

# PHARMACY POLICY STATEMENT

## Marketplace

<b>DRUG NAME</b>	<b>Lyfgenia (lovotibeglogene autotemcel)</b>
BENEFIT TYPE	Medical
STATUS	Prior Authorization Required

Lyfgenia, initially approved by the FDA in 2023, is an autologous hematopoietic stem cell-based gene therapy indicated for the treatment of patients 12 years of age or older with sickle cell disease and a history of vaso-occlusive crises (VOCs). After Lyfgenia infusion, the transduced CD34+ hematopoietic stem cells (HSCs) -T87Q-

-T87Q-globin (HbAT87Q). HbAT87Q has similar oxygen-binding affinity and oxygen hemoglobin dissociation curve to wild type HbA, reduces intracellular and total hemoglobin S (HbS) levels, and is designed to sterically inhibit polymerization of HbS thereby limiting the sickling of red blood cells. SCD is caused by an inheri

**CareSource considers Lyfgenia (lovotibeglogene autotemcel) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.**

DATE	ACTION/DESCRIPTION
12/18/2023	New policy for Lyfgenia created.

References:

1. Lyfgenia [prescribing information]. Somerville, MA: Bluebird bio, Inc.; 2023
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3. Yawn BP, Buchanan GR, Afenyi-Annan AN, et al. Management of sickle cell disease: summary of the 2014 evidence-based report by expert panel members [published correction appears in JAMA. 2014 Nov 12;312(18):1932] [published correction appears in JAMA. 2015 Feb 17;313(7):729]. *JAMA.* 2014;312(10):1033-1048. doi:10.1001/jama.2014.10517
4. Kanter J, Liem RI, Bernaudin F, et al. American Society of Hematology 2021 guidelines for sickle cell disease: stem cell transplantation. *Blood Adv.* 2021;5(18):3668-3689. doi:10.1182/bloodadvances.2021004394C
5. Kanter J, Thompson AA, Pierciey FJ Jr, et al. Lovo-cel gene therapy for sickle cell disease: Treatment process evolution and outcomes in the initial groups of the HGB-206 study. *Am J Hematol.* 2023;98(1):11-22. doi:10.1002/ajh.26741
6. Institute for Clinical and Economic Review (ICER). Exa-cel and Lovo-cel: Final Policy Recommendations. August 2023.
7. Institute for Clinical and Economic Review (ICER). Gene Therapies for Sickle Cell Disease: Effectiveness and Value. August 2023.
8. IPD Analytics. Accessed December 15, 2023.

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