Health Alliance™ Pharmacy Drug Policy Checklist

POLICY NAME	Zolgensma (onasemnogene abeparvovec)	POLICY #	2708P

Criteria

Coverage Criteria

- ☐ Diagnosis of Spinal Muscular Atrophy (SMA) that has been confirmed through gene tests with documentation of two mutations in the survival motor neuron 1 (SMN1) gene (deletions or point mutations) and no more than four copies of SMN2 gene
- ☐ Documentation that therapy will occur before the member's 2nd birthday
- ☐ Neonatal (pre-term) patients born prematurely must have reached full-term gestational age
- ☐ Prescribed by a Neurologist (nervous system doctor) with expertise in the treatment of SMA
- ☐ Medical record documentation (chart notes, laboratory values, etc.) showing the member does not have advanced SMA, including but not limited to any of the following:
  - CHOP-INTEND score greater than or equal to 40
  - Complete paralysis (immobility) of limbs, or
  - Invasive ventilator support (tracheostomy), or
  - Respiratory assistance for 16 or more hours per day (including non-invasive respiratory support) continuously for 14 or more days in the absence of acute reversible illness (excluding perioperative ventilation)
- ☐ Medical record documentation including any prior treatments, clinical responses, and overall evaluation
- ☐ Documentation that the member has an anti-adeno-associated virus 9 (AAV9) antibody titer less than or equal to 1:50 as determined by Enzyme-linked Immunosorbent Assay (ELISA) binding immunoassay
- ☐ Documented weight less than or equal to 13.5 kilograms or 30 pounds
- ☐ Review of chart notes and labs documenting diagnosis and confirming that patient has met all of the above requirements for treatment with Zolgensma by both a pharmacist and medical director

Exclusion Criteria – Any of the following prevents coverage

- ☐ Zolgensma will not be covered in combination with Spinraza or Evrysdi
  - If member is currently on Sprinraza or Evrysdi, documentation will be required to indicate that it will be stopped prior to initiation of Zolgensma
  - Any previous authorizations for Spinraza or Evrysdi will be removed from the system with an approval for Zolgensma

- ☐ Requests for repeat administration of Zolgensma will not be covered because the effectiveness of this approach has not been established and is therefore considered experimental/ investigational
  - Includes patients that have received Zolgensma while covered under a prior health plan
- ☐ Patients age 2 years or older
- ☐ Patients weighing 13.6 kg (30 pounds) or more Statement of the Policy References

Approval Criteria

- ☐ One-time approval per lifetime
  - Approval will be placed on file for 6 months or through the member's 2nd birthday, whichever comes first
  - Zolgensma medical claims will only be approved from a contracted vendor and will not allow provider offices to buy and bill. CPT Codes HCPCS Codes