Updated: 07/2019
DMMA Approved: 09/2019

Request for Prior Authorization for Zolgensma (Onasemnogene Abeparvovec-XIOI)
Website Form – www.highmarkhealthoptions.com
Submit request via: Fax - 1-855-476-4158

All requests for Zolgensma (Onasemnogene Abeparvovec-VIOI) 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:

Coverage may be provided with a diagnosis of spinal muscular atrophy (SMA) and the following criteria is met:

- Documentation of genetic testing confirming 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 must be less than 2 years of age
- 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
- Member must have an anti-AAV9 antibody titer below or equal to 1:50
- If member has previously been initiated on therapy with Spinraza, member must been on therapy with Spinraza for greater than or equal to 6 months prior to initiating therapy with Zolgensma. Once therapy with Zolgensma is initiated, Spinraza will be discontinued.
- The prescriber attests that the member's weight for dosing must be confirmed within 14 days of dose administration.
- Medication must be prescribed by or in association with a neurologist or pediatric neurologist
- The prescriber attests that member will receive prophylactic prednisolone (or glucocorticoid equivalent) prior to and approximately 30 days following therapy
- Member must not have received this therapy previously either through Highmark Health Options® or other Payer.
- The requested dose and frequency is in accordance with FDA-approved labeling, nationally recognized compendia, and/or evidence-based practice guidelines
- **Duration of Approval:** Once per lifetime

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.

Updated: 07/2019
DMMA Approved: 09/2019

ZOLENGSMA
PRIOR AUTHORIZATION FORM

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:** (855) 476-4158
If needed, you may call to speak to a Pharmacy Services Representative.
PHONE: (844) 325-6253 Monday through Friday 8:30am to 5:00pm

PROVIDER INFORMATION

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

MEMBER INFORMATION

Member Name:	DOB:
Health Options ID:	Member weight: _____pounds or _____kg

REQUESTED DRUG INFORMATION

Medication:	Strength:
Frequency:	Duration:
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 (if medically please provide a 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)

1) Has the diagnosis of Spinal Muscular Atrophy (SMA) been confirmed by genetic testing including ALL of the following (please provide documentation):
   i) Bi-allelic *SMN1* deletions or pathogenic variants
   ☐ Yes ☐ No

   ii) Two copies of *SMN2* gene
   ☐ Yes ☐ No

   iii) Lack of the c.859G>C modification in exon 7 of the SMN2 gene
   ☐ Yes ☐ No

2) Is member less than 2 years of age?
   ☐ Yes ☐ No

3) Is member dependent on either of the following?
   a) Invasive ventilation or tracheostomy
      ☐ Yes ☐ No

   b) Use of non-invasive ventilation beyond use for naps and nighttime sleep
      ☐ Yes ☐ No

4) Does member have an anti-AAV9 antibody titer below or equal to 1:50?
   ☐ Yes ☐ No

5) Does the member have a complete paralysis of limbs?
   ☐ Yes ☐ No

6) If member was initiated on therapy with Spinraza, has member been on therapy with Spinraza for a total of 6 months?
   ☐ Yes ☐ No

7) Does the prescriber attest that member's weight for dosing must be confirmed within 14 days of dose administration?
   ☐ Yes ☐ No

8) Will the medication be prescribed by or in association with a neurologist or pediatric neurologist?
   ☐ Yes ☐ No

9) Does the prescriber attests that member will receive prophylactic prednisolone (or glucocorticoid equivalent) prior to and approximately 30 days following therapy?
   ☐ Yes ☐ No

10) Has the member received Zolengsma previously either through Gateway Health Plan® or other Payer?
   ☐ Yes ☐ No

CURRENT or PREVIOUS THERAPY			
Medication Name	**Strength/ Frequency**	**Dates of Therapy**	**Status (Discontinued & Why/Current)**

SUPPORTING INFORMATION or CLINICAL RATIONALE

Prescribing Provider Signature	Date