

lovotibeglogene autotemcel (Lyfgenia)

HCPCS: J3394 Injection, lovotibeglogene autotemcel, per treatment (Lyfgenia)

LOB:	MCAL
Duration of Approval:	DO NOT APPROVE-COVERED UNDER MCAL FFS
Quantity Limit:	DO NOT APPROVE-COVERED UNDER MCAL FFS
MCG Available:	No
DHCS Drug Policy:	No

Requires Prior Authorization (PA)

Lyfgenia (lovotibeglogene autotemcel) injection

****As of July 1st 2025, Lyfgenia, for the treatment of sickle cell disease will be carved out and covered by DHCS under the Fee-for-Service medical benefit. These therapies are not part of any inpatient bundled payment and must be billed separately. ****

For sickle cell disease: Request should be re-directed to DHCS Fee-for-Service.

OTHER INFORMATION:

HCPCS	Description	Brand name
J3394	Injection, lovotibeglogene autotemcel, per treatment	Lyfgenia

REFERENCES:

1. Lyfgenia Prescribing Information. www.bluebirdbio.com/-/media/bluebirdbio/Corporate%20COM/Files/Lyfgenia/LYFGENIA_Prescribing_Information.pdf. 12/2023.
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.
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