



Texas Medicaid Provider Procedures Manual

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Volume
2

Provider Handbooks

Outpatient Drug Services Handbook

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

Diagnosis Codes							
C969	C96A	C96Z	D030	D0310	D0311	D0312	D0320
D0321	D0322	D0330	D0339	D034	D0351	D0352	D0359
D0360	D0361	D0362	D0370	D0371	D0372	D038	D039
D588	D589	D590	D591	D592	D593	D594	D595
D596	D598	D599	D6101	D6109	D61810	D61811	D61818
D6182	D619	D62	D630	D631	D638	D640	D641
D642	D643	D644	D6481	D6489	D649	G620	H903
H905	H933X1	H933X2	H933X3	H933X9	K117	N059	T451X1A
T451X1D	T451X1S	T451X2A	T451X2D	T451X2S	T451X3A	T451X3D	T451X3S
T451X4A	T451X4D	T451X4S	T4591xA	T4591xD	T4591xS	T4592xA	T4592xD
T4592xS	T4593xA	T4593xD	T4593xS	T4594xA	T4594xD	T4594xS	T50905A
T50905D	T50905S	T66xxxA	T66xxxD	T66xxxS	Z510	Z5111	

7.6 Antibiotics and Steroids

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

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

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

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

7.7 Antisense Oligonucleotides (etepirsen, golodirsen, and nusinersen)

Antisense oligonucleotides, etepirsen (Exondys 51) (procedure code J1428), golodirsen (Vyondys 53) (procedure code J1429), nusinersen (Spinraza) (procedure code J2326), or viltolarsen (Viltepso) (procedure code J1427) may be benefits of Texas Medicaid with prior authorization.

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

7.7.1 Prior Authorization Requirements

Prior authorization requests for procedure codes J1247, J1428, J1429, and J2326, and must be submitted by the prescribing provider to the Special Medical Prior Authorization (SMPA) department at TMHP using the Special Medical Prior Authorization (SMPA) Request Form.

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

For situations in which procedure code J1247, J1428, J1429, or J2326 are being dispensed by a pharmacy via white bagging, the prescribing provider must provide the dispensing durable medical equipment (DME) pharmacy the authorization approval number.

The dispensing DME pharmacy may not request prior authorization.

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

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

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

Note: For additional information on white bag delivery, providers may refer to Subsection 10.5.1, "Pharmacy Delivery Method for Clinician-Administered Drugs" in this handbook.

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

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

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

7.7.1.1 Initial Requests (for all Antisense Oligonucleotides)

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

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

- A diagnosis specific to the requested antisense oligonucleotide
- Genetic testing specific to the requested antisense oligonucleotide

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

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

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

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

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

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

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

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

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

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

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

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

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

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

- Client age
- Baseline pulmonary status, including any requirements for invasive or non-invasive ventilation

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

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

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

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

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

- Brooke Upper Extremity Scale
- Baseline 6MWT (6-minute walk test)
- Pediatric Evaluation of Disability Inventory
- Viltepso should not be used concomitantly with other exon skipping therapies for DMD.

7.7.1.2 Recertification/Extension Requests (for all Antisense Oligonucleotides)

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

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

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

- A diagnosis specific to the requested antisense oligonucleotide
- Client age
- Current documentation of physical function
- Testing tools used to measure physical function must be age appropriate for the client being tested. Providers must use the same testing instrument as used in the initial evaluation. If re-use of the initial testing instrument is not appropriate, for example, due to change in client status or restricted age range of the testing tool, the provider must explain the reason for the change.
- The physical function testing tool results must include one of the following:

- An increase in physical function from baseline has been observed
- Baseline physical function has been maintained
- A neurology consultation dated no more than one rolling year of the recertification/extension date that includes the name, credentials, and contact information for the consulting neurologist recommending ongoing treatment with the requested antisense oligonucleotide
- Statement from prescribing clinician that the client has been compliant with the treatment
- Documentation of the requested antisense oligonucleotide dosage and administration schedule, including the number of injections to be administered during the prior authorization period, the requested units per injection, and the dosage calculation must be submitted in Section C of the Special Medical Prior Authorization (SMPA) Request Form under Statement of Medical Necessity.

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

The medical necessity documentation for golodirsen (Vyondys 53) and viltolarsen (Viltepso) recertification/extension requests must include the client's continual renal function test while on therapy and current client weight, including the date the weight was obtained. The weight must be dated no more than 30 days before the request date.

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

7.7.1.3 Exclusions

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

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

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