Reference number(s)
7318-A

Specialty Guideline Management Itvisma

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Itvisma	onasemnogene abeparvovec-brve

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-approved Indications[1]

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

All other indications are considered experimental/investigational and not medically necessary.

Documentation

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

- Genetic testing results demonstrating bi-allelic pathogenic variants in the survival motor neuron 1 (SMN1) gene
- Medical records (e.g., chart notes and/or laboratory reports) documenting baseline liver function, platelet count, troponin I levels, creatinine, and neurologic evaluation.

Prescriber Specialties

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

Coverage Criteria

Spinal Muscular Atrophy[1-2]

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

- Member has a genetically confirmed diagnosis of SMA, with documentation of bi-allelic pathogenic variants in the survival motor neuron 1 (SMN1) gene (deletions or point mutations).
- Member's onset of clinical signs and symptoms of disease occurred at 6 months of age or older.
- Member is 2 years of age or older.
- 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.
- Member has an anti-adeno-associated virus 9 (AAV9) antibody titer less than or equal to 1:50 as determined by Enzyme-linked Immunosorbent Assay (ELISA) binding immunoassay.
- Member does not have an active infectious process (e.g. viral, bacterial, or febrile illness) prior to treatment.
- Member does not have a serious concomitant illness (e.g., severe liver or kidney disease, symptomatic cardiomyopathy).
- Liver function, platelet count, troponin I, creatinine, and neurologic evaluation have been assessed at baseline and will be monitored after Itvisma administration as clinically appropriate.
- Member's vaccination status will be up to date prior to Itvisma administration.
- If the member is on nusinersen (Spinraza) or risdiplam (Evrysdi), it will be discontinued prior to administration of the requested drug.
- Member has not received Itvisma, Zolgensma, or other gene therapy previously.

References

1. Itvisma [package insert]. Bannockburn, IL. Novartis Gene Therapies, Inc; November 2025.
2. ClinicalTrials.gov. Efficacy and Safety of Intrathecal OAV101 (AVXS-101) in Pediatric Patients With Type 2 Spinal Muscular Atrophy (SMA) (STEER). Identifier NCT05089656. Updated July 4, 2025. Accessed November 26, 2025.