Maryland
DEPARTMENT OF HEALTH

Casgevy (exagamglogene autotemcel)

Casgevy is an autologous genome-edited hematopoietic stem cell-based gene therapy indicated for the treatment of patients aged 12 years and older with:

- Sickle cell disease (SCD) with recurrent vaso-occlusive crises (VOCs).
- Transfusion-dependent β-thalassemia (TDT).

I. Criteria for Initial Approval

Casgevy will be considered for coverage when all of the criteria below are met, confirmed with supporting medical documentation.

- For use in patients ages 12 years and older.
- Prescribed by or in collaboration with a Board Certified Hematologist with SCD expertise.
- Documentation of sickle cell disease (SCD) with recurrent vaso-occlusive crises (VOCs), OR transfusion-dependent β-thalassemia (TDT)[1].
    - **Transfusion-dependent β-thalassemia (TDT)**
        - Patients are eligible for the treatment if they have a history of requiring at least 100 mL/kg/year or 10 units/year of RBC transfusions within the 2 years preceding enrollment.
    - **Sickle Cell Disease with VOC:**
        - Experienced recurrent VOCs (defined as more than or equal to two (2) documented VOCs per year in the previous twenty-four (24) months, based on provider attestation)
        - Examples of a-VOC include the following types of events:
            - Acute pain event requiring a visit to a medical facility and administration of pain medications (opioids or intravenous [IV] non-steroidal anti-inflammatory drugs [NSAIDs]) or RBC transfusions
            - Acute chest syndrome
            - Priapism lasting > 2 hours and requiring a visit to a medical facility
            - Splenic sequestration.
- The patient has had confirmatory Genetic Testing.
- Prior use or intolerance of hydroxyurea (per health care professional judgement) at any point in the past.
- The patient is clinically fit and stable for transplantation.

- The prescriber is responsible for confirming that the patient meets the FDA-approved prescribing information clinical parameters for use, including the absence of contraindications and the completion of appropriate screening and monitoring.

II. Dosing/Administration

For autologous and one-time intravenous use only.

Casgevy must be administered according to the current FDA labeling guidelines for dosage and timing. Please review the most current FDA Dosing and Administration recommendations.

III. Length of Authorization For initial therapy

Casgevy will be authorized for one-time use only.
Any prior authorization once approved will be valid for at least 12 months.

IV. Billing Code/Information

CPT Code J3392: Injection, exagamglogene autotemcel, per treatment

[1] Transfusion-dependent β-thalassemia (TDT). Patients treated with Casgevy for TDT are not eligible for participation in the CMMI supplemental outcomes-based rebate agreement.

Prior authorization of benefits is not the practice of medicine nor a substitute for the independent medical judgment of a treating medical provider. The materials provided are a component used to assist in making coverage decisions and administering benefits. Prior authorization does not constitute a contract or guarantee regarding member eligibility or payment. Prior authorization criteria are established through a collaborative effort that incorporates input from the current medical literature and evidence available at the time.