

PA Criteria	Criteria Details						
Covered Uses (FDA approved indication)	Zolgensma is indicated for the treatment of pediatric patients less than 2 years of age with spinal muscular atrophy (SMA) with bi-allelic mutations in the survival motor neuron 1 (SMN1) gene.						
Exclusion Criteria	None.						
Required Medical Information	Medical records supporting the request must be provided.						
Other Criteria	Must follow NCD 110.24 for Chimeric Antigen Receptor (CAR) T-Cell Therapy. https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncdid=374						
Age Restriction	None.						
Prescriber Restrictions	None.						
Coverage Duration	In accordance with the FDA-approved labeling or accepted standards of medical practice.						
Other Criteria/Information	Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document. <table border="1" data-bbox="500 955 1511 1161"> <thead> <tr> <th>HCPDS</th> <th>Description</th> <th>Billing Units/How Supplied</th> </tr> </thead> <tbody> <tr> <td>J3399</td> <td>Zolgensma (onasemnogene abeparvovec)</td> <td>Billing unit: per each kit 5.5 mL or 8.3 mL SDV (each kit will provide sufficient number of vials based on patient weight)</td> </tr> </tbody> </table>	HCPDS	Description	Billing Units/How Supplied	J3399	Zolgensma (onasemnogene abeparvovec)	Billing unit: per each kit 5.5 mL or 8.3 mL SDV (each kit will provide sufficient number of vials based on patient weight)
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STATUS	DATE REVISED	REVIEW DATE	APPROVED/REVIEWED BY	EFFECTIVE DATE
Created	3/26/2025	3/26/2025	Dawn Shojai, PharmD, Senior Pharmacy Benefit Consultant (PSG)	N/A
Approved	N/A	5/15/2025	Pharmacy & Therapeutics (P&T) Committee	5/15/2025