TX CLINICAL CRITERIA & PROCEDURE

CRITERIA NAME: Betibeglogene autotemcel (Zynteglo®)	**CRITERIA ID:** TX.CC.PHAR.24
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: 4/3/2024, 7/31/2024	
REGULATOR MOST RECENT APPROVAL DATE(S): N/A	

POLICY STATEMENT:
The purpose of this clinical criteria is to provide a guide to medical necessity reviews for betibeglogene autotemcel (Zynteglo®).

PURPOSE:
Consistent with the regulation at 42 CFR Section 438.210 and 42 CFR Section 457.1230(d), services covered under managed care contracts, including clinician-administered drugs, must be furnished in an amount, duration, and scope that is no less than the amount, duration, and scope for the same services specified in the state plan. While MCOs may place appropriate limits on drugs, MCOs may not use a standard for determining medical necessity that is more restrictive than what is used in the state plan, i.e., developed by the Vendor Drug Program. For example, if a member is denied a clinician administered drug in managed care because of the MCO's prior authorization criteria but would have received the drug under the criteria specified in the state plan, then the MCO's prior authorization criteria would violate the amount, duration, and scope requirements cited above. HHSC intends to amend the Managed Care Contracts at the next opportunity to include this requirement. This same standard applies to CHIP formulary and CAD coverage.

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

This medication is a non-risk based (NRB) 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 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.

Additionally, this medication is a Precision Drug. Centene's Precision Drug Action Committee (PDAC) creates a standardized approach for Centene to manage precision drugs and the associated costs for their administration, prior to members presenting with a request for one of these agents. All precision drug requests or potential requests must be reported to the PDAC for tracking, regardless of whether agents are carved out, passed through, etc. All precision drug medical necessity determinations will be supported by PDAC UM recommendation, utilizing specialist input as directed and allowed by turnaround times.

The procedure code J3393 (used for Zynteglo) will be limited to once per lifetime, by any provider. If the code is updated in the future it will still be limited to once per lifetime. Zynteglo may be infused as a single infusion in one or more infusion bags.

SCOPE:
This criteria applies to all directors, officers, and employees of Centene Corporation, its affiliates, health plans, and subsidiary companies (collectively, the "Company").

DEFINITIONS:
NRB = non-risk based
PDAC = Precision Drug Action Committee
UM = Utilization Management
CPS = Centene Pharmacy Service
SHP = Superior HealthPlan

POLICY:
It is the policy of Superior HealthPlan to follow state guidance for medical necessity review of betibeglogene autotemcel (Zynteglo®); procedure code: J3393.

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.

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.

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.

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. A Medical Director is required to review and approve or deny all requests. A pharmacy clinician will make a recommendation on the prior authorization, but ultimate determination will be made by the Medical Director only.
2. Medical necessity determinations will be supported by PDAC UM recommendation. The pharmacy clinician will review the UM recommendation with the prior authorization request for clinical appropriateness and make a recommendation to the Medical Director but will not make the ultimate determination on any case.
3. The client is age 4 years of older.
4. The client has a documented diagnosis of β-thalassemia (diagnosis code: D56.1) and other forms of thalassemia have been ruled out.
5. The client is RBC transfusion dependent and has documented history of receiving red blood cell transfusions 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.
6. The client has not had prior hematopoietic stem cell transplant (HSCT) and is unable to find a matched related donor.
7. The 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
8. Prescriber attestation that client's platelet count will be monitored for thrombocytopenia and bleeding during the treatment period with Zynteglo.
9. Prescriber attestation that client will be monitored for at least 15 years post Zynteglo infusion for possible hematologic malignancies.
8. Prescriber attestation that use of anti-retroviral medications or hydroxyurea will be avoided for one month prior to mobilization and until all cycles of apheresis are completed.
9. Prescriber attestation that iron chelators will be discontinued at least 7 days prior to initiation of myeloablative conditioning and use of myelosuppressive iron chelators will be avoided for 6 months after Zynteglo infusion.

Approval duration: Only 1 dose per lifetime will be provided on this drug regardless of provider and may be infused as a single infusion in one or more infusion bags.

REFERENCES:

Texas Medicaid Provider Procedures Manual: Outpatient Drug Services Handbook.

ATTACHMENTS: N/A

REVISION LOG

REVISION TYPE	REVISION SUMMARY	DATE APPROVED & PUBLISHED
New Policy Document		8/1/2023
Ad hoc review	Updated to TX.CC.PHAR format template Added Centene copyright statement as well as PDAC criteria requirement	4/3/2024
Ad hoc review	Updated approval duration to include: "and may be infused as a single infusion in one or more infusion bags" Updated Jcode from J3590 to J3393	7/31/2024