Sentara Health Plans

Commercial

Allogeneic Hematopoietic Stem Cell Transplantation

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Effective Date	1/1993
Next Review Date	3/1/2024
Coverage Policy	Surgical 213
Version	3

Member-specific benefits take precedence over medical policy and benefits may vary across plans. Refer to the individual's benefit plan for details *.

Purpose:

This policy addresses the medical necessity of Allogeneic hematopoietic stem cell transplantation.

Description & Definitions:

Allogeneic hematopoietic stem cell transplantation involves transferring of stem cells from a healthy person with a similar genetic makeup (the donor) to the individual's body after high-intensity chemotherapy or radiation.

Criteria:

Allogeneic Hematopoietic Stem Cell Transplantation is considered medically necessary for **All** of the following:

- Individual has no comorbidities that would reduce life expectancy
- Individual is medically compliant
- Individual is free of an active substance abuse problem
- Individual has diagnosis of **1 or more** of the following:
    - Acute lymphocytic or lymphoblastic leukemia with **1 or more** of the following:
        - First complete remission and has **ALL** of the following:
            - A human leukocyte antigen (HLA) matched sibling or a matched unrelated donor or using a partially matched family member, donor or umbilical cord blood is a reasonable option for individuals who do not have an identical matched donor
            - Individual has a high risk prognostic factor including **1 or more** of the following:
                - White blood cell count at the time of diagnosis greater than 25,000 cells/mm3 to 35,000 cells/mm3
                - More than 4 weeks needed to induce remission
                - Poor risk cytogenetic abnormalities present
                - Central nervous system involvement
                - Extensive lymphadenopathy
                - Hepatosplenomegaly

        - Myeloid antigens
        - Extra nodal disease
    - Second complete remission with **1 or more** of the following:
        - Adult who relapses after primary chemotherapy
        - Child who relapses during the first year after diagnosis if either sibling or unrelated matched donor available;
        - Individual is a child who relapses 1 to 4 years after the first diagnosis, if a sibling donor is available
    - Individual has primary refractory disease
- Acute Myeloid Leukemia (AML) for **1 or more** of the following:
    - Individual has relapsed following a previous autologous hematopoietic cell transplantation and can medically endure the procedure
    - After first complete remission for individual in intermediate or poor risk group
    - After first relapse or second complete remission for individual with better prognosis
    - Individual with refractory disease (greater than 4% marrow blasts at time of transplant)
- Alpha-mannosidosis
- Chediak-Higashi syndrome
- Chronic granulomatous disease
- Chronic myelo-monocytic leukemia (CMML) and juvenile myelo-monocytic leukemia (JMML) for individuals with **All** of the following:
    - When a human leukocyte antigen (HLA) matched donor (at least 5 of 6 match) is available
- Chronic Myeloid Leukemia (CML) allogeneic stem cell transplantation for **1 or more** of the following indications:
    - Individual fails to respond, or becomes refractory to, fludarabine-based chemotherapy regimen
    - Individual has a human leukocyte antigen (HLA) matched sibling donor available
- Diamond-Blackfan anemia (DBA)
- Fanconi's anemia (FA)
- Fucosidosis
- Globoid cell leukodystrophy (Krabbe Disease)
- Hemophagocytic Lymphohistiocytosis (HLH)
- High-risk neuroblastoma
- Homozygous sickle cell disease or Thalassemia major with **ALL** of the following:
    - Individual is less than 16 years old with homozygous sickle cell disease or thalassemia major with **1 or more** of the following:
        - Ischemic or hemorrhagic stroke
        - Documented increase in neurologic disfunction
        - Sickle cell lung disease
        - Repetitive hospitalization requiring transfusion or treatment for acute chest syndrome.
        - Increase in neuropathic symptoms related to sickle cell process
- Infantile malignant osteopetrosis (Albers-Schonberg disease or marble bone disease)
- Kostmann's syndrome (severe congenital neutropenia, infantile genetic agranulocytosis)
- Leukocyte adhesion deficiencies
- Metachromatic leukodystrophy (MLD)
- Morquio syndrome
- Mucolipidoses (e.g., adrenoleukodystrophy, Childhood-onset adrenoleukodystrophy, Gaucher's disease, Metachromatic leukodystrophy)
- Mucopolysaccharidosis (e.g., Hunter's syndrome, Hurler's syndrome, Maroteaux-Lamy Syndrome, Sanfilippo's syndrome)
- Multiple myeloma for individuals with **1 or more** of the following:
    - A matched twin donor available

        - Newly diagnosed and is responsive to standard chemotherapy
        - Can do single or tandem transplant
        - Has a donor lymphocyte infusion (DLI) for multiple myeloma post allogenic stem cell transplant with recurrence
        - Post autologous transplantation
        - Repeat allogeneic stem cell transplantation due to primary graft failure, failure to engraft or rejection
    - Myelodysplastic syndrome for individuals with **1 or more** of the following:
        - Individual has low risk myelodysplastic syndrome with clinically relevant thrombocytopenia, neutropenia, or anemia and **All** of the following:
            - Individual has failed standard chemotherapy and supportive treatment
        - Individual has intermediate or high risk myelodysplastic syndrome (MDS) and there is an available human leukocyte antigen (HLA) matched donor
    - Myelofibrosis for individual with myelofibrosis and for symptoms that persist, or worsen despite standard supportive care.
    - Myeloid sarcoma for individual with **1 or more** of the following:
        - Human leukocyte antigen (HLA) matched related donor
        - Matched unrelated donor
        - Severe combined immune deficiency
    - Myeloproliferative disorders (MPD)
    - Non-Hodgkin's lymphoma for individuals with **All** of the following:
        - Individual with a human leukocyte antigen (HLA) identical sibling available
        - Individual with recurrent disease
    - Paroxysmal nocturnal hemoglobinuria (PNH)
    - Primary granulocyte dysfunction
    - Refractory Hodgkin disease or Hodgkin disease that relapsed after an initial first remission (regardless of remission status at the time of transplant)
    - Severe aplastic anemia with **ALL** of the following:
        - Individual with marrow cellularity below 25%
        - Individual with **2 or more** of the following:
            - Absolute neutrophil count less than 0.5 x 10^9/L
            - Absolute reticulocyte count less than 20 x 10^9/L
            - Platelet count less than 20 x 10^9/L
    - Severe combined immunodeficiency (SCID)
    - Sickle cell disease in children or young adults **ALL** of the following:
        - History of a stroke, increased risk of a stroke, or end-organ damage
        - Human leukocyte antigen (HLA) matched donor
    - Sly syndrome
    - Thalassemia (homozygous beta-thalassemia)
    - Wiskott-Aldrich Syndrome (WAS)
    - Wolman syndrome
    - X-linked Lymphoproliferative Syndrome

Allogeneic hematopoietic stem cell transplantation is **Not Medically Necessary** for any use other than those indicated in clinical criteria, to include but not limited to:

- Autoimmune diseases
- Bile duct cancer (cholangiocarcinoma)
- Cancer of the fallopian tubes
- Cervical cancer
- Colon cancer
- Epithelial ovarian cancers

- Esophageal cancer
- Ewing Sarcoma
- For the treatment of diabetes mellitus
- Gallbladder cancer
- Germ cell tumors
- Lung cancer
- Malignant Astrocytomas and Gliomas
- Melanoma
- Nasopharyngeal cancer
- Neuroendocrine tumors
- Osteosarcoma
- Pancreas cancer
- Paranasal sinus cancer
- POEMS Syndrome (polyneuropathy, organomegaly, endocrinopathy, M protein, and skin changes)
- Primitive neuro-ectodermal tumor (PNET)
- Prostate cancer
- Rectal cancer
- Renal cell cancer
- Retinoblastoma
- Rhabdomyosarcoma
- Soft tissue sarcoma
- Stomach cancer
- Thymus cancer
- Thyroid cancer
- Tumors of unknown primary origin
- Uterine cancer
- Wilms' tumor (nephroblastoma)

Coding:

Medically necessary with criteria:

Coding	Description
38240	Hematopoietic progenitor cell (HPC); allogeneic transplantation per donor

Considered Not Medically Necessary:

Coding	Description
	None

U.S. Food and Drug Administration (FDA) - approved only products only.

Document History:

Revised Dates:

- 2022: March
- 2019: November
- 2015: February, August, September
- 2014: February, May, November
- 2013: February
- 2012: March, November

- 2011: March
- 2010: February, August
- 2009: January, October
- 2008: January, September
- 2005: May
- 2003: April
- 2002: February
- 2001: December
- 1999: December

Reviewed Dates:

- 2023: March
- 2018: October
- 2017: November
- 2016: February
- 2012: February
- 2011: February
- 2010: June
- 2006: March, April, May, June
- 2004: April, September
- 2003: February
- 2000: December
- 1998: October
- 1996: June
- 1994: September

Effective Date:

- January 1993

References:

Specialty Association Guidelines; Government Regulations; Winifred S. Hayes, Inc; UpToDate; Literature Review; Specialty Advisors; National Coverage Determination (NCD); Local Coverage Determination (LCD).

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Special Notes: *

Medical policies can be highly technical and complex and are provided here for informational purposes. These medical policies are intended for use by health care professionals. The medical policies do not constitute medical advice or medical care. Treating health care professionals are solely responsible for diagnosis, treatment, and medical advice. Sentara Health Plan members should discuss the information in the medical policies with their treating health care professionals. Medical technology is constantly evolving, and these medical policies are subject to change without notice, although Sentara Health Plan will notify providers as required in advance of changes that could have a negative impact on benefits.

Services mean both medical and behavioral health (mental health) services and supplies unless We specifically tell You otherwise. We do not cover any services that are not listed in the Covered Services section unless required to be covered

under state or federal laws and regulations. We do not cover any services that are not Medically Necessary. We sometimes give examples of specific services that are not covered but that does not mean that other similar services are covered. Some services are covered only if We authorize them. When We say You or Your We mean You and any of Your family members covered under the Plan. Call Member Services if You have questions.

Keywords:

Acute lymphoblastic leukemia, Acute lymphocytic leukemia, Acute Myeloid Leukemia, adrenoleukodystrophy, Albers-Schonberg disease, Alpha-mannosidosis, aplastic anemia, Beta Thalassemia major, Breast cancer, Chediak-Higashi syndrome, Childhood-onset adrenoleukodystrophy, Chronic granulomatous disease, Chronic Myeloid Leukemia, Chronic myelo-monocytic leukemia, Diamond-Blackfan anemia, Fanconi's anemia, Fucosidosis, Gaucher's disease, Globoid cell , kodystrophy, Hemophagocytic Lymphohistiocytosis, Heritable Bone Marrow Syndrome, High-risk neuroblastoma, Hodgkin disease, homozygous beta-thalassemia, Homozygous sickle cell disease, Hunter's syndrome, Hurler's syndrome, infantile genetic agranulocytosis, Infantile malignant osteopetrosis, juvenile myelo-monocytic leukemia, Kostmann's syndrome, Krabbe Disease, leukemia, Leukocyte adhesion deficiencies, Lymphoma, marble bone disease, Maroteaux-Lamy Syndrome, Metachromatic leukodystrophy, Morquio syndrome, Mucolipidoses, Mucopolysaccharoidosis, Multiple myeloma, Myelodysplastic syndrome, Myelofibrosis, Myeloid sarcoma, Myeloma, Myeloproliferative disorders, Non-Hodgkin's lymphoma, Paroxysmal Nocturnal Hemoglobinuria, Primary granulocyte dysfunction, Refractory Hodgkin disease, SanFilippo's syndrome, Severe aplastic anemia, Severe combined immunodeficiency, severe congenital neutropenia, SHP Allogeneic Hematopoietic Stem Cell Transplantation, SHP Surgical 213, sickle beta thalassemia, Sickle Cell Disease, Sly syndrome, Thalassemia, Wiskott-Aldrich syndrome, Wolman syndrome, X-linked Lymphoproliferative Syndrome