Zolgensma

Adjudication Guideline

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Pharmaceutical	2026-PH-004	Version No.1	14/10/2026	N/A

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Abstract

1.1 For Members

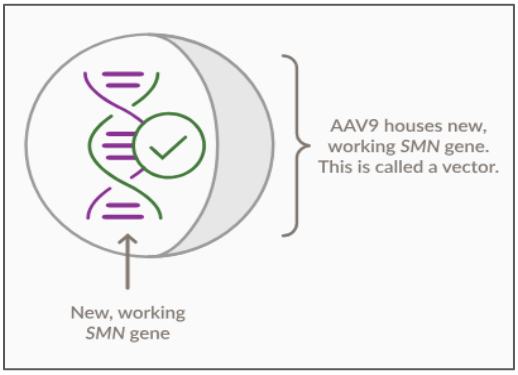
Zolgensma is a one-time adeno-associated virus (AAV) vector-based gene therapy indicated for the treatment of pediatric patients less than 12 months. With spinal muscular atrophy (SMA).

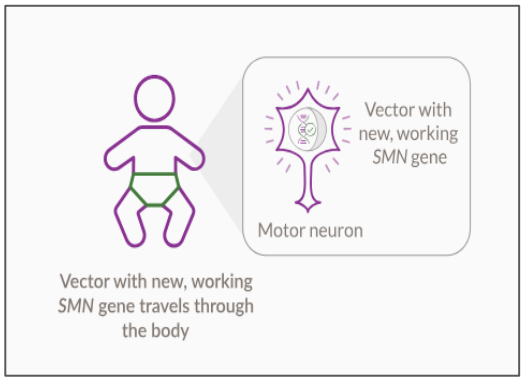
1.2 For Medical Professionals

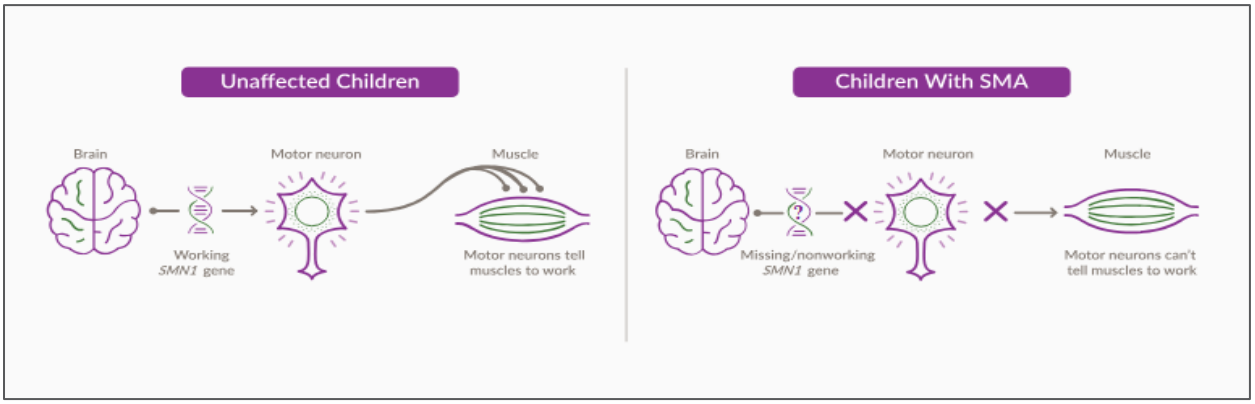
Zolgensma is a one-time adeno-associated virus (AAV) vector-based gene therapy indicated for the treatment of pediatric patients less than 12 months. With spinal muscular atrophy (SMA) with bi-allelic mutations in the survival motor neuron 1 (SMN1) gene.

1.3 Mechanism of Action:

Onasemnogene abeparvovec is a recombinant AAV9-based gene therapy designed to deliver a copy of the gene encoding the human SMN protein. SMA is caused by a bi-allelic mutation in the SMN1 gene, which results in insufficient SMN protein expression. Intravenous administration of ZOLGENSMA that results in cell transduction and expression of the SMN protein has been observed into human case studies







Scope

Scope of this adjudication rule is to highlight the medical indications, and coverage details of Zolgensma as per policy terms and conditions of each health insurance plan administered by Daman.

Adjudication Policy

Eligibility / Coverage Criteria

Zolgensma is a one-time adeno-associated virus (AAV) vector-based gene therapy indicated for the treatment of pediatric patients less than 12 months. With spinal muscular atrophy (SMA) with bi-allelic mutations in the survival motor neuron 1 (SMN1) gene

Requirements for Coverage

Age Criteria:

- pediatric patients less than 12 months
- A treatment administered only once during the patient's lifetime.

Diagnosis Confirmation:

Confirmed diagnosis of spinal muscular atrophy (SMA) by one of the below conditions:

- patients with 5q spinal muscular atrophy (SMA) with a bi-allelic mutation in the SMN1 gene and a clinical diagnosis of SMA Type 1
- patients with 5q SMA with a bi-allelic mutation in the SMN1 gene and up to 3 copies of the SMN2 gene.

The treatment only recommended for these groups if neither tracheostomy nor permanent ventilation for more than 16 hours per day is needed.

ZOLGENSMA Dose:

- 1.1×10^{14} vector genomes (vg) per kg of body weight
- Administer ZOLGENSMA as an intravenous infusion over 60 minutes.
- Dose volume is calculated using the upper limit of the patient weight range for pediatric patients aged less than 12 months with weight range between 2.6 kg and 21.0 kg as per the below dosing table.

Patient weight range (kg)	Dose volume[a] (mL)
2.6 – 3.0	16.5
3.1 – 3.5	19.3
3.6 – 4.0	22.0
4.1 – 4.5	24.8
4.6 – 5.0	27.5
5.1 – 5.5	30.3
5.6 – 6.0	33.0
6.1 – 6.5	35.8
6.6 – 7.0	38.5
7.1 – 7.5	41.3
7.6 – 8.0	44.0
8.1 – 8.5	46.8
8.6 – 9.0	49.5
9.1 – 9.5	52.3
9.6 – 10.0	55.0
10.1 – 10.5	57.8
10.6 – 11.0	60.5
11.1 – 11.5	63.3
11.6 – 12.0	66.0

Patient weight range (kg)	Dose volume[a] (mL)
12.1 – 12.5	68.8
12.6 – 13.0	71.5
13.1 – 13.5	74.3
13.6 – 14.0	77.0
14.1 – 14.5	79.8
14.6 – 15.0	82.5
15.1 – 15.5	85.3
15.6 – 16.0	88.0
16.1 – 16.5	90.8
16.6 – 17.0	93.5
17.1 – 17.5	96.3
17.6 – 18.0	99.0
18.1 – 18.5	101.8
18.6 – 19.0	104.5
19.1 – 19.5	107.3
19.6 – 20.0	110.0
20.1 – 20.5	112.8
20.6 – 21.0	115.5

Additional Criteria:

- Testing for the below parameters should be done as pre-treatment to ensure patient safety:

  - Creatinine
  - Complete blood count, Liver function, Clotting Profile
  - Troponin-1
  - Anti AAV-9 Antibody testing

Read Flag:

- Zolgensma cannot deliver to any pediatric patient without diagnosis confirmation.
- Zolgensma is a high-cost medication almost 8 M AED, and the final approval should be obtained from DOH.

Eligible clinician specialities

Clinician Specialties
Pediatric Neurology

1.4 Non-Coverage

- Basic and visitor's policy
- Policy with restricted Formularies based on Schedule of benefits

1.5 Payment and Coding Rules

Kindly apply regulator payment rules and regulations and relevant coding manuals for ICD, Drugs.

Denial Codes

Code	Code Description
CODE-014	Activity/diagnosis is inconsistent with the patient's age/gender
MNEC-005	Service/supply may be appropriate, but too frequent
CODE-010	Activity/diagnosis inconsistent with clinician specialty
MNEC-004	Service is not clinically indicated based on good clinical practice, without additional supporting diagnoses/activities
AUTH-001	Prior approval is required and was not obtained

Appendices

1.6 References

zolgensma
Information for the public | Onasemnogene abeparvovec for treating spinal muscular atrophy | Guidance | NICE
Zolgensma | European Medicines Agency (EMA)
Zolgensma 2 x 10^13 vector genomes/mL solution for infusion - Summary of Product Characteristics (SmPC) - (emc) | 11572
https://www.fda.gov/media/126109/download?attachment
https://www.medicines.org.uk/emc/product/11572/smpc#gref
https://www.nice.org.uk/guidance/hst15/chapter/1-Recommendations
https://www.sciencedirect.com/science/article/pii/S0960896617312841
https://www.zolgensma.com

1.7 Revision History

Date	Version No.	Change(s)
14/10/2026	V.1	New Guideline

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