

# Money Back If Progression of Healing Does Not Occur

# exogen<sup>®</sup>

## PERFORMANCE PROGRAM

The **EXOGEN Performance Program** is a Bioventus program that refunds patients their out-of-pocket payment for EXOGEN if progression of healing is not shown per criteria below. It is also designed to help reinforce patients' adherence to the prescribed treatment.

### Criteria

All patients who have purchased an EXOGEN designed for the treatment of a fracture, which was prescribed by a qualified physician to treat a stable, non-displaced, established nonunion, delayed union or acute fracture with a fracture gap less than 10 millimeters (excluding vertebra and skull fractures) are eligible. All patients will automatically be enrolled in the program.

Patients must treat their fracture with EXOGEN per product instructions, for a minimum of 120 days and achieve a minimum adherence of 90%.

### Evaluation

Absence of healing progression, defined as progression to bony union, is determined by the prescribing physician, comparing the patient's X-rays taken prior to using EXOGEN to one taken at 120 days or later.

The EXOGEN device contains an internal patient usage monitor that records the date, time and duration of each treatment session. This monitor will be used by Bioventus to confirm that at least 90% treatment adherence is met.

### Exclusions

- Fracture types:
  - Unstable
  - Displaced
  - Greater than 10-millimeter fracture gap
  - Vertebra and skull
  - Pathological
- Modified or altered devices
- Patient treated with EXOGEN 4000+ model
- The Performance Program is void if alternative interventions occur during the 120-day treatment period. If alternative intervention is needed, a new 120-day treatment period begins
- EXOGEN must be purchased and received by the patient directly from Bioventus
- The EXOGEN Performance Program applies only to patients for whom the device was prescribed
- Any other costs associated with the purchase – only the patient's out-of-pocket payment to Bioventus will be refunded
- Valid only in Canada

### Claims

Patients may contact a Customer Care Representative at **1-855-771-0606** for assistance. All claims must be accompanied by the following:

1. Prescribing physician's assessment: completion of the Evaluation Form
2. Letter from the patient requesting a refund (including name, address and payment method)
3. Prescribed EXOGEN device returned to Bioventus

Claims must be received by Bioventus within one year of first EXOGEN treatment date.

Bioventus reserves the right to amend or cancel the program at any time.

# Money Back If Progression of Healing Does Not Occur

# 38%

faster healing of fresh fractures<sup>1,2</sup>

# 86%

heal rate for fractures not healing on their own<sup>3</sup>

# 20<sup>min</sup>

daily treatment that easily fits into your day



Ask your doctor about

# exogen<sup>®</sup>

ultrasound bone healing system

**References:** 1. 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. 2. 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):961-73. 3. Nolte PA, van der Krans A, Patka P, Janssen IMC, Ryaby JP, Albers GHR. Low-intensity pulsed ultrasound in the treatment of nonunions. *J Trauma.* 2001;51(4):693-703.

**Summary of Indications for Use:** EXOGEN is indicated for the non-invasive treatment of all osseous defects (excluding vertebra and skull), including 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 [www.exogen.com](http://www.exogen.com), or by calling customer service at 1-855-771-0606 (toll free).

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

**Bioventus Canada ULC**

Customer Service: 1-855-771-0606 (toll-free)

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