Hematopoietic Cell Transplantation for Primary Amyloidosis

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Disclaimer

Highmark Health Options medical policy is intended to serve only as a general reference resource regarding coverage for the services described. This policy does not constitute medical advice and is not intended to govern or otherwise influence medical decisions.

POLICY STATEMENT

Highmark Health Options may provide coverage under medical surgical benefits of the Company's Medicaid products for medically necessary hematopoietic cell transplantation for primary amyloidosis.

This policy is designed to address medical necessity guidelines that are appropriate for the majority of individuals with a particular disease, illness, or condition. Each person's unique clinical circumstances warrant individual consideration, based upon review of applicable medical records.

The qualifications of the policy will meet the standards of the National Committee for Quality Assurance (NCQA) and the Delaware Department of Health and Social Services (DHSS) and all applicable state and federal regulations.

DEFINITIONS

Highmark Health Options (HHO) – Managed care organization serving vulnerable populations that have complex needs and qualify for Medicaid. Highmark Health Options members include individuals and families with low income, expecting mothers, children, and people with disabilities. Members pay nothing to very little for their health coverage. Highmark Health Options currently services Delaware Medicaid: Delaware Healthy Children Program (DHCP) and Diamond State Health Plan Plus members.

Primary amyloidosis – A group of diseases with an underlying clonal plasma cell dyscrasia. These diseases are classified by the type of amyloidogenic protein involved and by the distribution of amyloid deposits.

Systemic amyloidosis – The unnatural protein is produced at a site that is remote from the site(s) of deposition, whereas, in localized disease, the amyloid light chain protein is produced at the site of deposition.

Primary or amyloid light chain amyloidosis (AL) – The most common type of systemic amyloidosis, can cause organ dysfunction, most frequently in the kidneys, heart, and liver, although the central nervous system and brain may be affected.

HCT – Involves the intravenous (IV) infusion of allogeneic (donor) or autologous stem cells to reestablish hematopoietic function in individuals whose bone marrow or immune system is damaged or defective. They can be harvested from bone marrow, peripheral blood, or umbilical cord blood and placenta shortly after delivery of neonates.

PROCEDURES

1. A prior authorization is required.

   Autologous HCT may be considered medically necessary to treat AL when ALL of the following patient selection criteria are met:

   - Age greater than 18 years; and
   - Tissue diagnosis of amyloidosis by abdominal fat aspirate or biopsy of involved organ; and
   - Eastern Cooperative Oncology Group (ECOG) performance status score of zero-two (0-2); and
   - New York Heart Association class I/II and no more than two involved major organs (liver, heart, kidney, autonomic nerve); and
   - Supine systolic blood pressure greater than 90 mm/Hg; and
   - Asymptomatic or compensated cardiac function (e.g. absence of congestive heart failure),echocardiographic left ejection fraction greater than 40%; and cardiac interventricular septal thickness is greater than 12 mm; and
   - Renal function with a creatinine clearance of at least 30 ml/min.

   Note: When available, a clinical trial should be utilized.

   Autologous HCT not meeting the above criteria is considered not medically necessary.

   Allogeneic HCT is considered experimental/investigational and therefore noncovered to treat AL because the safety and/or effectiveness of this service cannot be established by the available published peer-reviewed literature.

2. Post-payment audit statement

   The medical record must include documentation that reflects the medical necessity criteria and is subject to audit by Highmark Health Options at any time pursuant to the terms of your provider agreement.

3. Place of service: inpatient/outpatient

   Experimental/investigational (E/I) services are not covered regardless of place of service.

   Hematopoietic cell transplantation for primary amyloidosis is typically an outpatient procedure which is only eligible for coverage as an inpatient procedure in special circumstances, including, but not limited to, the presence of a comorbid condition that would require monitoring in a more controlled environment such as the inpatient setting.

CODING REQUIREMENTS

CPT codes	Description
38206	Blood-derived hematopoietic progenitor cell harvesting for transplantation, per collection; autologous.
38230	Bone marrow harvesting for transplantation.
38232	Bone marrow harvesting for transplantation; autologous.
38240	Hematopoietic progenitor cell (HPC); allogeneic transplantation per donor.
38241	Hematopoietic progenitor cell (HPC); autologous transplantation.

COVERED DIAGNOSIS CODES APPLIES TO AUTOLOGOUS HEMATOPOIETIC CELL TRANSPLANTS

Code	Description
E85.0	Non-neuropathic heredofamilial amyloidosis.
E85.1	Neuropathic herodofamilial amyloidosis.
E85.2	Herodofamilial amyloidosis, unspecified.
E85.81	Light Chain (AL) amyloidosis.
E85.89	Other amyloidosis.
E85.9	Amyloidosis, unspecified.

REIMBURSEMENT

Participating facilities will be reimbursed per their Highmark Health Options contract.

POLICY SOURCES

National Comprehensive Cancer Network (NCCN) – 2019

The National Comprehensive Cancer Network guidelines on systemic light chain amyloidosis (v.1.2019) recommend assessing organ involvement based on amyloidosis consensus. Next patients should be evaluated for stem cell transplant candidacy. In patients eligible for stem cell transplant, stem cells may be collected, and transplant delayed for a later line of therapy. The dose of melphalan as part of stem cell transplantation can be adjusted based on factors such as age, presence/absence of cardiac involvement, and number of organs involved. In eligible patients, high-dose chemotherapy followed by autologous stem cell transplant has demonstrated higher response rates and improved overall survival compared with chemotherapy alone.

American Society for Blood and Marrow Transplantation (ASBMT) – 2015

The ASBMT (2015) issued guidelines on indications for autologous and allogeneic hematopoietic cell transplantation (HCT). ASBMT gave the rating of N (not generally recommended; neither evidence nor clinical practice supports the routine use) for the use of allogeneic HCT in the treatment of primary amyloidosis in adults. ASBMT gave a rating of C (standard of care; clinical evidence available) for the use of autologous HCT in the treatment of primary amyloidosis in adults.

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POLICY UPDATE HISTORY

<Date>	<Event>