06/29/2023

HHSC to Add Zynteglo as Medicaid and CHIP Benefit July 1, Prior Authorization Effective Sept. 1

Background:

On July 1, 2023, Zynteglo will become a benefit of Medicaid and CHIP. HHSC will require prior authorization for Zynteglo (procedure code J3590) for Medicaid and CHIP effective Sept. 1, 2023.

Key Details:

Zynteglo (Betibeglogene autotemcel) is an autologous stem cell-based gene therapy indicated for treating adult and pediatric clients with #-thalassemia who require regular blood cell (RBC) transfusion.

Authorization requirements

Prior authorization is required for Zynteglo (betibeglogene autotemcel). The request for this single-dose therapy must include all the following documentation to support that client meets all approval criteria:

- Client is age 4 years and older.
- Client has a documented diagnosis of #-thalassemia (ICD 10 – D56.1) and other forms of thalassemia have been ruled out.
- Client is RBC transfusions 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 transfusion of regular red blood cell per year or 2 years.
- Client has not had prior hematopoietic stem cell transplant (HSCT) and is unable to find a matched related donor.
- Client is stable and is eligible for HSCT.
    - 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
- Prescriber must monitor the client's platelet count for thrombocytopenia and bleeding during the treatment period with Zynteglo.

· Prescriber must monitor client for at least 15 years post Zynteglo infusion for possible hematologic malignancies.

· 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.

· Prescriber attestation to discontinue iron chelators at least 7 days prior to initiation of myeloablative conditioning and the use of myelosuppressive iron chelators should be avoided for 6 months after Zynteglo infusion.

· Zynteglo (betibeglogene autotemcel), J3590 is limited to one transfusion treatment per lifetime. Zynteglo may be infused as a single infusion in one or more infusion bag.

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

Additional Information:

HHSC approved this updated clinical prior authorization for use by MCOs. FFS criteria will implement on Sept. 1, 2023. MCOs do not need to wait for publication in the TMPPM before implementation. MCOs may choose to implement the updated requirements but shall not make them more restrictive.

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Type: Informational

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From: VDP