GOLD COAST HEALTH PLAN TOTAL Care ADVANTAGE℠

TOTAL CARE ADVANTAGE PART B CLINICAL GUIDELINES

ITVISMA *(onasemnogene abeparvovec-brve)* susp, for intrathecal injection

<table>
<tr><th>PA Criteria</th><th>Criteria Details</th></tr>
<tr><td>Description</td><td>ITVISMA is an adeno-associated virus (AAV) vector-based gene therapy.</td></tr>
<tr><td>Covered Uses
(FDA approved indication)</td><td>ITVISMA is indicated for the treatment of spinal muscular atrophy (SMA) in adult and pediatric patients 2 years of age and older with confirmed mutation in SMN1 gene.</td></tr>
<tr><td>Dosing and Administration</td><td>
<table>
<tr><th>Indication</th><th>Dosing Regimen</th></tr>
<tr><td>Spinal Muscular Atrophy</td><td>1.2×10^{14} vector genomes administered as intrathecal bolus injection over one to two minutes as single-dose. DO NOT READMINISTER.

Starting one day prior to ITVISMA injection, administer systemic corticosteroids equivalent to PO prednisolone at 1 mg/kg of body weight per day for a total of 30 days.
At the end of the 30-day period, check liver function by clinical examination and by laboratory testing.
For patients with unremarkable findings, taper the corticosteroid dose gradually over the next 28 days.
If liver function abnormalities persist, continue systemic corticosteroids (equivalent to PO prednisolone at 1 mg/kg/day) until findings become unremarkable, and then taper the corticosteroid dose gradually over the next 28 days or longer if needed.</td></tr>
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<tr><td>Billing and Coding Information</td><td>
<table>
<tr><th>10-digit NDC</th><th>11-digit NDC</th></tr>
<tr><td>Vial: 71894-200-01
Carton: 71894-200-02</td><td>Vial: 71894-0200-01
Carton: 71894-0200-02</td></tr>
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<table>
<tr><th>HCPCS Code</th><th>Description</th></tr>
<tr><td>J3590</td><td>Unclassified biologics</td></tr>
<tr><td>C9399</td><td>Unclassified drugs or biologicals</td></tr>
</table>
<table>
<tr><th>CPT Procedural Codes</th><th>Description</th></tr>
<tr><td>96450</td><td>Chemotherapy administration, into central nervous system (e.g., intrathecal), requiring and including spinal puncture</td></tr>
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<tr><td>Product Availability</td><td>Each single-dose vial contains 1.2×10^{14} vg in 3 mL of suspension.

ITVISMA has a nominal concentration of 4×10^{13} vg/mL, and each vial contains an extractable volume of not less than 3 mL.</td></tr>
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Contraindications	None.
Recommended Medical Monitoring	**BLACK BOX WARNING: Serious Liver Injury** – Acute serious liver injury and elevated aminotransferases can occur with ITVISMA. Patients with preexisting liver impairment may be at higher risk. • Prior to intrathecal injection, assess liver function by clinical examination and laboratory testing. Administer systemic corticosteroid before and after ITVISMA injection. • Continue to monitor liver function for at least three months after injection, and at other times as clinically indicated. ITVISMA has also been associated with: • Hepatotoxicity • Thrombocytopenia • Peripheral Sensory Neuropathy • Thrombotic Microangiopathy (TMA) • Elevated Cardiac Troponin I • AAV Vector Integration and Risk of Tumorigenicity
Approval Criteria	a. Physician administered intrathecal injection; in-office or HOPD i. Cannot be self-administered b. Spinal Muscular Atrophy **(must meet all)**: i. Diagnosis of Spinal Muscular Atrophy (SMA) 1. Confirmation of SMN1 gene deletion 2. Documentation of onset of clinical signs and symptoms of SMA ii. Baseline anti-AAV9 antibody test iii. Baseline liver function tests (clinical exam, AST, ALT, albumin, PT, PTT, INR, total bilirubin) iv. Baseline creatinine and CBC v. Vaccination status should be up-to-date prior to administration; recommend seasonal RSV prophylaxis vi. Patient should be clinically stable in overall baseline health status (e.g., hydration, nutritional status, absence of infection, respiratory status) prior to administration. vii. Age ≥ 2 years viii. Prescribed by or in consultation with a neurologist, neuromuscular specialist or pediatric neurologist ix. Dose does not exceed 1.2×10^{14} vector genomes via intrathecal bolus injection over one to two minutes as single-dose; do NOT readminister
Age Restriction	Age ≥ 2 years old
Coverage Duration	**Initial/Reauthorization:** One dose per lifetime Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice.

Other Criteria (LCD, NCD, etc.)	None.
Misc Info, Appendix Etc.	None.

STATUS	DATE REVISED	REVIEW DATE	APPROVED/REVIEWED BY	EFFECTIVE DATE
Created	1/23/26	1/23/26	Tamara Chinarian, PharmD, Clinical Pharmacist	N/A
Approved	N/A	2/12/26	Pharmacy & Therapeutics (P&T) Committee	2/12/26