Medical Benefit Drug Policy

Spinraza (nusinersen) Injection

Policy Number: MC/PC 042
Effective Date: July 1, 2025

Instructions for Use

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Coverage Rationale

Spinal Muscular Atrophy (SMA)

For initial coverage of Spinraza (nusinersen) Injection, the following will be required:

- Diagnosis of spinal muscular atrophy (SMA) Type I, II, or III **and**
- Both of the following:
  - The mutation or deletion of genes in chromosome 5q resulting in one of the following:
    - Homozygous gene deletion or mutation (e.g., homozygous deletion of exon 7 at locus 5q13) **or**
    - Compound heterozygous mutation (e.g., deletion of *SMN1* exon 7 [allele 1] and mutation of *SMN1* [allele 2])
  - Patient has at least 2 copies of *SMN2*
- Patient is not dependent on invasive ventilation or tracheostomy **and**
- Patient is not dependent on the use of non-invasive ventilation beyond use for naps and nighttime sleep **and**
- At least one of the following exams (based on patient age and motor ability) has been conducted to establish baseline motor ability:
  - Hammersmith Infant Neurological Exam Part 2 (HINE-2) (infant to early childhood)
  - Hammersmith Functional Motor Scale Expanded (HFMSE)
  - Revised Upper Limb Module (RULM) Test (Non ambulatory)
  - Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP INTEND)
- Prescribed by or in consultation with a neurologist with expertise in the diagnosis and treatment of SMA **and**
- Spinraza is to be administered intrathecally by, or under the direction of, healthcare professionals experienced in performing lumbar punctures **and**
- Patient is not to receive concomitant chronic survival motor neuron (SMN) modifying therapy for the treatment of SMA (e.g., Evrysdi) **and**
- One of the following:
  - Patient has not previously received gene replacement therapy for the treatment of SMA (e.g., Zolgensma) **or**
  - Both of the following:

- Patient has previously received gene therapy for the tr… **nd**
- Documentation of an inadequate response to gene the… east one motor test score over a period of 6 months)

For reauthorization coverage of Spinraza, the following will be required:

- Presence of positive clinical response to therapy from pretreatment baseline status as demonstrated by the most recent results from one of the following exams:
  - One of the following HINE-2 milestones:
    - Improvement or maintenance of previous improvement of at least a 2 point (or maximal score) increase in ability to kick
    - Improvement or maintenance of previous improvement of at least a 1 point increase in any other HINE-2 milestone (e.g., head control, rolling, sitting, crawling, etc.), excluding voluntary grasp
    - Patient exhibited improvement, or maintenance of a previous improvement in more HINE motor milestones than worsening, from pretreatment baseline (net positive improvement)
    - Patient has achieved and maintained any new motor milestones from pretreatment baseline when they would otherwise be unexpected to do so (e.g., sit unassisted, stand, walk) **or**
  - One of the following HFMSE milestones:
    - Improvement or maintenance of a previous improvement of at least a 3 point increase in score from pretreatment baseline
    - Patient has achieved and maintained any new motor milestone from pretreatment baseline when they would otherwise be unexpected to do so (e.g., sit unassisted, stand, walk) **or**
  - One of the following RULM test milestones:
    - Improvement or maintenance of a previous improvement of at least a 2 point increase in score from pretreatment baseline
    - Patient has achieved and maintained any new motor milestone from pretreatment baseline when they would otherwise be unexpected to do so (e.g., sit unassisted, stand, walk) **or**
  - One of the following CHOP INTEND milestones:
    - Improvement or maintenance of a previous improvement of at least a 4 point increase in score from pretreatment baseline
    - Patient has achieved and maintained any new motor milestone from pretreatment baseline when they would otherwise be unexpected to do so (e.g., sit unassisted, stand, walk) **and**
- Patient continues to not be dependent on invasive ventilation or tracheostomy **and**
- Patient continues to not be dependent on the use of non-invasive ventilation beyond use for naps and nighttime sleep **and**
- Prescribed by or in consultation with a neurologist with expertise in the diagnosis and treatment of SMA **and**
- Spinraza is to be administered intrathecally by, or under the direction of, healthcare professionals experienced in performing lumbar punctures **and**
- Patient is not to receive concomitant chronic survival motor neuron (SMN) modifying therapy for the treatment of SMA (e.g., Evrysdi) **and**
- One of the following:
  - Patient has not previously received gene replacement therapy for the treatment of SMA (e.g., Zolgensma) **or**
  - Both of the following:
    - Patient has previously received gene therapy for the treatment of SMA (e.g., Zolgensma) **and**
    - Documentation of an inadequate response to gene therapy (e.g., sustained decrease in at least one motor test score over a period of 6 months)

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
J2326	Injection, nusinersen, 0.1 mg

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

Background

Nusinersen is an antisense oligonucleotide designed to treat spinal muscular atrophy (SMA) caused by mutations in chromosome 5q that lead to SMN protein deficiency. Nusinersen binds to sites within *SMN2* pre-mRNA, promoting inclusion of exon 7 in *SMN2* mRNA transcripts and increasing production of full-length, functional SMN protein (*Finkel et al 2016*).

Spinal muscular atrophy 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, National Institutes of Health [NIH] 2025). SMA is caused by an inherited genetic mutation and is the most common genetic cause of infant mortality (Bodamer 2025).* 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, Glascock et al 2018, NIH 2025, 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 post-natal 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, NIH 2025*). 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

Spinraza (nusinersen)
Key clinical trials supporting the safety and efficacy of nusinersen include ENDEAR, CHERISH, and NURTURE. The pivotal trial ENDEAR (N = 121) was a 13-month, Phase 3, randomized, sham-controlled, double-blind, multicenter trial in patients 7 months or younger who had an onset of SMA symptoms at ≤ 6 months of age and had homozygous deletion or mutation of *SMN1* and 2 copies of the *SMN2* gene (*Finkel et al 2017).* At interim analysis, a higher proportion of patients treated with nusinersen had a motor milestone response than those in the control group (41% vs 0%, p < 0.001), prompting early termination of the trial. The final analysis showed that 51% of the nusinersen-treated group had a motor milestone response, compared with no patients in the control group. Motor milestones reached included achievement of full head control (22%), ability to roll over (10%), ability to sit independently (8%), and ability to stand (1%). A co-primary endpoint of event-free survival also favored nusinersen vs placebo (61% vs 32%; p = 0.005). Patients in the nusinersen group also had a 63% lower risk of death compared with the control group (hazard ratio, 0.37; 95% confidence interval [CI], 0.18 to 0.77; p = 0.004).

CHERISH (N = 126) was a Phase 3, randomized, sham-controlled, double-blind, multicenter trial in patients aged 2 to 12 years with SMA type 2. The primary endpoint was the least-squares mean change from baseline in the Hammersmith Functional Motor Scale-Expanded (HFMSE) score at 15 months of treatment (*Mercuri 2018[b]).* In the pre-planned interim analysis, there was a significant improvement in the HFMSE from baseline to 15 months in the nusinersen group vs the control group (mean difference in change, 5.9 points; 95% CI, 3.7 to 8.1; p < 0.001).
Results of the final analysis were consistent with results of the interim analysis. In the final analysis, 57% of the children in the nusinersen group vs 26% in the control group had an increase from baseline to month 15 in the HFMSE score of at least 3 points (p < 0.001), and the overall incidence of adverse effects was similar in the nusinersen group and the control group (93% vs 100%, respectively).

The NURTURE study is an ongoing, Phase 2, open-label, single-arm trial to evaluate the use of nusinersen in patients with SMA and 2 or 3 copies of *SMN2* who were ≤ 6 weeks of age and asymptomatic at the time of treatment initiation. The primary endpoint was time to death or respiratory intervention (invasive or non-invasive for ≥ 6 hours per day continuously for ≥ 7 days or tracheostomy). At an interim analysis published in 2019, 25 patients had been enrolled, of whom 15 had 2 *SMN2* copies and 10 had 3 *SMN2* copies. At the time of the interim analysis, 4 participants (16%) had utilized a respiratory intervention. All patients were alive and none required permanent ventilation. Efficacy was further supported by the achievement of motor milestones by HINE-2 and motor function by CHOP INTEND. Of note, all patients achieved the milestone of “sitting without support” and 23 of 25 patients (92%) achieved “walking with assistance” (*De Vivo et al 2019*).

An additional interim analysis was performed in 2021 and published in 2023; this analysis reported data through a median 4.9 years of treatment. At the time of this analysis, all 25 infants enrolled in the study were alive and none required permanent ventilation. All children with 3 SMN2 copies achieved all motor milestones; all but 1 milestone in 1 child were achieved within the normal developmental timeframe. All children with 2 SMN2 copies achieved the motor milestone of “sitting without support”; 14 of 15 children achieved “walking with assistance,” and 13 of 15 children achieved “walking alone” (Crawford et al 2023).

An additional trial, EMBRACE, was a randomized, double-blind, sham procedure-controlled trial examining the efficacy of nusinersen in infants and young children with SMA who were ineligible for the pivotal ENDEAR and CHERISH studies. This trial only enrolled 21 patients before it was terminated early based on the benefits demonstrated in an interim analysis of ENDEAR. Despite the early termination, motor milestone responder rates (assessed using HINE-2) were higher among patients receiving nusinersen (93% vs 29% with the sham procedure at the last available assessment) (Acsadi et al 2021).

SMA Newborn Screening Working Group. Treatment algorithm for infants dia screening (*Glascock et al 2018, Glascock et al 2020*).

- Clinical and preclinical data indicate that early treatment will be critical in order to modulate the rapid, progressive degeneration seen in SMA, particularly SMA type 1. Animal studies also show that the best results occur when drugs are given as early as possible.
- Recommendations for the use of SMN-upregulating treatment for patients with a confirmed positive result for SMA on newborn screening are based on the number of *SMN2* copies, as follows:
  - 1 *SMN2* copy: probable SMA type 0. Treatment is recommended if the patient is truly pre-symptomatic. If symptoms are present, physician discretion is recommended. (Most patients with 1 copy of *SMN2* will be symptomatic at birth.)
  - 2 *SMN2* copies: probable SMA type 1. Treatment is recommended.
  - 3 *SMN2* copies: probable SMA type 2 or type 3. Treatment is recommended.
  - 4 *SMN2* copies: probable SMA type 3 or type 4. Treatment is recommended.
  - 5 *SMN2* copies: Waiting to treat is recommended.
- The working group acknowledges that the future availability of new FDA-approved therapies will prompt the need for additional consideration by physicians and patients, as each drug will present unique benefits, risks, and burdens.

SMA update in best practices. Recommendations for diagnosis considerations (*Schroth et al 2024*) and treatment considerations (*Schroth et al 2025*). The following recommendations outline considerations associated with pharmacological care:

- Infants with SMA identified by newborn screening should be characterized by *SMN2* copy number, current motor function, age at symptom onset, and severity of symptoms prior to treatment initiation.
- When considering treatment initiation in patients with newly diagnosed SMA, *SMN2* copy number and age are important patient characteristics that guide treatment. When considering treatment initiation, modification, or addition in patients with SMA who are not newly diagnosed, current clinical status (including comorbidities, complex spine anatomy, and/or decreased function following treatment) should be a major factor that drives decision-making. Patient and family perspectives, along with treatment safety and side effects, should always be considered when determining whether to start, change, add, or discontinue treatment.
- When considering a medication or treatment plan change, outcomes should be monitored for a minimum of 6 to 12 months before making a change, unless there is an urgent indication for treatment modification (ie, significant side effects or intolerance to the medication or administration route; significant disease progression; loss of motor milestones).
- Factors that guide decision-making in the treatment of adolescent and adult patients with SMA should include treatment intolerance, quality of life, benefit/burden ratio, treatment side effects, loss of functionality, reproductive concerns, pregnancy, disease progression despite treatment, and patient perspective.

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.

Spinraza is a survival motor neuron-2 (SMN2)-directed antisense oligonucleotide indicated for the treatment of spinal muscular atrophy (SMA) in pediatric and adult patients.

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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, clinical evidence and references.
6/18/2025	Annual review. Updated background section, clinical evidence, guidelines, and 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.

Archived Policy Versions (Internal Only)

Effective Date	Policy Number	Policy Title
mm/dd/yyyy – mm/dd/yyyy	######	Title of Policy Hyperlinked to KL or Other Internal Location

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).