onasemnogene abeparvovec-brve (Itvisma)

Medical Benefit Drug Policy

Place of Service

Hospital Administraton
Outpatient Facility Infusion Administration

Drug Details

USP Category: GENETIC OR ENZYME OR PROTEIN DISORDER: REPLACEMENT, MODIFIERS, TREATMENT
Mechanism of Action: Adeno-associated virus vector-based gene therapy
HCPCS:
J3405:Injection, onasemnogene abeparvovec-brve, per treatment
How Supplied:
Each single-dose vial contains 1.2 × 10^14 vg of onasemnogene abeparvovec in 3 mL of suspension. Itvisma has a nominal concentration of 4 ×10^13 vg/mL, and each vial contains an extractable volume of not less than 3 mL.

Condition(s) listed in policy *(see coverage criteria for details)*

- Spinal Muscular Atrophy (SMA)

Any condition not listed in this policy requires a review to confirm it is medically necessary. For conditions that have not been approved for intended use by the Food and Drug Administration (i.e., off-label use), the criteria outlined in the California Code of Regulations (CCR), Title 22, Section 51303 and 51313 must be met.

Special Instructions and Pertinent Information

Provider must submit documentation (such as office chart notes, lab results or other clinical information) to ensure the member has met all medical necessity requirements.

The member's specific benefit may impact drug coverage. Other utilization management processes, and/or legal restrictions may take precedence over the application of this clinical criteria.

Coverage Criteria
The following condition(s) require Prior Authorization/Preservice.

Spinal Muscular Atrophy (SMA)
Meets medical necessity if all the following are met:

1. Prescribed by or recommended by a neurologist
2. Diagnosis of SMA confirmed by genetic testing demonstrating a mutation in the *survival motor neuron 1 (SMN1)* gene by one of the following:
   a. Deletion of both copies of the *SMN1* gene
   b. Identification of pathogenic variant(s) in both copies of the *SMN1* gene
3. Patient is greater than or equal to 2 years of age

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4. Documentation that the patient can sit up but has never been able to walk independently (i.e., Type 2 SMA)
5. No prior treatment with Zolgensma
6. Not being used in combination with Spinraza or Evrysdi

Covered Doses:
Up to 1.2 × 10^14 vector genomes (vg)

Coverage Period:
One treatment course per lifetime

ICD-10:
G12.0, G12.1, G12.25, G12.8, G12.9

References

1. Itvisma (onasemnogene abeparvovec-brve) Prescribing Information. Novartis Gene Therapies Inc., Bannockburn, IL: 11/2025.

Review History

Date of Last Annual Review: 1Q2026
Changes from previous policy version:

- Added HCPCS J3405, effective 7/1/2026.

Blue Shield of California Medication Policy to Determine Medical Necessity
Reviewed by P&T Committee