Pharmacy Drug Policy & Procedure

Policy Name:	Casgevy (exagamglogene autotemcel)	Policy#:	3231P

Purpose of the Policy

The purpose of this policy is to define coverage criteria for Casgevy (exagamglogene autotemcel)

Statement of the Policy

Health Alliance Medical Plans will approve the use of Casgevy (exagamglogene autotemcel) under the specialty medical benefit if the following criteria are met.

Criteria

1. Coverage Criteria for Sickle Cell Disease

1.1 Diagnosis of sickle cell disease confirmed by genetic testing
- Must have βS/βS, βS/β0 or βS/β+ genotype

1.2 Documented severe disease as evident by history of recurrent vaso-occlusive crises defined as at least 2 events per year in the last 2 years prior to therapy

1.3 Prescribed by or in consultation with a hematologist (blood doctor) or other sickle cell specialist

1.4 Age 12 years or older

1.5 Documented trial and failure of standard of care including hydroxyurea, Endari, Oxbryta, or Adakveo
- Standard of care treatments must be discontinued for 2 months prior to Casgevy infusion

1.6 Review of clinical information confirming that patient has met all of the above requirements for treatment completed by both a pharmacist and medical director

2. Coverage Criteria for Transfusion Dependent Beta-Thalassemia

2.1 Diagnosis of transfusion dependent beta thalassemia with a history of requiring at least 100 mL/kg/year or 10 units/year of RBC transfusions in the past 2 years
- Must be non-β0/β0 genotype confirmed through genetic testing

2.2 Prescribed by or in consultation with a hematologist (blood doctor)

2.3 Age 12 years or older

2.4 Eligible for hematopoietic stem cell transplant but does not have a suitable HLA donor

2.5 Review of clinical information confirming that patient has met all of the above requirements for treatment completed by both a pharmacist and medical director

3. Exclusion Criteria

3.1 Significant liver dysfunction
- Patients with advanced liver disease were excluded from clinical trials (NCT03745287). Safety and efficacy has not been established in this patient population.

3.2 Diagnosis of any hematologic disorder other than sickle cell disease or transfusion dependent beta thalassemia
- Casgevy has only been studied in patients with confirmed diagnosis of sickle cell disease with the βS/βS, βS/β0 or βS/β+ genotype or beta thalassemia with non-β0/β0 genotype. Use of Casgevy for the treatment of any other hematologic disorder is considered experimental and excluded from coverage.

3.3 Prior treatment with an allogenic or autologous stem cell transplant

- Patients with prior stem cell transplant or those with eligible matched donors were excluded from clinical trials. Safety and efficacy of Casgevy in patients with a history of stem cell transplant has not been established and treatment is not recommended in these patients (package insert).

3.4 Casgevy will not be covered in patients who have previously received Lyfgenia or any other gene therapy

- Safety and efficacy has not been established in patients who were previously treated any gene therapy.

4. Approval Period

4.1 One-time approval over 6 months

4.2 Limit one infusion per lifetime

CPT Codes	
HCPCS Codes	
J3392	Injection, exagamglogene autotemcel, per treatment

References

1. Casgevy (exagamglogene autotemcel) [prescribing information]. Boston, MA: Vertex Pharmaceuticals Incorporated; January 2024.
2. Kingwell K. First CRISPR therapy seeks landmark approval. Nat Rev Drug Discov. 2023 May; 22 (5): 339 - 41.
3. Yawn BP, Buchanan GR, Afenyi-Annan AN, et al. Management of sickle cell disease: summary of the 2014 evidence-based report by expert panel members. JAMA. 2014 Sep 10;312(10):1033-48.
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 Jan 21;384(3):252-260.
5. Cappellini MD, Farmakis D, Porter J, Taher A. 2021 Guidelines for the Management of Transfusion Dependent Thalassemia (TDT). Hemasphere. 2022 Jul 29;6(8):e732.

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