Hematopoietic Stem Cell Transplantation (HSCT), Surgical 08

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All requests for authorization for the services described by this medical policy will be reviewed per Early and Periodic Screening, Diagnostic and Treatment (EPSDT) guidelines. These services may be authorized under individual consideration for Medicaid members under the age of 21-years if the services are judged to by medically necessary to correct or ameliorate the member's condition. Department of Medical Assistance Services (DMAS), Supplement B - EPSDT (Early and Periodic Screening, Diagnosis and Treatment) Manual.*.

Purpose:

This policy addresses 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.

Autologous hematopoietic stem cell transplantation is when the individual's own stem cells are removed before high dose chemotherapy or radiation, frozen for storage then thawed and returned. This process is used to replace damaged or destroyed bone marrow with blood-forming stem cells from the individual's own blood after treatment.

Criteria:

Hematopoietic Stem Cell Transplantation (HSCT) is considered **medically necessary** for **1 or more** of the following:

- **Allogeneic Hematopoietic Stem Cell Transplantation** (HSCT) 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 **in an adult** 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 **pediatric** lymphoblastic leukemia and **1 or more** of the following:
    - B-cell acute lymphoblastic leukemia in first remission and **1 or more** of the following:
        - Infant younger than 3 months of age with KMT2A mutation
        - Infant younger than 6 months of age with KMT2A mutation and WBC count at initial diagnosis 300,000/mm3 (300 x109/L) or greater
        - Minimal residual disease of 0.01% or more at post consolidation
    - B-cell acute lymphoblastic leukemia and **1 or more** of the following:
        - Relapsed refractory not responding to treatment (less than complete remission)
        - Minimal residual disease of 0.01% or more at post consolidation
    - T-cell acute lymphoblastic leukemia and **1 or more** of the following:
        - Minimal residual disease positivity of more than 0.1% at consolidation
        - Induction failure
        - Medullary or extramedullary relapse
        - 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)
    - Consolidation therapy after complete remission
- Acute promyelocytic leukemia and **1 or more** of the following:
    - Molecular remission after second-line therapy, and autologous transplant not feasible
    - Persistent disease after autologous transplant or salvage therapy
- Acute leukemia of ambiguous lineage
- Alpha-mannosidosis
- Aplastic anemia and **ALL** of the following:
    - Marrow cellularity below 25%
    - Severely abnormal cell counts, as indicated by **2 or more** of the following:
    - Absolute neutrophil count less than 500/mm3 (0.5 x109/L)
    - Absolute reticulocyte count less than 20,000/mm3 (20 x109/L)
    - Platelet count less than 20,000/mm3 (20 x109/L)
- BCR-ABL1 negative myeloproliferative neoplasm (also called atypical chronic myeloid leukemia)
- Breast cancer

- Burkitt lymphoma with relapsed or refractory disease
- Chediak-Higashi syndrome
- Chronic granulomatous disease
- Chronic lymphocytic leukemia or small lymphocytic lymphoma and **1 or more** of the following(52):
    - 17p deletion or TP53 mutation with refractory disease or in a clinical trial
    - Complex karyotype (3 or more abnormalities) in remission with or after Bruton tyrosine kinase (BTK) inhibitor therapy
    - Relapsed or refractory disease to small molecule inhibitor therapy
    - Richter transformation
    - Pure red cell aplasia refractory to treatment
- 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
    - Advanced phase (blast phase or accelerated phase) at diagnosis
    - Tyrosine kinase inhibitor-resistant (eg, due to mutation)
    - Failure to respond to tyrosine kinase inhibitors
    - Intolerant of tyrosine kinase inhibitor
    - Accelerated or blast phase of disease while on tyrosine kinase inhibitor therapy
    - Relapsed disease after transplant
    - Atypical chronic myeloid leukemia, BCR-ABL negative
- Diamond-Blackfan anemia (DBA)
- Essential thrombocythemia with secondary myelofibrosis
- Fanconi's anemia (FA)
- Fucosidosis
- Globoid cell leukodystrophy (Krabbe Disease)
- Hemophagocytic Lymphohistiocytosis (HLH)
- Heritable Bone Marrow Syndrome
- High-risk neuroblastoma
- Hodgkin disease that is refractory or relapsed after an initial first remission (regardless of remission status at the time of transplant)
- 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)
- Large B-cell lymphoma with **1 or more** of the following:
    - Pediatric or young adult with diffuse disease that has relapsed or refractory
    - Adult with diffuse disease and partial or complete response to chemotherapy
- Leukocyte adhesion deficiencies

- Mantle cell lymphoma with relapse or refractory disease that is in remission following second-line therapy
- 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
- Mycosis fungoides or Sezary syndrome that is refractory or progressive
- 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
    - Repeat transplant in relapse if successful prolonged remission with first transplant
- Myelofibrosis for individual with myelofibrosis and for symptoms that persist or worsen despite standard supportive care.
- Myelodysplastic myeloproliferative overlap neoplasm, including **1 or more** of the following:
    - Juvenile myelomonocytic leukemia
    - Chronic myelomonocytic leukemia
    - Overlap syndrome (unclassifiable)
- 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)
- Nasal type extranodal NK/T-cell lymphoma and **one or more** of the following:
    - Stage I or stage II nasal disease with partial or refractory response to induction therapy
    - Stage I to IV extra-nasal disease
    - Stage IV nasal disease
- NK-cell leukemia that is aggressive for consolidation therapy
- 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)
- Peripheral T-cell lymphoma with partial or refractory response
- Polycythemia rubra vera with secondary myelofibrosis
- Primary granulocyte dysfunction
- Primary Myelofibrosis and related conditions (e.g., PRV)
- 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
        - Acute chest syndrome requiring 2 or more hospitalizations within 2 years despite hydroxyurea therapy
        - Vaso-occlusive pain crisis requiring 2 or more hospitalizations within 2 years despite hydroxyurea therapy
        - Transfusion requirement of 8 or more transfusions per year for 1 or more years
        - Tricuspid valve regurgitant jet of 2.7 m/sec or more on echocardiogram
    - Sly syndrome
    - T-cell leukemia/lymphoma with acute or lymphoma subtype responsive to chemotherapy
    - Thalassemia (homozygous beta-thalassemia)
    - Waldenstrom macroglobulinemia (lymphoplasmacytic lymphoma) that has relapsed
    - Wiskott-Aldrich Syndrome (WAS)
    - Wolman syndrome
    - X-linked Lymphoproliferative Syndrome
- Autologous Hematopoietic Stem Cell Transplantation (HSCT) is considered medically necessary for individuals 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 myelogenous leukemia for **ALL** of the following:
            - Individual with **1 or more** of the following:
                - Acute promyelocytic leukemia
                - Acute myelocytic leukemia
        - Individual with **1 or more** of the following:
            - First or second remission if responsive to previous chemotherapy
            - Relapsed acute myelogenous leukemia if responsive to previous chemotherapy
        - Adult medulloblastoma with no evidence of disease after conventional dose chemotherapy
        - Amyloidosis
        - Blastic plasmacytoid dendritic cell neoplasm with response to chemotherapy
        - Breast cancer
        - Breast implant associated anaplastic large cell lymphoma with response to systemic therapy
        - Chronic inflammatory demyelinating polyneuropathy
        - Chronic lymphocytic leukemia with **ALL** of the following:
            - Individual has exhausted all other traditional treatments
            - Richter transformation
            - Patient not a candidate for allogeneic transplant
        - Embryonal Tumors with Multi-layered Rosettes (ETMR). Formerly known as Primitive Neuroectodermal Tumor (PNET)
        - Ewing Tumor (Ewing Sarcoma)
        - Follicular lymphoma
        - Germ cell tumors for individual with **1 or more** of the following:
            - After relapse or metastatic
            - Chemosensitive tumor
            - Primary refractory disease
        - Hepatosplenic T-cell lymphoma with complete or partial response to chemotherapy and allogeneic transplant not feasible
        - Heritable Bone Marrow Syndrome
        - Hodgkin's lymphoma in an adult (over the age of 39) with **1 or more** of the following:

        - First relapse in chemosensitive disease
        - Partial remission after radiotherapy for isolated lesions
        - Primary refractory disease
    - Hodgkin lymphoma in a child or young adult (39 or younger) with relapse and response (eg, Deauville of 3 or less on PET scan) to induction therapy
    - Immunoglobulin light chain amyloidosis and **ALL** of the following:
        - Ejection fraction on cardiac imaging of 40% or more
        - Supine systolic blood pressure of 90 mm Hg or more
        - Pulmonary diffusion capacity of 40% or more
        - Three or fewer organs involved with disease
        - No persistent symptomatic pleural effusions
    - Large B-cell lymphoma and **1 or more** of the following:
        - In an adult (over the age of 39) with diffuse disease **1 or more** of the following:
            - Relapsed
            - Treatment refractory and chemosensitive
            - Double or triple cytogenetic rearrangement of MYC, BCC2, and/or BCL6
        - In a child or young adult (age 39 years or younger) with diffuse disease that has relapsed or is refractory
    - Medulloblastoma
    - Multiple myeloma and **1 or more** of the following:
        - After induction chemotherapy in patient judged appropriate for transplant (eg, able to tolerate)
        - Primary progressive disease
        - Planned tandem autologous transplant[I]
        - Repeat autologous transplant for relapsed disease
        - Refractory disease
    - Multiple sclerosis refractory to treatment or with relapsing-remitting course
    - Myasthenia gravis refractory to treatment
    - Nasal type extranodal NK/T-cell lymphoma and **1 or more** of the following:
        - Stage I or stage II nasal disease with partial or refractory response to induction therapy
        - Stage IV nasal disease
        - Stage I to IV extra-nasal disease
    - Neuroblastoma is considered medically necessary with **ALL** of the following:
        - Stage IV or high-risk stage III neuroblastoma
        - No disease progression after initial course of chemotherapy
    - Non-Hodgkin's Lymphoma with **ALL** of the following:
        - Individual with **1 or more** of the following:
            - Burkitt lymphoma that is relapsed or refractory to treatment
            - Diffuse large B-cell lymphoma with **1 or more** of the following:
                - High international prognostic index (IPI) at diagnosis
                - Intermediate international prognostic index (IPI) at diagnosis
            - Follicular B-cell lymphoma
            - Lymphoblastic lymphoma
            - Mantel cell lymphoma with partial or complete response following induction chemotherapy (ie, consolidation therapy)
            - Mixed cell lymphoma
            - Small cell lymphoma
            - Small cleaved cell lymphoma
            - T-cell lymphoma
        - Individual with a chemosensitive tumor
        - Individual with **1 or more** of the following:
            - Relapse and second or greater complete remission
            - First complete remission
    - Oligodendroglioma
    - Peripheral T-cell lymphoma
    - Pineoblastoma
    - Plasmablastic lymphoma

- Polyneuropathy, organomegaly, endocrinopathy, M protein, and skin changes (POEMS syndrome)
- Primitive neuroectodermal tumors (PNET) and ependymoma (with or without associated radiotherapy, for the treatment of primitive neuroectodermal tumors, such as medulloblastoma and ependymoma, arising in the central nervous system or pineal blastoma)
- Primary CNS lymphoma and relapsed or refractory disease with at least partial response to chemotherapy
- Prolymphocytic Leukemia
- Scleroderma (also known as diffuse cutaneous systemic sclerosis)
- Stiff Person syndrome with antibodies to glutamic acid decarboxylase (GAD) that is refractory to treatment
- T-cell prolymphocytic leukemia with complete or partial response to induction therapy and allogeneic transplant not feasible
- Testicular cancer for individuals who relapse after an initial course of standard dose chemotherapy
- Waldenstrom macroglobulinemia (lymphoplasmacytic lymphoma) with relapse

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
38241	Hematopoietic progenitor cell (HPC); autologous transplantation

Considered Not Medically Necessary:

Coding	Description
	None

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

Document History:

Revised Dates:

- 2024: July
- 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

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- 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

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Special Notes: *

This medical policy express Sentara Health Plan's determination of medically necessity of services, and they are based upon a review of currently available clinical information. These policies are used when no specific guidelines for coverage are provided by the Department of Medical Assistance Services of Virginia (DMAS). Medical Policies may be superseded by state Medicaid Plan guidelines. Medical policies are not a substitute for clinical judgment or for any prior authorization requirements of the health plan. These policies are not an explanation of benefits.

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.

The Early and Periodic Screening, Diagnostic and Treatment (EPSDT) covers services, products, or procedures for children, if those items are determined to be medically necessary to "correct or ameliorate" (make better) a defect, physical or mental illness, or condition (health problem) identified through routine medical screening or examination, regardless of whether coverage for the same service or support is an optional or limited service under the state plan. Children enrolled in the FAMIS Program are not eligible for all EPSDT treatment services. All requests for authorization for the services described by this medical policy will be reviewed per EPSDT guidelines. These services may be authorized under individual consideration for Medicaid members under the age of 21-years if the services are judged to by medically necessary to correct or ameliorate the member's condition. *Department of Medical Assistance Services (DMAS), Supplement B - EPSDT (Early and Periodic Screening, Diagnosis and Treatment) Manual.*

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