

onasemnogene abeparvovec-brve (Itvisma)

Commercial Medical Benefit Drug Policy

Place of Service

Hospital Administration

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:

C9399:Unclassified drugs or biologicals

J3590:Unclassified biologics

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 Health and Safety Code section 1367.21 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.

For billing purposes, drugs must be submitted with the drug's assigned HCPCS code (as listed in the drug policy) and the corresponding NDC (national drug code). An unlisted, unspecified, or miscellaneous code should not be used if there is a specific code assigned to the drug.

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

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:

Not to exceed 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:

- New policy

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