Umbilical Cord Blood Transplantation

Humana

Medicaid Medical Coverage Policy

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State(s): SC

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Description

Hematologic malignancies (blood cancers) are caused by abnormal cell growth in the bone marrow, where stem cells form into different types of blood cells. Hematopoietic stem cells assure a lifelong supply of differentiated populations that are responsible for critical bodily functions, including oxygen transport, immunological protection and coagulation.[5] Hematopoietic stem cell transplantation (HSCT) is a potentially curative therapy for a variety of conditions, most commonly blood or bone marrow cancers, in which an individual cannot produce enough normal blood cells. HSCT involves transplanting stem cells isolated from either the individual (autologous or auto-HSCT) or a donor (allogeneic or allo-HSCT), growing them in number, and transplanting them into an individual who lacks sufficient functional stem cells of their own.

A common treatment for blood cancers is stem cell transplantation from umbilical cord blood (UCB), the blood remaining in the umbilical cord and placenta following the birth of an infant. A major disadvantage of UCB is the low stem cell dose available for transplantation, compared to mobilized peripheral blood or bone marrow. This low stem cell dose can compromise the chances of engraftment and contributes to delayed kinetics of neutrophil and platelet recovery, as well as other transplant outcomes. The aim of ex vivo (outside the living body) expansion of cord blood is to provide a graft with sufficient numbers of cells that have rapid and robust in vivo (inside the living body) neutrophil and platelet producing potential to enable successful transplantation.

Omisirge is indicated for use in adult and pediatric individuals, 12 years of age and older, with hematologic malignancies who are planned for UCB transplantation following myeloablative conditioning to reduce the time to neutrophil recovery and the incidence of infection.[17] This nicotinamide (NAM) modified allogeneic hematopoietic progenitor cell therapy is given as a single dose and one-time infusion. The infusion is a mixture of hematopoietic stem cells and differentiated immune cells, derived from a single unit of UCB which purportedly enhances the treatment of an individual undergoing allo-HSCT who has no matched donor for bone marrow or peripheral blood. In addition, the therapy purports to restore blood and immune cells and improve resistance to infections and related complications efficiently and quickly. **Omisirge (omidubicel-onlv)** is intended to reduce the risk of opportunistic infection, a potentially serious complication of myelosuppressive conditioning, when used instead of conventional umbilical blood cord cell preparations.[4]

Regenecyte is an allogeneic cord blood hematopoietic progenitor cell (HPC) therapy indicated for use in unrelated donor HPC transplantation procedures in conjunction with an appropriate preparative regimen for hematopoietic and immunologic reconstitution in an individual with disorders affecting the hematopoietic system that are acquired, inherited or result from myeloablative treatment. Regenecyte consists of granulocytes (immune cells), HPCs, monocytes (white blood cells), lymphocytes and from human cord blood for intravenous infusion. Blood recovered from the umbilical cord and placenta is volume reduced and partially depleted of red blood cells and plasma.[18]

Requests for both Omisirge (omidubicel-onlv) and Regenecyte *require review by a medical director*.

Coverage Determination

Refer all requests or questions regarding Omisirge (omidubicel-onlv) and Regenecyte to the Corporate Transplant Department.

Phone	***Fax***	***Email***
1-866-421-5663	*502-508-9300*	*transplant@humana.com*

Humana members may be eligible under the Plan for **Omisirge (omidubicel-onlv)** when **ALL** the following criteria are met[17]:

- Absence of limitations; **AND**

- Individual is 12 through 65 years of age **AND** diagnosed with a hematological malignancy (eg, acute lymphoblastic leukemia, acute myelogenous leukemia), planned for umbilical cord blood transplantation following myeloablative conditioning; **AND**

- Administered at an approved treatment facility

Humana members may be eligible under the Plan for **Regenecyte** when **ALL** the following criteria are met[18]:

- Absence of limitations; **AND**
- Individual with disorder affecting the hematopoietic system (acquired, inherited or resulting from myeloablative treatment) for use in unrelated donor hematopoietic progenitor cell transplantation procedures in *conjunction* with an appropriate preparative regimen for hematopoietic and immunologic reconstitution

Coverage Limitations

Humana members may **NOT** be eligible under the Plan for **Omisirge (omidubicel-onlv)** for any indications other than those listed above including, but may not be limited to[17]:

- Individual has desire to become pregnant/reproduce OR unwilling to use effective contraception; **OR**
- Individual is pregnant or breastfeeding

Humana members may **NOT** be eligible under the Plan for **Regenecyte** for any indications other than those listed above including, but may not be limited to[18]:

- Individual is over 65 years of age; **OR**
- Individual is pregnant or breastfeeding; **OR**
- Individual has renal disease (failure or insufficiency)

A review of the current medical literature shows that the **evidence is insufficient** to determine that these services are standard medical treatment. There is an absence of current, widely-used treatment guidelines or acceptable clinical literature examining benefit and long-term clinical outcomes establishing the value of these services in clinical management.

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**
C9399	Unclassified drugs or biologicals	
J3490	Unclassified drugs	
J3590	Unclassified biologics	

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Change Summary

01/01/2025 New Policy.
06/03/2025 Annual Review, Coverage Change.