PHARMACY POLICY STATEMENT
TRICARE

DRUG NAME	Itvisma (onasemnogene abeparvovec-brve)
BENEFIT TYPE	Medical
STATUS	Prior Authorization Required

Itvisma is an adeno-associated virus (AAV) vector-based gene therapy indicated for the treatment of spinal muscular atrophy (SMA) in adult and pediatric patients 2 years of age and older with confirmed mutation in SMN1 gene.
Spinal muscular atrophy (SMA) is a genetic, autosomal recessive neuromuscular disorder caused by a defect in the survival of the motor neuron 1 (SMN1) gene. SMA is the leading genetic cause of infant mortality and affects approximately 1 in every 10,000 infants. There are multiple types of SMA, and the age of onset and severity of the disease varies with each type.

Itvisma (onasemnogene abeparvovec-brve) will be considered for coverage when the following criteria are met:

Spinal Muscular Atrophy (SMA)

For **initial** authorization:

1. Member is between 2 and 17 years of age; AND
2. Medication must be prescribed by or in consultation with a neurologist; AND
3. Member has a diagnosis of SMA confirmed by genetic testing showing any of the following:
   a) Homozygous gene deletion of the survival motor neuron 1 (SMN1) gene (e.g., absence of SMN1 gene);
   b) 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]); AND
4. Member has documentation of 2 to 3 copies of SMN2; AND
5. Chart notes include documentation that member can sit independently, but has never been able to walk independently; AND
6. Member has an anti-AAV9 antibody titer ≤ 1:50; AND
7. Documentation of liver function tests (AST, ALT, etc.) and platelet count is documented in chart notes; AND
8. Medication must **NOT** be concurrently used with SMN-targeting therapies (such as Evrysdi and Spinraza). *Of note:* a washout period of 4 months for Spinraza and 15 days for Evrysdi is required; AND
9. Member does **NOT** have any of the following:
   a) Previous gene therapy;
   b) Clinical signs or symptoms of infection;
   c) Ventilation dependence or tracheostomy

10. **Dosage allowed/Quantity limit:** 1.2 × 10^{14} vector genomes (vg) given intrathecally.

If all the above requirements are met, the medication will be approved for 3 months.

For **reauthorization**:
1. Itvisma will not be reauthorized.

Scenarios that do not meet the above requirements may be considers Itvisma (onasemnogene abeparvovec-brve) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
12/09/2025	New policy for Itvisma created.
03/16/2026	Added washout period requirement of 4 months for Spinraza and 15 days for Evrysdi

References:

1. Itvisma [prescribing information]. Novartis Gene Therapies, Inc.; 2025.
2. Proud CM, Vũ DC, Wilmshurst JM, et al. Intrathecal onasemnogene abeparvovec in treatment-naive patients with spinal muscular atrophy: a phase 3, randomized controlled trial. *Nat Med*. Published online December 8, 2025. doi:10.1038/s41591-025-04103-w
3. Schroth M, Deans J, Arya K, et al. Spinal Muscular Atrophy Update in Best Practices: Recommendations for Diagnosis Considerations. *Neurol Clin Pract*. 2024;14(4):e200310. doi:10.1212/CPJ.0000000000200310
4. Glascock J, Sampson J, Haidet-Phillips A, et al. Treatment Algorithm for Infants Diagnosed with Spinal Muscular Atrophy through Newborn Screening. *J Neuromuscul Dis*. 2018;5(2):145-158. doi:10.3233/JND-180304
5. Schroth MK, Deans J, Bharucha Goebel DX, et al. Spinal Muscular Atrophy Update in Best Practices: Recommendations for Treatment Considerations. *Neurol Clin Pract.* 2025;15(1):e200374. doi:10.1212/CPJ.0000000000200374
6. Glascock J, Sampson J, Connolly AM, et al. Revised Recommendations for the Treatment of Infants Diagnosed with Spinal Muscular Atrophy Via Newborn Screening Who Have 4 Copies of SMN2. *J Neuromuscul Dis*. 2020;7(2):97-100. doi:10.3233/JND-190468

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