Health Plans

Manual: IU Health Plans
Department: Utilization Management
Policy: MP105
Effective Date:02/01/2025
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□ X **Medicare Advantage** **X Commercial**

Stem Cell, Blood, and Bone Marrow Products Therapy Policy

I. Purpose

Indiana University Health Plans considers clinical indications when making a medical necessity determination for the non-hematopoietic uses of stem cell, blood, and bone marrow products.

II. Scope

This policy applies to all IU Health Plans and utilization management staff having decision-making responsibility for authorization is required for Fully Insured and Medicare Advantage (MA) plans.

III. Exceptions/Variations

1. This policy addresses the use of stem cell and autologous cells for the prevention and treatment of peripheral vascular disease, orthopedic, autoimmune, inflammatory, and degenerative conditions.
2. This policy does NOT address the therapeutic uses of stem cells for hematopoietic indications that are inherited, acquired, or result from myeloablative treatment including autologous or allogenic stem cells and stem cell-based gene therapy (FDA-approved products derived from stem cells that are approved for limited use in individuals with disorders involving the hematopoietic system).
3. This policy does not address the use of recombinant human platelet- derived growth factor (becaplermin [Regranex] or bioengineered autologous skin derived products.
4. Stem cell therapy, including but not limited to mesenchymal stem cell therapy is considered investigational and not medically necessary for the prevention and treatment of all of the following conditions, including but not limited to:
    a. Peripheral vascular disease
    b. Orthopedic conditions
    c. Autoimmune conditions
    d. Inflammatory conditions
    e. Degenerative conditions
5. Autologous cell therapy, including but not limited to, skeletal myoblasts, mesenchymal cells, endothelial progenitor cells (EPC), or bone marrow mononuclear cells (BMMC) is considered investigational and not medically necessary for all indications, including but not limited to treatment of damaged myocardium.
6. Autologous blood derived wound products (examples: Aurix, Vitagel) are considered investigational and not medically necessary for all applications.

7. Use of platelet rich plasma (PRP), including autologous conditioned plasma (ACP), is considered investigational and not medically necessary for all indications, including the treatment of any of the following:
    a. Cutaneous wounds
    b. Soft tissue injuries (including epicondylitis and sinus surgery
    c. Bone injuries (including surgically created wounds and non-unions)
8. Use of bone marrow aspirate concentrate (BMAC) is considered investigational and not medically necessary for all indications, including for the treatment of critical limb ischemia.
9. Use of autologous protein solution (example-nSTRIDE), also known as autologous white blood cell concentrate, is considered investigational and not medically necessary for all indications.

IV. Definitions

Stem Cells: can also be called somatic stem cells or tissue specific stem cells. Cells in the body that can renew themselves and develop into many different cell types.

Autologous Cell Therapy- cells that are obtained from the individual's own body and body products.

Mesenchymal Stem Cells (MSC)- non hematopoietic stem cells that can differentiate into a variety of cell types. The four major cell types are osteophytes (bone), myocytes (muscle), adipocytes (fat), and chondrocytes (cartilage). MSC can be isolated from various sites including dermis, amniotic fluid, adipose tissue, endometrium, dental tissue, synovial fluid, placenta, and umbilical cord tissue. It has been proposed as a treatment option for orthopedic indications including torn cartilage, osteoarthritis, and bone grafting. MSC therapy is being investigated for use in chronic, autoimmune inflammatory, severe pulmonary syndromes and degenerative conditions.

Pluripotent stem cells come from early mammalian embryos at the blastocyst stage and can be made from mature adult cells reprogrammed into an embryonic stem cell like state. The reprogramed stem cells are called induced pluripotent stem cells (iPSCs)

Adult stem cells- populations of adult stem cells serve as an internal repair system that generates replacements for cells that are lost through normal wear and tear, injury, or disease. Adult stem cells have been identified in many organs and tissues and are generally associated with specific anatomical locations. These stem cells may remain quiescent (non-dividing) for long periods of time until they are activated by a normal need for more cells to maintain and repair tissues.

V. Policy Statement

IU Health plans considers the use of stem cell therapy for the prevention and treatment of health conditions, including but not limited to, peripheral vascular disease, orthopedic, autoimmune, inflammatory, and degenerative conditions to be experimental and investigational.

CODES
THE FOLLOWING CODES ARE CONSIDERED EXPERIMENTAL AND

INVESTIGATIONAL

CODE	Description
0232T	Injection(s) of platelet rich plasma, any tissue, including image guidance, harvesting and preparation when performed
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 including unilateral or bilateral bone marrow harvest
0265T	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
0481T	Injection(s), autologous white blood cell concentrate (autologous protein solution), any site, including image guidance, harvesting, and preparation, when performed
0748T	Injections of stem cell product into perianal perifistular soft tissue, including fistula preparation (eg, removal of setons, fistula curettage, closure of internal openings)
17999	Unlisted procedure, skin, mucous membrane and subcutaneous tissue [when specified as harvesting or administration of stem cells for therapy to repair damaged cells or body tissues]
20999	Unlisted procedure, musculoskeletal system, general [when specified as harvesting and injection of bone marrow aspirate concentrate or harvesting or administration of stem cells for therapy to repair damaged cells or body tissues]
33999	Unlisted procedure, cardiac surgery [when specified as autologous cell therapy for damaged myocardium, including harvesting and preparation of cells]
38999	Unlisted procedure, hemic or lymphatic system [when specified as bone marrow cell therapy or stem cell therapy such as IM, IV, or IA for peripheral vascular disease]
64999	Unlisted procedure, nervous system [when specified as harvesting or administration of stem cell for therapy to repair damaged cells or body tissue]
CODES	**DEPENDING ON REASON FOR USE**
38205	Blood derived hematopoietic progenitor cell harvesting for transplantation, per collection, allogenic
38206	Blood derived hematopoietic progenitor cell harvesting for transplantation, per collection, autologous
38230	Bone marrow harvesting for transplantation, allogenic
38232	Bone marrow harvesting for transplantation, autologous

VI. Procedure

None

VII. Rationale

Stem cells, originally identified in the hematopoietic system, are believed to exist in many other tissues. They can be obtained from human embryos, adult somatic tissues, or generated by reprogramming differentiated somatic cells to increase their potency. Examples of adult stem cells (also referred to as somatic or tissue-specific stem cells) used outside of hematopoietic applications include mesenchymal (also called stromal stem cells), neural, epithelial, epidermal, and follicular stem cells. Sources for extracting adult stem cells include blood, bone marrow, adipose tissue, umbilical cords, placentas, and amniotic fluid. Additionally, stem cells such as peripheral blood mononuclear cells (PBMNCs) and bone marrow mononuclear cells (BMMNCs) are also utilized in transplantation.

VIII. References/Citations

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3. National Institutes of Health. NIH Stem Cell Information. (n.d.) Stem Cell Basics. Stem Cell Basics | STEM Cell Information (nih.gov)
4. Kim, G. B., Seo, M. S., Park, W. T., & Lee, G. W. (2020). Bone Marrow Aspirate Concentrate: Its Uses in Osteoarthritis. *International journal of molecular sciences*, *21*(9), 3224. https://doi.org/10.3390/ijms21093224
5. Lana, J. F. S. D., da Fonseca, L. F., Macedo, R. D. R., Mosaner, T., Murrell, W., Kumar, A., Purita, J., & de Andrade, M. A. P. (2021). Platelet-rich plasma *vs* bone marrow aspirate concentrate: An overview of mechanisms of action and orthobiologic synergistic effects. *World journal of stem cells*, *13*(2), 155–167. https://doi.org/10.4252/wjsc.v13.i2.155
6. Marks, P. W., Witten, C. M., & Califf, R. M. (2017). Clarifying Stem-Cell Therapy's Benefits and Risks. *The New England journal of medicine*, *376*(11), 1007–1009. https://doi.org/10.1056/NEJMp1613723
7. U.S. Food and Drug Administration. (December 8, 2023). Approved Cellular and Gene Therapy Products. Approved Cellular and Gene Therapy Products | FDA

VIII. Responsibility

Medical Director