

January 21, 2020

Physician Administered Drug Prior Authorization Criteria for Zolgensma[®]

Version 1, 1-21-20

Zolgensma[®] onasemnogene abeparvovec-xioi

Zolgensma[®] is an adeno-associated virus vector-based gene therapy designed to deliver a copy of the gene encoding the human SMN protein.

Indications¹:

Zolgensma[®] is indicated for the treatment of pediatric patients less than 2 years of age with spinal muscular atrophy (SMA) with biallelic mutations in the survival motor neuron 1 (SMN1) gene.

Criteria for Approval^{1,2}:

1. Member is less than 2 years of age; AND
2. Member has reached full-term gestational age; AND
3. Member experienced onset of clinical symptoms consistent with SMA before 6 months of age; AND
4. Genetic testing has confirmed bi-allelic SMN1 gene deletions or pathogenic variants and ≤ 2 copies of the SMN2 gene; AND
5. Member is not paralyzed or ventilator-dependent; AND
6. Member has baseline anti-AAV9 antibody titer of ≤ 1.50 ; AND
7. Member has not previously received Zolgensma[®]; AND
8. Medication is prescribed by a neurologist specializing in SMA; AND
9. Baseline liver function tests, platelet counts, and troponin-1 have been performed and will continue to be assessed after treatment until they return to baseline; AND
10. Member does not have an active viral infection; AND
11. Therapy with Spinraza, if applicable, will be discontinued.

Quantity Limit:

Limited to 1 infusion at weight appropriate dose per lifetime.

Criteria for Renewal Authorization Approval:

Reauthorization not appropriate

References:

1. Zolgensma® [package insert] Bannockburn, IL; AveXis Inc.; 05/2019, Accessed January 20, 2020.
2. [Bodamer, Olaf. Spinal muscular atrophy. Dashe, John, ed. UpToDate. Waltham, MA: UpToDate Inc. http://www.uptodate.com \(Accessed on January 20, 2020\)](#)
3. Lexicomp Online®, Lexi-Drugs®, Hudson, Ohio: Lexi-Comp, Inc.; January 20, 2020