Pharmacy Drug Policy & Procedure

Policy Name:	Zolgensma (onasemnogene abeparvovec)	Policy #:	2708P

Purpose of the Policy

The purpose of this policy is to establish the criteria for coverage of Zolgensma.

Statement of the Policy

Health Alliance Medical Plans and Health Alliance Northwest will approve the use of Zolgensma under the Specialty Medical benefit when the following criteria have been met.

Criteria

1. Coverage Criteria

1.1 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

1.2 Documentation that therapy will occur before the member's 2nd birthday

1.3 Neonatal (pre-term) patients born prematurely must have reached full-term gestational age

1.4 Prescribed by a Neurologist (nervous system doctor) with expertise in the treatment of SMA

1.5 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)

1.6 Medical record documentation including any prior treatments, clinical responses, and overall evaluation

1.7 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

1.8 Documented weight less than or equal to 13.5 kilograms or 30 pounds

1.9 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

2. Exclusion Criteria

2.1 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

2.2 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

2.3 Patients age 2 years or older

2.4 Patients weighing 13.6 kg (30 pounds) or more

3. Approval Criteria

3.1 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	

References

1. Day JW, Finkel RS, Chiriboga CA, et al. Onasemnogene abeparvovec gene therapy for symptomatic infantile-onset spinal muscular atrophy in patients with two copies of SMN2 (STR1VE): an open-label, single-arm, multicentre, phase 3 trial. Lancet Neurol 2021; 20:284.
2. Mendell JR, Al-Zaidy SA, Lehman KJ, et al. Five-Year Extension Results of the Phase 1 START Trial of Onasemnogene Abeparvovec in Spinal Muscular Atrophy. JAMA Neurol 2021; 78:834.
3. Zolgensma - one-time gene therapy for spinal muscular atrophy. Med Lett Drugs Ther 2019; 61:113.
4. Zolgensma (onasemnogene abeparvovec) [prescribing information]. Bannockburn, IL: Novartis Gene Therapies Inc; October 2023.

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