

June 30, 2004

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Department of Health & Human Services
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Dear Dr. Salive:

Enclosed is our "formal" request for reconsideration of the previous decision requiring a surgical intervention for the Medicare Patient prior to utilization of the Exogen Bone Growth Stimulator. This formal request would seek your review of the national decision with limitation on coverage.

We strongly believe that the information that was previously submitted was reviewed and materially mis-interpreted and inaccurately reflects only an outcome of the surgically treated patient population (80%). However, in an in-depth re-analysis of the subsequent non-surgically treated patient population (20%), the highly successful heal rate of 80% proved to be clinically and statistically significant.

The issues of similarity of the products listed in the enclosed TABLE I – FDA PMA study analysis reflect that the total number of non-surgical n=55 show 80% success for the total population and for the Medicare 100% heal rate n=7.

Table I I – Medicare review for all products indicates clearly the positive results of the success rate for Exogen is superior to other approved products (EBI, Biomet, Orthofix, Orthlogic). However, these products do not have the failed surgical restriction imposed. In addition to note on data available, it appears unlikely that the competitor devices studied as high a number of total Medicare fractures as was clearly demonstrated by Exogen, yet they did not receive the surgical impediment.

Similarly, when addressing the question of Osteoporosis in the Medicare population healing rate, 74.2% again is a very clinically significant successful rate.

In the Medicare as well as general population, there is no detrimental effect on the success rate of the fracture's not having a prior surgical intervention as those with surgical intervention, 100% versus 75%, respectively.

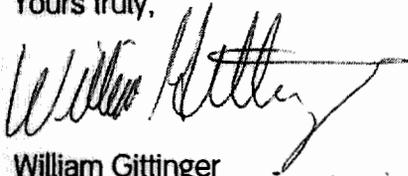
Table V – It is our assumption that CMS placed the requirement for there to have been at least one surgical intervention prior to use of Exogen based upon the observation that the majority of the patients had received at least one prior surgery. From the information available it appears that non-invasive electrical stimulator studies included similar percentages of patients and/or fractures with no prior surgical intervention, had lower core group study numbers, and would have been unlikely to demonstrate success rates for nonunion fractures in patients with no prior surgical intervention any higher than those demonstrated for Exogen Bone Healing System.

In addition, there continue to be requests for utilization of Exogen Bone Stimulators by large orthopaedic population. The need for those Medicare patients presently not eligible, who have significant co-morbidities and are not surgical candidates continues as the intervention produces the most compliance, as well as ease of utilization for time and placement. The physician concern over Medicare's restriction over FDA approved guideline continues to be communicated to Smith & Nephew in our ability to utilize this clinically effective treatment choice.

I have enclosed the DME approval document and the four DMERC's documents, demonstrating Exogen's code (E0760). I have also enclosed an article from JBJ detailing the use of low-intensity ultrasound to accelerate healing of fractures. This has also been submitted on the CD.

Enclosed are CV's of physicians willing to personally speak to reviewers.

Yours truly,



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Encls.