Casgevy (exagamglogene autotemcel, exa-cel)

HCPCS J3590 (NOC) · First CRISPR-edited therapy · Autologous HSC, SCD/TDT ≥12 yr

CareCost Estimate · Q2 2026
Reviewed May 22, 2026

INSTANT ANSWER

HCPCS (CURRENT)	MIN DOSE	HSC INFUSION CPT
J3590	**≥3 × 10^6 CD34+/kg**	**38241**
NOC unclassified biologics; C9399 alt for HOPPS	Typical 4–20 × 10^6/kg	Autologous HSCT

APHERESIS CPT	BUSULFAN	AGE CUTOFF
38206 / 0540T	**J0594**	**≥12 yr**
Autologous HSC harvest	PK-adjusted myeloablation, 4 d	Both SCD and TDT labels

PRODUCT WAC	INPATIENT STAY	FDA APPROVALS
~$2.2M	**~30–45 d**	**Dec 8, 2023 SCD; Jan 16, 2024 TDT**
One-time; plus facility ~$500K–$1M+	Busulfan + HSC + engraftment	First CRISPR therapy ever approved

Top denial driver: SCD/TDT genetic confirmation missing. Submit hemoglobinopathy genotyping (HbSS / HbSC / HbS-β-thal for SCD; β-thal major / HbE-β-thal for TDT) plus recurrent VOC log (SCD) or transfusion-dependence log (TDT) at PA intake. #2 = administration at non-ATC facility.

MULTI-STAGE ENCOUNTER (5 PHASES)

PHASE	TIMING	SETTING	KEY CODES
1. Apheresis HSC collection	~6 mo pre-infusion	ATC outpatient (POS 22)	CPT 38206 or 0540T + plerixafor J2562 (SCD)
2. Ex vivo CRISPR manufacturing	4–6 mo at Vertex facility	Vertex (no provider billing)	n/a (manufacturer internal)
3. Busulfan myeloablative conditioning	4 days pre-infusion	ATC inpatient (POS 21)	J0594 (busulfan, per mg) + 96413 chemo admin
4. Autologous HSC infusion	Day 0	ATC inpatient (POS 21)	**J3590** + CPT **38241** (HSCT autologous)
5. Engraftment monitoring	30–45 d inpatient, then outpatient mo 1–24+	ATC inpatient then outpatient	Bundled into HSCT DRG; outpatient E/M + labs after discharge

GENE THERAPY CLASS COMPARISON

THERAPY	MECHANISM	INDICATION	BILLING PATHWAY	PRODUCT LIST
Casgevy (J3590)	CRISPR/Cas9 BCL11A edit (ex vivo HSC)	SCD / TDT ≥12 yr	Multi-stage HSCT	~$2.2M
Lyfgenia (NOC)	Lentiviral bA-T87Q (ex vivo HSC)	SCD ≥12 yr	Multi-stage HSCT	~$3.1M (BOXED warning)
Zolgensma (J3399)	AAV9 + SMN1 (in vivo)	Pediatric SMA <2 yr	Single IV infusion	~$2.125M
Hemgenix (J1411)	AAV5 + FIX-Padua (in vivo)	Adult hemophilia B	Single IV infusion	~$3.5M
Roctavian (J1412)	AAV5 + FVIII-SQ (in vivo)	Adult hemophilia A	Single IV infusion	~$2.9M

ICD-10 BY INDICATION

SCD (RECURRENT VOCS)

HbSS with crisis (VOC)	`D57.00` / `D57.01`
HbSC with crisis	`D57.20x` / `D57.21x`
HbS-β-thal with crisis	`D57.40x` / `D57.41x`
Sickle-cell trait (NOT eligible)	`D57.3`

TDT (TRANSFUSION-DEPENDENT B-THAL)

β-thalassemia major (Cooley's)	`D56.1`
HbE-β-thalassemia	`D56.5`
Long-term chelator use	`Z79.899`
Hx stem cell transplant (post)	`Z94.81`

SITE OF CARE — ATC ONLY

Authorized Treatment Centers (ATCs) only. Vertex credentials a network of FACT-accredited HSCT-eligible facilities with established autologous HSCT programs, busulfan dose-banding experience, apheresis capability, and cryopreservation chain-of-custody. Office-based, AIC, and home administration are categorically not appropriate. Directory at casgevy.com/hcp.

TOP 6 DENIALS

#	REASON	FIX
1	SCD/TDT genetic confirmation missing	Submit hemoglobinopathy genotyping + electrophoresis
2	Non-ATC facility	Re-route to credentialed ATC (casgevy.com/hcp)
3	Recurrent VOC docs gap (SCD)	Submit detailed VOC log; document hydroxyurea trial
4	TDT severity not documented	Submit transfusion log + chelation history
5	Patient < 12 yr	Not FDA-approved; maintain supportive care
6	HSCT eligibility incomplete	Complete standard pre-HSCT workup at ATC

PATIENT ASSISTANCE & PAYER MODEL

HUB

Vertex Patient Support: 1-877-752-5933 / casgevy.com/hcp — ATC referral, apheresis logistics, manufacturing chain-of-custody, fertility-preservation counseling, travel/lodging, outcomes-based contract administration, 15-yr long-term follow-up registry.

FOUNDATIONS

Sickle Cell Disease Association of America (SCDAA), Cooley's Anemia Foundation, BMT InfoNet, PAN Foundation (rare disease), HealthWell Foundation, Patient Advocate Foundation.

OUTCOMES-BASED CONTRACTS

Common with all major commercial payers and CMS CGT Access Model (Medicaid). 3–5 yr milestone tracking (absence of severe VOCs, transfusion independence). Provider documents outcomes data at mo 6, 12, 24, 60.

CMS CGT ACCESS MODEL

Launched January 2025. CMS negotiates OBAs for SCD gene therapies (Casgevy + Lyfgenia) on behalf of >20 participating state Medicaid agencies. Standardized outcomes metrics, pricing, and milestone tracking.