Medical Policy

Section

Medicine

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Issue

12:2013

Description

The standard treatment of problem fractures or osseous defects has been an autologous cancellous bone graft harvested from the iliac crest. Limitations of this approach include morbidity at the graft site and the lack of adequate bone stock in some patients. Autologous bone graft is considered the gold standard because it includes components of all three processes considered to be essential for bone healing: osteoconductivity (i.e., a support structure), osteoinductivity (i.e., ability of graft to induce nondifferentiated stem cells to differentiate into osteoblast) and osteogenic cells. Therefore, bone graft substitutes, used either alone or in combination are designed to reproduce these components. The extracellular bone matrix includes a wide range of bone growth factors, proteins and other bioactive materials necessary of osteoinduction. These factors can be removed from allograft bone by using a demineralizing agent, resulting in demineralized bone matrix (DBM). Several different preparations of DBM are commercially available, including putty, gel and paste, which can be used as an adjunct to a variety of open surgical procedures. In contrast, the Ignite™ ICS product consists of a DBM that is designed to be injectable, thus enabling percutaneous treatment. Autologous bone marrow aspirate is designed to provide marrow stromal cells and osteogenic cells, and has been investigated as a stand alone treatment of fracture, or in conjunction with demineralized bone marrow. The Ignite™ ICS product is specifically designed to be used in conjunction with bone marrow aspirate, and has the following labeled indication:

“After the powder is mixed with autologous bone marrow aspirate, the resultant composite material can then be injected into the defect site. Ignite™ ICS is indicated only for bone voids or gaps that are not intrinsic to the stability of the bony structure. Ignite™ ICS is intended to be injected into bony voids or gaps of the skeletal system (i.e., the extremities, spine and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone.”

Various different preparations of DBM are commercially available, regulated by the U.S. Food and Drug Administration (FDA) as either human tissue or cleared through the 510(k) marketing...
Bone morphogenetic protein (BMP) is another bone graft alternative and consists of a bioengineered equivalent of one of the components of bone matrix. Various BMP preparations have been FDA approved through the more rigorous PMA process, which does require evidence of clinical efficacy. BMP is discussed in MPRM policy 7.01.100.

Policy

The percutaneous treatment of fracture non-unions of bone defects with the use of bone marrow aspirate with or without demineralized bone matrix is considered investigational.

Policy Guidelines

There are no specific CPT codes for the above procedure and no specific coding for the BMP products. If autologous bone marrow aspirate is used, the CPT code 38220 will be used for the aspiration procedure.

Rationale

In the treatment of fractures, an autologous bone graft is considered when a fracture nonunion is present (usually defined as a 3-month period without evidence of further fracture healing). However, the minimally invasive nature of a percutaneous approach may prompt a broadening of the patient selection criteria. For example, on the manufacturer’s website for the Ignite™ ICS product, the following indications are listed (1):

- Suspect delayed union at 6-8 weeks following index procedure with no sign of callus formation
- Delayed union with well-fixed hardware
- Fresh fracture for “high risk” patients with one or more co-morbidities such as smoking, diabetes, steroid use, etc.
- Stable non-unions with no prior surgical intervention.

A literature search based on the MEDLINE database did not identify any controlled trials comparing the standard treatment of autologous bone graft to treatment with autologous bone marrow aspirate used either alone or in conjunction with demineralized bone matrix (DBM). The published literature, including citations from the 1990s, consisted primarily of single institution case series with heterogeneous groups of patients. In 1995, Connolly published a retrospective review of the use of bone marrow aspirate used either alone or in combination with DBM in 100
cases (2). The author states that the results were at least equivalent to autologous grafting, but did not provide detailed results or statistical analysis. Skoff reported on a prospective case series of 19 patients with a localized skeletal defect requiring bone grafting. (3) The patients were treated with cancellous cubes of allograft bone that were combined with autologous bone marrow aspirate. The composite graft was implanted through a stab incision over the skeletal defect. A total of 100% of patients achieved clinical healing. In 2003 Wilkins and colleagues reported on a prospective study of 66 patients with stiff non-unions (i.e., no gross motion) who were treated with a percutaneous administration of a mixture of autologous bone marrow and DBM. (4) A total of 88% of patients achieved union at 8.1 months. Finally, Goel and colleagues reported on a prospective case series of 20 patients with tibial non-unions who received a percutaneous bone marrow injection alone. The authors reported a 75% union rate. (5) In summary there is inadequate published data to permit scientific conclusions.

2006-2007 Update

A search of the MEDLINE database for the period of September 2005 through December 2006 did not identify any evidence that would alter the previous conclusion. One study with 60 patients reported the clinical healing rate along with the number and concentration of progenitor cells that were transplanted for the treatment of nonunion. (6) The investigators found a significant relation between bone union and the number of progenitor cells that had been aspirated and concentrated prior to treatment. The development of appropriate graft materials is evolving; randomized controlled trials comparing outcomes of percutaneous injection of bone marrow aspirate with bone grafts are lacking.

2008 Update

A search of the MEDLINE database was performed for the period of January 2007 through April 2008. The search identified one randomized trial from the multicenter Simple Bone Cyst Trial Group. (7) This study compared percutaneous bone marrow with methylprednisone injection for the treatment of bone cysts in 90 children. At 2-year follow-up, 23% of the cysts in the bone marrow group (87% follow-up) had healed, compared with 42% in the steroid group (84% follow-up); the odds ratio was 4.9. There was no difference between the two groups in pain function, or adverse events. Subsequent fracture was associated with cyst healing at 2 years. Based on the available evidence, percutaneous treatment of bone cysts with bone marrow has not been shown to be as beneficial as the established alternative. This treatment is considered to be investigational.

References:

1. http://www.wmt.com


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Fracture nonunion, bone marrow aspirate and demineralized bone matrix
Ignite™ ICS