Medica Coverage Policy

Policy Name: Stem Cell Therapy for Orthopedic Applications
Effective Date: 12/17/2018

Important Information – Please Read Before Using This Policy

These services may or may not be covered by all Medica plans. Please refer to the member’s plan document for specific coverage information. If there is a difference between this general information and the member’s plan document, the member’s plan document will be used to determine coverage. With respect to Medicare and Minnesota Health Care Programs, this policy will apply unless those programs require different coverage. Members may contact Medica Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions about this Medica coverage policy may call the Medica Provider Service Center toll-free at 1-800-458-5512.

Medica coverage policies are not medical advice. Members should consult with appropriate health care providers to obtain needed medical advice, care and treatment.

Coverage Policy

Stem cell therapy for orthopedic applications, including but not limited to, treatment of osteoarthritis, bone fractures and nonunions, and as an adjunct to spinal fusion, is investigative and unproven and therefore NOT COVERED. There is insufficient reliable evidence in the form of high quality peer-reviewed medical literature to establish the safety and efficacy or effects on health care outcomes.

This includes:
- Concentrated, engineered or expanded stem cells
- Allograft bone products containing stem cells

Description

During normal bone healing, mesenchymal stem cells (MSCs) migrate out of the bone marrow to the affected site where they differentiate into either osteoblasts or chondroblasts to aid in cartilage formation and repair of the bone. Stem cells have the potential to change into many different types of cells that can generate new cartilage within joints or strengthen and regenerate spinal discs.

Occasionally, MSCs are inadequate for healing and autologous/allogeneic stem cell therapy has been proposed as a way to stimulate and promote bone healing. MSCs are obtained from bone marrow aspirate. This procedure involves aspiration of bone marrow from the individual or donor and injecting the stem cells into the affected site. Stem cells may also be administered by combining the cells with an allograft bone product, such as demineralized bone matrix (DBM), or a synthetic bone graft substitute. Potential uses of this therapy include, but are not limited to, treatment of osteoarthritis, bone fractures and nonunions, and intervertebral discs.

FDA Approval

Stem cell transplantation is a procedure and therefore not subject to FDA regulation. However, any medical devices, drugs or tests used as part of the procedure may be subject to FDA regulation.
Concentrated autologous MSCs (processed by clinicians in the office by centrifuge without manipulating or adding agents to the mix) do not require FDA approval. To date, no products using engineered or expanded MCSs have been approved by the FDA for orthopedic applications. Examples of products containing MSCs include but are not limited to:

1. Regenexx (Regenerative Sciences)
2. Osteocel® Plus (NuVasive)
3. Trinity® Evolution™ (Orthofix)
4. AlloStem®
5. Cellentra™ VCBM

**Prior Authorization**
Prior authorization is not applicable. Claims for this service are subject to retrospective review and denial of coverage, as investigative services are not eligible for reimbursement.

**Coding Considerations**
Use the current applicable CPT/HCPCS code(s). The following codes are included below for informational purposes only, and are subject to change without notice. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement.

**CPT Codes:**
- 20939 - Bone marrow aspiration for bone grafting, spine surgery only, through separate skin or fascial incision (List separately in addition to code for primary procedure)

Original Effective Date: 1/1/2013

Re-Review Date(s):
- 10/21/2015
- 1/1/2018 – administrative update; code added
- 10/17/2018
- 3/1/2020 – administrative update; format