exogen®

PERFORMANCE PROGRAM

PROCESS FLOW CHART

1 EXOGEN Patient Identification

Follow the hospital's process to request the EXOGEN device.

After ordering EXOGEN, schedule an appointment for device fitting and patient training.

Scan the code for full EXOGEN patient treatment pathway

2 EXOGEN Patient Fitting

With the patient, complete the Performance Program Registration Form. Then, send to:
PerformanceProgramUK@Bioventus.com

To ensure consistent transducer placement, mark the fracture site and confirm the treatment plan with the patient.

Encourage patient to bring the device to every follow-up visit.

3 EXOGEN Patient Follow-Up

Check the EXOGEN device's calendar to confirm minimum 90% compliance.

IF:

Treatment is still required—

Send the patient home with the device to continue treatment. Remind the patient to bring the device back to the next follow-up visit.

Patient is healed—

Note the patient compliance rate and total treatment days on the original registration form. Retain and dispose of the device as directed by the hospital's disposal procedures or process for recycling with the EXOGEN Recycling Programme.

Healing has failed to progress; an alternate treatment course is recommended—

Complete the Performance Program Evaluation Form. Retain the device and contact the Bioventus territory manager to initiate a refund request.*

**EXOGEN must be used for a minimum of 120 consecutive days in order to qualify for a refund. If full union is not achieved after 120 days of use but there is progression towards healing, the refund program does not apply.*

EXOGEN PERFORMANCE PROGRAM CRITERIA

The EXOGEN Performance Program, offered by Bioventus, refunds the payment for EXOGEN if progression of healing (progression to bony union) is not shown per the criteria below. The program is also designed to help reinforce patients' adherence with the prescribed treatment.

Criteria: EXOGEN device must be prescribed by a qualified physician to treat a stable, well-aligned fracture with a fracture gap less than 10mm (excluding vertebra and skull fractures).
Patients must treat their fracture with EXOGEN per product instructions, for a minimum of 120 consecutive days and achieve a 90% minimum level of adherence.
The EXOGEN Performance Program Registration form must be completed by both patient and physician and submitted to Bioventus within 30 days of the start of patient treatment with EXOGEN

Exclusions: The EXOGEN Performance Program is not valid when: • The fracture is one or more of the following: Unstable, malaligned, greater than 10 millimeters fracture gap, vertebral or skull, pathological • Multiple fractures locations are treated (the guarantee is valid to treat only a defined fracture) • The device has been modified and/or altered • Alternative interventions occurred during the 120-day treatment period • The device was not purchased and received directly from Bioventus • The customer did not register for the EXOGEN Performance Program within 30 days of the initial treatment • Patients for whom EXOGEN was not prescribed • Costs other than the purchaser's payment to Bioventus for EXOGEN device • Valid only in the United Kingdom • Valid for EXOGEN 250 treatment devices or where EXOGEN 150 treatment devices have been purchased privately through self-payment • Extension SD card has been provided • Claims must be received by Bioventus within one year of first EXOGEN treatment date

Indications for Use: EXOGEN Ultrasound Bone Healing System 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.

*A nonunion 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, including warnings and precautions, can be found in product labeling, or at EXOGEN.com/prescribing-information.

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Innovations For Active Healing