Itvisma® (onasemnogene abeparvovec-brve) (Intrathecal)

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I. Length of Authorization

- Initial: Prior authorization validity will be provided initially for one treatment course (1 dose).
- Renewal: Prior authorization validity may NOT be renewed.

II. Dosing Limits

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

- 1 treatment of 1.2×10^{14} vg/3 mL

III. Initial Approval Criteria

Submission of supporting clinical documentation (including but not limited to medical records, chart notes, lab results, and confirmatory diagnostics) related to the medical necessity criteria is REQUIRED on all requests for authorizations. Records will be reviewed at the time of submission as part of the evaluation of this request. Please provide documentation related to diagnosis, step therapy, and clinical markers (i.e., genetic, and mutational testing) supporting initiation when applicable. Please provide documentation via direct upload through the PA web portal or by fax**.** Failure to submit the medical records may result in the denial of the request due to inability to establish medical necessity in accordance with policy guidelines.

Prior authorization validity is provided in the following conditions:

Spinal Muscular Atrophy (SMA) † Φ [1-11]

- Member must be at least 2 years of age; **AND**
- Member has a diagnosis of 5q spinal muscular atrophy confirmed by either bi-allelic deletion or dysfunctional point mutation of the *survival motor neuron 1 (SMN1)* gene; **AND**
- Patient must not have advanced disease (i.e., complete limb paralysis, permanent ventilation support, etc.); **AND**
    - Member is treatment-naïve for any SMN-targeting agents for SMA (e.g., nusinersen, risdiplam, etc.) AND is able to sit independently but has never had the ability to walk independently; **OR**

- Member has received prior SMN-targeting agents for SMA (e.g., nusinersen, risdiplam, etc.) AND has one or more of the following:
  - Able to sit independently, but has never had the ability to walk independently; **OR**
  - Has 3 or fewer copies of *SMN2* gene; **OR**
  - Achieved and subsequently lost the ability to walk independently; **AND**
- Will only be administered intrathecally using a lumbar puncture by healthcare professionals (e.g., interventional radiologist or neurologist) experienced in performing lumbar punctures; **AND**
- Member is clinically stable in their overall baseline health status (e.g., hydration and nutritional status, respiratory status, etc.) prior to administration; **AND**
- Member does not have an active infection, including clinically important localized infections; **AND**
- Member must have a baseline anti-AAV9 antibody titer of ≤ 1:50 measured by ELISA; **AND**
- Baseline liver function will be assessed prior to initiating therapy and will continue to be monitored for at least 3 months after therapy and as clinically indicated; **AND**
- Baseline platelet counts will be assessed prior to initiating therapy and will continue to be monitored on a regular basis (i.e., at least weekly for the first month and as clinically indicated until platelet counts return to baseline); **AND**
- Member is up to date with all vaccinations (including seasonal prophylaxis against respiratory syncytial virus (RSV), in accordance with current vaccination guidelines, prior to initiating therapy; **AND**
- Used concomitantly with systemic corticosteroids (see dosage/administration below); **AND**
- Member will be considered for neurologic or cardiac evaluation based on clinical presentation; **AND**
- Member must not have previously received treatment with SMA gene therapy (e.g., onasemnogene abeparvovec-xioi [Zolgensma], etc.); **AND**
- Will not be used in combination with other SMN-targeting agents for SMA (e.g., nusinersen, risdiplam, onasemnogene abeparvovec-xioi, etc.)

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Φ Orphan Drug

IV. Renewal Criteria [1]

- Duration of authorization has not been exceeded (refer to Section I)

V. Dosage/Administration [1]

Indication	Dose

Spinal Muscular Atrophy	**Preparing for Administration:** • One day prior to Itvisma injection, begin administration of systemic corticosteroids equivalent to oral prednisolone at 1 mg/kg of body weight per day for a total of 30 days, refer to prescribing information for full recommended corticosteroid dosing regimen. **Itvisma Injection:** • Administer Itvisma as an intrathecal bolus injection over approximately 1 to 2 minutes • The recommended dose of ITVISMA is 1.2×10^{14} vector genomes (vg).
NOTE (Vial Preparation): • Itvisma should be prepared aseptically. • Thaw in the refrigerator for approximately 4 hours, or at room temperature for approximately 1 hour. If thawed in the refrigerator, remove from refrigerator on day of dosing. Do not use unless it is thawed. DO NOT REFREEZE. • Prior to intrathecal injection, Itvisma should be brought to room temperature. DO NOT SHAKE. • When thawed, Itvisma is clear to slightly opaque, colorless to faint white liquid, free of particles. After withdrawal from the vial, a visual inspection is required. Do NOT use if particulates, cloudiness, or discoloration are visible. • Immediately prior to dosing, draw the content from the vial into the syringe, remove air from syringe, confirm the dose volume of 3 mL in the syringe, cap syringe and deliver to patient injection location. • Once dose is drawn into the syringe, it may be held in the refrigerator at 2°C to 8°C (36°F to 46°F) for up to 24 hours, including a 5-hour maximum time out-of-refrigeration allowance within the 24-hour period. Discard the vector-containing syringe if not injected within this time.	

VI. Billing Code/Availability Information

HCPCS code:

- J3590 – Unclassified biologics
- C9399 – Unclassified drugs or biologicals (hospital outpatient use)

NDC(s):

- Itvisma carton containing one 1.2×10^{14} vg/3 mL (4×10^{13} vg/mL) single-dose vial.
    - NDC Number 71894-0200-xx

VII. References

1. Itvisma [package insert]. Bannockburn, IL; Novartis Gene Therapies, Inc., November 2025. Accessed November 2025.
2. Proud, C., D. Vũ, J. Wilmshurst, O. Sanmaneechai, S. Gulati, H. Xiong, H. Ceja Moreno et al. "415PIntrathecal onasemnogene abeparvovec for patients with spinal muscular atrophy: phase 3, randomized, sham-controlled, double-blind STEER study." *Neuromuscular Disorders* 53 (2025): 105578..
3. Wang CH, Finkel RS, Bertini ES, et al. Consensus statement for standard of care in spinal muscular atrophy. J Child Neurol. 2007 Aug;22(8):1027-49.
4. Prior TW, Leach, ME, Finanger E. Spinal muscular atrophy. GeneReviews. www.ncbi.nlm.nih.gov/books/NBK1352/. Initial Posting: February 24, 2000; Last Revision: September 19, 2024. Accessed on November 22, 2024.

Appendix A – Non-Quantitative Treatment Limitations (NQTL) Factor Checklist

Non-quantitative treatment limitations (NQTLs) refer to the methods, guidelines, standards of evidence, or other conditions that can restrict how long or to what extent benefits are provided under a health

plan. These may include things like utilization review or prior authorization. The utilization management NQTL applies comparably, and not more stringently, to mental health/substance use disorder (MH/SUD) Medical Benefit Prescription Drugs and medical/surgical (M/S) Medical Benefit Prescription Drugs. The table below lists the factors that were considered in designing and applying prior authorization to this drug/drug group, and a summary of the conclusions that Prime's assessment led to for each.

Factor	Conclusion
Indication	Yes: Consider for PA
Safety and efficacy	Yes: Consider for PA
Potential for misuse/abuse	No: PA not a priority
Cost of drug	Yes: Consider for PA

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
G12.0	Infantile spinal muscular atrophy, type I [Werdnig-Hoffmann]
G12.1	Other inherited spinal muscular atrophy
G12.25	Progressive spinal muscle atrophy
G12.8	Other spinal muscular atrophies and related syndromes
G12.9	Spinal muscular atrophy, unspecified

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

The preceding information is intended for non-Medicare coverage determinations. 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 Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCA/LCD): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC