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:

☒ Fallon Medicare Plus

☒ MassHealth ACO

☒ NaviCare HMO SNP

☒ PACE (Summit Eldercare PACE, Fallon Health Weinberg PACE)

☒ Community Care

Prior authorization is required for autologous stem cell transplantation.

Fallon Health Clinical Coverage Criteria

Fallon Health Clinical Coverage Criteria apply to MassHealth and Community Care members.

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.

Medicare Variation

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. Wellpoint Federal (National Government Services, Inc. began operating as Wellpoint Federal on April 1, 2026), the Medicare Administrative Carrier with jurisdiction in the Plan’s service area, does not have an LCD related to autologous stem cell transplantation (Medicare Coverage Database Search 07/26/2026).

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

B. Nationally Covered Indications
II. Autologous Stem Cell Transplantation (AuSCT)

1. Effective for services performed on or after April 28, 1989, autologous stem cell transplantation is considered reasonable and necessary under §l862(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%.

C. Nationally Non-Covered Indications
II. Autologous Stem Cell Transplantation (AuSCT)

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 §l862(a)(1)(A) of the Act and is not covered under Medicare.

D. Other

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).

Medicare coverage criteria are not currently available for indications not otherwise noted within the NCD as nationally covered or non-covered. When coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs, or LCDs, the Plan may create publicly accessible internal coverage criteria that are based on current evidence in widely used treatment guidelines or clinical literature. Therefore, Fallon Health Clinical Coverage Criteria are applicable for conditions indications not otherwise noted within the NCD as nationally covered or non-covered. In the absence of Clinical Coverage Criteria, requests for autologous stem cell transplantation will be reviewed on an individual case-by-case basis in accordance with the definition of medical necessity.

MassHealth Variation

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 07/26/2026).

Summary of Evidence

N/A

Analysis of Evidence (Rationale for Determination)

N/A

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.

CPT codes 38207-38215 are not valid for physician billing under the Medicare Physician Fee Schedule.

CPT codes 38212-38215 are nonpayable by MassHealth. Claims will deny vendor liable.

HCPCS codes S2140, S2142 and S2150 are not nonpayable for all products.

The Medicare Claims Processing Manual, Chapter 32, §90 - Stem Cell Transplantation, provides ICD-10 diagnosis codes for autologous stem cell transplantation.

Code	Description	Prior Authorization Required (Yes/No)
38206	Blood-derived hematopoietic progenitor cell harvesting for transplantation, per collection; autologous	Yes
38207	Transplant preparation of hematopoietic progenitor cells; cryopreservation and Storage	No
38208	Transplant preparation of hematopoietic progenitor cells; thawing of previously frozen harvest, without washing, per donor	No
38209	Transplant preparation of hematopoietic progenitor cells; thawing of previously frozen harvest, without washing, per donor	No
38210	Transplant preparation of hematopoietic progenitor cells; specific cell depletion with harvest, T cell depletion	No
38211	Transplant preparation of hematopoietic progenitor cells; tumor cell depletion	No
38212	Transplant preparation of hematopoietic progenitor cells; red blood cell removal	No
38213	Transplant preparation of hematopoietic progenitor cells; platelet depletion	No
38214	Transplant preparation of hematopoietic progenitor cells; plasma (volume) depletion	No
38215	Transplant preparation of hematopoietic progenitor cells; cell concentration in plasma, mononuclear, or buffy coat layer	No

38232	Bone marrow harvesting for transplantation; autologous	Yes
38241	Hematopoietic progenitor cell (HPC); autologous transplantation	Yes
38243	HPC boost	No

References

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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.
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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), 06/24/2025 (annual review; added new sections for Medicare and MassHealth Variation; no changes to coverage criteria), 07/28/2026 (annual review; no changes to coverage).
Utilization Management Committee: 07/15/2025: (annual review; approved with no changes to coverage criteria), 08/18/2026 (annual review, approved with no changes to coverage criteria).

Instructions for Use

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).

Fallon Health generally 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.

For plan members enrolled in NaviCare, Fallon Health first follows 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.

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.

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.