



PERFORMANCE PROGRAM



EXOGEN Ultrasound Bone Healing System

EXOGEN Ultrasound Bone Healing System is a non-invasive device that uses low-intensity pulsed ultrasound to accelerate the repair of certain fresh fractures* and for the treatment of established non-unions*. EXOGEN works at the fracture site by increasing upregulation of genes and expression of proteins and growth factors critical to bone healing.¹ EXOGEN works at each stage of the fracture healing process with maximum impact achieved when applied throughout the fracture healing process.²

EXOGEN Performance Program

EXOGEN is the #1 prescribed fracture healing system.³ The goal of the EXOGEN Performance Program is to provide added confidence in and adhere to EXOGEN treatment.

The EXOGEN Performance Program guarantees that radiographic healing progression will be shown in non-union fractures. If the requirements of the program are met and no healing progression is shown, out of pocket costs will be refunded to the patient.

Guidelines for Assessment of Healing Progression

Absence of healing (progression to bony union) is measured by written evaluation of X-Rays taken prior to the patient's fitting of EXOGEN ultrasound and at least 120 days (or beyond) of first use. The assessment of absence of healing progression must be made by the prescribing physician and reflected in a completed EXOGEN Performance Program evaluation form.

Program Criteria

All EXOGEN patients who have been diagnosed by a health care professional as having a non-union fracture (skull & spine fractures excluded) are eligible to participate. A non-union fracture is considered to be established when the fracture site shows no visibly progressive signs of healing.

EXOGEN has been shown to be effective when used daily for 20-minute treatments. To be eligible for the program, participants must treat their non-union fracture with EXOGEN for 20 minutes a day, for a minimum of 120 days, with a 90% minimum adherence to the treatment regimen.

The EXOGEN device contains an internal patient usage monitor that records the date, time, and duration of each treatment. This monitor will be utilized to confirm that the 90% treatment compliance threshold is met and that the device has not been modified or altered. Any devices which have been modified and/or altered will not be eligible to participate in the EXOGEN Performance Program.

Patient Claims for Refunds:

Please contact the Bioventus Customer Service at 1-800-836-4080 for assistance. All claims must be accompanied by the following:

- Prescribing HCP written assessment
- The prescribed EXOGEN device

Claims must be received at Bioventus within one year after the EXOGEN device is applied.

No refund will be made if examination of the returned EXOGEN device reveals that it has been deliberately rendered inoperative or altered in any way.

The EXOGEN Performance Program is only for FDA approved non-union fractures and the patient for whom the device was prescribed.

References: 1. EXOGEN Package Insert. 2. Azuma Y, Ito M, Harada Y, et al. 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. 3. Based on company reports for global sales Jan-Dec 2012.

* Summary of Indications for Use: The EXOGEN Ultrasound Bone Healing System is indicated for the non-invasive treatment of established non-unions* excluding skull and vertebra. In addition, EXOGEN is indicated for accelerating the time to a healed fracture for fresh, closed, posteriorly displaced distal radius fractures and fresh, closed or Grade I open tibial diaphysis fractures in skeletally mature individuals when these fractures are orthopaedically managed by closed reduction and cast immobilization.

There are no known contraindications for the EXOGEN device.

Safety and effectiveness has 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.

† A non-union is considered to be established when the fracture site shows no visibly progressive signs of healing.

Full prescribing information can be found in product labeling, at www.exogen.com or by contacting customer service at 1-800-396-4080.

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