Roctavian (valoctocogene roxaparvovec-rvox)

HCPCS J3399 · One-time IV AAV5 gene therapy · Adult severe hemophilia A (FVIII deficiency)

CareCost Estimate · Q2 2026
Reviewed May 22, 2026

THE 6 THINGS YOU NEED TO BILL ROCTAVIAN

HCPCS
J3399
Gene therapy NOC; per-therapeutic-dose (one-time, lifetime event)

DOSE
6×10^{13} vg/kg
Weight-based; 70 kg adult = 4.2×10^{15} vg

ADMIN CPT
96365 + 96366
Therapeutic IV ~2–3 hr — NOT 96413 / 79101 / 96374 push

AAV5 ANTIBODY
Negative
Pre-treatment + no current/historical FVIII inhibitor

AGE + SEVERITY
≥ 18 yr · FVIII ≤ 1 IU/dL
Adults only with severe hemophilia A

WAC (ONE-TIME)
~$2.9M
Between Zolgensma $2.1M and Hemgenix $3.5M

WARNINGS & PRECAUTIONS (no boxed warning; prominent hepatotoxicity warning): Hepatotoxicity (ALT elevations in majority of GENEr8-1 patients — higher rate than Hemgenix's ~17%), infusion reactions, immune-mediated response, thromboembolic events (rare), theoretical malignancy risk from AAV vector integration (15-yr long-term registry). Monitor ALT/AST/ALP/total bili weekly × 6 months (longer than Hemgenix). Reactive or prophylactic prednisone 60 mg/day taper, often extended > 12 weeks.

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

WHEN	STEP	DOCUMENTATION
Pre-Dx workup	Severe hemophilia A confirmation	FVIII activity ≤ 1 IU/dL (chromogenic + one-stage); D66; family history (Z83.2 if applicable)
Day −28 to −14	Anti-AAV5 antibody + serology	Result negative (any detectable Ab excludes); hep B / C / HIV negative; coordinated via BioMarin patient support
Day −14	Baseline labs + eligibility verification	LFTs (ALT, AST, ALP, total bili), CBC, PT/INR, FVIII activity ≤ 1 IU/dL, FVIII inhibitor (Bethesda) negative + **lifetime inhibitor history review (NO prior inhibitors ever)**; age ≥ 18; weight; FVIII prophylaxis / Hemlibra history (product, dose, ABR)
Day 0	Roctavian IV infusion (~2–3 hr)	J3399 × 1 unit + CPT 96365 + 96366 add-on hours; kit lot, total volume, infusion times recorded; HTC inpatient or extended observation; NOC documentation attached
Weeks 1–26	Weekly LFT; clinical bleed assessment	Hepatotoxicity surveillance (6 months — longer than Hemgenix's 3); bill outpatient labs + E/M; reactive / prophylactic prednisone taper standard
3 / 6 / 12 / 24 / 36 / 60 mo	Outcomes-based contract milestone assessments	FVIII activity (chromogenic + one-stage); ABR; FVIII product utilization; coordinated via BioMarin
Annual × 15 yr	Long-term safety registry	Malignancy + thromboembolic surveillance per AAV integration theoretical risk; durability tracking

ICD-10 (ADULT SEVERE HEMOPHILIA A, ≥ 18 YR)

`D66`	Hereditary factor VIII deficiency (hemophilia A) — PRIMARY
`Z79.899`	Long-term use of antithrombotic / coagulation factor (FVIII or Hemlibra history)
`Z87.2`	History of major bleeding (life-threatening or repeated spontaneous)
`M25.4` series	Hemarthrosis (acute joint bleed) — supports bleed phenotype
`Z83.2`	Family history of bleeding disorder (X-linked recessive)
`D68.311`	FVIII inhibitor — **CONTRAINDICATION current OR historical**

Documentation must include FVIII activity ≤ 1 IU/dL, anti-AAV5 antibody negative, age ≥ 18, FVIII / Hemlibra prophylaxis history, FVIII inhibitor negative AND no lifetime history. **NOT D67 (that is hemophilia B / Hemgenix).**

HEMOPHILIA A CLASS — NOT INTERCHANGEABLE

`J3399`	Roctavian — one-time IV AAV5 gene therapy (this page)
`J7170`	Hemlibra — SC FVIIIa mimetic prophylaxis (works with inhibitors)
`J7173`	Alhemo — SC anti-TFPI prophylaxis (A or B w/ inhibitors)
`J7170` family	Multiple FVIII replacement codes (Advate, Adynovate, Eloctate, Altuviiio, Kovaltry, Esperoct, Jivi)
`J1411`	Hemgenix — one-time AAV5 gene therapy for hemophilia **B** (FIX)

SITE OF CARE — CERTIFIED HTC ONLY

POS 22 (HOPD)	HTC HOPD extended observation — primary at many HTCs for 2–3 hr infusion
POS 21 (IP)	HTC-affiliated planned admission — alternative routing

POS 11 / 49 / 12	**NOT eligible** — certified HTC only

TOP DENIAL #1: Anti-AAV5 antibody not documented or positive (any detectable Ab is an exclusion; ~30% of adults are seropositive). **#2:** Current OR historical FVIII inhibitor (lifetime exclusion). Coordinate testing through BioMarin patient support: 1-866-906-6100.

PAYER POLICIES & OUTCOMES-BASED CONTRACTING

PAYER	PA?	OBA?	KEY DOCUMENTATION
UnitedHealthcare (Optum)	Yes	Yes	FDA-label-aligned; HTC; D66; FVIII ≤ 1 IU/dL; anti-AAV5 Ab negative; lifetime inhibitor-naive
Aetna	Yes	Case-by-case	FDA label; site-of-care; hematology specialty review
BCBS plans (vary)	Yes	Common at large plans	NBDF/MASAC + FDA label; durability counseling documentation
Cigna / Accredo	Yes	Yes	FDA label; Hemlibra trial/failure or contraindication often required
State Medicaid (most)	Yes	Yes	State-specific SRA + OBA; CMS Cell & Gene Therapy (CGT) Access Model (2025+, expanding to hem A)
Medicare Part B	MAC LCD	Limited	FDA label; HTC; baseline LFTs / serology; NOC documentation

Outcomes-based contracting nutshell: Pay full WAC at administration; manufacturer refunds % of WAC if FVIII activity / ABR / FVIII product use milestones not met over multi-year window (up to 5 yr). BioMarin OBAs often include explicit **durability** milestones because GENEr8-1 follow-up showed FVIII declining faster than projected. Provider documents outcomes at 3/6/12/24/36/60 mo via BioMarin; rebate flow is payer-side. CMS CGT Access Model (launched 2025) provides multi-state Medicaid framework expanding to hemophilia.

TOP DENIALS & FIXES

DENIAL	FIX
#1 Anti-AAV5 antibody not documented or positive	Order via BioMarin patient support; result negative within 2–4 wk of infusion; ~30% of adults excluded by seropositivity
#2 Current OR historical FVIII inhibitor	Lifetime exclusion — switch to `J7170` Hemlibra or `J7173` Alhemo (both work in inhibitor patients)
#3 FVIII activity > 1 IU/dL (not severe)	Roctavian labeled for severe only (FVIII ≤ 1 IU/dL); continue prophylaxis
#4 Pediatric attempted (adults only)	Not eligible — pediatric continues FVIII or Hemlibra prophylaxis
#5 Hepatic monitoring plan missing	Document weekly LFTs × 6 months (longer than Hemgenix's 3 mo) + corticosteroid plan
NOC documentation incomplete (J3399)	Attach drug name, dose in vg, NDC, invoice, manufacturer product sheet; modifier KX per payer
Kit lot / NDC / volume missing	Resubmit with N4 + 68135-0150-01 + ML + total volume + lot in claim notes
Active hep B / C or uncontrolled HIV	Treat to undetectable; re-screen and re-submit PA
Hemlibra step therapy not met	Document Hemlibra history (dose, schedule, ABR) OR contraindication OR shared-decision-making note
Site of care not certified HTC	Re-route to certified HTC; BioMarin maintains directory
Wrong admin CPT (96413 / 79101 / 96374 push)	Use 96365 + 96366 (therapeutic IV ~2–3 hr); Roctavian is NOT a FVIII push
Wrong HCPCS (J3490 / J3590 generic NOC)	Use J3399 (gene therapy NOC) with full attachments

BIOMARIN PATIENT SUPPORT & ADVOCACY

BIOMARIN PATIENT & CAREGIVER RESOURCES

Phone: **1-866-906-6100**
Web: biomarin.com/products/roctavian
Services: benefits investigation, PA assistance, anti-AAV5 antibody testing logistics, certified HTC referral, travel/lodging support, FVIII / Hemlibra bridging coordination, outcomes-based contract operations, durability counseling resources

NBDF (BLEEDING.ORG) & HFA (HEMOPHILIAFED.ORG)

Federally-funded HTC directory · MASAC clinical guidelines (gene therapy in hemophilia A) · HFA helping hands grants · peer/patient support · emergency travel/lodging assistance · mentorship for adults considering gene therapy