

Zolgensma (onasemnogene abeparvovec-xioi)

HCPCS J3399 · One-time IV AAV9 gene therapy · Pediatric SMA <2 yr

CareCost Estimate · Q2 2026
Reviewed May 22, 2026

THE 5 THINGS YOU NEED TO BILL J3399

HCPCS J3399 Per-treatment (one-time, lifetime event)	DOSE 1.1 × 10¹⁴ vg/kg Weight-based; 10 kg infant = 1.1 × 10 ¹⁵ vg	ADMIN CPT 96365 (+96366) Therapeutic IV 60 min — NOT 96413 / 79101
AAV9 ANTIBODY GATE ≤ 1:50 Required pre-treatment titer (FDA label)	GLUCOCORTICOID Prednisolone 1 mg/kg/d Start 24 hr pre → ≥30 d post; taper if LFTs OK	WAC (ONE-TIME) ~\$2.125M Outcomes-based contracts (5-yr milestones)

BOXED WARNING: Acute serious liver injury and acute liver failure. Monitor LFTs (ALT, AST, total bilirubin, PT) weekly × 1 month, then bi-weekly through month 3. CBC weekly × 1 month for TMA / thrombocytopenia surveillance. Document monitoring schedule in PA packet.

PRE-TREATMENT GATING WORKFLOW (ONE-TIME PER PATIENT)

WHEN	STEP	DOCUMENTATION
Pre-NBS / clinical Dx	Bi-allelic SMN1 confirmation (MLPA or sequencing)	Genetic report; SMN2 copy number; SMA type (G12.0 / G12.1 / G12.9)
Day -28 to -14	Anti-AAV9 antibody titer	Result ≤ 1:50 (FDA gate); coordinated via OneGene Program
Day -14	Baseline labs + age/weight verification	LFTs (ALT, AST, total bili, PT), CBC, troponin-I; age <2 yr; weight ≤21 kg (practical ceiling)
Day -1	Start oral prednisolone 1 mg/kg/day	Glucocorticoid prophylaxis start date documented; continues ≥30 d post
Day 0	Zolgensma IV infusion (60 min, syringe pump)	J3399 × 1 unit + CPT 96365; kit lot, total volume, infusion times recorded
Weeks 1-4	Weekly LFT + CBC; clinical neuromuscular check	Boxed-warning monitoring; bill outpatient labs + E/M
Weeks 5-12	Bi-weekly LFT + CBC	Continued monitoring through month 3; taper steroids if LFTs normal
6 / 12 / 24 / 36 / 60 mo	Outcomes-based contract milestone assessments	CHOP-INTEND / HFMSE / RHS / ventilator-free survival; coordinated via OneGene

ICD-10 (PEDIATRIC SMA, <2 YR, BI-ALLELIC SMN1)

G12.0	SMA type 1 (Werdnig-Hoffmann)
G12.1	SMA types 2, 3, 4 / juvenile / Kugelberg-Welander
G12.9	SMA, unspecified
Z13.228	NBS-identified pre-symptomatic (paired w/ G12.x)
Z82.0	Family history of SMA (sibling history)
Z00.121	Routine pediatric exam during workup window

Documentation must include bi-allelic SMN1 genetic confirmation, age <24 mo at infusion, weight, AAV9 antibody titer ≤1:50.

SMA CLASS — NOT INTERCHANGEABLE

J3399	Zolgensma — one-time IV gene therapy (this page)
J2326	Spinraza — intrathecal antisense; q4mo indefinitely
(pharmacy)	Evrysdi (risdiplam) — oral daily; not medical benefit

SITE OF CARE

POS 21 (IP)	Planned pediatric hospital admission — primary at many centers
POS 22 / 19	HOPD; OPPS pass-through historically applied
POS 11 / 49 / 12	NOT eligible — certified specialty center only

TOP DENIAL #1: AAV9 antibody titer not documented or expired (must be ≤1:50, current within 2 weeks of infusion). Coordinate testing through OneGene Program: 1-855-441-4363.

PAYER POLICIES & OUTCOMES-BASED CONTRACTING

PAYER	PA?	OBA?	KEY DOCUMENTATION
UnitedHealthcare (Optum)	Yes	Yes	FDA-label-aligned; certified center; bi-allelic SMN1; AAV9 ≤1:50

PAYER	PA?	OBA?	KEY DOCUMENTATION
Aetna	Yes	Case-by-case	FDA label; site-of-care; pediatric specialty review
BCBS plans (vary)	Yes	Common at large plans	Cure SMA Standard of Care + FDA label
Cigna / Accredo	Yes	Yes	FDA label; comprehensive documentation packet
State Medicaid (most)	Yes	Yes	State-specific SRA + OBA; >30 states have CMS-approved VBP arrangements

Outcomes-based contracting nutshell: Pay full WAC at administration; manufacturer refunds % of WAC if clinical milestones (motor function, ventilator-free survival) not met over 5-year window. Provider documents outcomes at 6/12/24/36/60 mo via OneGene; rebate flow is payer-side and does not affect provider payment at infusion.

TOP DENIALS & FIXES

DENIAL	FIX
#1 AAV9 antibody titer not documented or >1:50	Order via OneGene; result ≤1:50 within 2 weeks of infusion
#2 SMA type / bi-allelic SMN1 missing	Submit MLPA / sequencing showing 0 functional SMN1 copies
#3 Age >2 yr at planned infusion	Not eligible — transition to Spinraza or Evrysdi
#4 Weight >21 kg (practical ceiling)	Verify with OneGene; if exceeded, alternative therapy
#5 Glucocorticoid plan missing	Document prednisolone 1 mg/kg/d starting 24 hr pre, ≥30 d post
#6 LFT monitoring plan missing	Document weekly × 1 mo, bi-weekly through mo 3 (boxed warning)
Wrong admin CPT (96413 / 79101 / 96374)	Use 96365 (therapeutic IV 60 min)
Wrong HCPCS (J3490 / C9399)	Use J3399 (permanent per-treatment code)

ONEGENE PROGRAM & PATIENT SUPPORT

NOVARTIS ONEGENE PROGRAM

Phone: **1-855-441-4363**

Web: zolgensma.com/onegene

Services: benefits investigation, PA assistance, AAV9 testing logistics, certified center referral, travel/lodging support, outcomes-based contract operations

CURE SMA (CURESMA.ORG)

NBS advocacy · SMA Care Center directory (certified specialty centers) · peer/family support · emergency travel/lodging assistance · SMA Care Center accreditation program