

**SOUTH DAKOTA MEDICAID
PRIOR AUTHORIZATION CRITERIA**

Physician Administered Drugs, Vaccines, and Immunizations

Betibeglogene autotemcel (Zynteglo) – PA Criteria

HCPC: J3393

Betibeglogene autotemcel (Zynteglo) is an autologous cellular gene therapy indicated for the treatment of beta thalassemia in adults and pediatric patients ≥ 4 years of age. It is covered by South Dakota Medicaid following prior authorization when the patient meets the following criteria:

** All requests under this policy require SD medical director review in addition to meeting specified criteria below **

- **Initial Therapy (must meet all):**
 - Therapy is prescribed by a hematologist
 - Individual has a diagnosis of beta thalassemia with a $\beta 0/\beta 0$, $\beta 0/\beta 0$ -like or non- $\beta 0/\beta 0$ -like genotype
 - Individual has a history of ≥ 8 transfusions/year or ≥ 100 ml/kg/year pRBCs in the 2 years prior to enrollment
 - Attestation from provider that member is clinically stable and able to undergo gene therapy
 - Individual does not have a known, human leukocyte antigen (HLA)-matched donor
 - Screening has been done within the last 6 months and documentation is provided indicating that the individual is negative for the following active diseases: HIV, Hepatitis B, and Hepatitis C
 - Individual has not previously received a hematopoietic stem cell transplant or prior gene therapy
 - Individual does not have advanced liver disease (defined as AST, ALT or direct bilirubin values $>3X$ upper limit of normal, baseline prothrombin time or partial thromboplastin time $>1.5x$ upper limit of normal or history of cirrhosis or any evidence of bridging fibrosis, or active hepatitis on liver biopsy)
 - If female, documentation of negative pregnancy test must be submitted prior to therapy
 - Male and female members of reproductive potential must use an effective method of contraception at start of treatment and at least 6 months following Zynteglo administration
 - Individual is ≥ 4 - ≤ 50 years of age
 - Approval duration: one dose
- **Continuation of Therapy: not authorized**