Louisiana Medicaid
Onasemnogene abeparvovec-brve (Itvisma®)

The *Louisiana Uniform Prescription Drug Prior Authorization Form* should be utilized to request clinical authorization for onasemnogene abeparvovec-brve (Itvisma®).

Additional Point-of-Sale edits may apply.

By submitting the authorization request, the prescriber attests to the conditions available HERE.

Approval Criteria

- The recipient is ≥ 2 years of age on the date of the request; **AND**
- This medication is prescribed by, or the request states that the medication is being prescribed in consultation with, a neurologist experienced in the treatment of SMA; **AND**
- The following are true and **stated on the request**:
    - The recipient has a diagnosis of spinal muscular atrophy (SMA) with a confirmed mutation in the *survival motor neuron 1 (SMN1)* gene; **AND**
    - The recipient is able to sit independently but never had the ability to walk independently; **AND**
    - The recipient **DOES NOT HAVE advanced SMA** (e.g., complete paralysis of limbs, permanent ventilator dependence); **AND**
    - The recipient **has never received a dose** of Itvisma® or Zolgensma®; **AND**
    - The recipient has a baseline anti-AAV9 antibody titer ≤ 1:50, measured using an enzyme-linked immunosorbent assay (ELISA) **[date and results must be written on the request]**; **AND**
- If request is for a non-preferred agent – **ONE** of the following is required: (see Spinal Muscular Atrophy agents on PDL)
    - The recipient has had a *treatment failure* with at least one preferred product; **OR**
    - The recipient has had an *intolerable side effect* to at least one preferred product; **OR**
    - The recipient has *documented contraindication(s)* to all of the preferred products that are appropriate to use for the condition being treated; **OR**
    - There is *no preferred product that is appropriate* to use for the condition being treated**.**

Duration of approval: 1 month – allow 1 dose per lifetime

References

ClinicalTrials.gov. Efficacy and Safety of Intrathecal OAV101 (AVXS-101) in Pediatric Patients With Type 2 Spinal Muscular Atrophy (SMA) (STEER). https://clinicaltrials.gov/study/NCT05089656?cond=NCT05089656&rank=1

Itvisma (onasemnogene abeparvovec-brve) [package insert]. Bannockburn, IL: Novartis Gene Therapies, Inc; November 2025. https://www.novartis.com/us-en/sites/novartis_us/files/Itvisma.pdf

Kwon JM, Munell F, Le Goff L et al. Intrathecal onasemnogene abeparvovec for treatment-experienced patients with spinal muscular atrophy: a phase 3b, open-label trial. Nat Med. 2025 Dec.

Proud CM, Chí Vũ D, Wilmshurst JM et al. Intrathecal onasemnogene abeparvovec in treatment-naive patients with spinal muscular atrophy: a phase 3, randomized controlled trial. Nat Med. 2025 Dec.

Schroth M, Deans J, Arya K, et al. Spinal muscular atrophy update in best practices: recommendations for diagnosis considerations. Neurol Clin Pract. 2024 Aug;14(4): e200310. doi: 10.1212/CPJ.0000000000200310.

U.S. National Library of Medicine. Genetics Home Reference. (2018, September 25). Spinal Muscular Atrophy. https://ghr.nlm.nih.gov/condition/spinal-muscular-atrophy

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