Medical Benefit Drug Policy

Zolgensma (onasemnogene abeparvovec-xioi) suspension

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Instructions for Use

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Related Policies

- N/A

Coverage Rationale

Spinal Muscular Atrophy

For coverage of Zolgensma (onasemnogene abeparvovec-xioi) suspension, the following will be required:

- Submission of medical records (e.g., chart notes) confirming the presence of a SMN1 gene mutation as detected by an FDA-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)
- One of the following:
  - Both of the following:
    - Diagnosis of symptomatic spinal muscular atrophy (SMA) confirmed by a neurologist with expertise in the diagnosis and treatment of SMA **and**
    - Patient is less than or equal to 2 years of age **or**
  - All of the following:
    - Diagnosis of SMA based on the results of SMA newborn screening **and**
    - Patient has 4 copies or less of Survival of Motor Neuron 2 (*SMN2*) **and**
    - Patient is less than or equal to 6 months of age **and**
- Patient is not dependent on invasive ventilation **and**
- Patient is not dependent on the use of non-invasive ventilation beyond use for naps and nighttime sleep **and**
- Submission of medical records (e.g., chart notes) confirming anti-AAV9 antibody titers are less than or equal to 1:50 **and**
- Both of the following:
  - Provider attests that the patient has never received onasemnogene abeparvovec treatment in their lifetime
  - Provider attests that the patient is not receiving concomitant survival motor neuron (SMN) modifying therapy for the treatment of SMA (e.g. Spinraza, Evrysdi) **and**
- Prescribed by a neurologist with expertise in the diagnosis and treatment of SMA

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

HCPCS Code	Description
J3399	Injection, onasemnogene abeparvovec-xioi, per treatment, up to $5x10^{15}$ vector genomes

ICD-10 Code	Description
G12.0	Infantile spinal muscular atrophy, type I [Werdnig-Hoffman]
G12.1	Other inherited spinal muscular atrophy
G12.8	Other SMAs and related syndromes
G12.9	SMA, unspecified

Background

Onasemnogene abeparvovec is a gene therapy that uses a viral vector to deliver a copy of the gene encoding the human SMN protein. The virus enters the nucleus of neurons and forms an episome (a DNA molecule that replicates independently of chromosomal DNA). The episome is transcribed and translated to produce the missing SMN protein.

Spinal muscular atrophy (SMA) is a serious neuromuscular disease characterized by the degeneration of motor neurons in the spinal cord and brainstem, leading to progressive muscular atrophy and weakness (Bodamer 2025, MedlinePlus 2018). SMA is an autosomal recessive inherited disorder. The overall incidence is between 5 and 13 per 100,000 live births, and 1 person in 45 to 100 is a carrier of a mutation that can cause SMA (Bodamer 2025). There are several forms of SMA with varying degrees of severity and ages of onset (Bodamer 2025, MedlinePlus 2018, Glascock et al 2018, Rao et al 2018).

The *SMN1* gene is responsible for the production of SMN protein, which is ubiquitously expressed in all cells throughout fetal and postnatal development. Deletion or mutations in the *SMN1* gene lead to a shortage of the protein. Without this protein, motor neurons degenerate, and nerve impulses are not carried between the brain and muscles, resulting in characteristic muscle weakness and impaired movement (Bodamer 2025, MedlinePlus 2018). In SMA type 1, untreated patients have severe weakness and hypotonia and never gain the ability to sit unsupported. Patients with SMA type 1 typically have an onset of symptoms between the age of 0 and 6 months and have a typical lifespan of < 2 years without permanent ventilation. Patients with SMA type 2 (intermediate), 3 (mild), or 4 (adult-onset) experience a later onset and less severe symptoms usually characterized by varying degrees of muscle weakness. Type 0 (prenatal) is the rarest and most severe form, with newborns typically living for < 6 months.

There is also a modifying (or “backup”) gene called *SMN2*, which generates a smaller amount of functional SMN protein. The number of *SMN2* gene copies varies among individuals, and patients with a higher number of *SMN2* gene copies tend to have a less severe SMA type (Bodamer 2025, Calucho et al 2018).

Clinical Evidence

Zolgensma (onasemnogene abeparvovec-xioi)
The FDA approval of Zolgensma was based on the results from START, a Phase 1, OL, SA, dose-escalation study in 15 patients with SMA type 1 with 1 or 2 copies of the *SMN2* gene. There were 2 dosing cohorts; 3 patients received 6.7 x

10^{13} vg/kg and 12 patients received the therapeutic dose of 1.1 x 10^{14} vg/kg, via IV injection. Key outcomes from the therapeutic dose group are as follows (Mendell et al 2017, Mendell et al 2021):

- All therapeutic-dose patients remained alive and free of permanent ventilation at long-term follow-up (mean, 4.5 years after dosing in patients 4.3 to 5.6 years of age).
- All therapeutic-dose patients maintained previously achieved milestones over years of follow-up.
- Two children continued to gain new milestones, including standing with assistance, even years after the single treatment.
- No child receiving the therapeutic dose lost previously acquired motor abilities.
- No treatment-related deaths or discontinuations occurred.

The efficacy of Zolgensma in patients with SMA Type 1 (and 1 to 2 *SMN2* gene copies) was demonstrated in the Phase 3 STR1VE trial. In STR1VE, 22 patients < 6 months of age received a one-time IV dose of Zolgensma 1.1 x 10^{14} vg/kg. The mean patient age at study day 1 was 3.7 months (Day et al 2019).

- For the primary endpoint of independent sitting ≥ 30 seconds at 18 months, 13/22 (59%) patients achieved functional independent sitting. This compares to 0/23 untreated infants in the Pediatric Neuromuscular Clinical Research Network (PNCR) natural history cohort.
- For the 14 patients who achieved independent sitting, this developmental milestone was achieved at a median patient age of 12.6 months (interquartile range [IQR], 10.2 to 15.2). Twenty of 22 patients (91%; 95% CI, 79 to 100) survived without requirement of permanent ventilation at 14 months of age, compared with 6/23 (26%) patients in the PNCR natural history cohort (95% CI, 8 to 44; $p < 0.0001$).
- At age 18 months, 18 (82%; 97.5% CI, 59.7 to 100.0) patients did not use ventilatory support vs 0/23 patients in PNCR cohort; $p < 0.0001$). Overall, 15 (68%) patients did not use non-invasive ventilatory support at any time during the STR1VE study.
- Nine (41%; 97.5% CI, 21 to 100; $p < 0.0001$) patients maintained the ability to thrive (vs 0 patients in PNCR).
- Fourteen (64%) patients maintained a weight consistent with age at 18 months.

The efficacy of Zolgensma was demonstrated in the Phase 3 SPR1NT trial, a Phase 3, OL, SA, MC study in 14 presymptomatic patients with SMA with 2 copies of the SMN2 gene. Patients received a one-time IV dose of Zolgensma 1.1 x 10^{14} vg/kg (Strauss et al 2022).

- For the co-primary endpoint of independent sitting at 18 months, all 14 patients achieved the primary endpoint of independent sitting for ≥ 30 seconds at any visit up to 18 months of age. When comparing these results to PNCR historical cohort, 0/23 untreated patients with SMA type 1 achieved this milestone ($p < 0.0001$).
- For the co-primary endpoint of standing at 18 months, all 14 (100%) patients achieved motor milestones as defined by both the Bayley Scale of Infant Development version 3 (BSID-III) and the World Health Organization Multicentre Growth Reference Study (WHO-MGRS).
- For the co-primary endpoint of walking at 18 months, 9/14 (64%) patients walked independently at a median age of 526 (range, 367 to 564) days based on BSID-III criteria and 10/14 patients (71%) walked alone based on WHO-MGRS criteria, at a median age of 493 (range, 367 to 564) days.
- For the secondary endpoint of permanent ventilation, all 14 patients were alive and free of permanent ventilation at 14 months of age, compared to 6/23 (26%) patients in the PNCR cohort ($p < 0.0001$).
- For the secondary endpoint of ability to maintain weight, 13/14 (93%) patients maintained weight at or above the third percentile without the need for non-oral/mechanical feeding support at all visits up to 18 months of age ($p < 0.0001$).
- With regard to safety, the following AEs of interest occurred:
    - Hepatotoxicity: Seven hepatotoxicity-related AEs occurred in 3/14 (21%) patients. All events were mild or moderate, clinically asymptomatic, considered related to treatment, and resolved.
    - Cardiac AEs: Two patients experienced a total of 4 cardiac AEs, all of which were mild or moderate elevations of creatine phosphokinase, creatine phosphokinase-MB, or troponin I that were

asymptomatic and resolved with (n = 1) or without (n = 3) a temporary increase in the prednisolone dose.
    - Thrombocytopenia and Thrombocytopenia in Thrombotic Microangiopathy (TMA): Three thrombocytopenia-related AEs occurred in 3 patients (n = 1, thrombocytopenia, n = 1, vessel puncture site bruise, and n = 1, platelet count decreased), all of which were mild and resolved without intervention. No cases of TMA were reported.

Clinical Guidelines

SMA update in best practices: Recommendations for treatment considerations (Schroth et al 2025)
The Health Care Provider Working Group (HCPWG), which includes 17 practicing neurologists (14 in the U.S. and 3 in Europe), 1 U.S. pediatric critical care physician, as well as a community working group of caregivers and patients with SMA, provided best practices/treatment considerations for patients with SMA. Key points from this guidance are listed below as follows.

- When considering initiating treatment for patients newly diagnosed with SMA (either symptomatically or before symptom onset) *SMN2* copy number and age are the 2 important patient characteristics that guide treatment.
    - SMN enhancing treatment should be initiated as soon as feasible for newly diagnosed patients.
    - Infants with 2 *SMN2* copies have an extremely short time during which rapid irreversible motor neuron loss occurs. In contrast, infants with 3 or 4 *SMN2* copies diagnosed before symptom onset may have a somewhat longer yet highly variable time course for irreversible motor neuron loss and the appearance of symptoms. Of note, rapid loss of motor neurons occurs before symptom presentation; therefore, treatment cannot be delayed.
    - Initiating treatment for newly diagnosed SMA is recommended and is considered urgent for all infants with ≤ 4 *SMN2* copies.
- Observations in natural history and clinical trials have shown that the outcomes response to DMTs is positive across all age groups and severity.
- Physical route of administration limitations may drive consideration of initial DMT and may also drive a treatment plan modification from intrathecal administration to a DMT with an alternative route of administration.
    - For example, a patient with complex spine anatomy is at risk for or may have difficulty tolerating the administration of intrathecal DMT.
    - Similarly, patients with underlying liver disease or elevated liver transaminases on initial screening may not be able to receive gene therapies (Itvisma or Zolgensma), as these treatments may exacerbate preexisting liver disease.
- When considering a medication or treatment plan change, unless there is an urgent indication, a treatment and associated patient outcomes should be monitored for a minimum of 6 to 12 months before making a change. Examples of an urgent indication to consider treatment change before a 6 to 12 month trial include significant AEs or intolerance to medication not acceptable to patient or health care provider (HCP), intolerance to medication administration route, significant disease progression as determined by the HCP and patient/caregiver, loss of motor milestones (infancy and young child), or pregnancy.
    - Add-on treatment, such as any SMN-enhancing treatment that is given after receiving Itvisma or Zolgensma and Evrysdi (risdiplam) and Spinraza (nusinersen) given concurrently, is being explored in clinical trials. There are still unanswered questions regarding the possible benefits of add-on treatment, safety, and timing (ie, as to when to add on).
- When determining a treatment plan with an adolescent or adult with SMA, factors such as quality of life, burden vs benefit of treatment, and reproductive issues should be considered.
    - Comorbidities play a significant role such as having complex spine anatomy or underlying renal disease, and reproductive planning also affects decision-making.
    - Expectations for response to treatment for adults have a different focus compared to those for young children. Anticipated outcomes for adults are slowed progression of SMA disease, maintaining current motor function to perform activities of daily living, and optimizing independence. Thus, the effect of SMN-enhancing treatments may require a longer time course to observe, i.e., ≥ 12 months.

- **European consensus statement on gene therapy for spinal muscular atrophy** (Kirschner et al 2024). The statement was updated in 2024 to reflect the growing body of evidence regarding gene therapy in SMA. Key points are as follows:
  - Selection criteria:
    - SMA should be included in newborn screening programs in countries where disease-modifying treatments are available; patients identified by newborn screening should be evaluated by a pediatric neurologist as soon as possible. Disease-modifying treatment should be initiated without delay as soon as symptoms or low SMN2 copy numbers (≤ 3) are detected.
    - Traditional SMA types (0 to 4) alone are not enough to define patients who would most benefit from gene therapy. Age at onset, disease duration, and motor function status are key factors that predict response to treatment in symptomatic patients, whereas treatment decisions for presymptomatic patients should primarily be based on *SMN2* copy number. Data on the efficacy of Zolgensma in older and heavier patients remain limited; for these patients, it is particularly important for physicians to discuss the benefit/risk ratio and to carefully manage parents' or patients' expectations. Risks with gene therapy increase with the dose administered; since dose is proportional to weight and age, heavier and older patients should be treated cautiously. Treatment with other disease-modifying treatments or future intrathecal administration of Zolgensma, if it shows an acceptable efficacy-safety ratio, should be considered as a valuable alternative and discussed with parents.
    - In patients presenting with severe symptomatic disease, there is a high risk of living with severe disability despite the use of gene therapy. Palliative care is recommended as an alternative treatment option in these patients.
    - There is no convincing evidence that combination therapy (e.g., Zolgensma plus nusinersen; Zolgensma plus risdiplam) is superior to any single treatment alone. Before more evidence is available, combinations of approved therapies should not be part of routine care.
  - Structural requirements for administration: Providers performing gene therapy should have broad expertise in the assessment and treatment of SMA according to international standards. In newly diagnosed patients, any delay in treatment should be avoided, and the time frame between diagnosis and initiation of disease-modifying therapy should be as short as possible. Patients with SMA type 1 and/or 2 copies of *SMN2* should be considered medically urgent.
  - Generation of additional evidence: Data regarding safety and effectiveness should be collected for all treated patients. Institutions using Zolgensma should be adequately equipped with resources to provide long-term monitoring. The statement suggests that older and heavier patients should only receive Zolgensma under a rigorous protocol with continuous monitoring of safety and efficacy; use of Zolgensma in patients weighing > 21 kg cannot be recommended.

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

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

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Policy History/Revision Information

Date	Summary of Changes
9/20/2023	Approved by OptumRx P&T Committee
6/19/2024	Annual review. Updated ICD-10 codes and references.
6/18/2025	Annual review. Updated ICD-10 codes, clinical guidelines, and references.
05/14/2026	Annual review. Under coverage rationale, update to include submission of medical records for genetic testing, removed reference to tracheostomy, and replaced "documenting" verbiage with "confirming" to align with standard verbiage throughout. Updated references.

Instructions for Use

This Medical Benefit Drug Policy provides assistance in interpreting standard benefit plans. When deciding coverage, the member specific benefit plan document must be referenced as the terms of the member specific benefit plan may differ from the standard plan. In the event of a conflict, the member specific benefit plan document governs. Before using this policy, please check the member specific benefit plan document and any applicable federal or state mandates. The insurance reserves the right to modify its Policies and Guidelines as necessary. This Medical Benefit Drug Policy is provided for informational purposes. It does not constitute medical advice.

OptumRx may also use tools developed by third parties, to assist us in administering health benefits. OptumRx Medical Benefit Drug Policies are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

Nondiscrimination & Language Access Policy

Discrimination is Against the Law. Aspirus Health Plan, Inc. complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex, (including sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation, gender identity and sex stereotypes), consistent with the scope of sex discrimination described at 45 CFR § 92.101(a)(2). Aspirus Health Plan, Inc. does not exclude people or treat them less favorably because of race, color, national origin, age, disability, or sex.

Aspirus Health Plan, Inc.:
Provides people with disabilities reasonable modifications and free appropriate auxiliary aids and services to communicate effectively with us, such as:

- Qualified sign language interpreters.
- Written information in other formats (large print, audio, accessible electronic formats, other formats).

Provides free language assistance services to people whose primary language is not English, which may include:

- Qualified interpreters.
- Information written in other languages.

If *you* need reasonable modifications, appropriate auxiliary aids and services, or language assistance services, contact the Nondiscrimination Grievance Coordinator at the address, phone number, fax number, or email address below.

If *you* believe that Aspirus Health Plan, Inc. has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, *you* can file a *grievance* with:

Nondiscrimination Grievance Coordinator
Aspirus Health Plan, Inc.
PO Box 1890
Southampton, PA 18966-9998
Phone: 1-866-631-5404 (TTY: 711)
Fax: 763-847-4010
Email: customerservice@aspirushealthplan.com

You can file a *grievance* in person or by mail, fax, or email. If *you* need help filing a *grievance*, the Nondiscrimination Grievance Coordinator is available to help *you*.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at:

U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 509F, HHH Building
Washington, D.C. 20201
1.800.368.1019, 800.537.7697 (TDD)

Complaint forms are available at http://www.hhs.gov/ocr/office/file/index.html. This notice is available at Aspirus Health Plan, Inc.'s website: https://aspirushealthplan.com/webdocs/70021-AHP-NonDiscrim_Lang-Assist-Notice.pdf.

Language Assistance Services

Albanian: KUJDES: Nëse flitni shqip, për ju ka në dispozicion shërbime të asistencës gjuhësore, pa pagesë.Telefononi në 1-800-332-6501 (TTY: 711).

Arabic تنبيه: إذا كنت تتحدث اللغة العربية، فإن خدمات المساعدة اللغوية متاحة لك مجاناً. اتصل بن اعلى رقم الهاتف1-800-332-6501(رقم هاتف الصم والبك : 711)

French: ATTENTION: Si vous parlez français, des services d'aide linguistique vous sont proposés gratuitement. Appelez le 1-800-332-6501 (ATS: 711).

German: ACHTUNG: Wenn Sie Deutsch sprechen, stehen Ihnen kostenlos sprachliche Hilfsdienstleistungen zurVerfügung. Rufnummer: 1-800-332-6501 (TTY: 711).

Hindi: _यान द_: य_द आप ि हंदी बोलते ह_ तो आपके ि लए मु_त म_ भाषा सहायता सेवाएं उपल_ध ह_।1-800-332-6501 (TTY: 711) पर कॉल कर_।

Hmong: LUS CEEV: Yog tias koj hais lus Hmoob, cov kev pab txog lus, muaj kev pab dawb rau koj. Hu rau 1-800-332-6501 (TTY: 711).

Korean: 주의: 한국어를 사용하시는 경우, 언어 지원 서비스를 무료로 이용하실 수 있습니다.1-800-332-6501 (TTY: 711)번으로 전화해 주십시오.

Polish: UWAGA: Jeżeli mówisz po polsku, możesz skorzystać z bezpłatnej pomocy językowej. Zadzwoń pod numer1-800-332-6501 (TTY: 711).

Russian: ВНИМАНИЕ: Если вы говорите на русском языке, то вам доступны бесплатные услуги перевода.Звоните 1-800-332-6501 (телетайп: 711).

Spanish: ATENCIÓN: si habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. Llame al1-800-332-6501 (TTY: 711).

Tagalog: PAUNAWA: Kung nagsasalita ka ng Tagalog, maaari kang gumamit ng mga serbisyo ng tulong sa wika nangwalang bayad. Tumawag sa 1-800-332-6501 (TTY: 711).

Traditional Chinese: 注意：如果您使用繁體中文， 您可以免費獲得語言援助服務。請 致電 1-800-332-6501 (TTY: 711)

Vietnamese: CHÚ Ý: Nếu bạn nói Tiếng Việt, có các dịch vụ hỗ trợ ngôn ngữ miễn phí dành cho bạn. Gọi số 1-800-332-6501 (TTY: 711).

Pennsylvania Dutch: Wann du Deitsch (Pennsylvania German / Dutch) schwetzscht, kannscht du mitaus Koschte ebbergricke, ass dihr helft mit die englisch Schprooch. Ruf selli Nummer uff: Call 1-800-332-6501 (TTY: 711).

Lao: ໂປດຊາບ: ຖ້າວ່າ ທ່ານເວົ້າພາສາ ລາວ, ການບໍລິການຊ່ວຍເຫຼືອດ້ານພາສາ,ໂດຍບໍ່ເສັງຄ່າ, ແມ່ນມີພ້ອມໃຫ້ທ່ານ. ໂທຣ 1-800-332-6501 (TTY: 711).

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