

AUGMENT® Bone Graft
Sample Appeal Letter to Support Medical Necessity

(Date)
(Name)
(Address)
(City), (State) (Zip)

Re: (Patient Name)
(Insured's ID#)
(Date of Service)
(Product)

To Whom It May Concern,

I am writing to appeal the recent denial in reference to the above-referenced patient and service, and formally request reconsideration of AUGMENT® Bone Graft as a clinically-proven, FDA approved, and medically necessary bone graft substitute in the *(insert the hindfoot and/or ankle fusion procedure[s])* performed on *(insert patient name)*. I am further requesting the reconsideration be conducted by a board-certified, foot and ankle specialist orthopaedic surgeon. I am including additional information on the Level 1 clinical trial evidence, and peer-reviewed papers, for review in the reconsideration.

PATIENTS MEDICAL HISTORY AND TREATMENT RATIONALE

(insert patient's case history, patient's condition, clinical course prior to treatments and the treatment rationale explaining why this procedure was chosen for this particular patient.)

PRODUCT AND PROCEDURE DESCRIPTION

AUGMENT® Bone Graft was Approved¹ under a PMA by the FDA on September 1, 2015, and has an FDA label indicating its use as an alternative to autograft in arthrodesis (i.e., surgical fusion procedures) of the ankle (tibiotalar joint) and/or hindfoot (including subtalar, talonavicular, and calcaneocuboid joints, alone or in combination), due to osteoarthritis, posttraumatic arthritis, rheumatoid arthritis, psoriatic arthritis, avascular necrosis, joint instability, joint deformity, congenital defect, or joint arthropathy in patients with preoperative or intraoperative evidence indicating the need for supplemental graft material.

The use of AUGMENT® Bone Graft eliminates the need for a second surgery to harvest autologous bone, thereby avoiding donor site morbidity which may occur (e.g., pain, infection, etc.). AUGMENT® Bone Graft combines recombinant human platelet-derived growth factor B homodimer (rhPDGF-BB) with a bioresorbable synthetic bone matrix (beta-tricalcium phosphate or β -TCP). The rhPDGF-BB is chemotactic for fibroblasts, neutrophils,

¹ FDA did not base its approval of AUGMENT® Bone Graft on radiologic findings from the pivotal study, but instead relied on the clinical outcomes.

and monocytes, cell types important for the early phases of tissue repair. The rhPDGF-BB is mitogenic for fibroblasts, osteoblasts, chondrocytes, and mesenchymal stem cells, which are important for later-stage tissue formation. The rhPDGF-BB functions as a chemo-attractant and mitogen for cells involved in wound healing and through its promotion of angiogenesis at the site of healing. The β -TCP acts as bone void filler to prevent soft tissue from collapsing into the void. When the β -TCP is placed near a viable host bone, it acts as a scaffold for new bone growth (osteoconductive).

CLINICAL EVIDENCE

A randomized, controlled, double-blinded, multi-center (37 sites), non-inferiority, pivotal clinical trial was conducted comparing AUGMENT® Bone Graft to autograft harvest under a 2:1 randomization protocol.

In the pivotal trial, 434 subjects were enrolled and a total of 414 subjects completed study surgery. Of these, 397 were treated per protocol and comprise the primary analysis population for the CT radiographic assessment of bridging bone at 24 weeks as the primary outcome measure. The autograft control group for the clinical trial was autologous bone graft (autograft), which is considered the gold standard for graft material for ankle and hindfoot arthrodesis procedures. Analysis of patient demographics showed no differences between the treatment groups. Secondary efficacy outcomes included clinical, functional, quality of life assessment in addition to further radiologic outcomes. Safety outcomes included adverse event frequency, severity and potential relationship to AUGMENT® Bone Graft, surgical site complications and patient dropout.

The primary endpoint of the clinical trial was met; at 24 weeks the fusion rate determined by CT scan was 61.2% in the AUGMENT® Bone Graft group compared to 62% in the autograft group ($p=0.038$), at 52 weeks the secondary endpoint of clinical healing rate was 83.1% in the AUGMENT® Bone Graft group compared to 83.9% in the autograft group ($p=0.010$). Non-inferiority of AUGMENT® Bone Graft was established for 15 of the 16 secondary endpoints at 52 weeks. At 24 and 52 weeks 12.4% and 8.8% of patients in the autograft group experienced prolonged pain at the autologous bone graft harvest site. This complication was obviously avoided in the AUGMENT® Bone Graft group. Combining the results of the 414 patient pivotal randomized controlled trial, and prior preliminary clinical trials, AUGMENT® Bone Graft has been clinically studied in over 500 patients without any report of serious device-related events or other significant adverse events.² Please refer to the enclosed peer-reviewed paper presenting the findings of the pivotal clinical trial published in the Journal of Bone and Joint Surgery (J Bone Joint Surg Am. 2013;95:1184-92).

In issuing its PMA Approval³, the FDA concluded *“the preclinical and clinical data in this application support the reasonable assurance of safety and effectiveness of Augment® Bone Graft when used in accordance with the indications for use when compared to autograft. Based on the clinical trial results, the clinical benefits of the use of Augment® Bone Graft outweigh the risks in terms of pain and functional improvements and the elimination of harvest site complications, when used in the intended population in accordance with the directions for use, and*

² AUGMENT® Bone Graft has been used since 2011 in Australia and since 2009 in Canada. To date there have been no reported serious adverse events associated with the device.

³ FDA did not base its approval of AUGMENT® Bone Graft on radiologic findings from the pivotal study, but instead relied on the clinical outcomes.

as compared to the autograft control treatment in the same intended population. The valid scientific evidence presented in the preceding sections provides reasonable assurance that Augment® Bone Graft is a safe and effective alternative to autograft for use in arthrodesis procedures of the ankle and/or hindfoot when bone grafting procedures of the ankle and/or hindfoot are warranted.”

INSERT PHYSICIAN’S CONCLUDING STATEMENT

Example:

AUGMENT® Bone Graft should not be confused with stem cell therapies such as Trinity Elite or Bio4 DBM with mesenchymal stem cells, or with platelet-rich plasma, or with allograft or bone substitute products that may be used alone or mixed with autologous bone marrow. Stem cell therapies contain a variable mixture of proteins and cellular components with diverse and sometimes conflicting bioactivities, whereas the purified rhPDGF-BB in AUGMENT® Bone Graft is a manufactured, biosynthetic replica of endogenous PDGF using recombinant DNA technology under highly controlled, reproducible conditions. Moreover, stem cell therapies are not supported by clinical evidence and do not require FDA clearance or approval. AUGMENT® Bone Graft is the **only** FDA approved, proven alternative to autograft in hindfoot and ankle fusions.

I believe AUGMENT® Bone Graft provided clinical advantages for this patient. Based on the patient’s medical history, and other pertinent medical information contained in this letter, the use of AUGMENT® Bone Graft in the *(insert hindfoot and/or ankle)* fusion procedure was medically necessary to achieve the fusion outcome.

Thank you in advance for your kind consideration. Please feel free to contact me directly should you require additional information

Sincerely,

(Physician’s Name)
(Address)
(City), (State) (Zip)
(Phone Number)