

Evidence Discussion (CMM-612: Grafts)

Risks and complications associated with the use of recombinant human bone morphogenetic protein-2 (rhBMP-2) have been well documented in the literature. [1-6] Complications include but are not limited to swelling, edema, heterotopic ossification, osteolysis, seroma/hematoma, infection, arachnoiditis, dysphagia/airway obstruction (anterior cervical surgery) and neurological deficits (myelopathy, radiculopathy). [1-6] Given the potential possibility for serious complications, proper patient selection is critical to minimize the risk benefit ratio.

There have been over 20 randomized control trials which have shown equivalent or superior efficacy of rhBMP-2 to iliac crest bone graft (ICBG). [9, 10] The literature supports the use of rhBMP-2 for stand-alone anterior lumbar interbody fusion (ALIF) [5-9]. rhBMP-2 is also supported for posterolateral lumbar fusion (PLF), posterior lumbar interbody fusion (PLIF) and transforaminal lumbar interbody fusion (TLIF) when there is high risk for nonunion with autogenous bone graft or in those patients with inadequate or poor quality autogenous bone available. [5-9] The North American Spine Society (NASS) Coverage Policy Recommendations: *rhBMP-2* (2014) includes the following high-risk conditions: revision posterior fusion; patients with poor quality or unavailable iliac crest autograft (trauma patients with concomitant pelvic injury, rheumatoid patients, etc.); multilevel surgeries (> 3 levels), particularly those extending to the sacrum or pelvis; elderly patients with osteoporosis; previous radiation or other insult to the fusion bed; metabolic factors that are likely to interfere with proper autograft incorporation, such as smokers and diabetics patients. [7] Use of rhBMP-2 is not recommended for routine single level posterior/posterolateral fusions in healthy adults and routine pediatric spine fusion procedures (e.g. adolescent idiopathic scoliosis). Due to risks of airway obstruction and dysphagia with the use of rhBMP-2 as an adjunct in cervical spine surgery [11, 12], it is only recommended for patients at very high risk for fusion failure (neuromuscular scoliosis, occipitocervical pathology) and not for routine anterior and posterior cervical fusion procedures. [7] rhBMP-2 is not recommended for patients who are skeletally immature. [13] It should also be of note that there is insufficient evidence to support the use of rhBMP-7. [14, 15]

The literature pertaining to the use of bone marrow aspirate concentrate (BMAC) in spine surgery consists mainly of small observational studies. [16-21] There have been few randomized controlled trials and the trials contained low numbers of participants. [18, 19] Although the studies have supported the use of BMAC, strong evidence-based conclusions are unable to be made at this time.

There is also lack of sufficient high-level evidentiary support for the use of platelet rich plasma, mesenchymal stem cell therapy, human amniotic membrane bone graft substitute, human growth factors (e.g., fibroblast growth factor, insulin-like growth), bone graft substitutes used to reduce donor site morbidity, ceramic based products, allograft graft substitutes used exclusively as stand-alone stabilization devices for fusion, OptiMesh® deployable grafting system and INFUSE/MASTERGRAFT™ Posterolateral Revision Device for the enhancement of bone healing. [22-34]

As risk for major complications exists with grafting procedures, it is critical to optimally ensure that patients receive treatment that is appropriate, safe and effective. Although

the use of any coverage criteria includes the possible risk of delayed care, application of evidence based criteria best ensure patient safety and highly outweigh any clinical harms.

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