Clinical Oversight Review Board (CORB) Criteria for Prescribing/ Criteria-Based Consultation (CBC) Criteria for Coverage

Betibeglogene autotemcel (Zynteglo)

Notes:
- Quantity Limits: Yes (one time dose)
- * Intolerance excludes adverse drug reactions that are expected, mild in nature, resolve with continued treatment, and do not require medication discontinuation

Non-Formulary **Betibeglogene autotemcel (Zynteglo)** requires a clinical review. Appropriateness of therapy will be based on the following criteria:

Initiation (new start) criteria: Non-formulary **Betibeglogene autotemcel (Zynteglo)** will be covered on the prescription drug benefit when the following criteria are met:

- Patient has a diagnosis of transfusion dependent beta thalassemia (TDT)
- Must be prescribed by pediatric or adult hematology/oncology specialist
- Patient Must have history of at least 100 ml/kg/year OR 10 units/year of RBC transfusion
- Karnofsky performance status of ≥80% or Lansky performance stats of > 80% (if < 16 years old)
- Clinically stable and eligible to undergo hematopoietic stem cell transplant
- Must be reviewed by the Interregional Consultative Physician Panel prior to initiation

Criteria for *current Kaiser Permanente members* already taking the medication who have not been reviewed previously -OR- Criteria for *new members* entering Kaiser Permanente already taking the medication who have not been reviewed previously:
Non-formulary **Betibeglogene autotemcel (Zynteglo**) will be covered on the prescription drug benefit when the following criteria are met:
- Patient has a diagnosis of transfusion dependent beta thalassemia (TDT)
- Must be prescribed by pediatric or adult hematology/oncology specialist
- Patient Must have history of at least 100 ml/kg/year OR 10 units/year of RBC transfusion
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