

PA Criteria	Criteria Details						
Covered Uses (FDA approved indication)	Zynteglo is a autologous hematopoietic stem cell-based gene therapy for treatment of adult and pediatric patients with beta-thalassemia who require regular red blood cell (RBC) transfusions. Zynteglo is a one-time therapy. It is administered as a single dose and is a customized treatment created using an individual's own cells that are genetically modified to produce functional beta-globin.						
Exclusion Criteria	Must not have a prior hematopoietic stem cell transplant (HSCT) or history of previous gene therapy (the safety and efficacy of Zynteglo following a previous HSCT or gene therapy has not been established).						
Required Medical Information	<ol style="list-style-type: none"> 1. Medical records supporting the request must be provided; 2. Must have a diagnosis of transfusion dependent beta thalassemia (defined as a history of at least 100 mL/kg/year of packed red blood cells (pRBC) in the previous two years OR at least eight transfusions of pRBCs per year in the previous two years; 3. Must not have a known and available HLA matched donor as determined by the hematologist and/or transplant specialist; 4. Provider attests that, in the absence of a known or available HLA-matched family donor, the patient would be otherwise clinically stable and eligible to undergo HSCT. 						
Age Restriction	None.						
Prescriber Restrictions	Must be prescribed by or in consultation with a hematologist, transplant specialist, or another board-certified prescriber with qualifications to treat specified condition.						
Coverage Duration	One lifetime dose (safety and effectiveness of repeat administration have not been evaluated).						
Other Criteria/Information	<p>Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document.</p> <table border="1"> <thead> <tr> <th>HCPCS</th> <th>Description</th> <th>Billing Units/How Supplied</th> </tr> </thead> <tbody> <tr> <td>J3393</td> <td>Zynteglo (betibeglogene autotemcel)</td> <td>Billing unit: per dose 20 mL infusion bag</td> </tr> </tbody> </table>	HCPCS	Description	Billing Units/How Supplied	J3393	Zynteglo (betibeglogene autotemcel)	Billing unit: per dose 20 mL infusion bag
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STATUS	DATE REVISED	REVIEW DATE	APPROVED/REVIEWED BY	EFFECTIVE DATE
Created	3/26/2025	3/26/2025	Dawn Shojai, PharmD, Senior Pharmacy Benefit Consultant (PSG)	N/A
Approved	N/A	5/15/2025	Pharmacy & Therapeutics (P&T) Committee	5/15/2025