

SENTARA HEALTH PLANS

MEDICAL PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request. All other information may be filled in by office staff; **fax to 1-844-668-1550**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If information provided is not complete, correct, or legible, authorization can be delayed.**

For Medicare Members: Medicare Coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: <https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx>. Additional indications may be covered at the discretion of the health plan.

Drug Requested: Itivisma[®] (onasemnogene abeparvovec-brve) **(Medical) (J3590/C9399)**

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member Sentara #: _____ Date of Birth: _____

Prescriber Name: _____

Prescriber Signature: _____ Date: _____

Office Contact Name: _____

Phone Number: _____ Fax Number: _____

NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Form/Strength: _____

Dosing Schedule: _____ Length of Therapy: _____

Diagnosis: _____ ICD Code, if applicable: _____

Weight (if applicable): _____ Date weight obtained: _____

Standard reviews. In checking this box, the timeframe does not jeopardize the life or health of the member or the member's ability to regain maximum function and would not subject the member to severe pain.

Dosing Limits:

A. Quantity Limit (max daily dose) [NDC Unit]:

- 1 carton
- Injection, onasemnogene abeparvovec-brve, per treatment, up to 1.2×10^{14} vector genomes

B. Max Units (per dose and over time) [HCPCS Unit]:

- 1 carton
- 1 billable unit = 1 treatment, up to 1.2×10^{14} vector genomes

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Recommended Dosing: The recommended dose of ITVISMA is 1.2×10^{14} vector genomes (vg). Administer ITVISMA as an intrathecal bolus injection over approximately 1 to 2 minutes.

CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

Coverage will be provided for one treatment course and may NOT be renewed.

- Member is between 2 years and less than 18 years of age
- Medication is prescribed by a physician who has consulted with or who specializes in the management of patients with spinal muscular atrophy and/or neuromuscular disorders
- Prescriber must submit baseline documentation of **ONE** of the following [**NOTE:** Actual completed assessment with results provided must be submitted. Do not send the result number within progress notes]:
 - Hammersmith Functional Motor Scale Expanded (HFMSSE)
 - Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND)
 - Revised Upper Limb Module (RULM)
- Member has had a genetic test confirming the diagnosis of spinal muscular atrophy with bi-allelic pathogenic variants in the survival motor neuron 1 (SMN1) gene (**submit documentation**) [**NOTE:** Pathogenic variants may include homozygous deletion, compound heterozygous mutation, or a variety of other rare mutations and absence of the c.859G>C single base substitution modification in exon 7 of the survival motor neuron 2 (SMN2) gene]
- Member has < 3 copies of the survival motor neuron 2 (SMN2) gene
- Member does **NOT** have advanced disease (i.e., complete limb paralysis, invasive ventilation, awake noninvasive ventilation for >6 hours during a 24-hour period, noninvasive ventilation for >12 hours during a 24-hour period, scoliosis with Cobb angle >40 degrees)
- Member has no serious concomitant illness (for example, severe liver or kidney disease, symptomatic cardiomyopathy, active infection)
- According to the prescribing physician, member has started or will receive systemic corticosteroids equivalent to oral prednisolone at a dose of 1 mg/kg per day commencing 1 day prior to Itvisma[®] infusion and for a total of 30 days
- Baseline anti-AAV9 antibody titers are $\leq 1:50$ (**submit documentation**)
- Member has undergone a liver function assessment within the last 30 days and meets **ALL** the following (**submit documentation**):
 - Alanine aminotransferase levels are ≤ 2 times the upper limit of normal
 - Aspartate aminotransferase levels are ≤ 2 times the upper limit of normal
 - Total bilirubin levels are ≤ 2 times the upper limit of normal [**NOTE:** Members with elevated bilirubin levels due to neonatal jaundice are acceptable]
 - Prothrombin time results are ≤ 2 times the upper limit of normal

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- Member has undergone a renal function assessment within the last 30 days and has a creatinine level < 1.0 mg/dL (**submit documentation**)
- A complete blood count has been obtained within the last 30 days and the member meets **BOTH** of the following (**submit documentation**):
 - White blood cell count is $\leq 20,000$ cells per mm^3
 - Hemoglobin levels are between 8 g/dL and 18 g/dL
- Member has **NOT** received Zolgensma[®] or Itvisma[®] in the past (**verified by medical paid claims**)
[**NOTE**: Verify through claims history that the member has not previously received Zolgensma[®] or Itvisma[®]. If no claim for Zolgensma[®] or Itvisma[®] is present, the prescribing physician confirms that the member has not previously received Zolgensma[®] or Itvisma[®]]
- Medication will **NOT** be used in combination with other agents for SMA (e.g., Spinraza[®], Evrysdi[®], Zolgensma[®])

Medication being provided by (check box below that applies):

- Location/site of drug administration:** _____
NPI or DEA # of administering location: _____

OR

- Specialty Pharmacy**

For urgent reviews: Practitioner should call Sentara Health Plans Pre-Authorization Department if they believe a standard review would subject the member to adverse health consequences. Sentara Health Plan's definition of urgent is a lack of treatment that could seriously jeopardize the life or health of the member or the member's ability to regain maximum function.

*****Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.*****
****Previous therapies will be verified through pharmacy paid claims or submitted chart notes.****