Reference number(s)
7320-A

Standard Medicare Part B 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 adult and pediatric patients 2 years of age and older with confirmed mutation in survival motor neuron 1 (SMN1) gene.

All other indications will be assessed on an individual basis. Submissions for indications other than those listed in this criteria should be accompanied by supporting evidence from Medicare approved compendia.

Documentation

The following documentation must be available, upon request, for all submissions: genetic testing results demonstrating bi-allelic pathogenic variants in the survival motor neuron 1 (SMN1) gene.

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Coverage Criteria

Spinal Muscular Atrophy[1]

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 bi-allelic pathogenic variants in the survival motor neuron 1 (SMN1) gene (deletions or point mutations).
- Member is 2 years of age or older.
- If the member is on nusinersen (Spinraza) or risdiplam (Evrysdi), it will be discontinued prior to administration of the requested drug.
- The member has not received Itvisma, Zolgensma, or other gene therapy previously.

Summary of Evidence

The contents of this policy were created after examining the following resources:

- The prescribing information for Itvisma.
- The available compendium
    - National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
    - Micromedex DrugDex
    - American Hospital Formulary Service- Drug Information (AHFS-DI)
    - Lexi-Drugs
    - Clinical Pharmacology

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Itvisma are covered.

Explanation of Rationale

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

References

1. Itvisma [package insert]. Bannockburn, IL. Novartis Gene Therapies, Inc; November 2025.

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