

onasemnogene (Itvisma, Zolgensma)

HCPCS: J3399 Injection, onasemnogene abeparvovec-xioi, per treatment, up to 5×10^{15} vector genomes (Zolgensma), J3405 Injection, onasemnogene abeparvovec-brve, per treatment (Itvisma)

LOB:	MCAL
Duration of Approval:	One treatment per lifetime
Quantity Limit:	Per FDA-Approved/Compendia-Supported Dosing
MCG Available:	Yes (Zolgensma)
DHCS Drug Policy:	No

Requires Prior Authorization (PA)

Zolgensma (onasemnogene abeparvovec-xioi) injection Itvisma (onasemnogene abeparvovec-brve) injection
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****All requests must be approved by a Medical Director****

PA CRITERIA FOR APPROVAL:

1. The member has a diagnosis for a Food and Drug Administration (FDA)-approved indication (refer to package insert under References) **OR** a compendia-supported (Drugdex or American Hospital Formulary Service [AHFS]) indication **AND**
2. The medication is prescribed by a neurologist or neuromuscular/neuromusculoskeletal specialist **AND**
3. The member is 2 or more years old (for Itvisma) **OR** under 2 years old (for Zolgensma) **AND**
4. Documentation of genetic mutation analysis is provided confirming biallelic survival motor neuron 1 (SMN1) mutations (deletions or point mutations) **AND** the number of copies of SMN2 (up to four copies) **AND**
5. Documentation of anti-adenovirus serotype 9 (AAV9) antibody titers $\leq 1:50$ is provided **AND**
6. Chart notes showing neuromotor assessment (such as Children's hospital of Philadelphia infant test of neuromuscular disorders [CHOP INTEND], Hammersmith infant neurological examination [HINE-2], Hammersmith functional motor scale expanded [HFMSE]) with score to establish clinical baseline **AND**
7. **For Zolgensma:** The member does **NOT** have advanced spinal muscular atrophy (SMA) (e.g., complete paralysis of limbs, permanent ventilator dependence) **AND**
8. The member has not previously received Itvisma or Zolgensma (**Note:** only one treatment of Itvisma or Zolgensma per lifetime is allowed)

OTHER INFORMATION:

HCPCS	Description	Brand name
J3399	Injection, onasemnogene abeparvovec-xioi, per treatment, up to 5×10^{15} vector genomes	Zolgensma
J3405	Injection, onasemnogene abeparvovec-brve, per treatment	Itvisma
**Refer to DHCS Physician-Administered Drugs (PADs) Special Billing for Itvisma/Zolgensma for billing information and follow allowable number of units to approve. **		

REFERENCES:

1. Zolgensma Prescribing Information. www.novartis.com/us-en/sites/novartis_us/files/zolgensma.pdf. 2/2025.
2. Itvisma Prescribing Information. www.novartis.com/us-en/sites/novartis_us/files/Itvisma.pdf. 11/2025.
3. Glascock J, Sampson J, Connolly AM, et al. Revised recommendations for the treatment of infants diagnosed with spinal muscular atrophy via newborn screening who have 4 copies of SMN2. *J Neuromuscul Dis*. 2020;7(2):97-100. [pmc.ncbi.nlm.nih.gov/articles/PMC7175931/](https://pubmed.ncbi.nlm.nih.gov/articles/PMC7175931/)
4. DHCS Cell and Gene Therapy Overview. mcweb.apps.prd.cammiis.medi-cal.ca.gov/assets/821726E2-2EAB-4A86-AA42-4778E89A38FD/celgenover.pdf?access_token=6UyVkrRfByXTZEWIh8j8QaYyIPyP5ULO. 09/2025.

P&T APPROVAL HISTORY:

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1. August 2019 P&T Drug Review
2. May 2026 P&T Drug Review

UMC REVIEW:

6/2026