

EXOGEN serial number \_\_\_\_\_

### Patient Information

Patient initials \_\_\_\_\_

Date of birth (DD/MM/YYYY) \_\_\_\_\_

Date of injury (DD/MM/YYYY) \_\_\_\_\_

I authorise my treating facility and its staff, including my physician, to communicate my personal data (including sensitive health information) to Bioventus. Bioventus is permitted to collect, store and use this information to provide benefits in relation to the EXOGEN Performance Program and review the results of my EXOGEN treatment. Bioventus may store and access my personal data in countries outside of Great Britain and the EU, whose laws are less protective of personal data. Where it does so, Bioventus will ensure that the level of data protection applied meets applicable laws. I agree to be a minimum of 90% compliant with treatment over the course of a minimum of 120 consecutive treatment days, or when advised by my prescribing physician to end treatment.

Patient signature \_\_\_\_\_ Date \_\_\_\_\_



### Prescribing Physician Information

Name \_\_\_\_\_

Email address \_\_\_\_\_

Hospital name \_\_\_\_\_

Defined fracture location \_\_\_\_\_

Diagnosis  Acute  Delayed union  Nonunion

Comorbidities  Diabetes  NSAID use / chronic opioid use

Smoking  Vascular insufficiency

Obesity  Nutritional deficiency

Osteoporosis

I confirm that the fracture to be treated is:

Stable and well-aligned

Fracture gap  $\leq$  10 millimeters

Aligned with all other EXOGEN Performance Program criteria, as described on the back of this form

I understand that if all of the above boxes are not checked, refund is not eligible under the Performance Program if there is failure of progression in healing.

Physician signature \_\_\_\_\_ Date \_\_\_\_\_

## PERFORMANCE PROGRAM

The EXOGEN Performance Program is a Bioventus program that refunds the payment for EXOGEN if progression of healing (progression to bony union) is not shown per criteria below. The program is also designed to help reinforce patients' adherence with 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, well-aligned fracture with a fracture gap less than 10 millimeters (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.

### Exclusions

- Fracture types:
  - Unstable
  - Malaligned fracture
  - Greater than 10 millimeters fracture gap
  - Vertebra and skull
  - Pathological
- Treatment of multiple fractures locations (the guarantee is only valid to treat a defined fracture)
- Modified and/or altered devices
- Alternative interventions occurred during the 120-day treatment period
- EXOGEN devices that were not purchased and received directly from Bioventus
- Customers who did not register to the EXOGEN Performance Program within the first 30 days of the initial treatment
- Patient who was not prescribed treatment with EXOGEN
- Other costs associated with the purchase (only the cost of the EXOGEN device will be refunded)
- Valid only in the United Kingdom and Ireland



**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, 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 can be found in product labeling, at [EXOGEN.com](http://EXOGEN.com).

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