Clinical Policy: Exagamglogene autotemcel (Casgevy)

Reference Number: PA.CP.PHAR.603
Effective Date: 07/15/2024
Last Review Date: 07/2025

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.
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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.
7. ClinicalTrials.gov. A safety and efficacy study evaluating CTX001 in subjects with severe sickle cell disease. Last updated June 1, 2022. Available at: https://clinicaltrials.gov/ct2/show/NCT03745287. Accessed November 18, 2024.
8. Yawn BP, Buchanan GR, Afenyi-Annan AN, et al. Evidence-based management of sickle cell disease: Expert Panel Report, 2014. National Heart, Lung, and Blood Institute (NHLBI). Available at: https://www.nhlbi.nih.gov/sites/default/files/media/docs/sickle-cell-disease-report%20020816_0.pdf. Accessed November 18, 2024.
9. Clinical Pharmacology [database online]. Philadelphia, PA: Elsevier. Updated periodically. Available at: http://www.clinicalkey.com/pharmacology. Accessed November 18, 2024.
10. ClinicalTrials.gov. A safety and efficacy study evaluating CTX001 in subjects with transfusion-dependent β-thalassemia. Last updated June 1, 2022. Available at: https://clinicaltrials.gov/study/NCT03655678. Accessed January 21, 2024.

Coding Implications
Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J3392	Injection, exagamglogene autotemcel, per treatment

Reviews, Revisions, and Approvals	Date
Policy created	07/2024
1Q 2025 annual review: HCPCS code added [J3392] and removed codes [J3590,C9399]; references reviewed and updated.	07/2025