

exagamglogene autotemcel (Casgevy)

HCPCS: J3392 Injection, exagamglogene autotemcel, per treatment (Casgevy)

LOB:	MCAL
Duration of Approval:	One dose per lifetime
Quantity Limit:	Per FDA Approved/Compendia Supported Dosing
MCG Available:	Yes
DHCS Drug Policy:	No

Requires Prior Authorization (PA)

Casgevy (exagamglogene autotemcel) injection

****All requests must be approved by a Medical Director ********As of October 1st 2025, Casgevy, for the treatment of sickle cell disease will be carved out and covered by DHCS Fee-for-Service. These therapies are not part of any inpatient bundled payment and must be billed separately.******PA CRITERIA FOR APPROVAL:**

- **For sickle cell disease:** Request should be re-directed to DHCS Fee-for-Service.
- **For transfusion-dependent B thalassemia:** Following the criteria below:
 1. The member has a diagnosis for an FDA approved indication (*refer to package insert under References*) OR a compendia supported (Drugdex or AHFS) indication **AND**
 2. The medication is prescribed by a Hematologist **AND**
 3. The member is transfusion-dependent, as indicated by at least ONE of the following:
 - a. At least 100 mL/kg per year of packed red blood cells (pRBC) transfusions in previous 2 years
 - b. At least 10 units per year of pRBC transfusions in previous 2 years**AND**
 4. The member is eligible for hematopoietic stem cell transplant (HSCT) and has not had prior HSCT **AND**
 5. The member does NOT have any of the following:
 - a. Severely elevated iron in the heart (i.e., cardiac T2* < 10msec by MRI or left ventricular ejection fraction (LVEF) < 45% by ECHO)
 - b. Advanced liver disease (i.e., AST or ALT > 3x ULN, bilirubin > 2.5 x ULN, bridging fibrosis, cirrhosis, or liver iron content ≥ 15mg/g by MRI)**AND**
 6. The member has negative serology test for HIV-1/HIV-2, HBV, or HCV **AND**
 7. The member has not been previously treated with Casgevy or other gene therapy

OTHER INFORMATION:

HCPCS	Description	Brand name
J3392	Injection, exagamglogene autotemcel, per treatment	Casgevy

REFERENCES:

1. Casgevy Prescribing Information. pi.vrtx.com/files/uspi_exagamglogene_autotemcel.pdf 03/2026.
2. CMS Cell and Gene Therapy Access Model. mcweb.apps.prd.cammis.medi-cal.ca.gov/assets/D1E22E34-A79F-44A5-9F1E-F44904944515/celgenacc.pdf?access_token=6UyVkRRfByXTZEWIh8j8QaYyIPyP5ULO. 10/2025.
3. DHCS Publications. DHCS Approved to Participate in Medi-Cal Cell and Gene Therapy Access Model. www.dhcs.ca.gov/formsandpubs/publications/oc/Pages/041425-Stakeholder-News.aspx#:~:text=The%20Center%20for%20Medicare%20and,information%20as%20it%20becomes%20available.04/2025.

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4. DHCS Cell and Gene Therapy (CGT) Access Model. General Frequently Asked Questions (FAQs)
www.dhcs.ca.gov/services/medi-cal/Pages/CGT-FAQ.aspx. 08/2025.
5. DHCS All Plan Letter 25-013. Subject: Medi-Cal Rx Pharmacy Benefits, and Cell and Gene Therapy Coverage.
www.dhcs.ca.gov/formsandpubs/Documents/MMCDAPLsandPolicyLetters/APL%202025/APL25-013.pdf . 09/2025.
6. DHCS Cell and Gene Therapy Overview. mcweb.apps.prd.cammis.medi-cal.ca.gov/assets/821726E2-2EAB-4A86-AA42-4778E89A38FD/celgenover.pdf?access_token=6UyVkRRfByXTZEWIh8j8QaYyIPyP5ULO. 09/2025.

UMC REVIEW:

6/2026