exogen®

ultrasound bone healing system

BONE HEALING.

PROVEN.

Over double the number of Level 1, 2 and 3 clinical studies than all competitors combined.[1]

EXOGEN has the most clinical evidence for efficacy of any licenced bone healing device worldwide.[2]

LEVEL 1 *

16 Randomized Controlled Clinical Studies[3-18]

15 fresh fracture studies[3-17]

1 nonunion study[18]

LEVEL 2 *

3 Cohort Studies[19-21]

2 fresh fracture studies[19,20]

1 nonunion study[21]

LEVEL 3 *

12 Case Controlled Studies[22-33]

1 fresh fracture study[22]

11 nonunion studies[23-33]

*The *Journal of Bone & Joint Surgery* Level of Evidence 2015 Ratings Table was used to define the level of each clinical study.

Learn more at **exogen.com**

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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 (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.

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

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.

References: **1.** Bioventus LLC. EXOGEN Studies and Competitor Studies Analysis. Data on file. RPT-000557. 2016. **2.** Bioventus LLC. Data on file. 12000.08. **3.** Dudda M, Hauser J, Muhr G, Esenwein SA. *J Trauma*. 2011;71(5):1376-80. **4.** El-Mowafi H, Mohsen M. *Int Orthop*. 2005;29(2):121-4. **5.** Emami A, Petrén-Mallmin M, Larsson S. *J Orthop Trauma*. 1999;13(4):252-7. **6.** Handolin L, Kiljunen V, Arnala I, et al. *Scand J Surg*. 2005;94(3):239-42. **7.** Handolin L, Kiljunen V, Arnala I, et al. *Arch Orthop Trauma Surg*. 2005;125(5):317-21. **8.** Heckman JD, Ryaby JP, McCabe J, Frey JJ, Kilcoyne RF. *J Bone Joint Surg Am*. 1994;76(1):26-34.**9.** Kristiansen TK, Ryaby JP, McCabe J, Frey JJ, Roe LR. *J Bone Joint Surg Am*. 1997;79(7):961-73. **10.** Leung KS, Lee WS, Tsui HF, Liu PP, Cheung WH. *Ultrasound Med Biol*. 2004;30(3):389-95. **11.** Lubbert PH, van der Rijt RH, Hoorntje LE, van der Werken C. *Injury.* 2008;39(12):1444-52. **12.** Mayr E. Rudzki MM, Rudzki M, Borchardt B, Häusser H, Rüter A. *Handchir Mikrochir Plast Chir*. 2000;32(2):115-22. **13.** Rue JP, Armstrong DW 3rd, Frassica FJ, Deafenbaugh M, Wilckens JH. *Orthopedics*. 2004;27(11):1192-5. **14.** Salem KH, Schemlz A. *Int Orthop*. 2014;38(7):1477-82. **15.** Strauss E, Ryaby JP, McCabe J. *J Orthop Trauma*. 1999;13(4):310. **16.** Tsumaki N, Kakiuchi M, Sasaki J, Ochi T, Yoshikawa H. *J Bone Joint Surg Am*. 2004;86-A(11):2399-405. **17.** Zacherl M, Gruber G, Radl R, Rehak PH, Windhager R. *Ultrasound Med Biol*. 2009;35(8):1290-7. **18.** Schofer MD, Block JE, Aigner J, Schmelz A. *BMC Musculoskelet Disord*. 2010;11:229. doi: 10.1186/1471-2474-11-229.**19.** Coughlin MJ, Smith BW, Traughber P. *Foot Ankle Int*. 2008;29(10):970-7. **20.** Gold SM, Wasserman R. *J Orthop Trauma*. 2005;19(1):10-6. **21.** Romano C, Messina J, Meani E. *Guarderni di infezione osteoarticolari*. 1999;83-93. **22.** Kinami Y, Noda T, Ozaki T. *J Orthop Sci*. 2013;18(3):410-8. **23.** Farkash U, Bain O, Gam A, Nyska M, Sagiv P. *J Orthop Surg Res*. 2015;10:72. doi: 10.1186/s13018-015-0221-9.**24.** Gebauer D, Mayr E, Orthner E, Ryaby JP. *Ultrasound Med Biol*. 2005;31(10):1391-402. **25.** Jingushi S, Mizuno K, Matsushita T, Itoman M. *J Orthop Sci*. 2007;12(1):35-41.**26.** Lerner A, Stein H, Soudry M. *Ultrasonics*. 2004;42(1-9):915-7. **27.** Mayr E, Möckl C, Lenich A, Ecker M, Rüter A. *Unfallchirurg*. 2002;105(2):108-15. **28.** Nolte PA, van der Krans A, Patka P, Janssen IM, Ryaby JP, Albers GH. *J Trauma*. 2001;51(4):693-702. **29.** Pigozzi F, Moneta MR, Giombini A, et al. *J Sports Med Phys Fitness*. 2004;44(2):173-8. **30.** Roussignol X, Currey C, Duparc F, Dujardin F. *Orthop Traumatol Surg Res*. 2012;98(2):206-13. **31.** Rutten S, Nolte PA, Guit GL, Bouman DE, Albers GH. *J Trauma*. 2007;62(4):902-8. **32.** Watanabe Y, Arai Y, Takenaka N, Kobayashi M, Matsushita T. *J Orthop Sci*. 2013;18(5):803-10. **33.** Zura R, Della Rocca GJ, Mehta S, et al. *Injury*. 2015;46(10):2036-41.

Summary of Indications for Use: EXOGEN Ultrasound Bone Healing System is indicated for the non-invasive treatment of osseous defects (excluding vertebra and skull) including:

- Treatment of delayed union and nonunion†
- Accelerating the time to heal of fresh fractures
- Treatment of stress fractures
- Accelerating repair following osteotomy
- Accelerating repair in bone transport procedures
- Accelerating repair in distraction osteogenesis procedures
- Treatment of joint fusion

† 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 www.exogen.com.

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