Zynteglo (betibeglogene autotemcel)

INDEPENDENT CARE HEALTH PLAN

Effective Date: 01/01/2024
Revision Date: Click or tap to enter a date.
Review Date: Click or tap to enter a date.
Policy Number: WI.PA-1239
Line of Business: Medicare

Medicare Advantage Medical Coverage Policy

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Related Medicare Advantage Medical/Pharmacy Coverage Policies

None

Related Documents

Please refer to CMS website for the most current applicable CMS Online Manual System (IOMs)/National Coverage Determination (NCD)/ Local Coverage Determination (LCD)/Local Coverage Article (LCA)/ Transmittals.

There are no NCDs and/or LCDs for Zynteglo.

Description

Zynteglo (betibeglogene autotemcel) is a one-time gene therapy product administered as a single dose. Each dose of Zynteglo is a customized treatment created using an individual's own cells (bone marrow stem cells) that are genetically modified to produce functional beta-globin (a hemoglobin component). This autologous hematopoietic stem cell-based gene therapy is indicated for the treatment of adult and pediatric individuals with β-thalassemia who require regular red blood cell (RBC) transfusions.

Preparation of Zynteglo (betibeglogene autotemcel) requires collection of an individual's own stem cells through an apheresis procedure. A viral vector is used to transduce a normal beta-globin gene into the stem cells, which are then infused back into the individual as an autologous hematopoietic stem cell transplant after myeloablative conditioning. Full myeloablative conditioning must be administered before the infusion of Zynteglo.

Zynteglo (betibeglogene autotemcel) is provided as a single dose for infusion containing a suspension of CD34+ cells in one or more infusion bags. The minimum recommended dose of Zynteglo is 5.0 × 106 CD34+ cells/kilogram (kg).

Beta-thalassemia (also known as β-thalassemia or Cooley's Anemia) is a type of inherited blood disorder that causes a reduction of normal hemoglobin and red blood cells in the blood, through mutations in the beta-globin subunit, leading to insufficient delivery of oxygen in the body. The reduced levels of red blood cells can lead to several health issues including dizziness, weakness, fatigue, bone abnormalities and more serious complications.

Transfusion-dependent beta-thalassemia (TDT), the most severe form of the condition, generally requires life-long red blood cell transfusions as the standard course of treatment. These regular transfusions can be associated with multiple health complications of their own, including problems in the heart, liver and other organs due to an excessive build-up of iron in the body.

Coverage Determination

iCare follows the CMS requirements that only allows coverage and payment for services that are reasonable and necessary for the diagnosis and treatment of illness or injury or to improve the functioning of a malformed body member except as specifically allowed by Medicare.

In interpreting or supplementing the criteria above and in order to determine medical necessity consistently, iCare may consider the following criteria:

Zynteglo

The use of the criteria in this Medicare Advantage Medical Coverage Policy provides clinical benefits highly likely to outweigh any clinical harms. Services that do not meet the criteria above are not medically necessary and thus do not provide a clinical benefit. Medically unnecessary services carry risks of adverse outcomes and may interfere with the pursuit of other treatments which have demonstrated efficacy.

Coverage Limitations

US Government Publishing Office. Electronic code of federal regulations: part 411 – 42 CFR § 411.15 - Particular services excluded from coverage

Coding Information

Any codes listed on this policy are for informational purposes only. Do not rely on the accuracy and inclusion of specific codes. Inclusion of a code does not guarantee coverage and/or reimbursement for a service or procedure.

CPT® Code(s)	Description	Comments
No code(s) identified		
CPT® Category III Code(s)	**Description**	**Comments**
No code(s) identified		
HCPCS Code(s)	**Description**	**Comments**
J3590	Unclassified biologics	
C9399	Unclassified drugs or biologicals	

Change Summary

- 01/01/2024 New Policy.
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