YouthCare
HealthChoice Illinois

Clinical Policy: Onasemnogene Abeparvovec (Zolgensma), Onasemnogene Abeparvovec-brve (Itvisma)

Reference Number: IL.PHAR.421
Effective Date: 10.08.20
Last Review Date: 12.1.25
Line of Business: Medicaid

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Onasemnogene abeparvovec xioi (Zolgensma®), Onasemnogene abeparvovec-brve (Itvisma®) are an adeno-associated virus (AAV) vector-based gene therapy.

FDA Approved Indication(s)

Zolgensma is indicated for the treatment of pediatric patients less than 2 years of age with spinal muscular atrophy (SMA) with bi-allelic mutations in survival motor neuron 1 (SMN1) gene.

Itvisma is indicated for the treatment of spinal muscular atrophy (SMA) in adult and pediatric patients ≥ 2 years of age with confirmed mutation in the *SMN1* gene.

Limitation(s) of use:

- The safety and effectiveness of repeat administration of Zolgensma and Itvisma have not been evaluated.
- The use of Zolgensma and Itvisma in patients with advanced SMA (e.g., complete paralysis of limbs, permanent ventilator dependence) has not been evaluated.

All requests reviewed under this policy require Precision Drug Action Committee (PDAC) Utilization Management Review. Refer to CC.PHAR.21 for process details.

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that Zolgensma and Itvisma are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Spinal Muscular Atrophy (must meet all)**:**

**Only for initial treatment dose; subsequent doses will not be covered.*

1. Diagnosis of SMA confirmed by the presence of one of the following (a or b):
   a. If request is for Zolgensma:
      i. Diagnosis of spinal muscular atrophy (SMA) confirmed with documentation of bi-allelic mutations in the SMN1 gene 2)
   b. If request is for Itvisma one of the following (i, ii, or iii)
      i. Homozygous deletions of SMN1 gene (e.g., absence of the SMN1 gene);

ii. Homozygous mutation in the SMN1 gene (e.g., biallelic mutations of exon 7);
iii. Compound heterozygous mutation in the SMN1 gene (e.g., deletion of SMN1 exon 7 (allele 1) and mutation of SMN1 (allele 2));

2. Genetic testing quantifying number of copies of SMN2 gene, and one of the following (a or b):
   a. If request is for **Zolgensma**, documentation confirming 4 or fewer copies of the SMN2 gene;
   b. If request is for **Itvisma**, documentation confirming two or three copies of SMN2 gene;
3. Prescriber is board certified in one of the following pediatric specialties or subspecialties: neurology, pulmonology, orthopedics, neonatal-perinatal medicine, clinical genetics and genomics, physical medicine and rehabilitation, neuromuscular medicine, or neurodevelopmental disabilities;
4. Member meets one of the following (a or b):
   a. If request is for **Zolgensma**, then both of the following (i and ii):
      i. Age < 2 years;
      ii. Participant has reached full-term gestational age
   b. If request is for **Itvisma**, then all of the following (i, ii, iii, iv, and v):
      i. Age 2 years to < 18 years;
      ii. If treatment-naïve, onset of symptoms after 6 months and before 18 months;
      iii. Documentation that member is able to sit independently;
      iv. Documentation that member never had the ability to walk independently;
      v. Documentation of one of the following baseline scores (1, 2, 3, 4, or 5; *see Appendix D*):
         1. Hammersmith functional motor scale expanded (HFMSE) score;
         2. Revised Hammersmith Scale (RHS);
         3. Upper Limb Module (ULM)
         4. Revised Upper Limb Module (RULM);
         5. 6-Minute Walk Test (6MWT);
5. Documentation of both of the following (a and b):
   a. Baseline laboratory tests demonstrating Anti-AAV9 antibody titers ≤ 1:50 as determined by ELISA binding immunoassay;
   b. AST, ALT, total bilirubin, prothrombin time, platelet count, and troponin I levels within 30 days of request;
6. If request is for Zolgensma, must meet all of the following (a, b:
   a. Participant does not have advanced SMA, AND does not have complete paralysis of limbs, AND is breathing independently (there are no studies which show Zolgensma reliably restores normal independent breathing in a patient requiring chronic respiratory support - BiPAP, CPAP, or mechanical ventilation)
   b. Member will not be approved for concomitant treatment with nusinersen (Spinraza) or risdipam (Everysdi) following Zolgensma infusion (current authorizations for risdiplam or nusinersen will be discontinued upon Zolgensma approval). Use of nusinersen (Spinraza) or risdiplam (Everysdi) in participants previously treated with Zolgensma will be rarely approved and only in exceptional cases after intense review for compelling medical necessity on a case-by-case basis

7. If request is for Itvisma must meet all of the following (a and b):
   a. Member does not have advanced SMA as defined by one of the following:
      i. Member does not have complete paralysis of limbs, invasive ventilation, awake noninvasive ventilation for 6 hours or more during a 24-hour period, tracheostomy, or non-invasive ventilation for 12 hours or more during a 24-hour period;
   b. If the member is currently on Spinraza or Evrysdi, one of the following (i or ii):
      i. Provider must submit evidence of clinical deterioration (e.g., sustained decrease in CHOP-INTEND or HFMSE score over a period of 3 to 6 months) upon completion of all loading doses of Spinraza/Evrysdi;
      ii. Documentation of provider attestation of clinical deterioration and Spinraza/Evrysdi discontinuation;
8. Member has not been previously treated with Zolgensma or Itvisma;
9. Member does not have presence of prodrome or an active viral infection (*see Appendix D*);
10. Prescriber verifies vaccine schedule has been reviewed and modified, if necessary;
11. Systemic corticosteroids equivalent to oral prednisolone dosed at 1mg/kg per day will be initiated one day prior to infusion for a total of 30 days and continued or tapered per prescribing information based on liver function;
12. Total dose does not exceed a single infusion of one of the following (a or b):
    a. Zolgensma: 1.1×10^{14} vector genomes (vg) per kilogram (kg);

Itvisma: 1.2×10^{14} vg dose does not exceed 1.1×10^{14} vector genomes (vg) per kilogram (kg).**Approval duration: 4 weeks (one time infusion per lifetime)**

B. Other diagnoses/indications (must meet 1 or 2):
1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.PMN.53 for Medicaid.

II. Continued Therapy

A. Spinal Muscular Atrophy

1. Re-authorization is not permitted.

Approval duration: Not applicable

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):

a. For drugs on the PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.PMN.255 for Medicaid; or
b. For drugs NOT on the PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.PMN.16 for Medicaid; or

2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.PMN.53 for Medicaid

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.PMN.53 for Medicaid or evidence of coverage documents;
B. Advanced SMA.
C. SMA Type 4

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

ELISA: enzyme-linked immunosorbent assay
FDA: Food and Drug Administration
HFMSE: Hammersmith functional motor scale expanded
RHS: Revised Hammersmith scale
RULM: Revised upper limb module
SMA: spinal muscular atrophy
SMN: survival motor neuron
ULM: upper limb module
6MWT: 6-minute walk test

Appendix B: Therapeutic Alternatives

Not applicable

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): none reported
- Boxed warning(s): acute serious liver injury (*Zolgensma, Itvisma*) and elevated aminotransferases (*Zolgensma only*)

Appendix D: General Information

- SMA is an autosomal recessive genetic disorder. It is caused by mutations in the SMN1 (survival motor neuron) gene that is found on chromosome 5 (hence the name 5q-SMA). To develop SMA, an individual must inherit two faulty (deletion or mutation) SMN1 genes, one from each parent.
- There are other types of SMA that are not related to chromosome 5 or SMN. Safety and efficacy of Zolgensma in non-SMN-related SMA have not been established.
- SMN-related SMA is classified as type 1 through 4 depending on time of onset. The age of disease onset of symptoms correlates with disease severity: the earlier the age of onset, the greater the impact on motor function. Children who display symptoms at birth or in infancy typically have the lowest level of functioning (type 1). SMA onset in children

(types 2 and 3), teens or adults (type 4) generally correlates with increasingly higher levels of motor function.

- SMN2 gene copy and SMA types
  - SMN2 gene copy numbers are variable in individuals with spinal muscular atrophy. Higher numbers typically correlate with less severe disease.
  - More than 95% of individuals with spinal muscular atrophy retain at least 1 copy of the SMN2 gene
  - About 80% of individuals with Type I spinal muscular atrophy have 1 or 2 copies of the SMN2 gene
  - About 82% of individuals with Type II spinal muscular atrophy have 3 copies of the SMN2 gene
  - About 96% of individuals with Type III spinal muscular atrophy have 3 or 4 copies of the SMN2 gene
- SMA Type I: onset of symptoms (e.g., hypotonia, muscle weakness, weak cry, lack of reflexes, difficulty swallowing, poor head control, round shoulder posture, inability to sit without support, tongue fasciculations, pooling secretions, poor suck and swallow reflexes, increased risk of aspiration, and failure to thrive) prior to the age of 6 months.
- Advanced SMA: complete paralysis of limbs, permanent ventilator dependence
- Permanent Ventilation: requiring invasive ventilation (tracheostomy), or respiratory assistance for 16 or more hours per day (including noninvasive ventilatory support) continuously for 14 or more days in the absence of an acute reversible illness, excluding perioperative ventilation.
- Active infections include HIV, HBC, HCV, Zika, upper or lower respiratory tract infection, non-respiratory tract infection within 2 weeks of administration.
- The CHOP-INTEND score is a validated 16-item, 64-point scale shown to be reliable and sensitive to change over time for SMA Type 1. In a prospective cohort study of SMA type I patients (n = 34), the mean rate of decline in the CHOP-INTEND score was 1.27 points/year (95% CI 0.21-2.33, p = 0.02). A CHOP-INTEND score greater than 40 is considered a clinically meaningful change.
- The HINE Section 2 motor milestone exam is an easily performed and relatively brief standardized clinical neurological examination that is optimal for infants aged between 2 and 24 months with good inter-observer reliability. This endpoint evaluates seven different areas of motor milestone development, with a maximum score between 2-4 points for each, depending on the milestone, and a total maximum score of 26 points.
- The HFSME score combines the Hammersmith Functional Motor Scale with a 13-item expansion module for ability to distinguish motor skills among individuals who may be older or with SMA types II and III. Each item is graded from 0 to 3, with 0 signifying no response, with a total of 66 points. HFMSE has demonstrated reliability and validity in patients with SMA. An increase of greater than 2 points in total score is unlikely in untreated SMA.
- The RHS is an ordinal scale which consist of 33 items with grades of 0,1 and 2. For individuals who can achieve the task without any compensation it is given a score of 2. For those who only attempt the movement or finish it with some form of compensation is scored 1 and sore of 0 is given when patients are unable to perform any part of the item. The total maximum score is 69 points.

- The RULM is a set of 19 tasks that measure motor function in non-ambulatory SMA patients. Each task is assessed with a 3-point ordinal scale, with a total maximum score of 37 points. Meanwhile, the maximum score for ULM was 18.
- The 6MWT is a clinical outcome measure for ambulatory SMA that has been determined to be functionally meaningful and capable of capturing disease severity.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Onasemnogene abeparvovec-xioi (Zolgensma)	Administer Zolgensma as a single-dose IV infusion over 60 minutes at the dose of 1.1×10^{14} vg/kg. One day prior to Zolgensma infusion, begin administration of systemic corticosteroids equivalent to oral prednisolone at 1 mg/kg/day for at least a total of 30 days. Afterwards, evaluate liver function. If no liver abnormalities, taper corticosteroids over the next 28 days. If liver abnormalities persist, continue systemic corticosteroids until resolution then taper over the next 28 days. If liver function abnormalities continue to persist ≥ 2 × ULN after the 30-day period of systemic corticosteroids, promptly consult a pediatric gastroenterologist or hepatologist	One dose per lifetime
Onasemnogene abeparvovec-brve (Itvisma)	Administer Itvisma as an intrathecal bolus injection over approximately 1 to 2 minutes through the lumbar puncture needle at the dose of 1.2×10^{14} vg. One day prior to Itvisma infusion, begin administration of systemic corticosteroids equivalent to oral prednisolone at 1 mg/kg/day for at least a total of 30 days. Afterwards, evaluate liver function. If no liver abnormalities, taper corticosteroids over the next 28 days. If liver abnormalities persist, continue systemic corticosteroids until resolution then taper over the next 28 days. If at any time patients do not respond adequately to the equivalent of 1 mg/kg/day oral prednisolone, based on the patient's clinical course, prompt consultation with a gastroenterologist or	One dose per lifetime

Indication	Dosing Regimen	Maximum Dose
	hepatologist and adjustment to the recommended corticosteroid regimen may be considered.	

VI. Product Availability

Drug Name	Availability
Onasemnogene abeparvovec-xioi (Zolgensma)	• Zolgensma is shipped frozen in 10 mL vials with either 5.5 mL or 8.3 mL fill volumes. Each vial has a nominal concentration is 2.0 x 10^{13} vg/mL. • The customized kits come in differing vial quantities based on the patient's weight in kilograms as reflected within the package insert.
Onasemnogene abeparvovec-brve (Itvisma)	Single dose vial: 1.2 x 10^{14} vg of onasemnogene abeparvovec in 3 mL of suspension

VII. References

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2. Itvisma Prescribing Information. Bannockburn, IL: Novartis Gene Therapies, Inc.; November 2025. Available at: https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products/itvisma. Accessed December 3, 2025.
3. Mendell JR, Al-zaidy S, Shell R, et al. Single-Dose Gene-Replacement Therapy for Spinal Muscular Atrophy. *N Engl J Med*. 2017;377(18):1713-1722.
4. Institute for Clinical and Economic Review (ICER). Final Evidence Report – Spinraza and Zolgensma for spinal muscular atrophy: effectiveness and value. Available at: https://icer.org/wp-content/uploads/2020/10/ICER_SMA_Final_Evidence_Report_110220.pdf. Accessed February 14, 2024.
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8. Maitre NL, Chorna O, Romeo DM, and Guzzetta A. Implementation of the Hammersmith Infant Neurological Examination in a High-Risk Infant Follow-Up Program. *Pediatric Neurology.* 2016; 65:31-38.
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12. National Institute for Health and Care Excellence. Onasemnogene abeparvovec for treating spinal muscular atrophy. July 2021. Available at: www.nice.org.uk/guidance/hst15. Accessed February 14, 2024.
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14. Kichula EA, Proud CM, Rarrar MA, et al. Expert recommendations and clinical considerations in the use of onasemnogene abeparvovec gene therapy for spinal muscular atrophy. Muscle & Nerve. 2021;64:413–427. 2021; DOI: 10.1002/mus.27363.

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J3399	Injection, onasemnogene abeparvovec-xioi, per treatment, up to 5x10^15 vector genomes

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	06.11.19	08.19
2Q 2020 annual review: no significant changes; clarified advanced SMA definition in initial approval criteria regarding permanent ventilation dependence; clarified that clinical deterioration from Spinraza should be upon all loading doses have been completed; references reviewed and updated.	04.28.20	05.20
Updated criteria language to restrict concomitant use with Evrysdi and require evidence of clinical deterioriation prior to switching; references reviewed and updated.	08.25.20	08.20
Policy created, adapted from CP.PHAR.421 **Onasemnogene Abeparvovec (Zolgensma)** for migration to HFS PDL. **Removed**: If the member is currently on Evrysdi, must meet the following (a and b):	10.08.20	

Reviews, Revisions, and Approvals	Date	P&T Approval Date
a. Provider must submit evidence of clinical deterioration (e.g., sustained decrease in CHOP-INTEND score over a period of 3 to 6 months); b. Documentation of provider attestation of clinical deterioration and Evrysdi discontinuation; 2. Documentation of one of the following baseline scores (*see Appendix D*) (a or b): a. Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorder (CHOP-INTEND) score; b. Hammersmith Infant Neurological Examination (HINE) Section 2 motor milestone score; 3. Genetic testing confirming 1, 2, or 3 copies of SMN2 gene; 4. Genetic testing confirms the presence of one of the following (a, b, or c): a. Homozygous deletions of SMN1 gene (e.g., absence of the SMN1 gene); b. Homozygous mutation in the SMN1 gene (e.g., biallelic mutations of exon 7); c. Compound heterozygous mutation in the SMN1 gene (e.g., deletion of SMN1 exon 7 (allele 1) and mutation of SMN1 (allele 2)); 5. Total dose does not exceed 1.1 x 10^{14} vector genomes (vg) per kilogram (kg). 6. If the member is currently on Spinraza, must meet the following (a and b): a. Provider must submit evidence of clinical deterioration (e.g., sustained decrease in CHOP-INTEND score over a period of 3 to 6 months) upon completion of all loading doses of Spinraza; b. Documentation of provider attestation of clinical deterioration and Spinraza discontinuation; Added:		

Reviews, Revisions, and Approvals	Date	P&T Approval Date
7. Member has reached full-term gestational age 8. Prescribed by board certified in one of the following pediatric specialties or subspecialties: neurology, pulmonology, orthopedics, neonatal-perinatal medicine, clinical genetics and genomics, physical medicine and rehabilitation, neuromuscular medicine, or neurodevelopmental disabilities. 9. Prescriber verifies member vaccine schedule has been reviewed and modified, if necessary. 10. Systemic corticosteroids equivalent to oral prednisolone dosed at 1mg/kg per day will be initiated one day prior to infusion for a total of 30 days and continued or tapered per prescribing information based on liver function. 11. After 30 days of required systemic-corticosteroid treatment, prescriber provides clinical update including AST, ALT, total bilirubin levels, prothrombin time, platelet count, and troponin I levels.		
3Q 2021 Annual Review References reviwed and updated	7.2.21	
2Q 2023 annual review: no significant changes; template changes applied to other diagnoses/indications, HCPS code added, references reviewed and updated.	4.15.23	
2Q 2024 annual review: no significant changes; updated boxed warnings description to “serious liver injury and acute liver failure” to align with prescriber information; references reviewed and updated.	5.31.24	
2Q 2025 annual review: for initial approval criteria, added option of “four copies of SMN2 gene, determined by a quantitative assay that is able to distinguish between four SMN2 gene copies and five or more SMN2 gene copies” to SMN2 gene copy criteria as supported by practice guidelines; corrected inconsistencies with MDN.CP.PHAR.421; updated age to <2; references reviewed and updated.	5.8.25	
1Q2026 Annual review: added newly approved dosage form, Itvisma, with the following revisions: added documentation for inability to walk independently per study protocol; defined advanced SMA for 2	2.26.26	

Reviews, Revisions, and Approvals	Date	P&T Approval Date
years and older; added SMA type 4 in section III; required or 3 SMN2 copies; updated Zolgensma criteria per HFS Zolgensma citeria update (1/1/26); references reviewed and updated.		

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Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.