



Autologous Stem Cell Transplantation Clinical Coverage Criteria

Overview

Autologous stem cell transplants are typically used in people who need to undergo high-dose chemotherapy or a combination of chemotherapy and radiation to cure their diseases. These treatments are likely to damage the bone marrow. Hematopoietic stem cells are collected from the patient in advance of the treatments and are frozen. Two sources of hematopoietic stem cells that can be used in autologous stem cell transplants are peripheral blood stem cells and bone marrow stem cells. After the patient undergoes treatment, the stem cells are returned to the body. The goal of an autologous stem cell transplant is to restore the body's ability to make normal blood cells. Most people have a single autologous transplant. Some may have a tandem transplant. A tandem transplant involves a planned second autologous stem cell transplant after the first autologous transplant).

Policy

This Policy applies to the following Fallon Health products:

- Medicare Advantage (Fallon Medicare Plus, Fallon Medicare Plus Central)
- MassHealth ACO
- NaviCare HMO SNP
- NaviCare SCO
- PACE (Summit Eldercare PACE, Fallon Health Weinberg PACE)
- Community Care

Prior authorization is required for autologous stem cell transplantation.

Medicare Advantage (Fallon Medicare Plus, Fallon Medicare Plus Central)

Fallon Health complies with CMS's national coverage determinations (NCDs), local coverage determinations (LCDs) of Medicare Contractors with jurisdiction for claims in the Plan's service area, and applicable Medicare statutes and regulations when making medical necessity determinations for Medicare Advantage members. When coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs, Fallon Health may create internal coverage criteria under specific circumstances described at § 422.101(b)(6)(i) and (ii).

Medicare statutes and regulations do not have coverage criteria for autologous stem cell transplants. Medicare has an NCD for Stem Cell Transplantation (110.23, formerly 110.8.1), Version Number 2, Effective Date of this Version 03/06/2024. National Government Services, Inc., the Medicare Administrative Carrier with jurisdiction in the Plan's service area does not have an LCD related to autologous stem cell transplantation (Medicare Database Search 06/28/2024).

Coverage for autologous stem cell transplantation for indications not otherwise specified in NCD 110.23 as covered or non-covered will be made by Fallon Health for Medicare Advantage plan members.

Link: [NCD for Stem Cell Transplantation \(110.23, formerly 110.8.1\)](#), Version Number 2, Effective Date of this Version 03/06/2024

Nationally Covered Indications

1. Effective for services performed on or after April 28, 1989, autologous stem cell transplantation is considered reasonable and necessary under §1862(a)(1)(A) of the Act for the following conditions and is covered under Medicare for patients with:
 - a. Acute leukemia in remission who have a high probability of relapse and who have no human leucocyte antigens (HLA)-matched;
 - b. Resistant non-Hodgkin's lymphomas or those presenting with poor prognostic features following an initial response;
 - c. Recurrent or refractory neuroblastoma; or,
 - d. Advanced Hodgkin's disease who have failed conventional therapy and have no HLA-matched donor.
2. Effective October 1, 2000, single autologous stem cell transplantation is only covered for Durie-Salmon Stage II or III patients that fit the following requirements:
 - Newly diagnosed or responsive multiple myeloma. This includes those patients with previously untreated disease, those with at least a partial response to prior chemotherapy (defined as a 50% decrease either in measurable paraprotein [serum and/or urine] or in bone marrow infiltration, sustained for at least 1 month), and those in responsive relapse; and
 - Adequate cardiac, renal, pulmonary, and hepatic function.
3. Effective for services performed on or after March 15, 2005, when recognized clinical risk factors are employed to select patients for transplantation, high dose melphalan (HDM) together with autologous stem cell transplantation is reasonable and necessary for Medicare beneficiaries of any age group with primary amyloid light chain (AL) amyloidosis who meet the following criteria:
 - Amyloid deposition in 2 or fewer organs; and,
 - Cardiac left ventricular ejection fraction (EF) greater than 45%.

Nationally Non-Covered Indications

Insufficient data exist to establish definite conclusions regarding the efficacy of AuSCT for the following conditions:

- a. Acute leukemia not in remission;
- b. Chronic granulocytic leukemia;
- c. Solid tumors (other than neuroblastoma);
- d. Up to October 1, 2000, multiple myeloma;
- e. Tandem transplantation (multiple rounds of AuSCT) for patients with multiple myeloma;
- f. Effective October 1, 2000, non-primary AL amyloidosis; and,
- g. Effective October 1, 2000, through March 14, 2005, primary AL amyloidosis for Medicare beneficiaries age 64 or older.

In these cases, autologous stem cell transplantation is not considered reasonable and necessary within the meaning of §1862(a)(1)(A) of the Act and is not covered under Medicare.

Coverage of all other indications for stem cell transplantation not otherwise specified above as covered or non-covered will be made by local Medicare Administrative Contractors under section 1862(a)(1)(A).

MassHealth ACO

Fallon Health follows Medical Necessity Guidelines published by MassHealth when making medical necessity determinations for MassHealth members. In the absence of Medical Necessity Guidelines published by MassHealth, Fallon Health may create clinical coverage criteria in accordance with the definition of Medical Necessity in 130 CMR 450.204.

MassHealth does not have Guidelines for Medical Necessity Determination for autologous stem cell transplantation, therefore, Fallon Health Clinical Coverage Criteria are applicable (MassHealth website search 06/28/2024).

NaviCare HMO SNP, NaviCare SCO

For plan members enrolled in NaviCare, Fallon Health first follow's CMS's national coverage determinations (NCDs), local coverage determinations (LCDs) of Medicare Contractors with jurisdiction for claims in the Plan's service area, and applicable Medicare statutes and regulations when making medical necessity determinations.

When coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs, or if the NaviCare member does not meet coverage criteria in applicable Medicare statutes, regulations, NCDs or LCDs, Fallon Health then follows Medical Necessity Guidelines published by MassHealth when making necessity determinations for NaviCare members.

PACE (Summit Eldercare PACE, Fallon Health Weinberg PACE)

Each PACE plan member is assigned to an Interdisciplinary Team. PACE provides participants with all the care and services covered by Medicare and Medicaid, as authorized by the interdisciplinary team, as well as additional medically necessary care and services not covered by Medicare and Medicaid. With the exception of emergency care and out-of-area urgently needed care, all care and services provided to PACE plan members must be authorized by the interdisciplinary team.

Fallon Health Clinical Coverage Criteria

Effective for dates of service on or after August 1, 2024, Fallon Health will use InterQual® Criteria when making medical necessity determinations for autologous stem cell transplantation.

For coverage criteria, refer to the InterQual® Criteria in effect on the date of service:

- InterQual® CP:Procedures, Transplantation, Autologous Stem Cell
- InterQual® CP:Procedures, Transplantation, Autologous Stem Cell (Pediatric)

Requests for autologous stem cell transplantation for indications not addressed in InterQual® Criteria will be reviewed on an individual case-by-case basis by a Plan Medical Director. Documentation including medical records and evidence supporting the request is required.

Fallon Health makes InterQual® Criteria available to the public through the transparency tool on our website, effective January 1, 2024.

Exclusions

- The Plan considers autologous stem cell transplantation not medically necessary in the presence of any significant co-morbid conditions which would significantly compromise the member's clinical care and chances of survival.
- The Plan considers autologous stem cell transplantation experimental/investigational and, therefore, not medically necessary for any indication not meeting coverage criteria described herein.

Coding

The following codes are included below for informational purposes only; inclusion of a code does not constitute or imply coverage or reimbursement.

Code	Description
38206	Blood-derived hematopoietic progenitor cell harvesting for transplantation, per collection; autologous
38232	Bone marrow harvesting for transplantation; autologous
38241	Hematopoietic progenitor cell (HPC); autologous transplantation
38243	HPC boost

References

1. Hatzimichael E, Tuthill M. Hematopoietic stem cell transplantation. *Stem Cells Cloning*. 2010;3:105-117.

2. Medicare National Coverage Determinations Manual., Chapter 1, Part 2, Section 110.23 - Stem Cell Transplantation (110.23). Version 2. Effective 03/06/2024. Available at: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/ncd103c1_Part2.pdf.
3. Majhail NS, Farnia SH, Carpenter PA, et al. Indications for Autologous and Allogeneic Hematopoietic Cell Transplantation: Guidelines from the American Society for Blood and Marrow Transplantation. *Biol Blood Marrow Transplant*. 2015;21(11):1863-1869.
4. Kanate AS, Majhail NS, Savani BN, et al. Indications for Hematopoietic Cell Transplantation and Immune Effector Cell Therapy: Guidelines from the American Society for Transplantation and Cellular Therapy. *Biol Blood Marrow Transplant*. 2020;S1083-8791(20)30114-2.
5. Oliansky DM, Camitta B, Gaynon P, et al. Role of cytotoxic therapy with hematopoietic stem cell transplantation in the treatment of pediatric acute lymphoblastic leukemia: update of the 2005 evidence-based review. *Biol Blood Marrow Transplant*. 2012;18:505–522.
6. Oliansky DM, Larson RA, Weisdorf D, et al. The role of cytotoxic therapy with hematopoietic stem cell transplantation in the treatment of adult acute lymphoblastic leukemia: update of the 2006 evidence-based review. *Biol Blood Marrow Transplant*. 2012;18:18–36.
7. Oliansky DM, Rizzo JD, Aplan PD, et al. The role of cytotoxic therapy with hematopoietic stem cell transplantation in the therapy of acute myeloid leukemia in children: an evidence-based review. *Biol Blood Marrow Transplant*. 2007;13:1–25.
8. Oliansky DM, Appelbaum F, Cassileth PA, et al. The role of cytotoxic therapy with hematopoietic stem cell transplantation in the therapy of acute myelogenous leukemia in adults: an evidence-based review. *Biol Blood Marrow Transplant*. 2008;14:137–180.
9. Shah N, Callander N, Ganguly S, et al. Hematopoietic stem cell transplantation for multiple myeloma: guidelines from the American Society for Blood and Marrow Transplantation. *Biol Blood Marrow Transplant*. 2015;21:1155–1166.
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11. Oliansky DM, Gordon LI, King J, et al. The role of cytotoxic therapy with hematopoietic stem cell transplantation in the treatment of follicular lymphoma: an evidence-based review. *Biol Blood Marrow Transplant*. 2010;16:443–468.
12. Oliansky DM, Czuczman M, Fisher RI, et al. The role of cytotoxic therapy with hematopoietic stem cell transplantation in the treatment of diffuse large B cell lymphoma: update of the 2001 evidence-based review. *Biol Blood Marrow Transplant*. 2011;17. 20-47.e30.

Policy history

Origination date:	01/01/2014
Approval(s):	Technology Assessment Committee 10/23/2013 (Adopted InterQual Criteria) 01/28/2015 (annual review), 01/27/2016 (annual review), 01/25/2017 (annual review), 01/24/2018 (annual review), 01/23/2019 (annual review); 5/27/2020 (adopted Fallon Health criteria), 6/22/2021 (annual review, no changes; 06/15/2021: Added clarifying language related to Medicare Advantage, NaviCare and PACE under policy section), 7/2/2024 (annual review; adopted InterQual Criteria).

Not all services mentioned in this policy are covered for all products or employer groups. Coverage is based upon the terms of a member's particular benefit plan which may contain its own specific provisions for coverage and exclusions regardless of medical necessity. Please consult the product's Evidence of Coverage for exclusions or other benefit limitations applicable to this service or supply. If there is any discrepancy between this policy and a member's benefit plan, the provisions of the benefit plan will govern. However, applicable state mandates take precedence with respect to fully-insured plans and self-funded non-ERISA (e.g., government, school boards, church) plans. Unless otherwise specifically excluded, federal mandates will apply to all plans.