exogen®

PERFORMANCE GUARANTEE

The EXOGEN Performance Guarantee is a Bioventus program that refunds to buyers participating in the program, the payment for EXOGEN if progression of healing (progression to bony-union) is not shown per criteria below. It is also designed to help reinforce patients' adherence for the prescribed treatment.

Criteria

Buyers of EXOGEN participating in the program are eligible when the device has been prescribed by a qualified physician to treat a stable, non-displaced, established non-union† fracture with a fracture gap less than 10 millimeters (excluding vertebra and skull fractures).

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

Evaluation

Absence of healing (progression to bony union e.g. callus formation) is determined by the prescribing physician comparing the patient's X-Rays taken prior to using EXOGEN to one taken at 120 days or beyond.

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

Exclusions

- Fracture types:
  - Fresh fractures
  - Unstable
  - Displaced
  - Greater than10 millimeters fracture gap
  - Vertebra and skull
  - Pathological
- Treatment of multiple fractures (the guarantee is only valid to treat a defined fracture)
- Modified and/or altered devices
- Guarantee is void if alternative interventions occur during the 120 day treatment period
- EXOGEN must be purchased and received directly from Bioventus
- Any other costs associated with the purchase (only the cost of the EXOGEN device will be refunded)
- Valid only in UK and Ireland

Claims

Customers may contact a Bioventus Customer Care Representative at 0800 05 16 384 (UK) or 1800 552 197 (Ireland) for assistance. All claims must be accompanied by the following:

1. Registration form to the Performance Guarantee Program sent to Bioventus within the first 30 days of the initial treatment.
2. Prescribing physician's written assessment, using the EXOGEN Claim Form
3. Prescribed EXOGEN device returned to Bioventus

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

Summary of Indications for Use

EXOGEN is indicated for the non-invasive treatment of osseous defects (excluding vertebra and skull) that includes the treatment of delayed unions, non-unions†, 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.

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

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.

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