STEM CELL THERAPY, ORTHOPEDIC APPLICATIONS

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member’s specific benefit plan. This Medical Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

The section identified as “Description” defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as “Criteria” defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Medical Coverage Guidelines are subject to change as new information becomes available.

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Description:

Mesenchymal stem cells (MSCs) can differentiate into a variety of tissue types including various musculoskeletal tissues. MSCs have been investigated for the treatment of orthopedic disorders including damaged cartilage, ligaments, tendons and intervertebral discs. MSCs are associated with the blood vessels within bone marrow, synovium, fat and muscle, where they can be mobilized for endogenous repair as occurs with healing of bone fractures. Bone marrow aspirate is considered to be the most accessible source and, thus, the most common place to isolate MSCs for treatment of musculoskeletal disease. MSC therapy refers to the procurement, processing and subsequent infusion or implantation of the MSCs into the intended anatomic area to promote healing or regeneration of damaged tissue. Concentrated autologous MSCs do not require approval by the U.S. Food and Drug Administration (FDA).
STEM CELL THERAPY, ORTHOPEDIC APPLICATIONS (cont.)

Description: (cont.)

Demineralized bone matrix (DBM), which is processed allograft bone is considered minimally processed tissue and does not require FDA approval. At least 4 commercially available DBM products are reported to contain viable stem cells:

- AlloStem®: partially demineralized allograft bone seeded with adipose-derived MSCs
- Map3™: contains cortical cancellous bone chips, DBM and multipotent adult progenitor cells
- Osteocell Plus®: allograft cellular bone matrix containing native MSCs
- Trinity Evolution Matrix™: allograft that is processed and cryopreserved to maintain viable MSCs and osteoprogenitor cells

Other products contain DBM and are designed to be mixed with bone marrow aspirate. Some of the products that are currently available are:

- Fusion Flex™: dehydrated moldable DBM scaffold that will absorb autologous bone marrow aspirate
- Ignite®: injectable graft with DBM that can be combined with autologous bone marrow aspirate

Other commercially available products are intended to be mixed with bone marrow aspirate and have received FDA approval, such as:

- Collage™: composed of type-1 bovine collagen and beta Tri-calcium phosphate
- Vitoss®: composed of beta tricalcium phosphate
- nanOss®: nanostructured hydroxyapatite and an open structured engineered collagen carrier

No products using engineered MSCs have been approved by the FDA for orthopedic applications to include, but not limited to Regenexx™ procedure.
STEM CELL THERAPY, ORTHOPEDIC APPLICATIONS (cont.)

Criteria:

- Mesenchymal stem cell therapy for all orthopedic applications is considered experimental or investigational based upon:
  1. Lack of final approval from the Food and Drug Administration, and
  2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  3. Insufficient evidence to support improvement of the net health outcome, and
  4. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
  5. Insufficient evidence to support improvement outside the investigational setting.

These indications include, but are not limited to:

- Repair or regeneration of musculoskeletal tissue

- Allograft bone products containing viable stem cells for all orthopedic applications are considered experimental or investigational based upon:

  1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  2. Insufficient evidence to support improvement of the net health outcome, and
  3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
  4. Insufficient evidence to support improvement outside the investigational setting.

Resources: