ATRIO HEALTH PLANS

Beta Thalassemia

Casgevy (exagamglogene autotemcel) J3392, Zynteglo (betibeglogene autotemcel) J3393

Prior Authorization Request Medicare Part B Form

*Instructions: * Indicates required information – Form may be returned if required information is not provided. Please fax this request to the appropriate fax number listed at the bottom of the page.*

☐	**Standard Request– (72 Hours)**	☐	**Urgent Request** (standard time frame could place the member's life, health or ability in serious jeopardy)
	Date Requested _____		
	Requestor _____ Clinic name: _____ Phone / Fax		

MEMBER INFORMATION

*Name:_____ *ID#:_____ *DOB:_____

PRESCRIBER INFORMATION

*Name:_____ ☐MD ☐FNP ☐DO ☐NP ☐PA *Phone:_____

*Address:_____ *Fax:_____

DISPENSING PROVIDER / ADMINISTRATION INFORMATION

*Name:_____ Phone:_____

*Address:_____ Fax:_____

PROCEDURE / PRODUCT INFORMATION

HCPC Code	Name of Drug	Dose (Wt: _____ kg Ht:_____)	Frequency	End Date if known

☐ **Self-administered** ☐ **Provider-administered** ☐ **Home Infusion**

☐Chart notes attached. **Other important information:**_____

Diagnosis: ICD10: _____ **Description**: _____

☐ Provider attests the diagnosis provided is an FDA-Approved indication for this drug

CLINICAL INFORMATION

☐ **New Start or Initial Request: (Clinical documentation required for all requests)**

☐ **Transfusion-Dependent Beta-Thalassemia (for gene therapy or luspatercept consideration)**
- ☐ Confirmed beta-thalassemia major or intermedia via hemoglobin electrophoresis or genetic testing AND
- ☐ Documentation of transfusion dependence (typically ≥6-8 red blood cell transfusions):
  - ☐ 100 mL/kg body weight of packed red blood cells per year in previous 2 years
  - ☐ 10 units of packed red blood cells per year in previous 2 years
- ☐ Adequate iron chelation therapy or documentation of iron overload status

☐ **Sickle cell anemia with recurrent severe vaso-occlusive crises**
- ☐ Crises are severe, as indicated by 1 or more of the following:
- ☐ Acute chest syndrome (ie, new pulmonary infiltrate and pneumonia-like symptoms)
- ☐ Acute pain that requires visit to medical facility for administration of intravenous pain medications (eg, opioids, nonsteroidal anti-inflammatory drugs) or red blood cell transfusion
- ☐ Priapism lasting greater than 2 hours and requiring medical evaluation
- ☐ Splenic sequestration
- ☐ History of 2 or more vaso-occlusive crises/year; 2 years prior to planned exagamglogene autotemcel therapy

If not, please provide **clinical rationale** for formulary exception: _____

_____

_____

☐ Continuation Requests: (Clinical documentation required for all requests)

☐ Patient had an **adequate response** or **significant improvement** while on this medication.

☐ Medical record documentation of positive response is included

If not, please provide clinical rationale for continuing this medication: _____

_____

ACKNOWLEDGEMENT

Request By (Signature Required): _____Date:_____/____/____

Any person who knowingly files a request for authorization of coverage of a medical procedure or service with the intent to injure, defraud or deceive any insurance company by providing materially false information or conceals material information for the purpose of misleading, commits a fraudulent insurance act, which is a crime and subjects such person to criminal and civil penalties. **THIS AUTHORIZATION IS NOT A GUARANTEE OF PAYMENT.** PAYMENT IS BASED ON BENEFITS IN EFFECT AT THE TIME OF SERVICE, MEMBER ELIGIBILITY AND MEDICAL NECESSITY.

Prior Authorization Group – Beta Thalassemia Prior Authorization

Drug Name(s):

CASGEVY	**EXAGAMGLOGENE AUTOTEMCEL**
ZYNTEGLO	**BETIBEGLOGENE AUTOTEMCEL**

Criteria for approval of Non-Formulary/Preferred Drug:

1. Prescribed for an approved FDA diagnosis (as listed below):
2. Member does not have any clinically relevant contraindications, or CMS/Plan exclusions, to the requested drug.

- If the member meets all these criteria, they may be approved by the Plan for the requested drug.
- Quantity limits and Tiering will be determined by the Plan.
- Continuation Requests: Provider must verify continued clinical benefit in confirmatory trial(s).

Exclusion Criteria:

N/A

Prescriber Restrictions:

Hematologist or other related specialist

Coverage Duration:

Approval will be for 6 months

FDA Indications:

Casgevy

- Beta thalassemia, Transfusion-dependent.
- Sickling disorder due to hemoglobin S, In patients with recurrent vaso-occlusive crises

Zynteglo

- Beta thalassemia, In patients who require regular red blood cell transfusions

Off-Label Uses:

N/A

Age Restrictions:

Casgevy indicated for patients 12 years or older.
Zynteglo indicated for patients 4 years or older.

Other Clinical Consideration:

N/A

Resources:

https://www.micromedexsolutions.com/micromedex2/librarian/PFDefaultActionId/evidencexpert.DoIntegratedSearch?SearchTerm=Casgevy&UserSearchTerm=Casgevy&SearchFilter=filterNone&navitem=searchGlobal#
https://www.micromedexsolutions.com/micromedex2/librarian/PFDefaultActionId/evidencexpert.DoIntegratedSearch?SearchTerm=betibeglogene%20autotemcel&UserSearchTerm=betibeglogene%20autotemcel&SearchFilter=filterNone&navitem=searchGlobal#