RX.PA.094.CCH CASGEVY

The purpose of this policy is to define the prior authorization process for Casgevy (exagamglogene autotemcel) for the following:

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

DEFINITIONS

VOC = vaso-occlusive crises

POLICY
It is the policy of the Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications. This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity, and approval by the Medical Policy Committee.

The drug, Casgevy (exagamglogene autotemcel), is subject to the prior authorization process.

PROCEDURE
Initial Authorization Criteria:
Must meet all the criteria listed under the respective diagnosis:

1. **Sickle cell Disease (SCD) with recurrent vaso-occlusive crises (VOCs)**
   - Must submit genetic testing results showing a diagnosis of SCD with one of the following genotypes:
     - SS genotype (βS/ βS)
     - $S\beta^0$ genotype (βS/B0)
     - $S\beta^+$ genotype (βS/B^+)
   - Member is ≥ 12 years of age
   - Must be prescribed by, or in consultation with, a hematologist or transplant specialist
   - Must have documentation of at least TWO severe VOC per year for the last 2 years, with severe VOC events being defined as having ONE or more:
     - Acute pain event requiring a visit to a medical facility and administration of

pain medications (opioids or intravenous 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, as defined by an enlarged spleen, left upper quadrant pain, and an acute decrease in hemoglobin concentration of ≥2 g/dL
- Must have continued VOC events while on the maximum tolerated dose of hydroxyurea or have an intolerance/contraindication to hydroxyurea
- Must submit laboratory screening/results or imaging documentation of ALL the following, **collected within the last 3 months:**
    - Estimated glomular filtration rate (GFR) ≥ 60mL/min/1.73m^2
    - Negative hepatitis B screening
    - Negative hepatitis C screening
    - Negative HIV-1 & HIV-2 screening
    - Complete Blood Count (CBC) with white blood cell (WBC) count >3×10^9/L and platelet count >100×10^9
        - *EXCEPTION*: If CBC results are below thresholds, results can be acceptable if attributable to hypersplenism
    - Liver function tests (LFTs) showing the following:
        - Alanine transaminase (ALT) < 3 × the upper limit of normal (ULN)
        - Direct bilirubin value <2.5 × ULN
        - Baseline prothrombin time (PT) (international normalized ratio [INR]) <1.5 × ULN
- Must have chart note documentation or an attestation from the provider of all the following:
    - Member must not have an HLA matched related donor available
    - Member has not received gene therapy or a hematopoietic stem cell transplant (HSCT) previously for sickle cell disease
    - Member does not have any prior or current malignancies OR myeloproliferative or significant immunodeficiency disorders
    - Member must not have a history of untreated Moyamoya disease or current Moyamoya disease
    - Member does not have a clinically significant and active bacterial, viral, fungal, or parasitic infection
    - Member does not have a history of cirrhosis or any evidence of bridging fibrosis, or active hepatitis on liver biopsy (if applicable)
    - If member is taking hydroxyurea, Oxybryta, or Adakveo, medication(s) must be discontinued at least 8 weeks prior to start of mobilization cycle and conditioning
    - If member is female of child-bearing age:
        - The provider will obtain a negative pregnancy test prior to starting mobilization, prior to conditioning procedures and before Casgevy administration

        - The member has been counseled on effective use of contraception during treatment
        - The member is not breast-feeding
    - If member is male capable of fathering a child, the member has been counseled on effective use of contraception during treatment

2. **Transfusion-Dependent Beta Thalassemia**
    - Must be prescribed by, or in consultation with, a hematologist or transplant specialist
    - Member is ≥ 12 years of age
    - Must have a diagnosis of β-thalassemia confirmed by genetic testing
    - Must be transfusion dependent as evidenced by ONE of the following occurring within the last 2 years preceding this request:
        - History of receiving at least 100 mL/kg/year of packed red blood cells (pRBCs)
        - History of receiving 10 units of pRBCs per year
    - Must submit laboratory screening/results or imaging documentation of ALL the following, **collected within the last 3 months:**
        - Estimated glomular filtration rate (GFR) ≥ 60mL/min/1.73m^2
        - Negative hepatitis B screening
        - Negative hepatitis C screening
        - Negative HIV-1 & HIV-2 screening
        - Complete Blood Count (CBC) with white blood cell (WBC) count >3×10^9/L and platelet count >100×10^9
            - *EXCEPTION*: If CBC results are below thresholds, results can be acceptable if attributable to hypersplenism
        - Liver function tests and any associated imaging that rules out advanced liver disease (i.e., bridging fibrosis, cirrhosis, active hepatitis)
        - MRI scan of the liver showing a liver iron content (LIC) of ≤15mg Fe/g dry weight
            - *EXCEPTION*: If liver biopsy is submitted showing no evidence of bridging fibrosis or cirrhosis, high LIC can be accepted
        - MRI scan of the heart showing a cardiac T2* >10ms
        - Left ventricular ejection fraction (LVEF) > 45%
        - Diffuse capacity of carbon monoxide (DLcO) >50% predicted
    - Must have chart note documentation or an attestation from the provider of all the following:
        - Member must not have an HLA matched related donor available
        - Member has not received gene therapy or a hematopoietic stem cell transplant (HSCT)
        - The member does not have hemoglobin S/β-thalassemia or α-thalassemia

- Member does not have a clinically significant and active bacterial, viral, fungal, or parasitic infection
- Member does not have any prior or current malignancies OR myeloproliferative or significant immunodeficiency disorders
- Member must not have history of significant bleeding disorder
- If member is female of child-bearing age:
  - The provider will obtain a negative pregnancy test prior to starting mobilization, prior to conditioning procedures and before Casgevy administration
  - The member has been counseled on effective use of contraception during treatment
  - The member is not breast-feeding
- If member is male capable of fathering a child, the member has been counseled on effective use of contraception during treatment

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	6 months
Reauthorization	N/A (Only single course allowed per lifetime)

If the established criteria are not met, the request is referred to a Medical Director for review, if required for the plan and level of request.

Codes:

CPT Codes / HCPCS Codes / ICD-10 Codes		
Code	Brand	Description
J3590	Casgevy	Exagamglogene autotemcel

References:

1. *Casgevy (exagamglogene autotemcel) [prescribing information]. Boston, MA: Vertex Pharmaceuticals Incorporated; January 2024.*
2. Frangoul et al, “Exagamglogene Autotemcel for Severe Sickle Cell Disease.” *N Engl J Med*. Online April 24, 2024. DOI: 10.1056/NEJMoa2309676.
3. Locatelli et al, “Exagamglogene Autotemcel for Transfusion-Dependent β-Thalassemia.” *N Engl J Med*. Online April 24, 2024. DOI: 10.1056/NEJMoa2309673.

Revision History

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
New Policy	08/2024

Record Retention

Records Retention for Evolent Health documents, regardless of medium, are provided within the Evolent Health records retention policy and as indicated in CORP.028.E Records Retention Policy and Procedure.

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