Prior Authorization Review Panel

CHC-MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

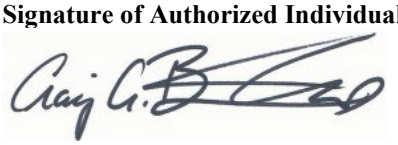
Plan: PA Health & Wellness	**Submission Date: 07/2024**
Policy Number: PA.CP.PHAR.603	**Effective Date: 07/15/2024** **Revision Date: 07/2024**
Policy Name: Exagamglogene autotemcel (Casgevy)	

Type of Submission – Check all that apply:

- ✓ **New Policy**
- ☐ **Revised Policy***
- ☐ **Annual Review - No Revisions**
- ✓ **Statewide PDL -** *Select this box when submitting policies for Statewide PDL implementation and when submitting policies for drug classes included on the Statewide PDL.*

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any changes or clarifying information for the policy below:

Name of Authorized Individual (Please type or print): **Craig A. Butler, MD MBA**	**Signature of Authorized Individual:** 

Clinical Policy: Exagamglogene autotemcel (Casgevy)

Reference Number: PA.CP.PHAR.603
Effective Date: 07/15/2024
Last Review Date: 07/2024

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of PA Health & Wellness® that Exagamglogene autotemcel (Casgevy) is **medically necessary** when the following criteria are met:

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 member:

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 medication; AND
6. Is not a prior recipient of gene therapy or an allogeneic hematopoietic stem cell transplant; AND
7. One of the following:
    a. For treatment of sickle cell disease, both of the following:
        i. Has sickle cell disease with a βS/βS, βS/β0, or βS/β+ genotype
        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 member does not meet the clinical review guidelines above but, in the professional judgement of the physician reviewer, the services are medically necessary to meet the medical needs of the member, 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 a 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 member

D. Approval Duration:
Requests for prior authorization of Casgevy (exagamglogene autotemcel) will be approved for 18 months for 1 infusion.

E. References

1. Casgevy [prescribing information]. Boston, MA: Vertex Pharmaceuticals Incorporated; January 2024.
2. The National Institutes of Health – National Heart, Lung, and Blood Institute Evidence-Based Management of Sickle Cell Disease, Expert Panel Report, 2014. Available at: https://www.nhlbi.nih.gov/sites/default/files/media/docs/sickle-cell-disease-report%20020816_0.pdf. Accessed March 2024.
3. Cappellini MD, Farmakis D, Porter J, Taher A, eds. 2021 Guidelines for the Management of Transfusion Dependent Thalassaemia (TDT). 4th ed. Thalassaemia International Federation (TIF). Available at: https://thalassaemia.org.cy/. Accessed March 2024.

4. Frangoul H, Altshuler D, Cappellini MD, et al. CRISPR-Cas9 gene editing for sickle cell disease and β-thalassemia. N Engl J Med. 2021;384:252-260.
5. Connor RF, Fosmarin AG, Tirnauer JS. What's new in hematology. UpToDate [internet database]. Waltham, MA: UpToDate Inc. Updated February 29, 2024. Accessed March 18, 2024.
6. Fitzjugh C. Investigational therapies for sickle cell disease. UpToDate [internet database]. DeBaun MR, Tirnauer JS, eds. Waltham, MA: UpToDate Inc. Updated December 22, 2023. Accessed March 15, 2024.

Reviews, Revisions, and Approvals	Date
Policy created	07/2024