

**NC Medicaid
Hematopoietic Stem-Cell
Transplantation for Multiple Myeloma,
POEMS Syndrome and Primary
Amyloidosis**

**Medicaid and Health Choice
Clinical Coverage Policy No: 11A-8
Amended Date:**

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.

Table of Contents

1.0	Description of the Procedure, Product, or Service.....	1
1.1	Definitions	4
1.1.1	Monoclonal (M) Protein	4
1.1.2	Salvage Therapy	4
1.1.3	Tandem Transplants.....	4
2.0	Eligibility Requirements	5
2.1	Provisions.....	5
2.1.1	General.....	5
2.1.2	Specific	5
2.2	Special Provisions.....	5
2.2.1	EPSDT Special Provision: Exception to Policy Limitations for a Medicaid Beneficiary under 21 Years of Age	5
2.2.2	EPSDT does not apply to NCHC beneficiaries	6
2.2.3	Health Choice Special Provision for a Health Choice Beneficiary age 6 through 18 years of age	6
3.0	When the Procedure, Product, or Service Is Covered.....	6
3.1	General Criteria Covered.....	7
3.2	Specific Criteria Covered.....	7
3.2.1	Specific criteria covered by both Medicaid and NCHC	7
3.2.2	Medicaid Additional Criteria Covered.....	7
3.2.3	NCHC Additional Criteria Covered	7
3.2.4	Policy Guidelines.....	8
4.0	When the Procedure, Product, or Service Is Not Covered.....	8
4.1	General Criteria Not Covered	8
4.2	Specific Criteria Not Covered.....	9
4.2.1	Specific Criteria Not Covered by both Medicaid and NCHC.....	9
4.2.2	Medicaid Additional Criteria Not Covered.....	9
4.2.3	NCHC Additional Criteria Not Covered.....	9
5.0	Requirements for and Limitations on Coverage	9
5.1	Prior Approval	9
5.2	Prior Approval Requirements	10
5.2.1	General.....	10
5.2.2	Specific	10
5.3	Specific Transplant Prior Approval Requirements.....	10
6.0	Provider(s) Eligible to Bill for the Procedure, Product, or Service	11
6.1	Provider Qualifications and Occupational Licensing Entity Regulations.....	11

**NC Medicaid
Hematopoietic Stem-Cell
Transplantation for Multiple Myeloma,
POEMS Syndrome and Primary
Amyloidosis**

**Medicaid and Health Choice
Clinical Coverage Policy No: 11A-8
Amended Date:**

6.2	Provider Certifications	11
7.0	Additional Requirements	11
7.1	Compliance	11
8.0	Policy Implementation/Revision Information.....	12
Attachment A: Claims-Related Information		14
A.	Claim Type	14
B.	International Classification of Diseases and Related Health Problems, Tenth Revisions, Clinical Modification (ICD-10-CM) and Procedural Coding System (PCS)	14
C.	Code(s).....	14
D.	Modifiers.....	15
E.	Billing Units.....	15
F.	Place of Service	15
G.	Co-payments	15
H.	Reimbursement	15
I.	Billing for Donor Expenses	15

**NC Medicaid
Hematopoietic Stem-Cell
Transplantation for Multiple Myeloma,
POEMS Syndrome and Primary
Amyloidosis**

**Medicaid and Health Choice
Clinical Coverage Policy No: 11A-8
Amended Date:**

Related Clinical Coverage Policies

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

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). Cord blood is discussed in greater detail in the NC Medicaid Clinical Coverage Policy 11A-14 “Placental and Umbilical Cord Blood as a Source of Stem Cells”.

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 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.

The success of autologous HSCT is predicated on the ability of cytotoxic chemotherapy with or without radiation to eradicate cancerous cells from the blood and bone marrow. This permits subsequent engraftment and repopulation of bone marrow space with presumably normal hematopoietic stem cells obtained from the patient prior to undergoing bone marrow ablation. As a consequence, autologous HSCT is typically performed as consolidation therapy when the patient's disease is in complete remission. Patients who undergo autologous HSCT are susceptible to chemotherapy-related toxicities and opportunistic infections prior to engraftment, but not GVHD.

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 total 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.

Multiple Myeloma

Multiple myeloma is a systemic malignancy of plasma cells that represents approximately 10% of all hematologic cancers. It is treatable but rarely curable, with estimated new cases and deaths in 2010 in the United States 20,180 and 10,650, respectively. At the time of diagnosis most patients have generalized disease, and, the selection of treatment is influenced by patient age, general health, prior therapy, and the presence of complications of the disease.

The disease is staged by estimating tumor mass, based on various clinical parameters like hemoglobin, serum calcium, number of lytic bone lesions, and the presence or absence of renal failure. Multiple myeloma usually evolves from an asymptomatic premalignant stage (termed "monoclonal gammopathy of undetermined significance" or MGUS). Treatment is usually reserved for patients with symptomatic disease (usually progressive myeloma), whereas asymptomatic patients are observed, as there is little evidence that early treatment of asymptomatic multiple myeloma prolongs survival when compared to therapy delivered at the time of symptoms or endorgan damage. In some patients, an intermediate asymptomatic but more advanced premalignant stage is recognized and referred to as smoldering multiple myeloma. The overall risk of disease progression from smoldering to symptomatic multiple myeloma is 10% per year for the first 5 years, approximately 3% per year for the next 5 years, and 1% for the next 10 years.

POEMS Syndrome

POEMS syndrome (also known as osteosclerotic myeloma, Crow-Fukase syndrome, or Takasaki syndrome) is a rare, paraneoplastic disorder secondary to a plasma-cell dyscrasia. This complex, multiorgan disease was first described in 1938, but the acronym POEMS was coined in 1980, reflecting hallmark characteristics of the syndrome: polyneuropathy, organomegaly, endocrinopathy, M protein, and skin changes. No single test establishes the presence of POEMS syndrome. Its pathogenesis is undefined, although some evidence suggests it is mediated by imbalance of proinflammatory cytokines including interleukin-1 β (IL-1 β), IL-6, and tumor necrosis factor- α ; vascular endothelial growth factor may also be involved. However, specific criteria have been established, and the syndrome may entail other findings in the constellation of signs and symptoms, as shown in the Table. Both major criteria and at least one of the minor criteria are necessary for diagnosis.

Major Criteria	Minor Criteria	Known Associations	Possible Associations
Polyneuropathy	Sclerotic bone lesions	Clubbing	Pulmonary hypertension
Monoclonal plasmaproliferative disorder	Castleman disease	Weight loss	Restrictive lung disease
	Organomegaly (splenomegaly, hepatomegaly, or lymphadenopathy)	Thrombocytosis	Thrombotic diathesis
	Edema (edema, pleural effusion, or ascites)	Hyperhidrosis	Cardiomyopathy (systolic dysfunction)
	Endocrinopathy (adrenal, thyroid, pituitary, gonadal, parathyroid, pancreatic)		Fever
	Skin changes (hyperpigmentation, hypertrichosis, plethora, hemangiomas, white nails)		Low vitamin B12 values
	Papilledema		Diarrhea

The prevalence of POEMS syndrome is unclear. A national survey in Japan showed a prevalence of about 0.3 per 100,000. Other large series have been described in the United States and in India. In general, patients with POEMS have a superior overall survival compared with that of multiple myeloma, nearly 14 years in a large series from the Mayo Clinic. However, given the rarity of POEMS, no randomized controlled trials of therapies have been reported. Numerous approaches have included ionizing radiation, plasmapheresis, intravenous immunoglobulin, interferon alfa, corticosteroids, alkylating agents, azathioprine, tamoxifen, transretinoic acid, and high-dose chemotherapy with autologous HSCT support. Optimal treatment involves eliminating the plasma cell clone, for example, by surgical excision or local radiation therapy for an isolated plasmacytoma, or systemic chemotherapy in patients with disseminated disease, such as medullary disease or multiple plasmacytomas. Given the underlying plasma cell dyscrasia of POEMS, newer approaches to multiple myeloma, including bortezomib, lenalidomide, and thalidomide, are also under investigation.

Primary Systemic Amyloidosis

The primary amyloidoses comprise a group of diseases with an underlying clonal plasma cell dyscrasia. They are characterized by the extracellular deposition of pathologic, insoluble protein fibrils with a beta-pleated sheet configuration that exhibit a pathognomonic red-green birefringence when stained with Congo red dye and examined under polarized light. These diseases are classified on the basis of the type of amyloidogenic protein involved, as well as by the distribution of amyloid deposits. In systemic amyloidosis, the unnatural protein is produced at a site that is remote from the site(s) of deposition, whereas in localized disease the protein is produced at the site of deposition. Light-chain amyloidosis (AL), the most common type of systemic amyloidosis, has an incidence similar to that of Hodgkin's lymphoma or chronic myelogenous leukemia, estimated at 5 to 12 people per million annually. The median age at diagnosis is around 60 years. The amyloidogenic protein in AL amyloidosis is an immunoglobulin (Ig) light chain or light-chain fragment that is produced by a clonal population of plasma cells in the bone marrow. While the plasma cell burden in AL amyloidosis is typically low, ranging from 5%–10%, this disease also may occur in association with multiple myeloma in 10%–15% of patients. Deposition of AL amyloidogenic proteins causes organ dysfunction, most frequently in the kidneys, heart, and liver, although the central nervous system and brain may be affected.

Historically, this disease has had a poor prognosis, with a median survival from diagnosis of about 12 months, although outcomes have improved with the advent of combination chemotherapy with alkylating agents and autologous HSCT. Emerging approaches include the use of immunomodulating drugs such as thalidomide or lenalidomide, and the proteasome inhibitor bortezomib. Regardless of the approach chosen, treatment of AL amyloidosis is aimed at rapidly reducing the production of amyloidogenic monoclonal light chains by suppressing the underlying plasma cell dyscrasia, with supportive care to decrease symptoms and maintain organ function. The therapeutic index of any chemotherapy regimen is a key consideration in the context of underlying organ dysfunction.

1.1 Definitions

1.1.1 **Monoclonal (M) Protein**

A type of protein made by myeloma cells, used to estimate the extent of myeloma disease. It is an abnormal type of antibody (or immunoglobulin) and is found in the blood or urine to estimate. M protein levels are used to determine the effectiveness of myeloma treatments.

1.1.2 **Salvage Therapy**

Second-line therapy; used to treat disease that has not responded to initial therapy or relapsed disease.

1.1.3 **Tandem Transplants**

A transplant technique where the preplanned intent for therapy involves sequential hematopoietic stem cell transplants.

None Apply.

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:

- 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;
- the procedure, product, or service can be safely furnished, and no equally effective and more conservative or less costly treatment is available statewide; and
- 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

Medicaid and NCHC shall cover hematopoietic stem cell transplantation ~~for in the treatment of~~ multiple myeloma or ~~primary amyloidosis~~ in **ANY** of the following situations:

- A single or second (salvage) autologous hematopoietic stem-cell transplantation ~~may be medically necessary~~ to treat multiple myeloma.
- Tandem autologous-autologous hematopoietic stem-cell transplantation ~~may be medically necessary~~ to treat multiple myeloma in beneficiaries who fail to achieve at least a near-complete or very good partial response after the first transplant **in tandem sequence**. (For definitions of near-complete response and very good partial response, refer to **Subsection 3.2.4, Policy Guidelines**).
- Tandem transplantation with an initial round of autologous hematopoietic stem-cell transplantation followed by a non-marrow-ablative conditioning regimen and allogeneic hematopoietic stem-cell transplantation (i.e., reduced-intensity conditioning transplant) ~~may be medically necessary~~ to treat newly diagnosed multiple myeloma ~~beneficiaries~~.
- ~~Autologous HSCT may be medically necessary to treat primary systemic amyloidosis.~~
- ~~The beneficiary and caregiver are willing and capable of complying with the post transplant treatment plan.~~

Medicaid and NCHC shall cover Hematopoietic Stem Cell Transplantation for POEMS syndrome and Primary Amyloidosis in the following situations:

- Autologous stem cell transplantation to treat disseminated POEMS syndrome (refer to Section 1.0);**
- Autologous stem cell transplantation to treat primary systemic amyloidosis.**

3.2.2 Medicaid Additional Criteria Covered

None Apply.

3.2.3 NCHC Additional Criteria Covered

None Apply.

3.2.4 Policy Guidelines

Response levels are defined as follows (refer to **Section 1.0** for definition of M protein):

- a. **Partial response (PR):** Treatment outcome where there is a greater than 50% decrease in M protein; also referred to as partial remission.
- b. **Very good partial response (VGPR):** Treatment outcome where there is a greater than 90% decrease in M protein; also known as very good partial remission.
- c. **Minimal response:** Treatment outcome where there is less than 50% decrease in M protein; also known as minor response. Some myeloma groups consider minimal response to be part of the definition of stable disease.
- d. **Near complete response (near CR):** Response to therapy where M protein is no longer detectable in the blood or urine using conventional tests, but is detectable with the more sensitive immunofixation test, and there are less than 5% plasma cells in the bone marrow.
- e. **Complete response (CR):** A treatment outcome where there are $\leq 5\%$ plasma cells in the bone marrow and no evidence of myeloma proteins in the serum or urine as measured by standard laboratory techniques.

~~a. A near complete response for multiple myeloma, as defined by the European Group for Blood and Marrow Transplant (EBMT), is the disappearance of M protein at routine electrophoresis, but positive immunofixation.~~

~~b. A very good partial response for multiple myeloma is defined as a 90% decrease in the serum paraprotein level.~~

~~c. The reference to HLA identical consists of an identical twin with a 6 of 6 HLA match.~~

~~d. Data on the use of allogeneic SCT to treat AL amyloidosis are sparse, with no systematic evaluation in a clinical trial. Concerns about the use of allogeneic SCT include high treatment-related mortality (more than 40%), morbidity secondary to graft versus host disease, and questions about the efficacy of a proposed graft versus malignancy effect on low grade plasma cell dyscrasias.~~

~~e. The 2011 National Comprehensive Cancer Network (NCCN) guidelines include autologous HSCT as primary therapy for systemic amyloidosis; however, they caution that the optimal therapy is not established and that such treatment would best be performed in a clinical trial.~~

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 do~~ not cover **Hematopoietic Stem Cell Transplantation for Multiple Myeloma, POEMS Syndrome, and Primary Amyloidosis** ~~HSCT for multiple myeloma or primary amyloidosis~~ in the following situations:

- a. When the criteria listed in **Subsection 3.2** are not met; ~~or~~
- b. Allogeneic hematopoietic stem cell transplantation, myeloablative or nonmyeloablative, as upfront therapy of newly diagnosed multiple myeloma or as salvage therapy; ~~is investigational; or~~
- c. Allogeneic ~~and tandem hematopoietic stem cell transplantation~~ **HSCT is investigational** to treat **POEMS syndrome and** primary systemic amyloidosis; ~~or~~
- d. ~~When the~~ beneficiary's psychosocial history limits the beneficiary's ability to comply with pre- and post-transplant medical care; or
- e. Current beneficiary or caretaker non-compliance would make compliance with a disciplined medical regimen improbable.

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 Hematopoietic Stem Cell Transplantation for Multiple Myeloma, **POEMS Syndrome**, and Primary Amyloidosis.

The provider shall obtain prior approval before rendering Hematopoietic Stem-Cell Transplantation for Multiple Myeloma, **POEMS Syndrome**, and Primary Amyloidosis.

If prior approval has been given for **Hematopoietic Stem Cell Transplantation for Multiple Myeloma, POEMS Syndrome, and Primary Amyloidosis**, actual donor transplant-related medical expenses (**procuring, harvesting, short-term storing and all associated laboratory costs**) are covered. ~~stem cell transplant, DMA shall reimburse for the following donor transplant-related medical expenses: **procuring, harvesting, short-term storage and all associated laboratory costs.**~~

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 Provider(s) 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	Throughout	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.
12/01/2006	Sections 3.0 and 4.0	Medicaid: A note regarding EPSDT was added to these sections.
05/01/2007	Sections 2 through 4	Medicaid: EPSDT information was revised to clarify exceptions to policy limitations for recipients under 21 years of age.
05/01/2007	Attachment A	Medicaid: Added the UB-04 as an accepted claims form.
07/01/2010	Throughout	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.
03/12/2012	Throughout	NCHC: To be equivalent where applicable to NC DMA's Clinical Coverage Policy # 11A-8 under Session Law 2011-145 § 10.41.(b)
03/12/2012	Throughout	Policy updated to reflect current community standards and changing transplant protocols
03/12/2012	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	"POEMS Syndrome" added to title and to policy coverage.

Date	Section Revised	Change
	Section 1.0	Description added for POEMS Syndrome.
	Section 1.1	Added definitions for M protein, salvage therapy, and tandem transplants.
	Section 3.2.1	Added coverage criteria for POEMS syndrome.
	Section 3.2.4	Policy Guidelines revised to define levels of response to treatment for multiple myeloma.
	Section 4.2.1	Non-coverage criteria added for POEMS syndrome.
	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.
	Attachment A	Added the UB-04 as an accepted claims form. Removed all CPT, HCPCS, and ICD-10 codes.

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 Codes			
30230AZ	30233Y4	30243Y0	30253Y1
30230G0	30240AZ	30243Y4	30260G0
30230G4	30240G0	30250G0	30260G1
30230Y0	30240G4	30250G1	30260Y0
30230Y4	30240Y0	30250Y0	30260Y1
30233AZ	30240Y4	30250Y1	30263G0
30233G0	30243AZ	30253G0	30263G1
30233G4	30243G0	30253G1	30263Y0
30233Y0	30243G4	30253Y0	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 Code(s)
38205
38206
38230
38232
38240
38241

38242

HCPCS
Code(s)
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

Providers 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, 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.