

Lyfgenia[®] (Lovotibeglogene Autotemcel) Prior Authorization Form

Member Name: _____ **Date of Birth:** _____ **Member ID#:** _____

Drug Information

Physician billing (HCPCS code: _____ **) Start Date:** _____

Billing Provider Information

Provider NPI: _____ **Provider Name:** _____

Provider Phone: _____ **Provider Fax:** _____

Prescriber Information

Prescriber NPI: _____ **Prescriber Name:** _____

Prescriber Phone: _____ **Prescriber Fax:** _____ **Specialty:** _____

Criteria

For Authorization: (Only one Lyfgenia[®] infusion will be approved per member per lifetime):

1. Please indicate the member's diagnosis:
 - Sickle Cell Disease (SCD) with a history of vaso-occlusive events (VOEs)
 - Other: _____
2. Does the member have evidence of severe disease as demonstrated by ≥ 4 VOEs in the last two years?
Yes___ No___
a. Dates of occurrence: _____
3. Does the member have >2 α -globin gene deletions? Yes___ No___
4. Is the prescriber a hematologist with expertise in the treatment of SCD and the administration of Lyfgenia[®]?
Yes___ No___
5. Does the member have a trial with at least 1 pharmacological treatment option for SCD (i.e., hydroxyurea, L-glutamine, crizanlizumab-tmca)? Yes___ No___
a. If no, please provide a patient-specific, clinically significant reason why a pharmacological treatment option is not appropriate for the member: _____
6. Does the member have a known and available human leukocyte antigen (HLA)-matched sibling donor?
Yes___ No___
7. Does the member have a prior history of hematopoietic stem cell transplantation (HSCT)? Yes___ No___
8. Has the member previously received treatment with Casgevy[™]? Yes___ No___
9. Does the member have a negative serology test for human immunodeficiency virus (HIV) prior to apheresis?
Yes___ No___
10. Is the member clinically stable and eligible to undergo HSCT? Yes___ No___
11. Have disease modifying therapies been discontinued 8 weeks prior to mobilization and conditioning?
Yes___ No___
12. Does prescriber verify that granulocyte-colony stimulating factor (G-CSF) will not be used for the CD34+ HSC mobilization? Yes___ No___

PLEASE PROVIDE THE INFORMATION REQUESTED AND RETURN TO:

University of Oklahoma College of Pharmacy
Pharmacy Management Consultants
Product Based Prior Authorization Unit
Fax: 1-800-224-4014
Phone: 1-800-522-0114 Option 4

CONFIDENTIALITY NOTICE

This document, including any attachments, contains information which is confidential or privileged. If you are not the intended recipient, be aware that any disclosure, copying, distribution, or use of the contents of this information is prohibited. If you have received this document in error, please notify the sender immediately by telephone to arrange for the return of the transmitted documents or to verify their destruction.

Lyfgenia[®] (Lovotibeglogene Autotemcel) Prior Authorization Form

Member Name: _____ **Date of Birth:** _____ **Member ID#:** _____

Criteria

***Page 2 of 2—Please complete and return all pages. Failure to complete all pages will result in processing delays.*
For Authorization, continued:**

13. If member is female:
 - a. Is member pregnant? Yes ___ No ___
 - b. Will member have a negative pregnancy test prior to the start of mobilization, prior to conditioning procedures, and prior to Lyfgenia[®] administration? Yes ___ No ___
14. If member is of reproductive potential, will they use an effective method of contraception from the start of mobilization through at least 6 months after administration of Lyfgenia[®]? Yes ___ No ___
15. If member is of reproductive potential, has the prescriber counseled them on the potential effects of myeloablative conditioning on fertility, and the potential risk of infertility is acceptable to the member? Yes ___ No ___
16. Will the prescriber evaluate the potential for drug interactions, according to package labeling, prior to and after administration of Lyfgenia[®]? Yes ___ No ___
17. Will member be monitored for hematologic malignancies lifelong, with a complete blood count (with differential) performed at month 6 and month 12 after treatment with Lyfgenia[®], then at least annually thereafter for at least 15 years, and with integration site analysis at months 6,12, and as warranted? Yes ___ No ___
18. Will Lyfgenia[®] be administered at a Lyfgenia[®] qualified treatment center? Yes ___ No ___
 - A. Please provide name of treatment center: _____
19. Does the receiving facility have a mechanism in place to track the patient-specific Lyfgenia[®] dose from receipt to storage to administration? Yes ___ No ___
 - A. Please provide name of facility: _____
20. Please provide a patient-specific, clinically significant reason why the member cannot use Casgevy[™]:

Additional information: _____

(Page 2 of 2)

Prescriber Signature: _____ **Date:** _____

I certify that the indicated treatment is medically necessary and all information is true and correct to the best of my knowledge. Failure to complete this form in full and attach requested clinical notes will result in processing delays.

PLEASE PROVIDE THE INFORMATION REQUESTED AND RETURN TO:

University of Oklahoma College of Pharmacy
Pharmacy Management Consultants
Product Based Prior Authorization Unit
Fax: 1-800-224-4014
Phone: 1-800-522-0114 Option 4

CONFIDENTIALITY NOTICE

This document, including any attachments, contains information which is confidential or privileged. If you are not the intended recipient, be aware that any disclosure, copying, distribution, or use of the contents of this information is prohibited. If you have received this document in error, please notify the sender immediately by telephone to arrange for the return of the transmitted documents or to verify their destruction.