



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:

- Commercial
- Medicare Advantage
- MassHealth ACO
- NaviCare
- PACE

Prior authorization is required.

Autologous stem cell transplantation is considered medically necessary for the following indications when all criteria are met.

Acute Lymphoblastic Leukemia (ALL), Pediatric

- In first complete remission with any of the following:
 - Poor treatment response to induction therapy at 6 weeks with high risk having $\geq 1\%$ minimal residual disease measured by flow cytometry,
 - Children with t- cell phenotype
 - Patients with either the t (9;22) or t (4;11) regardless of early response measures.
- In second or greater remission or refractory ALL

Acute Lymphoblastic Leukemia (ALL), Adult

- In first complete remission with any of the following:
 - Age older than 35 years
 - Leukocytosis at presentation of greater than 30,000/il (b-cell lineage) or greater than 100,000/il (t-cell lineage)
 - "poor prognosis" genetic abnormalities like the philadelphia chromosome (t[9;22]),
 - Extramedullary disease,
 - Time to attain complete remission longer than 4 weeks

Acute myeloid leukemia (AML)

- In remission or relapsed if responsive to intensified chemotherapy

Amyloidosis, primary systemic

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Effective June 1, 2020

Embryonal tumors of the central nervous system

- Previously untreated that show partial or complete response to induction chemotherapy,
- Recurrent disease
- Stable disease after induction therapy
- Tandem, either as salvage therapy or with platinum-refractory disease

Ewing sarcoma

- Initial treatment for high risk cases
- Recurrent or refractory

Germ cell tumors

- Salvage
 - With favorable prognostic factors that have failed a previous course of conventional-dose salvage chemotherapy, or
 - With unfavorable prognostic factors as initial treatment of first relapse and in patients with platinum-refractory disease
- Tandem, for testicular tumors either as salvage therapy or with platinum-refractory disease

Hodgkin's Lymphoma

- Primary refractory or relapsed
- Tandem, for primary refractory or in patients with relapsed disease with poor risk features who do not attain a complete remission to cytoreductive chemotherapy

Multiple Myeloma

- Primary or salvage
- Tandem (autologous-autologous) who fail to achieve at least a near-complete or very good partial response after the first transplant

Neuroblastoma

- Initial treatment for high risk cases, including tandem transplants
- Recurrent or refractory

Non-Hodgkin Lymphomas

Aggressive B-cell subtypes

Myeloablative conditioning or high dose chemotherapy

- Salvage therapy for those who do not achieve complete remission after first-line treatment with a full course of standard-dose chemotherapy
- Consolidate or achieve a complete remission during responding treatment of a relapse
- In patients with diffuse large B-cell lymphoma, with an adjusted International Prognostic Index score that predicts a high- or high-intermediate risk of relapse, who are in their first complete remission

Indolent B-cell subtypes

- Salvage therapy for those who do not achieve complete remission after first-line treatment with a full course of standard-dose chemotherapy
- Consolidate or achieve a complete remission during responding treatment of a relapse

Mantle cell lymphoma

- To consolidate a first complete remission

Mature T-cell or NK-cell (peripheral T-cell) lymphoma

- To consolidate a first complete remission
- Salvage therapy

POEMS syndrome with diffuse sclerotic lesions or disseminated bone marrow involvement

Retinoblastoma with metastasis

Scleroderma/systemic sclerosis with ALL of the following:

- Adult patients <60 years of age
- Maximum duration of condition of 5 years
- Modified Rodnan Scale Scores >15
- Abnormal electrocardiogram OR diffusing capacity of carbon monoxide (dlco) <80% of predicted value OR decline of forced vital capacity (FVC) of >10% in last 12 months OR pulmonary fibrosis OR ground glass appearance on high resolution chest CT OR scleroderma-related renal disease
- History of < 6 months' treatment with cyclophosphamide
- No active gastric antral vascular ectasia
- Do not have any of the following:
 - Left ventricular ejection fraction <50%
 - Tricuspid annular plane systolic excursion <1.8 cm
 - Pulmonary artery systolic pressure >40 mm hg
 - Mean pulmonary artery pressure >25 mm hg
 - Dlco <40% of predicted value
 - Fvc <45% of predicted value
 - Creatinine clearance <40 ml/minute

Waldenstrom macroglobulinemia

- Salvage therapy if chemosensitive

Exclusions

- Autologous stem cell transplant is considered experimental and therefore is not covered for the following conditions:
 - Cancer of the bile duct
 - Cancer of the fallopian tubes
 - Cervical cancer
 - Chronic inflammatory demyelinating polyneuropathy
 - Chronic myeloid leukemia
 - Colon cancer
 - Diabetes mellitus, Type 1
 - Ependymoma
 - Esophageal cancer
 - Gall bladder cancer
 - Juvenile idiopathic or rheumatoid arthritis
 - Lung cancer, any histology
 - Malignant melanoma.
 - Multiple sclerosis
 - Nasopharyngeal cancer
 - Neuroendocrine tumors
 - Osteosarcoma
 - Ovarian cancer
 - Pancreas cancer
 - Paranasal sinus cancer
 - Prostate cancer

- Rectal cancer
- Renal cell cancer
- Retinoblastoma without metastasis
- Rhabdomyosarcoma
- Soft tissue sarcomas
- Stomach cancer
- Systemic lupus erythematosus
- Thyroid tumors
- Tumors of the thymus
- Tumors of unknown primary origin, or
- Uterine cancer
- Wilms tumor

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). Effective January 27, 2016. 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.

Policy history

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