HIGHMARK HEALTH OPTIONS

Updated: 07/2024
Approved: 08/2024

Request for Prior Authorization for Zolgensma (onasemnogene Abeparvovec-xioi)
Website Form – www.wv.highmarkhealthoptions.com
Submit request via: Fax - 1-833-547-2030.

All requests for Zolgensma (onasemnogene Abeparvovec-xioi) require a Prior Authorization and will be screened for medical necessity and appropriateness using the criteria listed below.

Zolgensma (onasemnogene Abeparvovec-xioi) Prior Authorization Criteria:

For Zolgensma (onasemnogene abeparvovec-xioi) all of the following criteria must be met:

- Must be less than 2 years of age
- If the member was born prematurely, they have reached full-term gestational age
- Confirmed by genetic testing including ALL of the following:
  - Bi-allelic SMN1 deletions or pathogenic variants
  - Two copies of SMN2 gene
  - Lack of the c.859G>C modification in exon 7 of the SMN2 gene
- Member is not dependent on either of the following:
  - invasive ventilation or tracheostomy
  - Use of non-invasive ventilation beyond use for naps and nighttime sleep
- Prescribed by or in consultation with a neurologist with experience treating SMA or a neuromuscular specialist in the treatment of SMA
- The member has not been treated with medications for ongoing immunosuppressive therapy within the last three (3) months (e.g. corticosteroids, cyclosporine, tacrolimus, methotrexate, cyclophosphamide, intravenous immunoglobulin, rituximab)
- Member does not have any of the following clinically significant abnormal lab values:
  - Liver fuction levels (hepatic aminotransferases [AST and ALT] greater than or equal to 2 times the upper limit of normal) or has pre-existing hepatic insufficiency
  - Baseline anti-AAV9 antibodies greater than 1:50
  - Platelet count less than 150,000uL
  - Creatinine greater than or equal to 1.8mg/dL
- The prescriber attests that the member's weight for dosing is confirmed within 14 days of dose administration.
- The member does not have an active viral infection
- The member does not have advanced SMA (such as complete paralysis of limbs or permanent ventilator dependence*)
- The requested dose and frequency is in accordance with FDA-approved labeling, nationally recognized compendia, and/or evidence-based practice guidelines
- Member is receiving comprehensive treatment based on standards of care for SMA
- Member has documentation of a baseline evaluation, including a standardized assessment of motor function such as one of the following:
  - Hammersmith Functional Motor Scale Expanded (HFMSE)
  - Hammersmith Infant Neurologic Exam (HINE)
  - Upper limb module (ULM) score
  - Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP INTEND)
  - Six-minute walk test
- Member must not have received this therapy previously
- Member is not a participant or recent participant in a SMA treatment clinical trial that may cause risk for gene transfer or treatment with Zolgensma.
- The requested medication will not be used in combination with nusinersen (Spinraza)

- **Duration of Approval**: Once per lifetime

*Permanent ventilator dependence is defined as 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.

Coverage may be provided for any non-FDA labeled indication if it is determined that the use is a medically accepted indication supported by nationally recognized pharmacy compendia or peer-reviewed medical literature for treatment of the diagnosis(es) for which it is prescribed. These requests will be reviewed on a case by case basis to determine medical necessity.

When criteria are not met, the request will be forwarded to a Medical Director for review. The physician reviewer must override criteria when, in their professional judgment, the requested medication is medically necessary.

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ZOLGENSMA (ONASEMNOGENE ABEPARVOVEC-XIOI)
PRIOR AUTHORIZATION FORM – PAGE 1 OF 2

Please complete and fax all requested information below including any progress notes, laboratory test results, or chart documentation as applicable to Highmark Health Options Pharmacy Services. **FAX: (833)-547-2030.**
If needed, you may call to speak to a Pharmacy Services Representative.
PHONE: (844) 325-6251 Monday through Friday 8:00am to 7:00pm

PROVIDER INFORMATION

Requesting Provider:	NPI:
Provider Specialty:	Office Contact:
Office Address:	Office Phone:
	Office Fax:

MEMBER INFORMATION

Member Name:	DOB:	
Member ID:	Member weight:	Height:

REQUESTED DRUG INFORMATION

Medication:	Strength:	
Directions:	Quantity:	Refills:
Is the member currently receiving requested medication? ☐ Yes ☐ No	Date Medication Initiated:	
Is this medication being used for a chronic or long-term condition for which the medication may be necessary for the life of the patient? ☐ Yes ☐ No		

Billing Information

This medication will be billed: ☐ at a pharmacy **OR** ☐ medically, JCODE:_____
Place of Service: ☐ Hospital ☐ Provider's office ☐ Member's home ☐ Other

Place of Service Information

Name:	NPI:
Address:	Phone:

MEDICAL HISTORY (Complete for ALL requests)

Does the member have a confirmed diagnosis of spinal muscular atrophy (SMA) confirmed by genetic testing? ☐ Yes ☐ No
ICD10 code: _____

Please select all that apply to the member and submit documentation:
- ☐ Bi-allelic *SMN1* deletions or pathogenic variants
- ☐ Two copies of *SMN2* gene
- ☐ Lack of the c.859G>C modification in exon 7 of the SMN2 gene

If the member was born prematurely, have they reached full-term gestational age? ☐ Yes ☐
Is the member receiving comprehensive treatment based on standards of care for SMA? ☐ Yes ☐ No

Is member dependent on either of the following?
- Invasive ventilation or tracheostomy ☐ Yes ☐ No
- Use of non-invasive ventilation beyond use for naps and nighttime sleep ☐ Yes ☐ No

Will the member's weight for dosing be confirmed within 14 days of dose administration? ☐ Yes ☐ No
Has the member been treated with medications for ongoing immunosuppressive therapy within the last three (3) months (e.g. corticosteroids, cyclosporine, tacrolimus, methotrexate, cyclophosphamide, intravenous immunoglobulin, rituximab)? ☐ Yes ☐ No
Does the member have an active viral infection? ☐ Yes ☐ No
Does the member have advanced SMA (such as complete paralysis of limbs or permanent ventilator dependence*)? ☐ Yes ☐ No
Will the requested medication be used in combination with nusinersen (Spinraza)? ☐ Yes ☐ No
Has the member received Zolgensma previously? ☐ Yes ☐ No
Is the member participating or is a recent participant in a SMA clinical trial that may cause risk for gene transfer or treatment with Zolgensma? ☐ Yes ☐ No
Is the requested SMA medication being prescribed by or in consultation with a neurologist with experience treating SMA or a neuromuscular specialist in the treatment of SMA? ☐ Yes ☐ No

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ZOLGENSMA (ONASEMNOGENE ABEPARVOVEC-XIOI)
PRIOR AUTHORIZATION FORM (CONTINUED) – PAGE 2 OF 2

Please complete and fax all requested information below including any progress notes, laboratory test results, or chart documentation as applicable to Highmark Health Options Pharmacy Services. **FAX: (833)-547-2030.**
If needed, you may call to speak to a Pharmacy Services Representative.
PHONE: (844) 325-6251 Monday through Friday 8:00am to 7:00pm

MEMBER INFORMATION

Member Name:	DOB:	
Member ID:	Member weight:	Height:

MEDICAL HISTORY (continued)

Does the member have any of the following clinically significant abnormal lab values? Please select all that apply:
☐ Liver fuction levels (hepatic aminotransferases [AST and ALT] greater than or equal to 2 times the upper limit of normal) or has pre-existing hepatic insufficiency
☐ Baseline anti-AAV9 antibodies greater than 1:50
☐ Platelet count less than 150,000uL
☐ Creatinine greater than or equal to 1.8mg/dL
Has the member had a baseline assessment of motor function milestones? ☐ Yes ☐ No
Please select all that apply and submit documentation of baseline assessment:
☐ Hammersmith Functional Motor Scale Expanded (HFMSE)
☐ Hammersmith Infant Neurologic Exam (HINE)
☐ If non-ambulatory: Upper Limb Module (ULM), Revised Upper Limb Module (RULM)
☐ Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP INTEND)
☐ Six-minute walk test (6MWT)

CURRENT or PREVIOUS THERAPY

Medication Name	Strength/ Frequency	Dates of Therapy	Status (Discontinued & Why/Current)

REAUTHORIZATION

Is there documentation of an annual evaluation by a neurologist with experience treating and ongoing management of members with SMA? ☐ Yes ☐ No
Is there documentation demonstrating the member is stable or shows clinically significant improvement in SMA-associated symptoms, as demonstrated by stable or improved functional abilities test results compared to baseline or previous functional abilities test whichever is most recent. The current test and the comparator test being utilized for reauthorization purposes must be at least four (4) months apart (HINE, CHOP-INTEND, HFMSE, 6MWT ULM, RULM) ☐ Yes, documentation is provided ☐ No

SUPPORTING INFORMATION or CLINICAL RATIONALE

Prescribing Provider Signature	Date