

I. Requirements for Prior Authorization of Casgevy (exagamglogene autotemcel)

A. Prescriptions That Require Prior Authorization

All prescriptions for Casgevy (exagamglogene autotemcel) must be prior authorized.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for Casgevy (exagamglogene autotemcel), the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Is prescribed Casgevy (exagamglogene autotemcel) for an indication that is included in the U.S. Food and Drug Administration (FDA)-approved package labeling; **AND**
2. Is age-appropriate according to FDA-approved package labeling; **AND**
3. Is prescribed a dose and number of treatments that are consistent with FDA-approved package labeling; **AND**
4. Is prescribed Casgevy (exagamglogene autotemcel) by a specialist at an authorized treatment center for Casgevy (exagamglogene autotemcel); **AND**
5. Does not have a contraindication to the prescribed drug; **AND**
6. Is clinically stable for transplantation based on the prescriber's assessment; **AND**
7. **One** of the following:
 - a. For treatment of sickle cell disease, **both** of the following:
 - i. Has sickle cell disease with confirmatory genetic testing
 - ii. **One** of the following:
 - a) Has a history of vaso-occlusive episodes (e.g., pain crises, acute chest syndrome, splenic sequestration, priapism) that required a medical facility visit (e.g., emergency department, hospital)
 - b) Is currently receiving chronic transfusion therapy for recurrent vaso-occlusive episodes
 - b. For treatment of transfusion-dependent β -thalassemia, **both** of the following:
 - i. Has genetic testing confirming diagnosis of β -thalassemia
 - ii. Has a history of at least 100 mL/kg/year or 8 transfusion episodes/year of packed red blood cell transfusions in the prior 2 years.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to

meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for Casgevy (exagamglogene autotemcel). If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

D. Dose and Duration of Therapy

Requests for prior authorization of Casgevy (exagamglogene autotemcel) will be approved for 18 months.

CASGEVY (exagamglogene autotemcel) PRIOR AUTHORIZATION FORM (form effective 1/5/2026)

Beneficiary name:	Beneficiary ID#:	Beneficiary DOB:
Prescriber name:	Prescriber NPI:	
Prescriber address (street/city/state/zip):		
Prescriber specialty:	Prescriber phone:	Prescriber fax:
Office contact name:	Office contact phone:	Office contact fax:
Service provider name:		Service provider MA ID:
Service provider address (street/city/state/zip):		

Drug name: Casgevy	Beneficiary's weight (kg):	Dose: _____ x 10 ⁶ CD34+ cells/kg
Place of service:		Anticipated date of infusion:
Diagnosis (submit documentation):	Dx code (required):	HCPCS code (required):

Complete the sections below that apply to the beneficiary and this request.

Check all that apply and submit documentation (e.g., recent chart notes, diagnostic evaluations, test results, etc.) for each item.

1. For ALL DIAGNOSES:

☐ Is clinically stable for transplantation based on the prescriber's assessment.

2. For the treatment of SICKLE CELL DISEASE:

☐ Has sickle cell disease with confirmatory genetic testing.

☐ At least one of the following:

☐ Has a history of vaso-occlusive episodes (e.g., pain crises, acute chest syndrome, splenic sequestration, priapism) that required a medical facility visit (e.g., emergency department, hospital).

☐ Is currently receiving chronic transfusion therapy for recurrent vaso-occlusive episodes.

3. For the treatment of TRANSFUSION-DEPENDENT β -THALASSEMIA:

☐ Has genetic testing confirming the diagnosis of β -thalassemia.

☐ Has a history of at least 100 mL/kg/year or 8 transfusion episodes/year of packed red blood cell transfusions in the prior 2 years.

PLEASE FAX COMPLETED FORM WITH SUPPORTING CLINICAL DOCUMENTATION

Prescriber Signature:	Date:
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