JOHNS HOPKINS HEALTH PLANS	Johns Hopkins Health Plans **Pharmacy Public** **Medical Management Drug Policies**	*Policy Number*	MMDP100
		Effective Date	01/15/2025
		Approval Date	07/17/2024
	Subject **Lyfgenia**	*Supersedes Date*	N/A
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This document applies to the following Participating Organizations:

US Family Health Plan

Keywords: Lyfgenia

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I. POLICY

A. Lyfgenia (lovotibeglogene autotemcel)will require prior authorization for medical benefit coverage to ensure appropriate use. The process for initiating a prior authorization request can be found in policy PHARM 20.

II. POLICY CRITERIA

A. Lyfgenia may be approved for patients who meet the following:
   1. Patient is 12 years of age or older.
   2. Documentation has been submitted showing all the following:
      a. Diagnosis of sickle cell disease with one of the following genotypes confirmed by molecular or genetic testing:
         I. beta-s/beta-s
         II. beta-s/beta-0
         III. beta-s/beta+
      b. Patient has a documented history of at least 2 severe vaso-occlusive episodes per year during the previous two years. Examples of these events include:
         I. Acute pain event requiring a visit to a medical facility and administration of pain medications (opioids or intravenous [IV] non-steroidal anti-inflammatory drugs [NSAIDs]) or RBC transfusions
         II. Acute chest syndrome
         III. Priapism lasting greater than 2 hours and requiring a visit to a medical facility
         IV. Splenic sequestration
         V. Hepatic sequestration
      c. Patient is eligible for a hematopoietic stem cell transplant (HSCT) but is unable to find a human leukocyte antigen (HLA)-matched related donor
      d. Patient has not received a prior HSCT
      e. Patient has not previously received Lyfgenia or any other gene therapy
      f. Patient does not have more than two alpha-globin gene deletions

III. AUTHORIZATION PERIOD/LIMITATIONS

A. Approval will be limited to a one-time single dose.

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IV. EXCLUSIONS

A. Lyfgenia will not be covered for the following:
   1. Any indications or uses that are not FDA-approved, or guideline-supported

V. RECOMMENDED DOSE

Please refer to the FDA-approved prescribing information, or clinical guidelines, for indication-specific dosing details.

VI. CODES

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Note: The following CPT/HCPCS codes are included below for informational purposes. Inclusion or exclusion of a CPT/HCPCS code(s) below does not signify or imply member coverage or provider reimbursement. The member's specific benefit plan determines coverage.

Medication	HCPCS/CPT Code
Injection, lovotibeglogene autotemcel, per treatment	J3394

VII. REFERENCES

1. Lyfgenia [prescribing information]. Somerville, MA: bluebird bio, Inc.; December 2023.
2. Walters JK, Krishnamurti L, Mapara MY, et al. Biologic and clinical efficacy of LentiGlobin for sickle cell disease. NEJM. 2022;386(7):617-628.
3. Evidence-Based Management of Sickle Cell Disease: Expert Panel Report, 2014. National Institutes of Health. Available at https://www.nhlbi.nih.gov/sites/default/files/media/docs/sickle-cell-disease-report%20020816_0.pdf. Accessed July 9, 2024.

VIII. APPROVALS

Signature on file at JHHP

DATE OF REVISION	SUMMARY OF CHANGE
07/17/2024	Policy creation
01/15/2025	Removed prescriber specialty requirement

Review Date: 07/17/2024

Revision Date: 01/15/2025