Onasemnogene Abeparvovec-xioi (Zolgensma) Criteria Effective October 1, 2019, for Texas Medicaid

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Note: *Texas Medicaid managed care organizations (MCOs) must provide all medically necessary, Medicaid-covered services to eligible clients. Administrative procedures such as prior authorization, pre-certification, referrals, and claims/encounter data filing may differ from traditional Medicaid (fee-for-service) and from MCO to MCO. Providers should contact the client's specific MCO for details.*

Effective for dates of service on or after October 1, 2019, onasemnogene abeparvovec-xioi (Zolgensma) will be a benefit for Texas Medicaid, with prior authorization. Claims for onasemnogene abeparvovec-xioi (Zolgensma) must be submitted with unlisted procedure code J3590.

Onasemnogene abeparvovec-xioi (Zolgensma) is a one-time infusion therapy indicated for the treatment of spinal muscular atrophy (SMA) with biallelic mutations in the survival motor neuron 1 (SMN1) gene in clients who are 24 months of age or younger. Onasemnogene abeparvovec-xioi (Zolgensma) will not be a benefit for clients with a tracheostomy or invasive ventilator support.

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

Prior Authorization

Prior authorization requests for onasemnogene abeparvovec-xioi (Zolgensma) (unlisted procedure code J3590) must be submitted with a Special Medical Prior Authorization Request Form, and may be approved for a one-time intravenous infusion.

Documentation of the client’s dosage, administration schedule, 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 Request Form under Statement of Medical Necessity.

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

Documentation Requirements

The prior authorization request for an onasemnogene abeparvovec-xioi (Zolgensma) single-dose intravenous infusion must include documentation of all of the following:

- Client is 24 months of age or younger
- Onset of clinical signs and symptoms consistent with SMA at birth up to 6 months of age
- Medical record supporting the mutation or deletion of genes in chromosome 5q
    - Homozygous gene deletion of the SMN1 gene (e.g., absence of SMN1 gene)
    - Homozygous mutation of the SMN1 gene (e.g., biallelic mutation of exon 7)
    - Compound heterozygous mutation in the SMN1 gene (e.g., deletion of SMN1 exon 7 [allele 1] and mutation of SMN1 [allele 2])
- Confirmed diagnosis of Type I SMA (diagnosis code G120) based on gene mutation analysis with biallelic SMN1 mutation (deletion or point mutation) and 2 copies of SMN2
- Documentation of the Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorder (CHOP-INTEND) score to evaluate the client's motor skills
- Baseline documentation of AAV9 antibody titer of 1:50 or lower, as determined by enzyme-linked immunosorbent assay (ELISA)
- Physician attestation that client has not received prior onasemnogene abeparvovec-xioi (Zolgensma) therapy

If nusinersen (Spinraza) (procedure code J2326) has been previously prescribed, the prescriber must also provide the following documentation before switching to onasemnogene abeparvovec-xioi (Zolgensma) therapy:

- Evidence of clinical deterioration (e.g., decreased physical function and CHOP-INTEND score) while on nusinersen (Spinraza) therapy
- Neurologist attestation to the discontinuation of nusinersen (Spinraza) therapy

For more information, call the TMHP Contact Center at 1-800-925-9126.