



Government of District of Columbia Pharmacy Program

Lyfgenia (lovotibeglogene autotemcel)

Initial Prior Authorization Request

Request Date: _____

RECIPIENT INFORMATION

Recipient Medicaid ID: _____

Date of Birth: _____

Recipient Last Name: _____

Recipient First Name: _____ Middle Initial: _____

PRESCRIBER INFORMATION

Prescriber Last Name: _____

Prescriber First Name: _____

Prescriber Phone: _____

Prescriber Fax: _____

Prescriber DEA Number: _____

Prescriber NPI Number: _____

Prescriber Specialty: _____

PHARMACY INFORMATION

Pharmacy Name: _____

Pharmacy Phone: _____

Pharmacy Fax: _____

Pharmacy NPI Number: _____

Refer to FDA www.fda.gov for prescribing details and approved indications.

INFORMATION REQUIRED FOR PRIOR AUTHORIZATION APPROVAL

1. Will the recipient be 12 years of age at the expected time of gene therapy administration?
☐ Yes ☐ No
2. Does the recipient have a confirmed diagnosis of sickle-cell disease via genetic testing?
☐ Yes ☐ No
3. Has the recipient had a failure or intolerance to hydroxyurea (HU) (defined as being unable to take hydroxyurea per health care professional judgement) at any point in the past?
☐ Yes ☐ No

Member's Name (Last, First): _____

4. Is the recipient currently receiving chronic transfusion therapy for recurrent severe vaso-occlusive events (VOEs)?

☐ Yes ☐ No

If No, has the recipient experienced four or more VOEs in previous 24 months as determined by the treating clinician?

☐ Yes ☐ No

5. Is the recipient clinically stable and fit for transplantation?

☐ Yes ☐ No

Duration of approval: 12 months – allow 1 dose per lifetime

The following must be **true** and **stated on the request**:

- The recipient does not have advanced liver disease; **AND**
- The recipient has not tested positive for human immunodeficiency virus (HIV) infection; **AND**
- The recipient does not have inadequate bone marrow function, as defined by an absolute neutrophil count of less than 1000/ μ L (< 500/ μ L for subjects on HU treatment) or a platelet count of less than 100,000/ μ L; **AND**
- The recipient does not have prior or current malignancy or immunodeficiency disorder, except previously treated, non-life threatening, cured tumors such as squamous cell carcinoma of the skin; **AND**
- The recipient does not have an immediate family member with a known or suspected familial cancer syndrome; **AND**
- The recipient is not pregnant or breastfeeding; **AND**
- The recipient is eligible to receive hematopoietic stem cell (HSC) transplantation; **AND**
- The recipient does not have a clinically significant and active bacterial, viral, fungal, or parasitic infection.

By submitting the authorization request, the prescriber attests to the following:

- The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, and prior treatment requirements; **AND**
- All laboratory testing and clinical monitoring recommended in the prescribing information have been completed as of the date of the request and will be repeated as recommended; **AND**
- The recipient has no concomitant drug therapies or disease states that limit the use of the requested medication and will not be receiving the requested medication in combination with any other medication that is contraindicated or not recommended per FDA labeling.

Member's Name (Last, First): _____

I certify that the above information is correct and accurate to the best of my knowledge and that the form is complete (please sign and date). I understand that I may be subject to civil penalties or criminal prosecutions for any falsification, omission, or concealment of any material fact contained herein.

Attestation: I certify that the information provided is accurate and complete to the best of my knowledge, and I understand the Health Plan, insurer, or its designees may request additional medical information necessary to verify the accuracy of information reported, and that any falsification, omission, or concealment of material fact may subject me to civil or criminal liability.

Prescriber's Signature: _____ **Date:** _____

Submit completed PA request, letter of medical necessity, lab test results, and member education and commitment to treatment form to [Comagine Health DHCF DC Medicaid](https://comagine.org/program/dc-medicaid-um): <https://comagine.org/program/dc-medicaid-um>.