

THE 6 THINGS YOU NEED TO BILL J1411

HCPCS J1411 Per-therapeutic-dose (one-time, lifetime event)	DOSE 2 × 10¹³ vg/kg Weight-based; 70 kg adult = 1.4 × 10 ¹⁵ vg	ADMIN CPT 96365 (+96366) Therapeutic IV ~30–60 min — NOT 96413 / 79101 / 96374 push
AAV5 NAB GATE < 1:678 HOPE-B exclusion threshold (pre-treatment titer)	AGE ≥ 18 yr Adults only; pediatric continues FIX prophylaxis	WAC (ONE-TIME) ~\$3.5M World's most expensive drug; outcomes-based contracts

WARNINGS & PRECAUTIONS (no boxed warning): Hepatotoxicity (ALT elevations ~17% in HOPE-B), infusion reactions, immune-mediated response, theoretical malignancy risk from AAV vector integration (15-yr long-term registry). Monitor ALT/AST/ALP/total bili weekly × 3 months. Reactive prednisone 60 mg/day taper × 8–12 weeks if ALT > 2× baseline or > ULN.

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

WHEN	STEP	DOCUMENTATION
Pre-Dx workup	Hemophilia B confirmation	FIX activity assay (typically ≤ 2 IU/dL severe); D67; family history (Z83.2 if applicable)
Day –28 to –14	Anti-AAV5 NAb titer + serology	Result < 1:678 (HOPE-B gate); hep B / C / HIV negative; coordinated via CSL Behring patient support
Day –14	Baseline labs + eligibility verification	LFTs (ALT, AST, ALP, total bili), CBC, PT/INR, FIX activity, FIX inhibitor (Bethesda) negative; age ≥ 18; weight; FIX prophylaxis history (product, dose, ABR) OR documented life-threatening / repeated bleed
Day 0	Hemgenix IV infusion (~30–60 min)	J1411 × 1 unit + CPT 96365; kit lot, total volume, infusion times recorded; HTC inpatient or extended observation
Weeks 1–12	Weekly LFT; clinical bleed assessment	Hepatotoxicity surveillance; bill outpatient labs + E/M; reactive prednisone taper if ALT elevation
3 / 6 / 12 / 24 / 36 / 60 mo	Outcomes-based contract milestone assessments	FIX activity (chromogenic + one-stage); ABR; FIX product utilization; coordinated via CSL Behring
Annual × 15 yr	Long-term safety registry	Malignancy surveillance per AAV integration theoretical risk; durability tracking

ICD-10 (ADULT HEMOPHILIA B, ≥ 18 YR)

D67	Hereditary factor IX deficiency (hemophilia B / Christmas disease) — PRIMARY
Z79.899	Long-term use of antithrombotic / coagulation factor (FIX prophylaxis 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	FIX inhibitor — CONTRAINDICATION; Bethesda assay must be negative

Documentation must include FIX activity, anti-AAV5 NAb < 1:678, age ≥ 18, FIX prophylaxis history OR life-threatening/repeated bleed history, FIX inhibitor negative.

HEMOPHILIA B CLASS — NOT INTERCHANGEABLE

J1411	Hemgenix — one-time IV AAV5 gene therapy (this page)
J7202	IDELVION (rFIX-FP) — EHL FIX prophylaxis q7–14d
J7201	Alprolix (rFIX-Fc) — EHL FIX prophylaxis q7–14d
J7203	Rebinyon (rFIX-GlycoPEG) — EHL FIX q7d
J7193	IXINITY (rFIX) — SHL FIX 2–3×/wk
J7195	BeneFIX (rFIX) — SHL FIX 2–3×/wk
J7173	Alhemo (concizumab) — anti-TFPI prophylaxis (A or B w/ inhibitors)

SITE OF CARE — CERTIFIED HTC ONLY

POS 21 (IP)	HTC-affiliated planned admission — primary at many HTCs
POS 22 / 19	HTC HOPD extended observation; OPSPS pass-through verify Addendum B

TOP DENIAL #1: Anti-AAV5 NAb titer not documented or $\geq 1:678$ (must be $< 1:678$, current within 2–4 weeks of infusion). Coordinate testing through CSL Behring patient support: 1-800-676-4266.

PAYER POLICIES & OUTCOMES-BASED CONTRACTING

PAYER	PA?	OBA?	KEY DOCUMENTATION
UnitedHealthcare (Optum)	Yes	Yes	FDA-label-aligned; HTC; D67; anti-AAV5 NAb $< 1:678$; FIX inhibitor negative
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
Cigna / Accredo	Yes	Yes	FDA label; comprehensive packet
State Medicaid (most)	Yes	Yes	State-specific SRA + OBA; CMS Cell & Gene Therapy (CGT) Access Model (2025+)
Medicare Part B	MAC LCD	Limited	FDA label; HTC; baseline LFTs / serology

Outcomes-based contracting nutshell: Pay full WAC at administration; manufacturer refunds % of WAC if FIX activity / ABR / FIX product use milestones not met over 5-year window. Provider documents outcomes at 3/6/12/24/36/60 mo via CSL Behring; rebate flow is payer-side and does not affect provider payment at infusion. CMS CGT Access Model (launched 2025) provides multi-state Medicaid framework.

TOP DENIALS & FIXES

DENIAL	FIX
#1 Anti-AAV5 NAb not documented or $\geq 1:678$	Order via CSL Behring patient support; result $< 1:678$ within 2–4 wk of infusion
#2 Pediatric attempted (adults only)	Not eligible — pediatric continues FIX prophylaxis (IDELVION, Alprolix, etc.)
#3 No prior FIX prophylaxis OR bleed history	Document FIX product history (dose, schedule, ABR) OR life-threatening / repeated bleeds
#4 Hepatic monitoring plan missing	Document weekly LFTs $\times 3$ mo + reactive prednisone plan
#5 Kit lot / NDC / volume missing	Resubmit with N4 + 63833-0876-01 + ML + total volume + lot in claim notes
FIX inhibitor positive (Bethesda)	Hemgenix contraindicated; switch to bypass agents or J7173 Alhemo
Active hep B / C or uncontrolled HIV	Treat to undetectable; re-screen and re-submit PA
Site of care not certified HTC	Re-route to certified HTC; CSL Behring maintains directory
Wrong admin CPT (96413 / 79101 / 96374 push)	Use 96365 (therapeutic IV ~30–60 min); Hemgenix is NOT a FIX push
Wrong HCPCS (J3490 / J3590 / C9399)	Use J1411 (permanent per-therapeutic-dose code)

CSL BEHRING PATIENT SUPPORT & ADVOCACY

CSL BEHRING HEMGENIX SUPPORT

Phone: **1-800-676-4266**
 Web: cslbehring.com/products/hemgenix
 Services: benefits investigation, PA assistance, anti-AAV5 NAb testing logistics, certified HTC referral, travel/lodging support, FIX bridging coordination, outcomes-based contract operations

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

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