



National Institute for Health and Clinical Excellence Maintains Previous Recommendation for EXOGEN® Ultrasound Bone Healing System

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HOOFDDORP, THE NETHERLANDS – October 8, 2019 – Bioventus, a global leader in orthobiologic solutions, has received notice from the United Kingdom's [National Institute for Health and Clinical Excellence \(NICE\)](#) that it has updated its guidance ([MTG12](#)) regarding the use of the [EXOGEN Ultrasound Bone Healing System](#) for treatment of long bone fractures with nonunion. **EXOGEN** uses low-intensity pulsed ultrasound (LIPUS) to help stimulate the body's natural bone healing process and promote fracture healing. ¹ It also has an 86% heal rate for fractures not healing on their own² and provides 38% faster healing of fresh fractures.^{3,4}

NICE reviewed a large body of clinical evidence, and based on the findings of its external assessment centre (EAC), will maintain its recommended use specific to **EXOGEN** for treatment of long bone fractures with nonunion, which NICE defines as fractures that fail to heal after nine months.

In addition, the EAC reviewed and updated the cost parameters in its original cost modelling and found that while the cost of revision surgery has increased 25%, costs related to the use of **EXOGEN** to treat long bone fractures with nonunion has remained the same since its last published review in 2013. This has resulted in the doubling of cost savings to £2,407 (previously £1,164) per patient, compared with current care management, through avoiding surgery.

"**EXOGEN** has been a proven alternative to patients seeking to heal long bone nonunion fractures and avoid surgery for many years," said Tony Bihl, CEO, Bioventus. "This updated guidance from NICE continues its previous recommendation for use and underscores the cost savings gained by patients suffering from nonunions which provides significant economic relief to the health care system in the United Kingdom."

"**EXOGEN** has also been a proven adjunctive therapy for surgically treated fractures and has many Level-1 studies showing its positive effect on fracture healing," said Peter Shaw, MBBS DRCOG, Chief Medical Officer, Bioventus. "Both the updated clinical and economic evidence presented in this amended guidance to MTG12 strongly support a clinicians' decision to prescribe **EXOGEN** and, most importantly, provide positive outcomes for patients."

About Bioventus

Bioventus is an orthobiologics company that delivers clinically proven, cost-effective products that help people heal quickly and safely. Its mission is to make a difference by helping patients resume and enjoy active lives. The orthobiologic products from Bioventus include offerings for osteoarthritis, surgical and non-surgical bone healing. Built on a commitment to high quality standards, evidence-based medicine and strong ethical behavior, Bioventus is a trusted partner for physicians worldwide. For more information, visit www.BioventusGlobal.com and follow the company on Twitter [@Bioventusglobal](https://twitter.com/Bioventusglobal).

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EXOGEN is indicated for the non-invasive treatment of osseous defects (excluding vertebra and skull) that includes the treatment of delayed unions, nonunions,* stress fractures and joint fusion. EXOGEN is also indicated for the acceleration of fresh fracture heal time, repair following osteotomy, repair in bone transport procedures and repair in distraction osteogenesis procedures. There are no known contraindications for the EXOGEN device. Safety and effectiveness have not been established for individuals lacking skeletal maturity, pregnant or nursing women, patients with cardiac pacemakers, on fractures due to bone cancer, or on patients with poor blood circulation or clotting problems. Some patients may be sensitive to the ultrasound gel. Full prescribing information can be found in product labeling at exogen.com or by calling Bioventus Customer Care at 0800 05 16 384 (UK)/ 1800 552 197 (IR)

* A nonunion is considered to be established when the fracture site shows no visibly progressive signs of healing.

1. Azuma Y, Ito M, Harada Y, Takagi H, Ohta T, Jingushi S. Low-intensity pulsed ultrasound accelerates rat femoral fracture healing by acting on the various cellular reactions in the fracture callus. *J Bone Miner Res.* 2001; 16(4):671-680.
2. Nolte PA, van der Krans A, Patka P, Janssen IM, Ryaby JP, Albers GH Low-intensity pulsed ultrasound in the treatment of non-unions. *J Trauma.* 2001; 51(4):693-703.
3. Heckman JD, Ryaby JP, McCabe J, Frey JJ, Kilcoyne RF Acceleration of tibial fracture-healing by non-invasive, low intensity pulsed ultrasound. *J Bone Joint Surg [Am].*1994; 76(1):26-34.
4. Kristiansen TK, Ryaby JP, McCabe J, Frey JJ, Roe LR Accelerated healing of distal radial fractures with the use of specific, low-intensity ultrasound. A multicenter, prospective, randomized, double-blind, placebo controlled study. *J Bone Joint Surg [Am].* 1997; 79(7):961-973.