POLICY AND PROCEDURE

POLICY NAME: Betibeglogene autotemcel (Zynteglo)	**POLICY ID:** TX.PHAR.109
BUSINESS UNIT: Superior HealthPlan	**FUNCTIONAL AREA:** Pharmacy
EFFECTIVE DATE: 8/1/23	**PRODUCT(S):** STAR, STAR Kids, STAR Health, STAR Plus, CHIP, CHIP Perinate
REVIEWED/REVISED DATE:	
REGULATOR MOST RECENT APPROVAL DATE(S): N/A	

POLICY STATEMENT:
It is the policy of Superior HealthPlan to follow state guidance for medical necessity review of Betibeglogene autotemcel (Zynteglo).

PURPOSE:
This medication is a pass through drug (non-risk based payment drug) and should follow state guidance for medical necessity review for Medicaid/CHIP due to the manner in which it is reimbursed. All determinations will be performed by a Superior Medical Director. A pharmacy clinician will review the prior authorization request and make a recommendation to the Medical Director but will not make the ultimate determination on any case.

In addition, Betibeglogene autotemcel (Zynteglo), J3590 requests are limited to one approval per lifetime, by any provider. Zynteglo may be infused as a single infusion in one or more infusion bags.

Refer to the Outpatient Drug Services Handbook of the Texas Medicaid Provider Procedure Manual for more details on the clinical policy and prior authorization requirements.

SCOPE:
Superior HealthPlan Pharmacy Department, Medical Directors

DEFINITIONS: NRB = non-risk based

POLICY:
It is the policy of Superior HealthPlan to follow state guidance for medical necessity review of Betibeglogene autotemcel (Zynteglo).

Description/Mechanism of Action:
Betibeglogene autotemcel (Zynteglo) is an autologous stem cell-based gene therapy indicated for treating adult and pediatric clients with β-thalassemia who require regular blood cell (RBC) transfusion.

Formulations:
Betibeglogene autotemcel (Zynteglo): Cell suspension for intravenous infusion. A single dose contains a minimum of 5.0 x 10^6 CD34+ cells/kg of body weight, in one or more infusion bags.

FDA Approved Indications:
Betibeglogene autotemcel (Zynteglo) is indicated for the treatment of adult and pediatric clients with β-thalassemia who require regular blood cell (RBC) transfusions.

PROCEDURE:
Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria.

I. Initial Approval Criteria:

A. β-thalassemia

1. All prior authorization approvals or denials will be determined by a Superior HealthPlan Medical Director.
2. Client is age 4 years of older.
3. Client has a documented diagnosis of β-thalassemia (ICD 10 - D56.1) and other forms of thalassemia have been ruled out.

4. Client is RBC transfusion dependent and has documented history of receiving red blood cell transfusion of at least 100ml per kilogram per year (pRBC/kg/yr) or at least 8 or more transfusions of regular red blood cell per year for 2 years.
5. Client has not had prior hematopoietic stem cell transplant (HSCT) and is unable to find a matched related donor.
6. Client is stable and is eligible for HSCT by meeting all of following:
    - No advanced liver disease
    - No human immunodeficiency virus (HIV) positive diagnosis
    - No hepatitis B virus (HBV) or hepatitis C virus (HCV)
    - No prior or current malignancies
    - No bleeding disorders
    - Normal iron levels in the heart
    - Normal levels of white blood cells
    - Normal platelet counts
7. Prescriber must attest to monitor the client's platelet count for thrombocytopenia and bleeding during the treatment period with Zynteglo.
8. Prescriber must attest to monitor the client for at least 15 years post Zynteglo infusion for possible hematologic malignancies.
8. Prescriber attestation to avoid the use of anti-retroviral medications or hydroxyurea for one month prior to mobilization and until all cycles of apheresis are completed.
9. Prescriber attestation to discontinue iron chelators at least 7 days prior to initiation of myeloablative conditioning and use of myelosuppressive iron chelators should be avoided for 6 months after Zynteglo infusion.

Approval duration: Only 1 dose per lifetime will be provided on this drug regardless of Provider

REFERENCES:

Texas Medicaid Provider Procedures Manual: Outpatient Drug Services Handbook.

ATTACHMENTS: N/A

ROLES & RESPONSIBILITIES: N/A

REGULATORY REPORTING REQUIREMENTS: N/A

REVISION LOG

REVISION TYPE	REVISION SUMMARY	DATE APPROVED & PUBLISHED
New Policy Document		8/1/2023

POLICY AND PROCEDURE APPROVAL

The electronic approval retained in RSA Archer, the Company's P&P management software, is considered equivalent to a signature.