MASSACHUSETTS

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Gene Therapies for Sickle Cell Disease – Prior Authorization Request Form for Lyfgenia™ (Lovotibeglogene autotemcel), #079

Medical Policy #050 Gene Therapies for Sickle Cell Disease

CLINICAL DOCUMENTATION

- Clinical documentation that supports the medical necessity criteria for Lyfgenia must be submitted.
- If the patient does not meet all the criteria listed below, please submit a letter of medical necessity with a request for Clinical Exception (Individual Consideration) explaining why an exception is justified.

Requesting Prior Authorization Using Authorization Manager

Providers will need to use Authorization Manager to submit initial authorization requests for services. Authorization Manager, available 24/7, is the quickest way to review authorization requirements, request authorizations, submit clinical documentation, check existing case status, and view/print the decision letter. For commercial members, the requests must meet medical policy guidelines.

To ensure the request is processed accurately and quickly:

- Enter the facility's NPI or provider ID for where services are being performed.
- Enter the appropriate surgeon's NPI or provider ID as the servicing provider, *not* the billing group.

Authorization Manager Resources

- Refer to our Authorization Manager page for tips, guides, and video demonstrations.

For out of network providers: Requests should still be faxed to 888-973-0726.

Patient Information	
Patient Name:	Today's Date:
BCBSMA ID#:	Date of Treatment:
Date of Birth:	Place of Service: Outpatient ❒ Inpatient ❒ Distributor:

Physician Information	**Facility Information**
Name:	Name:
Address:	Address:
Phone #:	Phone #:
Fax#:	Fax#:
NPI#:	NPI#:

Please check off if the patient has the following diagnosis:	
Sickle Cell Disease	❒

Please check off that the patient meets ALL the following criteria:

1. At least 12 years of age; **AND**	❒
2. Diagnosis of sickle cell disease confirmed by genetic testing demonstrating the following: a. Homozygous sickle cell disease (e.g., Hb**SS**); **OR** b. Heterozygous sickle cell disease (e.g., Hb**SC**, Hb**Sβ$^+$**, Hb**Sβ^0**, Hb**SD**, Hb**SOArab**, Hb**SE**); **AND**	❒ ❒
3. Documented history of one of the following clinical signs or symptoms in the last 12 months in the setting of appropriate supportive care measures for sickle cell disease (e.g., pain management plan): a. Acute pain event requiring a visit to a medical facility and administration of pain medications (opioids or intravenous non-steroidal anti-inflammatory drugs) or red blood cell transfusions b. Acute chest syndrome c. Acute hepatic sequestration d. Acute splenic sequestration e. Priapism lasting > 2 hours and requiring a visit to a medical facility; **AND**	❒ ❒ ❒ ❒ ❒
4. Meet the institutional requirements for a stem cell transplant procedure where the individual is expected to receive gene therapy (see Policy Guidelines). These requirements may include: a. Adequate Karnofsky performance status or Lansky performance status; b. Absence of advanced liver disease; c. Adequate estimate glomerular filtration rate (eGFR); d. Adequate diffusing capacity of the lungs for carbon monoxide (DLCO); e. Adequate left ventricular ejection fraction (LVEF); f. Absence of clinically significant active infection(s); **AND**	❒ ❒ ❒ ❒ ❒ ❒
5. Have not received a previous allogenic hematopoietic stem cell transplant; **AND**	❒
6. Have not received any gene therapy or are under consideration for treatment for another gene therapy for sickle cell disease.	❒

HCPCS Codes	Code Description
C9399	Unclassified drugs or biologicals
J3490	Unclassified drugs
J3590	Unclassified biologics

Providers should enter the <u>relevant diagnosis code(s)</u> below:

Code	Description	
		❒
		❒

Providers should enter <u>other relevant code(s)</u> below:

Code	Description	
		❒
		❒