumab-uiyk (Trogarzo)

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

For initial therapy, the following criteria must be met:

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

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

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

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

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

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

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.

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

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.

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.

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.

28 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.*

29 Immunosuppressive Drugs

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

The following procedure codes are benefits of Texas Medicaid:

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

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

Procedure Code	Conditions
J0202	Multiple sclerosis (MS): For treatment of relapsing forms of MS and should be reserved for clients who have had an inadequate response to two or more drugs indicated for the treatment of MS.
J0257	Alpha-1 proteinase inhibitor deficiency: For the treatment of clients who have a deficiency of the alpha-1 proteinase inhibitor enzyme (also known as alpha-1 antitrypsin deficiency) in the treatment of emphysema.
J0480	Organ rejection: For the prophylaxis of acute organ rejection in patients receiving renal transplantation when used as part of an immunosuppressive regimen that includes cyclosporine and corticosteroids.
J0485	Organ rejection: For the prophylaxis of organ rejection in adults receiving a kidney transplant, to be used in combination with basiliximab injection, mycophenolate mofetil, and corticosteroids.
J0490	Systemic lupus erythematosus (SLE): For use in clients with moderate to severe SLE when other forms of treatment have failed to control moderate to severe symptoms
J0717	Psoriatic arthritis, Ulcerative colitis, Ankylosing spondylitis, Crohn's disease
J1595	Multiple sclerosis (MS): For the reduction of the frequency of relapses in clients with relapsing remitting MS, including clients who have experienced a first clinical episode and have magnetic resonance imaging (MRI) features consistent with MS.
J1602	Psoriatic arthritis, Rheumatoid arthritis, Ankylosing spondylitis
J7501	Renal homotransplantations: Adjunct for the prevention of rejection in renal homotransplantation. Rheumatoid arthritis: Azathioprine is indicated only in adult patients meeting the criteria for classic or definite rheumatoid arthritis as specified by the American Rheumatism Association.
J7516	Allogeneic transplants: For prophylaxis of organ rejection in kidney, liver, and heart allogeneic transplants.
J7525	Organ rejection prophylaxis: For the prophylaxis of organ rejection in clients receiving allogeneic liver, kidney, or heart transplants.

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

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

30 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
M0898	M450	M451	M452	M453	M454	M455	M456
M457	M458						

31 Inotuzumab ozogamicin (Besponsa)

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

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

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

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

31.1 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

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.

31.2 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.

31.3 Exclusions

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

32 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 AIDs-related Kaposi sarcoma Basal- and squamous-cell cancer Behcet syndrome Bladder tumors (local use for superficial tumors) Carcinoid tumor Chronic granulocytic leukemia Chronic hepatitis B virus Chronic hepatitis C virus Chronic myelogenous leukemia Condylomata acuminata Cutaneous T-cell lymphoma Cytolomegavirus Essential thrombocytopenia Essential thrombocytosis Follicular lymphoma Hairy cell leukemia Herpes simplex Hodgkin's disease Hypereosinophilic syndrome Melanoma Multiple myeloma Mycosis fungoides Non-Hodgkin's lymphoma Ovarian and cervical carcinoma Papilloma viruses Polycythemia vera Renal cell carcinoma Rhino viruses Varicella zoster
J9216	Chronic granulomatous disease Malignant osteoporosis

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

33 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.

34 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.

35 Leuprolide Acetate (Lupron Depot)

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

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

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

Frequency	Dosage	Limitations
Monthly	7.5 mg	Billed with a quantity of 1 Reimbursed once per month
3-month	22.5 mg	Billed with a quantity of 3 Reimbursed once every three months
4-month	30 mg	Billed with a quantity of 4 Reimbursed once every 4 months
6-month	45 mg	Billed with a quantity of 6 Reimbursed once every 6 months
The total dosage allowed within a 6-month period is 45 mg.		

36 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			

37 Mepsevii (Vestronidase alfa-vjbk)

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

For initial therapy, the following criteria must be met:

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

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

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

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.

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

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.

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.

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.

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

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

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

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

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

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

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

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 (mm3)*

- 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 (mm3)*

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 (mm3).*

- 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 wakening, or symptoms upon awakening
  - Tiredness
  - Wheezing/heavy breathing/fighting for air, and

- Member has not exhibited symptoms of hypersensitivity or anaphylaxis (bronchospasm, hypotension, syncope, urticaria, and/or angioedema) after administration of omalizumab, benralizumab, mepolizumab, or reslizumab.

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

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

39 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						

40 * Patisiran (Onpattro)

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

[Revised] Prior authorization requests for patisiran (Onpattro) (procedure code C9036) must be submitted with a Special Medical Prior Authorization (SMPA) Request Form and may be approved for 12 months per prior authorization request.

[Revised] The Special Medical Prior Authorization (SMPA) Request Form must be completed, signed, and dated by the prescribing provider. 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. The Special Medical Prior Authorization (SMPA) form will not be accepted later than 90 days after the date of the prescribing provider's signature.

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

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

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

- [Revised] The client has previously received treatment with patisiran (Onpattro) without an adverse reaction.

- [Revised] The client has a positive clinical response to patisiran (Onpattro) (e.g., improved neurologic impairment, improved motor function, slowing of disease progression).

[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.

41 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				

42 Tisagenlecleucel (Kymriah)

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.

43 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.

44 Triamcinolone Acetonide

Procedure code J3304 is a benefit of Texas Medicaid and is restricted to the following diagnosis codes:

Diagnosis Codes							
M170	M1711	M1712	M172	M1731	M1732	M174	M175

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

45 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.

46 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.

47 Voretigene neparvovec-rzyl (Luxturna)

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

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

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

47.1 Prior Authorization Requirements

Prior authorization is not required for the physician services associated with administration of Luxturna. Physician services include the procedural costs and the associated supplies for administration of the medication.

Prior authorization is required for voretigene neparvovec-rzyl (Luxturna) (procedure code J3398).

For situations in which voretigene neparvovec-rzyl (Luxturna) is being dispensed by a pharmacy via white bagging, the prescribing provider must provide the dispensing DME pharmacy the authorization approval number. The dispensing DME pharmacy may not request prior authorization.

The DME Pharmacy provider billing for voretigene neparvovec-rzyl (Luxturna) will be responsible for coordinating with the rendering provider to obtain the prior authorization request approval number.

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

The dispensing pharmacy must submit the authorization approval number when billing for the drug. Reimbursement for dispensing of the drug by the pharmacy may not occur unless an approved prior authorization for voretigene neparvovec-rzyl (Luxturna) is in place.

Refer to: Subsection 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 μm thickness shown on optimal coherence tomography (OCT)
- Greater than or equal to 3 disc areas of retina without atrophy or pigmentary degeneration within the posterior pole
    - Remaining visual field within 30 degrees of fixation as measured by a III4e isopter or equivalent
- Prescribed and administered by retinal surgeon at an ocular gene therapy treatment center with experience performing intraocular surgery
- Patient has not previously received RPE65 gene therapy in intended eye
- Injection of the second eye must be administered at least 6 days after the first eye
- Have not had intraocular surgery within 6 months in either eye indicated for treatment

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

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

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

47.2 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.

48 Claims Filing Information

Claims for clinician-administered drugs must be submitted to TMHP in an approved electronic format or on the CMS-1500 paper claim form. Providers may purchase CMS-1500 paper claim forms from the vendor of their choice. TMHP does not supply them.

When completing a CMS-1500 paper claim form, all required information must be included on the claim, as information is not keyed from attachments. Superbills and itemized statements are not accepted as claim supplements.

Refer to: "Section 3: TMHP Electronic Data Interchange (EDI)" (*Vol. 1, General Information*) for information on electronic claims submissions.

"Section 6: Claims Filing" (*Vol. 1, General Information*) for general information about claims filing.

Subsection 6.5, "CMS-1500 Paper Claim Filing Instructions" in "Section 6: Claims Filing" (*Vol. 1, General Information*) for instructions on completing paper claims. Blocks that are not referenced are not required for processing by TMHP and may be left blank.