

Stem Cell Transplantation

MEDICAL POLICY NUMBER: 282

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INSTRUCTIONS FOR USE: Company Medical Policies serve as guidance for the administration of plan benefits. Medical policies do not constitute medical advice nor a guarantee of coverage. Company Medical Policies are reviewed annually and are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. The Company reserves the right to determine the application of medical policies and make revisions to medical policies at any time. The scope and availability of all plan benefits are determined in accordance with the applicable coverage agreement. Any conflict or variance between the terms of the coverage agreement and Company Medical Policy will be resolved in favor of the coverage agreement. Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.

SCOPE: Providence Health Plan, Providence Health Assurance, and Providence Plan Partners as applicable (referred to individually as "Company" and collectively as "Companies").

## PLAN PRODUCT AND BENEFIT APPLICATION

Commercial

Medicaid/OHP\*

Medicare

### \*Medicaid/OHP Members

*Oregon*: Services requested for Oregon Health Plan (OHP) members follow the OHP Prioritized List and Oregon Administrative Rules (OARs) as the primary resource for coverage determinations. Medical policy criteria below may be applied when there are no criteria available in the OARs and the OHP Prioritized List.

Notice to Medicaid Policy Readers: For comprehensive rules and guidelines pertaining to this policy, readers are advised to consult the Oregon Health Authority. It is essential to ensure full understanding and compliance with the state's regulations and directives. Please refer to OHA's prioritized list for the following coverage guidelines:

Stem Cell Transplant: Guideline Notes 7, 11

### Medicare Members

This *Company* policy may be applied to Medicare Plan members only when directed by a separate *Medicare* policy. Note that investigational services are considered “**not medically necessary**” for Medicare members.

## COVERAGE CRITERIA

### Allogeneic Hematopoietic Stem Cell Transplantation (HSCT)

- I. Allogeneic hematopoietic stem cell transplantation (HSCT) may be considered **medically necessary** as a treatment for all of the following indications (A.-E.):
  - A. Leukemia or leukemia in remission;
  - B. Inherited and acquired marrow disorders, including but not limited to the following:
    1. Aplastic anemia
    2. Diamond-Blackfan anemia
    3. Fanconi's anemia
    4. Sickle cell anemia
    5. Beta thalassemia major
    6. Myelodysplastic syndromes (MDS)
    7. Paroxysmal nocturnal hemoglobinuria
    8. Pure red cell aplasia
    9. Amegakaryocytosis
    10. Congenital thrombocytopenia;

- C. The following autoimmune diseases and inborn errors in metabolism and congenital immune deficiencies:
    - 1. Severe combined immunodeficiency disease (SCID)
    - 2. X-linked adrenoleukodystrophy and adrenomyeloneuropathy
    - 3. Mucopolysaccharidoses
    - 4. Chronic granulomatous disease
    - 5. Krabbe disease
    - 6. NK cell deficiency syndromes
    - 7. DiGeorge (22q11.2 deletion) syndrome
    - 8. Wiskott-Aldrich syndrome;
  - D. Myelofibrosis for intermediate and high-risk individuals;
  - E. Relapsed or refractory lymphomas (e.g. angioimmunoblastic T-cell lymphoma, anaplastic large cell lymphoma) in patients who are not candidates for autologous stem cell transplantation.
- II. Allogeneic hematopoietic stem cell transplantation (HSCT) is considered **not medically necessary** when criterion I. above is not met, including but not limited to the treatment of multiple myeloma.
- III. Donor lymphocyte infusions may be considered **medically necessary** for the treatment of either of the following (A.-B.):
- A. Relapsed or refractory acute myeloid leukemia; **or**
  - B. Patients with relapsed acute lymphoblastic leukemia or multiple myeloma after receiving allogeneic HCST.
- IV. Donor lymphocyte infusions are considered **not medically necessary** when criterion III. above is not met.

#### **Autologous Stem Cell Transplantation (AuSCT)**

- V. Autologous stem cell transplantation (AuSCT) may be considered **medically necessary** as a treatment for **any** of the following indications (A.-E.):
- 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;
  - D. Relapsed or recurrent classic Hodgkin lymphoma with documented complete remission on PET/CT following salvage chemotherapy;
  - E. High-risk or relapsed neuroblastomas.
- VI. Autologous stem cell transplantation (AuSCT) may be considered **medically necessary** for the treatment of multiple myeloma following induction therapy.

VII. Autologous stem cell transplantation (AuSCT) for the treatment of multiple sclerosis may be considered **medically necessary** when all of the following criteria are met (A.–F.):

- A. The individual is 18–55 years of age; **and**
- B. The duration of multiple sclerosis is 10 years or less; **and**
- C. The individual has an Expanded Disability Status Scale (EDSS) score between 2.0 and 6.0 (see [Policy Guidelines](#)), documented within the last 60 days; **and**
- D. Either of the following are met (1.-2.):
  - 1. The individual has relapsing remitting multiple sclerosis (RRMS); or
  - 2. The individual has secondary progressive multiple sclerosis (SPMS) with superimposed inflammatory activity demonstrated by clinical relapses and/or MRI activity; **and**
- E. Unless medically contraindicated, the individual has received at least one FDA approved disease modifying therapy (e.g., natalizumab, ocrelizumab, rituximab, alemtuzumab), and has demonstrated inadequate response, intolerance, or disease activity despite this therapy, with each relapse or MRI event occurring after at least 3 months of treatment; **and**
- F. Documentation shows active disease within the past 12 months while on a disease modifying therapy, defined by either of the following (1.-2.):
  - 1. Two or more clinical relapses occurring at separate times; **or**
  - 2. One clinical relapse and at least one new, enlarging, or gadolinium enhancing MRI lesion, with the MRI activity occurring at a different time than the clinical relapse.

VIII. High dose melphalan (HDM) together with autologous stem cell transplantation (AuSCT) may be considered **medically necessary** for any age group with primary amyloid light chain (AL) amyloidosis who meet the following criteria (A-B):

- A. Amyloid deposition in 2 or fewer organs; **and**
- B. Cardiac left ventricular ejection fraction (EF) greater than 45%.

IX. Tandem transplant may be considered **medically necessary** when **both** of the following criteria are met (A.-B.)

- A. Patient is a candidate for autologous stem cell transplantation (AuSCT); **and**
- B. Treatment is for one of the following conditions (1.-5.):
  - 1. Testicular tumors, either as salvage therapy or for those with platinum-refractory disease
  - 2. High-risk neuroblastomas (see [Policy Guidelines](#))
  - 3. Multiple myeloma if **either** of the following are true (a.-b.):
    - a. Patient did not achieve at least a Very Good Partial Rate (VGPR) (see [Policy Guidelines](#)) after a previous autologous stem cell transplantation; **or**
    - b. Patient has high-risk features (e.g. plasma cell leukemia, extramedullary disease).

- X. Autologous stem cell transplantation (AuSCT) is considered **not medically necessary** when criteria V.-IX. are not met, or for the treatment of any of the following indications, including but not limited to when used as a treatment for any of the following:
- A. Acute leukemia not in remission
  - B. Chronic granulocytic leukemia
  - C. Solid tumors (other than neuroblastoma)
  - D. Non primary AL amyloidosis
  - E. Sickle cell disease.

## POLICY CROSS REFERENCES

- [Stem Cell Therapy for Orthopedic Applications](#), MP36

The full Company portfolio of current Medical Policies is available online and can be [accessed here](#).

## POLICY GUIDELINES

This policy may be partly based on the following Center for Medicare and Medicaid Services (CMS) guidance resources:

- Centers for Medicare & Medicaid Services National Coverage Determination (NCD) for Stem Cell Transplantation (Formerly 110.8.1) ([110.23](#)).<sup>1</sup>

### Very Good Partial Response (VGPR)

The NCCN defines VGPR as no measurable monoclonal protein on serum or urine electrophoresis, but positive immunofixation electrophoresis (IFE).<sup>2</sup>

### High Risk Neuroblastoma

Patients most commonly at the highest risk for disease progression and mortality are generally those who are older than 18 months of age and have either disseminated disease or localized disease with unfavorable markers such as *MYCN* amplification regardless of age.<sup>3</sup>

### Expanded Disability Status Scale (EDSS)

The Expanded Disability Status Scale (EDSS) is a standardized method for quantifying disability in multiple sclerosis. It ranges from 0 to 10 in 0.5-point increments and reflects impairment across eight functional systems. The EDSS is based on a neurological examination performed by a qualified clinician and is used to determine the member's eligibility for autologous hematopoietic stem cell

transplantation (AH SCT), as the procedure is supported primarily in individuals with moderate disability who remain ambulatory.

**EDSS 2.0–3.5:** Mild disability in one or more functional systems (see below).

**EDSS 4.0–5.0:** Fully ambulatory but with limitations impacting endurance or daily activities.

**EDSS 5.5:** Ambulatory without aid for roughly 100 meters; increased functional impact.

**EDSS 6.0:** Requires one assistive device for roughly 100 meters.

#### *Functional systems*

- Pyramidal - weakness or difficulty moving limbs
- Cerebellar - ataxia, loss of coordination or tremor
- Brainstem - problems with speech, swallowing and nystagmus
- Sensory - numbness or loss of sensations
- Bowel and bladder function
- Visual function
- Cerebral (or mental) functions
- Other

## **BACKGROUND**

### **Myelodysplastic Syndromes (MDS)**

Myelodysplastic Syndromes (MDS) refers to a group of diverse blood disorders in which the bone marrow does not produce enough healthy, functioning blood cells. These disorders are varied with regard to clinical characteristics, cytologic and pathologic features, and cytogenetics. The abnormal production of blood cells in the bone marrow leads to low blood cell counts, referred to as cytopenias, which are a hallmark feature of MDS along with a dysplastic and hypercellular-appearing bone marrow

### **Hematopoietic Stem Cells**

Hematopoietic stem cells are multi-potent stem cells that give rise to all the blood cell types; these stem cells form blood and immune cells. A hematopoietic stem cell is a cell isolated from blood or bone marrow that can renew itself, differentiate to a variety of specialized cells, can mobilize out of the bone marrow into circulating blood, and can undergo programmed cell death, called apoptosis – a process by which cells that are unneeded or detrimental will self-destruct.

### **Stem Cell Transplantation**

Stem cell transplantation is a process in which stem cells are harvested from either a patient's (autologous) or donor's (allogeneic) bone marrow or peripheral blood for intravenous infusion.

### **Autologous Stem Cell Transplantation (AuSCT)**

Autologous stem cell transplantation (AuSCT) is a technique for restoring stem cells using the patient's own previously stored cells. AuSCT must be used to effect hematopoietic reconstitution following severely myelotoxic doses of chemotherapy (HDCT) and/or radiotherapy used to treat various malignancies.

## **Allogeneic Hematopoietic Stem Cell Transplantation (HSCT)**

Allogeneic hematopoietic stem cell transplantation (HSCT) is a procedure in which a portion of a healthy donor's stem cell or bone marrow is obtained and prepared for intravenous infusion. Allogeneic HSCT may be used to restore function in recipients having an inherited or acquired deficiency or defect.

## **Donor Lymphocyte Infusion (DLI)**

DLI refers the infusion of a bone marrow transplant donor's lymphocytes into a recipient's body. This procedure may be done after the original transplant if the recipient of the transplant suffers a return of their cancer.

# **CLINICAL EVIDENCE AND LITERATURE REVIEW**

## **CLINICAL PRACTICE GUIDELINES**

### **National Multiple Sclerosis Society (NMSS)**

In 2021, the NMSS published recommendations addressing autologous hematopoietic stem cell (AHST) transplant in multiple sclerosis.<sup>4</sup> Authors wrote that AHST is a highly effective therapeutic option for appropriately selected individuals with aggressive relapsing forms of multiple sclerosis, particularly relapsing-remitting MS (RRMS). The NMSS identified emerging consensus around ideal candidate characteristics, highlighting younger individuals with highly active inflammatory disease, relatively short disease duration, and lower disability levels as those most likely to benefit. Overall, NMSS recommends that AHST be considered a reasonable and evidence-supported escalation therapy for patients with aggressive relapsing MS who have not responded adequately to high-efficacy disease-modifying treatments.

### **American Society for Blood and Marrow Transplantation**

In 2015, the American Society for Blood and Marrow Transplantation published guidelines on 'Indications for Autologous and Allogeneic Hematopoietic Cell Transplantation'. In the guidelines, they recommend allogeneic HCT for treating sickle cell anemia, categorizing the indication as a C for "standard of care, clinical evidence available. This category includes "indications for which large clinical trials and observational studies are not available. However, HCT has been shown to be an effective therapy with acceptable risk of morbidity and mortality in sufficiently large single- or multi-center cohort studies. HCT can be considered as a treatment option for individual patients after careful evaluation of risks and benefits. As more evidence becomes available, some indications may be reclassified as "Standard of Care".<sup>5</sup> Furthermore, aplastic anemia and Thalassemia were rated S or "standard of care". The following conditions were also rated R for the allogeneic HCT, "standard of care, rare indication": Fanconi's anemia, Dyskeratosis congenita, Blackfan-Diamond anemia, congenital amegakaryocytic thrombocytopenia, severe combined immunodeficiency, T cell immunodeficiency, SCID variants, Wiskott-Aldrich syndrome, Hemophagocytic disorders, Lymphoproliferative disorders, severe congenital neutropenia, chronic granulomatous disease, and other autoimmune and immune dysregulation disorders. These indications include "rare diseases for which clinical trials and observational studies with sufficient number of patients are not currently feasible because of their very low incidence. However,

single or multi-center or registry studies in relatively small cohorts of patients have show HCT to be effective treatment with acceptable risks of morbidity and mortality.” HCT can be considered as a treatment options for these patients after careful evaluation of risks and benefits. <sup>5</sup>

Autologous HCT for high risk or relapsed neuroblastoma was also rated as S, “standard of care”. <sup>5</sup>

The guidelines recommend against autologous HCT for sickle cell disease, aplastic anemia, or Thalassemia, because the current evidence and current practice do not support the routine use of HCT. The guidelines state, “However, this recommendation does not preclude investigation of HCT as a potential treatment and transplantation may be pursued for these indications within the context of a clinical trial.”<sup>5</sup>

### **National Comprehensive Cancer Network (NCCN)**

- NCCN guidelines on Hodgkin Lymphoma (version 1.2026) support autologous stem cell transplantation (AuSCT) as medically necessary for relapsed or refractory classic Hodgkin lymphoma. AuSCT is the preferred and standard approach in these cases. NCCN supports allogeneic SCT only in select post-AuSCT relapse scenarios or within clinical trials. <sup>6</sup>
- NCCN guidelines on T-Cell Lymphomas (version 1.2026) recommend allogeneic hematopoietic cell transplant as an option for “consolidation/additional therapy” in patients with relapsed/refractory peripheral T-cell lymphomas who experienced complete or partial response to clinical therapy or second-line therapy regimens. <sup>7</sup>
- NCCN guidelines on Myeloproliferative Neoplasms (version 1.2026) recommend the following:

“Allogeneic HCT is included as an option for patients with INT-1-risk MF [intermediate risk 1 myelofibrosis]. Although the outcomes following allogeneic HCT are better for patients with low-risk or INT-1-risk MF, due to high transplanted-related morbidity and mortality, treatment decisions regarding allogeneic HCT should be individualized for patients with INT-1-risk MF. Allogeneic HCT should be considered for low-risk or INT-1-risk MF inpatients with either refractory, transfusion-dependent anemia; circulating blast cells >2% in peripheral blood; or adverse cytogenetics.... Evaluation for allogeneic HCT is recommended for all patients with INT-2risk and high-risk MF.”<sup>8</sup>
- NCCN guidelines on Myelodysplastic Syndromes (version 3.2026) recommend the following:

“Evaluation for allogeneic HCT is recommended for patients with low platelet counts or complex cytogenetics. Identification of higher-risk mutations may be helpful in the decision-making regarding allogeneic HCT for patients with myelofibrosis.”<sup>9</sup>
- NCCN guidelines on Acute Lymphoblastic Leukemia (version 2.2025) recommend allogeneic HCT as a consolidative therapy following blinatumomab monotherapy. Authors also noted that optimal timing of HCT was not clear, but that proceeding to allogeneic HCT in patients with minimal residual disease detected is not optimal. In patients where MRD is unavailable, allogeneic HCT is recommended, especially in patients with high-risk features.<sup>10</sup>

- NCCN guidelines on Multiple Myeloma (version 5.2026) recommend the following:

“Patients presenting with active (symptomatic) myeloma are initially treated with primary therapy and primary therapy is followed by high-dose chemotherapy with autologous hematopoietic cell transplant (HCT) in transfer-eligible patients... Allogeneic stem cell transplant should preferentially be done in the context of a trial when possible.”<sup>2</sup>

“According to the NCCN Multiple Myeloma Panel, a tandem transplant with or without maintenance therapy can be considered for all patients who are candidates for HCT and is an option for patients who do not achieve at least a VGPR after the first autologous HCT and those with high-risk features.”<sup>2</sup>

## HEALTH EQUITY CONSIDERATIONS

The Centers for Disease Control and Prevention (CDC) defines health equity as the state in which everyone has a fair and just opportunity to attain their highest level of health. Achieving health equity requires addressing health disparities and social determinants of health. A health disparity is the occurrence of diseases at greater levels among certain population groups more than among others. Health disparities are linked to social determinants of health which are non-medical factors that influence health outcomes such as the conditions in which people are born, grow, work, live, age, and the wider set of forces and systems shaping the conditions of daily life. Social determinants of health include unequal access to health care, lack of education, poverty, stigma, and racism.

The U.S. Department of Health and Human Services Office of Minority Health calls out unique areas where health disparities are noted based on race and ethnicity. Providence Health Plan (PHP) regularly reviews these areas of opportunity to see if any changes can be made to our medical or pharmacy policies to support our members obtaining their highest level of health. Upon review, PHP creates a Coverage Recommendation (CORE) form detailing which groups are impacted by the disparity, the research surrounding the disparity, and recommendations from professional organizations. PHP Health Equity COREs are updated regularly and can be found online [here](#).

## BILLING GUIDELINES AND CODING

| CODES* |       |   |
|--------|-------|---|
| CPT    | 0263T | Intramuscular autologous bone marrow cell therapy, with preparation of harvested cells, multiple injections, one leg, including ultrasound guidance, if performed; complete procedure including unilateral or bilateral bone marrow harvest |
|        | 0264T | Intramuscular autologous bone marrow cell therapy, with preparation of harvested cells, multiple injections, one leg, including ultrasound guidance, if performed; complete procedure excluding bone marrow harvest                         |
|        | 0265T | Intramuscular autologous bone marrow cell therapy, with preparation of harvested cells, multiple injections, one leg, including ultrasound guidance, if performed;  |

|              |       |  |
|--------------|-------|--|
|              |       | unilateral or bilateral bone marrow harvest only for intramuscular autologous bone marrow cell therapy                     |
|              | 38204 | Management of Recipient Hematopoietic Progenitor Cell Donor Search and Cell Acquisition                                    |
|              | 38205 | Blood-derived hematopoietic progenitor cell harvesting for transplantation, per collection; allogeneic                     |
|              | 38206 | Blood-derived hematopoietic progenitor cell harvesting for transplantation, per collection; autologous                     |
|              | 38207 | Transplant preparation of hematopoietic progenitor cells; cryopreservation and storage                                     |
|              | 38208 | Transplant preparation of hematopoietic progenitor cells; thawing of previously frozen harvest, without washing, per donor |
|              | 38209 | Transplant preparation of hematopoietic progenitor cells; thawing of previously frozen harvest, with washing, per donor    |
|              | 38210 | Transplant preparation of hematopoietic progenitor cells; specific cell depletion within harvest, T-cell depletion         |
|              | 38211 | Transplant preparation of hematopoietic progenitor cells; tumor cell depletion   |
|              | 38212 | Transplant preparation of hematopoietic progenitor cells; red blood cell removal   |
|              | 38213 | Transplant preparation of hematopoietic progenitor cells; platelet depletion   |
|              | 38214 | Transplant preparation of hematopoietic progenitor cells; plasma (volume) depletion  |
|              | 38215 | Transplant preparation of hematopoietic progenitor cells; cell concentration in plasma, mononuclear, or buffy coat layer   |
|              | 38230 | Bone marrow harvesting for transplantation; allogeneic   |
|              | 38232 | Bone marrow harvesting for transplantation; autologous   |
|              | 38240 | Hematopoietic progenitor cell (HPC); allogeneic transplantation per donor  |
|              | 38241 | Hematopoietic progenitor cell (HPC); autologous transplantation  |
|              | 38242 | Allogeneic lymphocyte infusions  |
| <b>HCPCS</b> | None  |  |

**\*Coding Notes:**

- The above code list is provided as a courtesy and may not be all-inclusive. Inclusion or omission of a code from this policy neither implies nor guarantees reimbursement or coverage. Some codes may not require routine review for medical necessity, but they are subject to provider contracts, as well as member benefits, eligibility and potential utilization audit.
- All unlisted codes are reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is submitted for non-covered services addressed in this policy then it will be **denied as not covered**. If an unlisted code is submitted for potentially covered services addressed in this policy, to avoid post-service denial, **prior authorization is recommended**.
- **See the non-covered and prior authorization lists on the Company [Medical Policy](#), [Reimbursement Policy](#), [Pharmacy Policy](#) and [Provider Information website](#) for additional information.**
- HCPCS/CPT code(s) may be subject to National Correct Coding Initiative (NCCI) procedure-to-procedure (PTP) bundling edits and daily maximum edits known as “medically unlikely edits” (MUEs) published by the Centers for Medicare and Medicaid Services (CMS). This policy does not take precedence over NCCI edits or MUEs. Please refer to the CMS website for coding guidelines and applicable code combinations.

## REFERENCES

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## POLICY REVISION HISTORY

| DATE   | REVISION SUMMARY  |
|--------|---|
| 2/2023 | Converted to new policy template.   |
| 4/2023 | Annual review. Expanded criteria on noncancer indications, tandem transplant. |
| 5/2024 | Annual review. Changes to criteria. Code added.                               |
| 3/2025 | Annual review. No changes.  |
| 3/2026 | Annual review. Updated indications in criteria.                               |