Medical Policy

BlueCross BlueShield Kansas
An Independent licensee of the Blue Cross Blue Shield Association

Title: Itvisma

Professional / Institutional
Original Effective Date: July 23, 2026
Latest Review Date:
Current Effective Date: July 23, 2026

State and Federal mandates and health plan member contract language, including specific provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage. To verify a member's benefits, contact Blue Cross and Blue Shield of Kansas Customer Service.

The BCBSKS Medical Policies contained herein are for informational purposes and apply only to members who have health insurance through BCBSKS or who are covered by a self-insured group plan administered by BCBSKS. Medical Policy for FEP members is subject to FEP medical policy which may differ from BCBSKS Medical Policy.

The medical policies do not constitute medical advice or medical care. Treating health care providers are independent contractors and are neither employees nor agents of Blue Cross and Blue Shield of Kansas and are solely responsible for diagnosis, treatment and medical advice.

If your patient is covered under a different Blue Cross and Blue Shield plan, please refer to the Medical Policies of that plan.

POLICY AGENT SUMMARY – MEDICAL PRIOR AUTHORIZATION

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 × 1014 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.

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

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); ǂ Compendia Recommended Indication(s); Φ Orphan Drug

IV. Renewal Criteria [1]

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

Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

CLINICAL RATIONALE

See package insert for FDA preshttps://dailymed.nlm.nih.gov/dailymed/index.cfm

CODING

The following codes for treatment and procedures applicable to this policy are included below for informational purposes. This may not be a comprehensive list of procedure codes applicable to this policy.

Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

The code(s) listed below are medically necessary ONLY if the procedure is performed according to the "Policy" section of this document.

HCPCS code:

- J3405- Injection, onasemnogene abeparvovec[1]brve, per treatment

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

REVISIONS	
Posted: 06-23-2026 Effective: 07-23-2026	New medical policy added to the bcbsks.com web site. Policy is maintained by Prime Therapeutics LLC.

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.