



## PROVIDER POLICIES & PROCEDURES

### ITVISMMA<sup>®</sup> (ONASEMNOGENE ABEPARVOVEC-BRVE)

The primary purpose of this document is to assist providers enrolled in the Connecticut Medical Assistance Program (CMAP) with the information needed to support a medical necessity determination for Itvisma (onasemnogene abeparvovec-brve) therapy. By clarifying the information needed for prior authorization of services, HUSKY Health hopes to facilitate timely review of requests so that individuals obtain the medically necessary care they need as quickly as possible.

*Spinal muscular atrophy (SMA)* is an autosomal recessive neuromuscular disorder caused by an insufficient level of survival motor neuron (SMN) protein resulting in progressive muscle weakness and atrophy. SMA is classified as type 0 through 4 based upon the age of onset and clinical course, with type 0 (prenatal onset) and type 1 (infantile onset) being the most common and severe types.

**Itvisma** is an adeno-associated virus vector-based gene therapy indicated for the treatment of spinal muscular atrophy in adult and pediatric patients 2 years of age and older with confirmed mutation in SMN1 gene. Itvisma is given as a one-time intrathecal bolus injection.

#### CLINICAL GUIDELINE

Coverage guidelines for Itvisma are made in accordance with the Department of Social Services (DSS) Definition of Medical Necessity. The following criteria are guidelines *only*. Coverage determinations are based on an assessment of the individual and their unique clinical needs. If the guidelines conflict with the definition of Medical Necessity, the definition of Medical Necessity shall prevail.

Itvisma may be considered medically necessary as an intrathecal bolus for patients with SMA when ALL of the following criteria are met:

- A. The individual has a diagnosis of SMA which has been made by or in consultation with a physician with expertise in diagnosing SMA; **AND**
- B. Submission of genetic testing confirming 5q SMA; **AND**
- C. The individual is at least 2 years of age or older; **AND**
- D. Itvisma has been ordered by or in consultation with a physician specializing in the management of SMA or other neuromuscular disorders; **AND**
- E. The individual has not been previously treated with Itvisma or any other gene therapy for SMA (e.g., Zolgensma); **AND**
- F. If the individual is currently on other SMA therapy (e.g., Spinraza<sup>®</sup> [nusinersen] or Evrysdi<sup>®</sup> [risdiplam]), it will be discontinued prior to administration of Itvisma; **AND**
- G. The individual will receive a corticosteroid regimen prior to and following receipt of Itvisma as per the FDA approved labeling; **AND**

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- H. Submission of medical records confirming that testing for anti-AAV9 antibodies has been performed and the individual has an anti-AAV9 antibody titer of  $\leq 1:50$ ; **AND**
- I. The individual is clinically stable in their overall baseline health status (e.g., hydration and nutritional status, absence of infection, respiratory status). *Note: Itvisma must be postponed in patients with active or recent infections until the infection has resolved; clinical signs or symptoms of infection should not be evident at the time of Itvisma injection;* **AND**
- J. The individual is up to date on all guideline-recommended vaccines; **AND**
- K. **Both** of the following apply:
  - a. Baseline liver function has been evaluated (e.g., clinical exam, AST, ALT, total bilirubin, albumin, prothrombin time, partial thromboplastin time [PTT], and INR); **AND**
  - b. Provider attests that liver function will continue to be monitored after Itvisma infusion in accordance with the FDA approved labeling; **AND**
- L. **Both** of the following apply:
  - a. Baseline creatinine and complete blood count (CBC) including hemoglobin and platelet count has been obtained; **AND**
  - b. Provider attests that CBC will continue to be monitored after Itvisma infusion in accordance with the FDA approved labeling; **AND**
- M. A description of the benefits, risks, and treatment expectations has been provided to the individual and/or their parent or guardian if applicable; **AND**
- N. The treating provider attests that the individual will likely benefit from therapy based on the current status of their disease; **AND**
- O. The treating provider will follow all FDA approved labeling for dosing, administration, and monitoring for Itvisma.

### **Investigational and Not Medically Necessary**

The safety and efficacy of repeat administration of Itvisma has not been clinically evaluated and is therefore considered investigational and not medically necessary.

#### **NOTE: EPSDT Special Provision**

Early and Periodic Screening, Diagnosis, and Treatment (EPSDT) is a federal Medicaid requirement that requires the Connecticut Medical Assistance Program (CMAP) to cover services, products, or procedures for Medicaid enrollees under 21 years of age where the service or good is medically necessary health care to correct or ameliorate a defect, physical or mental illness, or a condition identified through a screening examination. The applicable definition of medical necessity is set forth in Conn. Gen. Stat. Section 17b-259b (2011) [ref. CMAP Provider Bulletin PB 2011-36].

### **PROCEDURE**

Prior authorization for Itvisma is required. Coverage determinations will be based upon a review of requested and/or submitted case-specific information.

#### **The following information is needed to review requests for Itvisma:**

1. Fully completed State of Connecticut, Department of Social Services HUSKY Health Program Itvisma (onasemnogene abeparvovec-brve) Prior Authorization Request Form (to include physician's order and signature);
2. Clinical documentation from the treating neurologist supporting the medical necessity of treatment with Itvisma should include the following:

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- a. Genetic testing confirming diagnosis of 5q SMA; **AND**
  - b. The following baseline labs confirming that above criteria are met, and that the individual is an appropriate candidate and safe to initiate treatment:
    - i. Liver function tests (e.g., AST, ALT, total bilirubin, albumin, prothrombin time, PTT, and INR); **AND**
    - ii. CBC; **AND**
    - iii. Creatinine; **AND**
    - iv. Anti-AAV9 antibody titer of < 1:50; **AND**
  - c. Signed provider attestation confirming the following:
    - i. The individual has not been previously treated with Ivivisima or any other gene therapy for SMA (e.g., Zolgensma); **AND**
    - ii. If the individual is currently on other SMA therapy, it will be discontinued prior to administration of Ivivisima; **AND**
    - iii. The individual is clinically stable in their overall baseline health status; **AND**
    - iv. The individual is up to date on all guideline-recommended vaccines; **AND**
    - v. The individual will receive a corticosteroid regimen prior to and following receipt of Ivivisima infusion as per the FDA approved labeling; **AND**
    - vi. The provider will continue to monitor liver function tests, CBC and creatinine after Ivivisima infusion as per FDA approved labeling; **AND**
    - vii. The individual will likely benefit from therapy based on the current status of their disease; **AND**
3. Other information as requested by CHNCT.

**Initial Authorization**

If approved, authorization will be given for a one-time, single-dose intrathecal bolus injection of Ivivisima. Authorization will be valid for 180 days.

**Reauthorization**

N/A

**EFFECTIVE DATE**

This Policy is effective for prior authorization requests for Ivivisima for HUSKY Health Program individuals on or after May 1, 2026.

**LIMITATIONS**

N/A

**CODES**

Code	Description
J3490	Unclassified drugs
J3590	Unclassified biologics
C9399	Unclassified drugs or biologicals

**DEFINITIONS**

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1. **HUSKY A:** Connecticut children and their parents or a relative caregiver; and pregnant women may qualify for HUSKY A (also known as Medicaid). Income limits apply.
2. **HUSKY B:** Uninsured children under the age of 19 in higher income households may be eligible for HUSKY B (also known as the Children’s Health Insurance Program) depending on their family income level. Family cost-sharing may apply.
3. **HUSKY C:** Connecticut residents who are age 65 or older or residents who are ages 18-64 and who are blind, or have another disability, may qualify for Medicaid coverage under HUSKY C (this includes Medicaid for Employees with Disabilities (MED-Connect), if working). Income and asset limits apply.
4. **HUSKY D:** Connecticut residents who are ages 19-64 without dependent children and who: (1) do not qualify for HUSKY A; (2) do not receive Medicare; and (3) are not pregnant, may qualify for HUSKY D (also known as Medicaid for the Lowest-Income populations).
5. **HUSKY Health Program:** The HUSKY A, HUSKY B, HUSKY C, HUSKY D and HUSKY Limited Benefit programs, collectively.
6. **HUSKY Limited Benefit Program or HUSKY, LBP:** Connecticut’s implementation of limited health insurance coverage under Medicaid for individuals with tuberculosis or for family planning purposes and such coverage is substantially less than the full Medicaid coverage.
7. **Medically Necessary or Medical Necessity:** (as defined in Connecticut General Statutes § 17b-259b) Those health services required to prevent, identify, diagnose, treat, rehabilitate or ameliorate an individual's medical condition, including mental illness, or its effects, in order to attain or maintain the individual's achievable health and independent functioning provided such services are: (1) Consistent with generally-accepted standards of medical practice that are defined as standards that are based on (A) credible scientific evidence published in peer-reviewed medical literature that is generally recognized by the relevant medical community, (B) recommendations of a physician-specialty society, (C) the views of physicians practicing in relevant clinical areas, and (D) any other relevant factors; (2) clinically appropriate in terms of type, frequency, timing, site, extent and duration and considered effective for the individual's illness, injury or disease; (3) not primarily for the convenience of the individual, the individual's health care provider or other health care providers; (4) not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the individual's illness, injury or disease; and (5) based on an assessment of the individual and his or her medical condition.
8. **Prior Authorization:** A process for approving covered services prior to the delivery of the service or initiation of the plan of care based on a determination by CHNCT as to whether the requested service is medically necessary.

## RESOURCES AND REFERENCES:

- Bodamer O. Spinal Muscular Atrophy. In: UpToDate, Nordli DR, Firth HV, Martin RJ, Dashe JF (Eds), Wolters Kluwer. Updated September 25, 2025. Accessed December 15, 2025
- Efficacy and Safety of Intrathecal OAV101 (AVXS-101) in Pediatric Patients With Type 2 Spinal Muscular Atrophy (SMA) (STEER). ClinicalTrials.gov identifier: NCT05089656. Updated December 8, 2025. Accessed December 16, 2025. <https://clinicaltrials.gov/study/NCT05089656>
- ITVISMA [package insert]. Bannockburn, IL: Novartis Gene Therapies, Inc.; Revised November 2025
- 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*. Published online December 8, 2025. doi:10.1038/s41591-025-04119-2
- Phase IIIb, Open-label, Multi-center Study to Evaluate Safety, Tolerability and Efficacy of OAV101 Administered Intrathecally to Participants With SMA Who Discontinued Treatment With Nusinersen or Risdiplam (STRENGTH). ClinicalTrials.gov identifier: NCT05386680. Updated October 16, 2025.

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Accessed December 16, 2025. <https://clinicaltrials.gov/study/NCT05386680>

- Proud CM, Vũ DC, Wilmshurst JM, et al. Intrathecal onasemnogene abeparvovec in treatment-naive patients with spinal muscular atrophy: a phase 3, randomized controlled trial. *Nat Med*. Published online December 8, 2025. doi:10.1038/s41591-025-04103-w

## PUBLICATION HISTORY

Date		Action Taken
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