SHP Allogeneic Hematopoietic Stem Cell Transplantation

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Coverage

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- Under EPSDT, any other medically necessary transplant procedures that are not experimental or investigational are limited to persons under the age of 21.
- Members must use contracted facilities unless approved by the Plan.
- Individuals with plans without transplant benefits are excluded from coverage.
- See the appropriate benefit document for specific coverage determination. Member specific benefits take precedence over medical policy.

Application to Products

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Policy is applicable to all products.

Authorization Requirements

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Pre-certification by the Plan is required.

Description of Item or Service

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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.

Exceptions and Limitations

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- There is insufficient scientific evidence to support the medical necessity of allogeneic hematopoietic stem cell transplantation for the following as they are not shown to improve health outcomes upon technology review:
    - Autoimmune diseases
    - Bile duct cancer (cholangiocarcinoma)
    - Breast cancer (except Optima Virginia Medicaid Plans)
    - 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)

- There is insufficient scientific evidence to support the medical necessity of Allogeneic Hematopoietic Stem Cell Transplantation for uses other than those listed in the clinical indications for procedure section.

Clinical Indications for Procedure

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- Allogeneic Hematopoietic Stem Cell Transplantation is considered medically necessary for **1 or more** of the following
  - Individual has Optima Medicare plan and request is for **1 or more** of the following
    - Leukemia, leukemia in remission, or aplastic anemia when it is reasonable and necessary
    - Severe combined immunodeficiency
    - Wiskott-Aldrich syndrome
  - Individual has Optima Virginia Medicaid Plan with **ALL** of the following
    - Individual has diagnosis of **1 or more** of the following
      - Aplastic Anemia
      - Beta Thalassemia major
      - Breast cancer
      - Heritable Bone Marrow Syndrome
      - Leukemia
      - Lymphoma
      - Myeloma
      - Paroxysmal Nocturnal Hemoglobinuria
      - Sickle Cell Disease
    - Current medical therapy has failed, and the individual has failed to respond to appropriate therapeutic management
    - The individual is not in an irreversible terminal state
    - The transplant is likely to prolong life and restore a range of physical and social function suited to activities of daily living
  - Individual has Optima Commercial Plan with **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 **ALL** of the following
    - 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)
- Mucopolysaccharoidosis (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 109/L
        - Absolute reticulocyte count less than 20 x 109/L
        - Platelet count less than 20 x 109/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 COVERED** for **ANY** of the following
    - Autoimmune diseases
    - Bile duct cancer (cholangiocarcinoma)
    - Breast cancer
    - 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)

Document History

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- 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

Coding Information

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- CPT/HCPCS codes covered if policy criteria is met:
  - CPT 38240 - Hematopoietic progenitor cell (HPC); allogeneic transplantation per donor
- CPT/HCPCS codes considered not medically necessary per this Policy:
  - None

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Codes

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