

DRUG POLICY

Itvisma® (onasemnogene abeparvovec-brve)

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the Itvisma policy is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. The indications below including FDA-approved indications and compendial uses are considered covered benefits provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

Itvisma is indicated for the treatment of spinal muscular atrophy (SMA) in adult and pediatric patients 2 years of age and older with confirmed mutation in the *survival motor neuron 1 (SMN1)* gene.

POLICY

Required Documentation

Submission of the following information is necessary to initiate the prior authorization review:

1. Genetic testing results demonstrating mutations in the *survival motor neuron 1 (SMN1)* gene
2. Medical records documenting that the patient is able to sit up independently but has never been able to walk independently
3. Enzyme-linked Immunosorbent Assay (ELISA) binding immunoassay results

Prescriber Specialties

The requested medication must be prescribed by or in consultation with a physician who specializes in treatment of spinal muscular atrophy.

Criteria for Initial Approval

Spinal Muscular Atrophy

Authorization of one dose total may be granted for treatment of spinal muscular atrophy when all of the following criteria are met:

1. Member has a genetically confirmed diagnosis of SMA with genetic documentation mutations in the *survival motor neuron 1 (SMN1)* gene (deletions or point mutations).
2. Member is older than 2 years of age but less than 18 years of age.
3. Member's onset of clinical signs and symptoms of disease occurred at 6 months of age or older.
4. Member has not received any prior gene therapies (Zolgensma or Itvisma) for SMA.
5. Member can sit but has never had the ability to walk independently.
6. Member has an anti-adenovirus 9 (AAV9) antibody titer less than or equal to 1:50 as determined by Enzyme-linked Immunosorbent Assay (ELISA) binding immunoassay.
7. Member does not require invasive ventilation, awake noninvasive ventilation for greater than 6 hours during a 24-hour period, noninvasive ventilation for greater than 12 hours during a 24-hour period, or require tracheostomy.
8. If the member is on nusinersen (Spinraza) or risdiplam (Evrysdi), it will be discontinued prior to administration of the requested drug.

Approval will be for one dose per lifetime with an authorization period of 14 days ending on the date of the anticipated administration from the provider.

Other

Itvisma (onasemnogene abeparvovec-brve) is considered **not medically necessary** for members who do not meet the criteria set forth above.

Dosing and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Quantity Limits Apply

Medication	Standard Limit	FDA Recommended Dosing
Itvisma (onasemnogene abeparvovec-brve) single-dose vial	1 dose per lifetime	1.2×10^{14} vector genomes (vg) as a single intrathecal injection

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

- J3405 – Injection, onasemnogene abeparvovec-brve, per treatment (effective 7/1/26)
- J3490 – Unclassified drugs
- J3590 – Unclassified biologics

REFERENCES

Itvisma. Prescribing information. Novartis Gene Therapies, Inc.; November 2025. Accessed January 6, 2026.

National Institute for Health and Care Excellence (NICE). Intrathecal onasemnogene abeparvovec for treating spinal muscular atrophy in people 2 years and over [ID6556]. Accessed December 5, 2025. <https://www.nice.org.uk/guidance/indevelopment/gid-ta11733>

Proud CM, Vu DC, Wilmschurst JM, et al. Intrathecal onasemnogene abeparvovec in treatment-naïve patients with spinal muscular atrophy: a phase 3, randomized controlled trial. *Nat Med*. 2025. doi: 10.1038/s41591-025-04103-w

Schroth MK, Deans J, Goebel DXB, 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

POLICY HISTORY

Policy #: 05.06.20

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Reviewed: June 2026

Revised:

Current Effective Date: March 6, 2026