

To all beneficiaries enrolled in a Prepaid Health Plan (PHP): for questions about benefits and services available on or after November 1, 2019, please contact your PHP.

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**NC Medicaid
Allogeneic Hematopoietic Stem-Cell &
Bone Marrow Transplantation for
Myelodysplastic Syndromes &
Myeloproliferative Neoplasms**

**Medicaid and Health Choice
Clinical Coverage Policy No: 11A-9
Amended Date:**

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Clinical Coverage Policy No: 11A-9
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Related Clinical Coverage Policies

Refer to <https://medicaid.ncdhhs.gov/> for the related coverage policies listed below:

11A-2, Hematopoietic Stem-Cell and Bone Marrow Transplant for Acute Myeloid Leukemia

11A-3, Hematopoietic Stem-Cell & Bone Marrow Transplantation for Chronic Myelogenous Leukemia

[11A-14, Placental and Umbilical Cord Blood as a Source of Stem Cells](#)

[1A-39, Routine Costs in Clinical Trial Services for Life Threatening Conditions](#)

1.0 Description of the Procedure, Product, or Service

Hematopoietic Stem-Cell Transplantation

Hematopoietic stem-cell transplantation (HSCT) refers to a procedure in which hematopoietic stem cells are infused to restore bone marrow function in cancer patients who receive bone-marrow-toxic doses of cytotoxic drugs with or without whole body radiation therapy.

Hematopoietic stem cells may be obtained from the transplant recipient (autologous HSCT) or from a donor (allogeneic HSCT). They can be harvested from bone marrow, peripheral blood, or umbilical cord blood shortly after delivery of neonates. Although cord blood is an allogeneic source, the stem cells in it are antigenically —naïve and thus are associated with a lower incidence of rejection or graft-versus-host disease (GVHD).

Immunologic compatibility between infused hematopoietic stem cells and the recipient is not an issue in autologous HSCT. However, immunologic compatibility between donor and patient is a critical factor for achieving a good outcome of allogeneic HSCT. Compatibility is established by typing of human leukocyte antigens (HLA) using cellular, serologic, or molecular techniques. HLA refers to the tissue type expressed at the HLA A, B, and DR loci on each arm of chromosome 6. Depending on the disease being treated, an acceptable donor will match the patient at all or most of the HLA loci.

Conventional Preparative Conditioning for HSCT

The conventional (“classical”) practice of allogeneic HSCT involves administration of cytotoxic agents (e.g., cyclophosphamide, busulfan) with or without total body irradiation at doses sufficient to destroy endogenous hematopoietic capability in the recipient. The beneficial treatment effect in this procedure is due to a combination of initial eradication of malignant cells and subsequent graft-versus-malignancy (GVM) effect that develops after engraftment of allogeneic stem cells within the patient’s bone marrow space. While the slower GVM effect is considered to be the potentially curative component, it may be overwhelmed by extant disease without the use of pretransplant conditioning. However, intense conditioning regimens are limited to patients who are sufficiently fit medically to tolerate substantial adverse effects that include pre-engraftment opportunistic infections secondary to loss of endogenous bone marrow function and organ damage and failure caused by the cytotoxic drugs. Furthermore, in any allogeneic HSCT, immune suppressant drugs are required to minimize graft rejection and GVHD, which also increases susceptibility of the patient to opportunistic infections.

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Reduced-Intensity Conditioning for Allogeneic HSCT

Reduced-intensity conditioning (RIC) refers to the pretransplant use of lower doses or less intense regimens of cytotoxic drugs or radiation than are used in conventional full-dose myeloablative conditioning treatments. The goal of RIC is to reduce disease burden, but also to minimize as much as possible associated treatment-related morbidity and non-relapse mortality (NRM) in the period during which the beneficial GVM effect of allogeneic transplantation develops. Although the definition of RIC remains arbitrary, with numerous versions employed, all seek to balance the competing effects of NRM and relapse due to residual disease.

RIC regimens can be viewed as a continuum in effects, from nearly totally myeloablative, to minimally myeloablative with lymphoablation, with intensity tailored to specific diseases and patient condition. Patients who undergo RIC with allogeneic HSCT initially demonstrate donor cell engraftment and bone marrow mixed chimerism. Most will subsequently convert to full-donor chimerism, which may be supplemented with donor lymphocyte infusions to eradicate residual malignant cells. For the purposes of this Policy, the term “reduced-intensity conditioning” will refer to all conditioning regimens intended to be nonmyeloablative, as opposed to fully myeloablative (conventional) regimens.

Myelodysplastic Syndromes

Myelodysplastic syndromes (MDS) refer to a heterogeneous group of clonal hematopoietic disorders characterized by impaired maturation of hematopoietic cells and a tendency to transform into acute myelocytic leukemia (AML). MDS can occur as a primary (idiopathic) disease, or be secondary to cytotoxic therapy, ionizing radiation, or other environmental insult. Chromosomal abnormalities are seen in 40%–60% of patients, frequently involving deletions of chromosome 5 or 7, or an extra chromosome as in trisomy 8. Signs and symptoms of anemia, often complicated by infections or bleeding, are common in MDS; some patients exhibit systemic symptoms or features of autoimmunity that may be indicative of their disease pathogenesis. The vast majority of MDS diagnoses occur in individuals over the age of 55–60 years, with an age-adjusted incidence of about 62% among individuals over age 70 years. Patients either succumb to disease progression to AML or to complications of pancytopenias. Patients with higher blast counts or complex cytogenetic abnormalities have a greater likelihood of progressing to AML than do other patients.

For the past 20 years, the French-American-British (FAB) system has been used to classify MDS into 5 subtypes as follows: 1) refractory anemia (RA); 2) refractory anemia with ringed sideroblasts (RARS); 3) refractory anemia with excess blasts (RAEB); 4) refractory anemia with excess blasts in transformation (RAEBT); and, 5) chronic myelomonocytic leukemia (CMML). However, the FAB system has been supplanted by that of the World Health Organization (WHO), which records the number of lineages in which dysplasia is seen (unilineage versus multilineage), separates the 5q- syndrome, and reduces the threshold maximum blast percentage for the diagnosis of MDS from 30% to 20% (see Policy Guidelines for WHO classification scheme for myeloid neoplasms).

Several prognostic scoring systems for MDS have been proposed; the most commonly used is the International Prognostic Scoring System (IPSS). The IPSS groups patients into one of four prognostic categories based on the number of cytopenias, cytogenetic profile and the percentage blasts in the bone marrow (see Policy Guidelines). This system underweights the clinical

importance of severe, life-threatening neutropenia and thrombocytopenia in therapeutic decisions and does not account for the rate of change in critical parameters, such as peripheral blood counts or blast percentage. However, the IPSS has been useful in comparative analysis of clinical trial results and its utility confirmed at many institutions. A second prognostic scoring system incorporates the WHO subgroup classification that accounts for blast percentage, cytogenetics, and severity of cytopenias as assessed by transfusion requirements. The WPSS uses a 6-category system which allows more precise prognostication of overall survival duration as well as risk for progression to AML. This system, however, is not yet in widespread use in clinical trials.

Treatment of smoldering or nonprogressing MDS has in the past involved best supportive care including red blood cell (RBC) and platelet transfusions and antibiotics. Active therapy was given only when MDS progressed to AML or resembled AML with severe cytopenias. A diverse array of therapies are now available to treat MDS, including hematopoietic growth factors (e.g., erythropoietin, darbepoetin, granulocyte colony-stimulating factor), transcriptional-modifying therapy (e.g., U.S. Food and Drug Administration-approved hypomethylating agents, nonapproved histone deacetylase inhibitors), immunomodulators (e.g., lenalidomide, thalidomide, antithymocyte globulin, cyclosporine A), low-dose chemotherapy (e.g., cytarabine), and allogeneic HSCT. Given the spectrum of treatments available, the goal of therapy must be decided upfront, whether it is to improve anemia, thrombocytopenia, or neutropenia; eliminate the need for RBC transfusion; achieve complete remission (CR); or, cure the disease. Allogeneic HSCT is the only approach with curative potential, but its use is governed by patient age, performance status, medical comorbidities, the patient's risk preference, and severity of MDS at presentation.

Chronic Myeloproliferative Neoplasms

In 2008, a new WHO classification scheme replaced the term chronic myeloproliferative disorder (CMPD) with the term myeloproliferative neoplasms (MPN). These are a subdivision of myeloid neoplasms that includes the four classic disorders chronic myeloid leukemia (CML), polycythemia vera (PCV), essential thrombocytopenia (ET), and primary myelofibrosis (PMF); the WHO classification also includes chronic neutrophilic leukemia (CNL), chronic eosinophilic leukemia/hypereosinophilic syndrome (CEL/HES), mast cell disease (MCD), and MPNs unclassifiable (refer to Policy Guidelines).

The MPNs are characterized by the slow but relentless expansion of a clone of cells with the potential evolution into a blast crisis similar to AML. They share a common stem cell-derived clonal heritage, with phenotypic diversity attributed to abnormal variations in signal transduction as the result of a spectrum of mutations that affect protein tyrosine kinases or related molecules. The unifying characteristic common to all MPNs is effective clonal myeloproliferation resulting in peripheral granulocytosis, thrombocytosis, or erythrocytosis that is devoid of dyserythropoiesis, granulocytic dysplasia, or monocytosis.

As a group, about 8,400 MPNs are diagnosed annually in the U.S. Like MDS, MPNs occur primarily in older individuals, with about 67% reported in patients aged 60 years and older. In indolent, nonprogressing cases, therapeutic approaches are based on relief of symptoms. Myeloablative allogeneic HSCT has been considered the only potentially curative therapy, but because most patients are of advanced age with attendant comorbidities, its use is limited to those who can tolerate the often-severe treatment-related adverse effects of this procedure. However, the use of RIC regimens for allogeneic HSCT has extended the potential benefits of this procedure to selected individuals with these disorders.

1.1 Definitions

1.1.1 Donor Lymphocyte Infusion (DLI)

A type of therapy in which lymphocytes from the blood of a donor are given to a beneficiary who has already received a stem cell transplant from the same donor. The donor lymphocytes may kill remaining cancer cells.

2.0 Eligibility Requirements

2.1 Provisions

2.1.1 General

(The term “General” found throughout this policy applies to all Medicaid and NCHC policies)

- a. An eligible beneficiary shall be enrolled in either:
 1. the NC Medicaid Program (*Medicaid is NC Medicaid program, unless context clearly indicates otherwise*); or
 2. the NC Health Choice (*NCHC is NC Health Choice program, unless context clearly indicates otherwise*) Program on the date of service and shall meet the criteria in **Section 3.0 of this policy**.
- b. Provider(s) shall verify each Medicaid or NCHC beneficiary’s eligibility each time a service is rendered.
- c. The Medicaid beneficiary may have service restrictions due to their eligibility category that would make them ineligible for this service.
- d. Following is only one of the eligibility and other requirements for participation in the NCHC Program under GS 108A-70.21(a): Children must be between the ages of 6 through 18.

2.1.2 Specific

(The term “Specific” found throughout this policy only applies to this policy)

- a. Medicaid
None Apply.
- b. NCHC
None Apply.

2.2 Special Provisions

2.2.1 EPSDT Special Provision: Exception to Policy Limitations for a Medicaid Beneficiary under 21 Years of Age

- a. **42 U.S.C. § 1396d(r) [1905(r) of the Social Security Act]**

Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) is a federal Medicaid requirement that requires the state Medicaid agency to cover services, products, or procedures for Medicaid beneficiary under 21 years of age **if** the service is **medically necessary health care** to correct or ameliorate a defect, physical or mental illness, or a condition [health

problem] identified through a screening examination (includes any evaluation by a physician or other licensed practitioner).

This means EPSDT covers most of the medical or remedial care a child needs to improve or maintain his or her health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

Medically necessary services will be provided in the most economic mode, as long as the treatment made available is similarly efficacious to the service requested by the beneficiary's physician, therapist, or other licensed practitioner; the determination process does not delay the delivery of the needed service; and the determination does not limit the beneficiary's right to a free choice of providers.

EPSDT does not require the state Medicaid agency to provide any service, product or procedure:

1. that is unsafe, ineffective, or experimental or investigational.
2. that is not medical in nature or not generally recognized as an accepted method of medical practice or treatment.

Service limitations on scope, amount, duration, frequency, location of service, and other specific criteria described in clinical coverage policies may be exceeded or may not apply as long as the provider's documentation shows that the requested service is medically necessary "to correct or ameliorate a defect, physical or mental illness, or a condition" [health problem]; that is, provider documentation shows how the service, product, or procedure meets all EPSDT criteria, including to correct or improve or maintain the beneficiary's health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

b. EPSDT and Prior Approval Requirements

1. If the service, product, or procedure requires prior approval, the fact that the beneficiary is under 21 years of age does **NOT** eliminate the requirement for prior approval.
2. **IMPORTANT ADDITIONAL INFORMATION** about EPSDT and prior approval is found in the *NCTracks Provider Claims and Billing Assistance Guide*, and on the EPSDT provider page. The Web addresses are specified below.

NCTracks Provider Claims and Billing Assistance Guide:

<https://www.nctracks.nc.gov/content/public/providers/provider-manuals.html>

EPSDT provider page: <https://medicaid.ncdhhs.gov/>

2.2.2 EPSDT does not apply to NCHC beneficiaries

2.2.3 Health Choice Special Provision for a Health Choice Beneficiary age 6 through 18 years of age

NC Medicaid shall deny the claim for coverage for an NCHC beneficiary who does not meet the criteria within **Section 3.0** of this policy. Only services included under the NCHC State Plan and the NC Medicaid clinical coverage policies, service definitions, or billing codes are covered for an NCHC beneficiary.

3.0 When the Procedure, Product, or Service Is Covered

Note: Refer to Subsection 2.2.1 regarding EPSDT Exception to Policy Limitations for Medicaid Beneficiaries under 21 Years of Age.

3.1 General Criteria Covered

Medicaid and NCHC shall cover the procedure, product, or service related to this policy when medically necessary, and:

- a. the procedure, product, or service is individualized, specific, and consistent with symptoms or confirmed diagnosis of the illness or injury under treatment, and not in excess of the beneficiary's needs;
- b. the procedure, product, or service can be safely furnished, and no equally effective and more conservative or less costly treatment is available statewide; and
- c. the procedure, product, or service is furnished in a manner not primarily intended for the convenience of the beneficiary, the beneficiary's caretaker, or the provider.

3.2 Specific Criteria Covered

3.2.1 Specific criteria covered by both Medicaid and NCHC

- a. Specific criteria covered by both Medicaid and NCHC Medicaid and NCHC shall cover allogeneic HSCT for the treatment of myelodysplastic syndromes and myeloproliferative neoplasms; when it is determined to be medically necessary because the medical criteria and guidelines in the Policy Guidelines are met.
- b. Medicaid and NCHC shall cover reduced-intensity conditioning (RIC) allogeneic HSCT for the treatment of myelodysplastic syndromes and myeloproliferative neoplasm for beneficiaries who for medical reasons would be unable to tolerate a myeloablative conditioning regime. when it is determined to be medically necessary because the medical criteria and guidelines in the Policy Guidelines are met.
- c. Donor lymphocyte infusion (DLI) (refer to Section 1.1) is considered medically necessary and, therefore, covered following allogeneic hematopoietic stem cell transplantation (HSCT) that is medically necessary for the treatment of myelodysplastic syndromes that have relapsed or are refractory, to prevent relapse in the setting of a high risk of relapse, or to convert an individual from mixed to full donor chimerism.

3.2.2 Medicaid Additional Criteria Covered

None Apply.

3.2.3 NCHC Additional Criteria Covered

None Apply.

3.2.4 Policy Guidelines

- a. Myeloablative chemotherapy with allogeneic HSCT is typically considered in those patients with increasing numbers of blasts, signaling a possible transformation to acute myeloid leukemia. Subtypes falling into this category include refractory anemia with excess blasts, refractory anemia with excess blasts in transformation, or chronic myelomonocytic leukemia.
- b. Patients with refractory anemia with or without ringed sideroblasts may be considered candidates for high dose chemotherapy when chromosomal abnormalities are present or the disorder is associated with the development of significant cytopenias (e.g., neutrophils less than 500/mm³, platelets less than 20,000/mm³).
- c. Health records should indicate the International Prognostic Scoring System (IPSS) Risk category, the biological or chronological age, Performance Status (ECOG 0,1,2), and document that the patient has adequate clinical status to undergo AML induction.
- d. **2016 2008 WHO Myeloid Neoplasm Classification Classification Scheme for Myeloid Neoplasms**
 1. Acute myeloid leukemia
 2. Myelodysplastic syndromes (MDS)
 3. Myeloproliferative neoplasms (MPN)
 - A. Chronic myeloid myelogenous leukemia (CML), *BCR-ABL1*⁺
 - B. Chronic neutrophilic leukemia (CNL)
 - C. Polycythemia vera (PV)
 - D. Primary myelofibrosis (PMF)
 - i. PMF, prefibrotic early stage
 - ii. PMF, overt fibrotic stage
 - E. Essential thrombocythemia (ET)
 - F. Chronic eosinophilic leukemia, not otherwise specified (NOS) categorized
 - G. Hypereosinophilic leukemia
 - H. Mast cell disease
 - I. MPNs, unclassifiable
 - J. Mastocytosis
 4. Myeloid/lymphoid neoplasms associated with eosinophilia and rearrangement abnormalities of *PDGFRA*, *PDGFRB*, or *FGFR1*, or with *PCMI-JAK2*
 - A. Myeloid/lymphoid neoplasms associate with *PDGFRA* rearrangement
 - B. Myeloid/lymphoid neoplasms associate with *PDGFRB* rearrangement
 - C. Myeloid/lymphoid neoplasms associate with *FGFR1* rearrangement (8p11 myeloproliferative syndrome)

- D. *Provisional entity: Myeloid/lymphoid neoplasms with PCMI-JAK2*
- 5. **Myelodysplastic/myeloproliferative neoplasms (MDS/MPN)**
 - A. Chronic myelomonocytic leukemia (CMML)
 - B. Atypical chronic myeloid leukemia (aCML), BCR-ABL1
 - C. Juvenile myelomonocytic leukemia (JMML)
 - D. MDS/MPN with ring sideroblasts and thrombocytosis (MDS/MPN-RS-T)
 - E. MDS/MPN, unclassifiable
- e. **2016 2008 WHO Classification of Myelodysplastic syndromes (MDS)**
 - 1. MDS with single lineage dysplasia
 - 2. Refractory anemia (RA)
 - 3. MDS RA with ring sideroblasts (MDS-RS) (RARS)
 - A. MDS-RS and single lineage dysplasia
 - B. MDS-RS and multilineage dysplasia
 - 4. MDS Refractory cytopenia with multilineage dysplasia (RCMD)
 - 5. MDS with excess blasts
 - 6. RCMD with ring sideroblasts
 - 7. RA with excess blasts 1 and 2 (RAEB 1 and 2)
 - 8. del 5q syndrome
 - 9. MDS with isolated del(5q)
 - 10. unclassified MDS, unclassifiable
 - A. *Provisional entity: Refractory cytopenia of childhood*
 - 11. Myeloid neoplasms with germ line predisposition

Risk Stratification of MDS

Risk stratification for MDS is performed using the IPSS. This system was developed after pooling data from 7 previous studies that used independent, risk-based prognostic factors. The prognostic model and the scoring system were built based on blast count, degree of cytopenia, and blast percentage. Risk scores were weighted relative to their statistical power. This system is widely used to divide patients into two categories: (1) low risk and (2) high-risk groups. The low-risk group includes low risk and Int-1 IPSS groups; the goals in low-risk MDS patients are to improve quality of life and achieve transfusion independence. In the high-risk group — which includes Int-2 and high-risk IPSS groups — the goals are slowing the progression of disease to AML and improving survival. The IPSS is usually calculated on diagnosis. The role of lactate dehydrogenase, marrow fibrosis, and beta 2-microglobulin also should be considered after establishing the IPSS. If elevated, the prognostic category becomes worse by one category change.

IPSS: MDS Prognostic Variables					
Variable	0	0.5	1.0	1.5	2.0
Marrow blasts	less than 5	5-10		11-20	21-30
Karyotype	Good	Intermediate	Poor		
Cytopenias	0/1	2/3			
IPSS: MDS Clinical Outcomes					
Risk Group, yrs	Total score	Median survival, yrs	Time for 25% to Progress AML, yrs		
Low	0	5.7	9.4		

Intermediate-1	0.5 – 1.0	3.5	3.3
Intermediate-2	1.5 – 2.0	1.2	1.12
High	2.5 or more	0.4	0.2

Given the long natural history of MDS, allogeneic HSCT is typically considered in those with increasing numbers of blasts, signaling a possible transformation to acute myeloid leukemia. Subtypes falling into this category include refractory anemia with excess blasts, refractory anemia with excess blasts in transformation, or chronic myelomonocytic leukemia.

Patients with refractory anemia with or without ringed sideroblasts may be considered candidates for allogeneic HSCT when chromosomal abnormalities are present or the disorder is associated with the development of significant cytopenias (e.g., neutrophils less than 500/mm³, platelets less than 20,000/mm³).

Patients with MPNs may be considered candidates for allogeneic HSCT when there is progression to myelofibrosis, or when there is evolution toward acute leukemia. In addition, allogeneic HSCT may be considered in patients with essential thrombocythemia with an associated thrombotic or hemorrhagic disorder. There are no suitable U.S. Food and Drug Administration (FDA) approved therapies for these patients, only supportive care. The use of allogeneic HSCT should be based on cytopenias, transfusion dependence, increasing blast percentage over 5%, and age.

Some patients for whom a conventional myeloablative allotransplant could be curative may be considered candidates for RIC allogeneic HSCT. These include those patients whose age (typically older than 60 years) or comorbidities (e.g., liver or kidney dysfunction, generalized debilitation, prior intensive chemotherapy, low Karnofsky Performance Status) preclude use of a standard myeloablative conditioning regimen. The ideal allogeneic donors are HLA-identical siblings, matched at the HLA-A, B, and DR loci (6 of 6). Related donors mismatched at one locus are also considered suitable donors. A matched, unrelated donor (MUD) identified through the National Marrow Donor Registry is typically the next option considered. Recently, there has been interest in haploidentical donors, typically a parent or a child of the patient, where usually there is sharing of only 3 of the 6 major histocompatibility antigens. The majority of patients will have such a donor; however, the risk of GVHD and overall morbidity of the procedure may be severe, and experience with these donors is not as extensive as that with matched donors.

Clinical input suggests RIC allogeneic HSCT may be considered for patients as follows:

MDS

- a. IPSS intermediate-2 or high risk
- b. RBC transfusion dependence
- c. Neutropenia
- d. Thrombocytopenia
- e. High risk cytogenetics
- f. Increasing blast percentage

MPN

- a. Cytopenias
- b. Transfusion dependence
- c. Increasing blast percentage over 5%
- d. Age 60-65 years

4.0 When the Procedure, Product, or Service Is Not Covered

Note: Refer to Subsection 2.2.1 regarding EPSDT Exception to Policy Limitations for Medicaid Beneficiaries under 21 Years of Age.

4.1 General Criteria Not Covered

Medicaid and NCHC shall not cover the procedure, product, or service related to this policy when:

- a. the beneficiary does not meet the eligibility requirements listed in **Section 2.0**;
- b. the beneficiary does not meet the criteria listed in **Section 3.0**;
- c. the procedure, product, or service duplicates another provider's procedure, product, or service; or
- d. the procedure, product, or service is experimental, investigational, or part of a clinical trial.

4.2 Specific Criteria Not Covered

4.2.1 Specific Criteria Not Covered by both Medicaid and NCHC

Medicaid and NCHC shall not cover allogeneic HSCT for myelodysplastic syndromes and myeloproliferative neoplasms when that do not meet the criteria and guidelines outlined in **Section 3.0** of this policy are not met, are considered investigational.

4.2.2 Medicaid Additional Criteria Not Covered

None Apply.

4.2.3 NCHC Additional Criteria Not Covered

- a. NCGS § 108A-70.21(b) "Except as otherwise provided for eligibility, fees, deductibles, copayments, and other cost sharing charges, health benefits coverage provided to children eligible under the Program shall be equivalent to coverage provided for dependents under North Carolina Medicaid Program except for the following:
 1. No services for long-term care.
 2. No nonemergency medical transportation.
 3. No EPSDT.
 4. Dental services shall be provided on a restricted basis in accordance with criteria adopted by the Department to implement this subsection."

5.0 Requirements for and Limitations on Coverage

Note: Refer to Subsection 2.2.1 regarding EPSDT Exception to Policy Limitations for Medicaid Beneficiaries under 21 Years of Age.

5.1 Prior Approval

Medicaid and NCHC shall require prior approval for Allogeneic Hematopoietic Stem Cell HSCT and bone marrow Transplantation for Myelodysplastic Syndromes and Myeloproliferative Neoplasms. The provider shall obtain prior approval before rendering

Allogeneic Hematopoietic Stem Cell HSCT and bone marrow Transplantation for Myelodysplastic Syndromes and Myeloproliferative Neoplasms.

If prior approval has been given for Allogeneic Hematopoietic Stem Cell HSCT Transplantation for Myelodysplastic Syndromes and Myeloproliferative Neoplasms, actual donor transplant-related medical expenses (procuring, harvesting, short-term storing and all associated laboratory costs) are covered.

If prior approval has been given for allogeneic HSCT for Myelodysplastic Syndromes and Myeloproliferative Neoplasms and a donor lymphocyte infusion (DLI) is later indicated (refer to Section 3.2), separate prior approval shall not be required for the DLI procedure.

5.2 Prior Approval Requirements

5.2.1 General

The provider(s) shall submit to the Department of Health and Human Services (DHHS) Utilization Review Contractor the following:

- a. the prior approval request; and
- b. all health records and any other records that support the beneficiary has met the specific criteria in **Subsection 3.2** of this policy.

5.2.2 Specific

None Apply.

5.3 Specific Transplant Prior Approval Requirements

The provider(s) shall submit the following to the NC Medicaid transplant nurse consultant:

- a. Letter of medical necessity **signed by the attending transplant physician**, which documents indications for transplant regimens and dates, the social history and the transplant evaluation;
- b. All health care records and any other records that support the beneficiary has met the specific criteria in **Subsection 3.2** of this policy including:
 1. Lab results (less than three months old) to include Complete Blood Count (CBC), complete electrolytes, liver enzymes, Prothrombin Time (PT), International Normalized Ratio (INR), glucose and A1C (Glycated Hemoglobin if Type I or Type II diabetic), and blood type;
 2. Serologies: to include Human Immunodeficiency Virus (HIV), Hepatitis, panel Rapid Plasma Reagin (RPR), Epstein-Barr Virus (EBV), Cytomegalovirus (CMV), Varicella, Rubella, Herpes Simplex Virus (HSV) I/II, and toxoplasmosis. (*Positive* serology results may be reported that are greater than three months old);
 3. Diagnostic studies (less than six months old) required in a complete packet include:
 - A. Cardiac: Echocardiogram, Electrocardiogram (ECG), and/or cardiac catheterization as appropriate for beneficiary's clinical status;
 - B. Pulmonary: Pulmonary Function Test if beneficiary has cardiac or pulmonary issues, or a history of smoking; and

- C. Chest x-ray for all transplant candidates;
- 4. Other diagnostic tests may be requested as appropriate;
- 5. Beneficiary's height and weight
- 6. All diagnostic and procedure results, including bone marrow aspiration (not more than six months old)
- c. Complete psychological and social evaluation to include:
 - 1. beneficiary's medical compliance;
 - 2. beneficiary's support network;
 - 3. post-transplant care plan, with identification of primary and secondary care providers; and
 - 4. history of mental health issues/substance use/legal issues
- d. Beneficiaries with a psychiatric history are required to have an evaluation by a psychiatrist with expertise in evaluating the specific psychiatric issues that relate to transplant candidates.

6.0 Providers Eligible to Bill for the Procedure, Product, or Service

To be eligible to bill for the procedure, product, or service related to this policy, the provider(s) shall:

- a. meet Medicaid or NCHC qualifications for participation;
- b. have a current and signed Department of Health and Human Services (DHHS) Provider Administrative Participation Agreement; and
- c. bill only for procedures, products, and services that are within the scope of their clinical practice, as defined by the appropriate licensing entity.

6.1 Provider Qualifications and Occupational Licensing Entity Regulations

None Apply.

6.2 Provider Certifications

None Apply.

7.0 Additional Requirements

Note: Refer to Subsection 2.2.1 regarding EPSDT Exception to Policy Limitations for Medicaid Beneficiaries under 21 Years of Age.

7.1 Compliance

Provider(s) shall comply with the following in effect at the time the service is rendered:

- a. All applicable agreements, federal, state and local laws and regulations including the Health Insurance Portability and Accountability Act (HIPAA) and record retention requirements; and
- b. All NC Medicaid's clinical (medical) coverage policies, guidelines, policies, provider manuals, implementation updates, and bulletins published by the Centers for Medicare and Medicaid Services (CMS), DHHS, DHHS division(s) or fiscal contractor(s).

8.0 Policy Implementation/Revision Information

Original Effective Date: January 1, 1994

Revision Information:

Date	Section Revised	Change
07/01/2005	Entire Policy	Medicaid: Policy was updated to include coverage criteria effective with approved date of State Plan amendment 4/1/05.
09/01/2005	Section 2.2	Medicaid: The special provision related to EPSDT was revised.
12/01/2005	Section 2.2	Medicaid: The web address for DMA's EDPST policy instructions was added to this section.
12/01/2006	Sections 2.2	Medicaid: The special provision related to EPSDT was revised.
07/01/2010	Throughout	NCHC Session Law 2009-451, Section 10.31(a) Transition of NC Health Choice Program administrative oversight from the State Health Plan to the Division of Medical Assistance (DMA) in the NC Department of Health and Human Services.
03/01/2012	Throughout	Policy updated to reflect current community standards and changing transplant protocols
03/01/2012	Throughout	NCHC: To be equivalent where applicable to NC DMA's Clinical Coverage Policy # 11A-9 under Session Law 2011-145, § 10.41.(b)
03/01/2012	Throughout	Technical changes to merge Medicaid and NCHC current coverage into one policy.
10/01/2015	All Sections and Attachments	Updated policy template language and added ICD-10 codes to comply with federally mandated 10/1/2015 implementation where applicable.
03/01/2017	Attachment A, Section B	ICD-10 update revisions.
03/15/2019	Table of Contents	Added, "To all beneficiaries enrolled in a Prepaid Health Plan (PHP): for questions about benefits and services available on or after November 1, 2019, please contact your PHP."
03/15/2019	All Sections and Attachments	Updated policy template language.
	Throughout	Removed "& Bone Marrow" from title.
	Section 1.1	Definition added for donor lymphocyte infusion.
	Section 3.2.1	Criteria added for DLI coverage.
	Section 3.2.4	Updated to 2016 WHO classifications.
	Section 5.1	Added text that if PA has been given for allogeneic HSCT and DLI is later indicated, separate PA is not required for the DLI procedure.
	Section 5.3	"Indications for transplant" added to letter of medical necessity requirements. Added "panel" to Hepatitis panel to reflect verbiage in the State Plan.

NC Medicaid
Allogeneic Hematopoietic Stem-Cell & Bone Marrow
Transplantation for Myelodysplastic Syndromes &
Myeloproliferative Neoplasms

Medicaid and Health Choice
Clinical Coverage Policy No: 11A-9
Amended Date:

	<u>Attachment A</u>	<u>Added the UB-04 as an accepted claims form.</u> <u>Removed all CPT, HCPCS, and ICD-10 codes.</u>
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Attachment A: Claims-Related Information

Provider(s) shall comply with the, *NCTracks Provider Claims and Billing Assistance Guide*, Medicaid bulletins, fee schedules, NC Medicaid’s clinical coverage policies and any other relevant documents for specific coverage and reimbursement for Medicaid and NCHC:

A. Claim Type

Professional (CMS-1500/837P transaction)

Institutional (UB-04/83711)

B. International Classification of Diseases and Related Health Problems, Tenth Revisions, Clinical Modification (ICD-10-CM) and Procedural Coding System (PCS)

Provider(s) shall report the ICD-10-CM and Procedural Coding System (PCS) to the highest level of specificity that supports medical necessity. Provider(s) shall use the current ICD-10 edition and any subsequent editions in effect at the time of service. Provider(s) shall refer to the applicable edition for code description, as it is no longer documented in the policy.

ICD-10 Procedure Code(s)			
30230G0	30240G0	30250G0	30260G0
30230G4	30240G4	30250G1	30260G1
30230Y4	30240Y4	30250Y1	30260Y1
30233G0	30243G0	30253G0	30263G0
30233G4	30243G4	30253G1	30263G1
30233Y4	30243Y4	30253Y1	30263Y1

C. Code(s)

Provider(s) shall report the most specific billing code that accurately and completely describes the procedure, product or service provided. Provider(s) shall use the Current Procedural Terminology (CPT), Health Care Procedure Coding System (HCPCS), and UB-04 Data Specifications Manual (for a complete listing of valid revenue codes) and any subsequent editions in effect at the time of service. Provider(s) shall refer to the applicable edition for the code description, as it is no longer documented in the policy.

If no such specific CPT or HCPCS code exists, then the provider(s) shall report the procedure, product or service using the appropriate unlisted procedure or service code.

CPT Codes
38205
38230
38240
38242

HCPCS

Codes
S2150

Unlisted Procedure or Service

CPT: The provider(s) shall refer to and comply with the Instructions for Use of the CPT Codebook, Unlisted Procedure or Service, and Special Report as documented in the current CPT in effect at the time of service.

HCPCS: The provider(s) shall refer to and comply with the Instructions For Use of HCPCS National Level II codes, Unlisted Procedure or Service and Special Report as documented in the current HCPCS edition in effect at the time of service.

D. Modifiers

Provider(s) shall follow applicable modifier guidelines.

E. Billing Units

Provider(s) shall report the appropriate code(s) used which determines the billing unit(s).

F. Place of Service

Inpatient hospital and Outpatient hospital

G. Co-payments

For Medicaid refer to Medicaid State Plan:

<https://medicaid.ncdhhs.gov/get-involved/nc-health-choice-state-plan>

For NCHC refer to NCHC State Plan:

<https://medicaid.ncdhhs.gov/get-involved/nc-health-choice-state-plan>

H. Reimbursement

Provider(s) shall bill their usual and customary charges.

For a schedule of rates, refer to: <https://medicaid.ncdhhs.gov/>

I. Billing for Donor Expenses

1. Billing for Donor Expenses for Medicaid Beneficiaries

Donor transplant-related medical expenses are billed on the Medicaid beneficiary's transplant claim using the beneficiary's Medicaid identification number.

Medicaid reimburses only for the actual donor's transplant-related medical expenses.

Medicaid does not reimburse for unsuccessful donor searches.

2. Billing for Donor Expenses for NCHC Beneficiaries

Donor transplant-related medical expenses donors are billed on the NCHC beneficiary's transplant claim.

NCHC reimburses only for the actual donor's transplant-related medical expenses. NCHC does not reimburse for unsuccessful donor searches.