

Exogen Ultrasound Bone Healing System

Prior Approval

Patients 18 Years & Older

Before consideration of referral for management in secondary care, please review advice on the Remedy website (www.remedy.bnssg.icb.nhs.uk/) or consider use of advice and guidance services where available.

Section A - Policy Criteria

Funding Approval for the provision of the Exogen Ultrasound Bone Healing System will only be provided by the ICB for patients meeting criteria set out below:

1. To treat long bone fractures of the femora, tibiae and fibulae of the legs or the humerus, radius and ulnae of the arms with non-union, defined as failure to heal after 9 months.

AND

2. Surgery will be required to correct the non-union of the long bone fracture. This includes primary and revision surgery where primary surgery has failed.

AND

3. The patient would be eligible, fit and appropriate for surgery to correct the non-union.

AND

4. Patients must be able and willing to fully comply with the treatment regime of administering the device for 20 minutes per days for a minimum of 120 days either through self-management or with the help of carers.

Exclusions

Funding approval will not normally be provided where the patient meets the following criteria as the clinical evidence reviewed by NICE does not support the provision of EXOGEN:

1. The patient has delayed healing of less than 9 months post fracture, **OR**
2. The patient has non-union of a fracture in a short bone, flat bone, irregular bone, scaphoid bone or Sesamoid bone or other long bones not subject to a clinical evidence review by NICE, **OR**
3. The patient has not reached skeletal maturity, i.e., the growth plates of children or adolescents that have not fully matured or "closed", a normal finding in the x-rays of young people. **OR**
4. The patient has an unstable surgical fixation, not well aligned or where inter-fragment gap is > 10mm, **OR**

Continued below

Exclusions – Continued

5. The patient has an infection in the fracture, **OR**
6. The patient is pregnant, has a pacemaker or vertebral/skull fracture, **OR**
7. Surgery is contra-indicated for the patient for any other reason.

BRAN

For any health- related decision, it is important to consider “**BRAN**” which stands for:

- **B**enefits
- **R**isks
- **A**lternatives
- **D**o **N**othing

Benefits

Exogen is a nonsurgical approach that can treat a chronic condition and support the healing of a non-healing fracture.

Risks

The intervention will not work for all patients and will not succeed where there is no active engagement from the patient.

Alternatives

Continue to treat conditions conservatively, or through other commissioned treatments, if appropriate.

Do Nothing

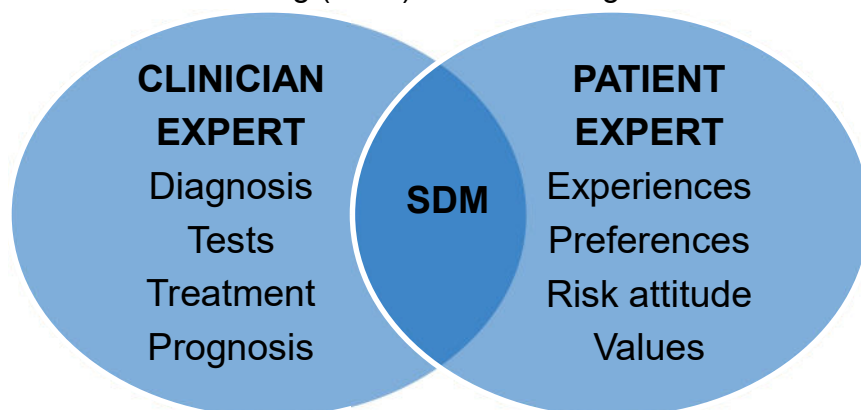
Remember, you always have the option to do nothing. Doing nothing is an equally reasonable option to doing something. Sometimes “not yet” is a good enough answer until you gather more information.



Shared Decision Making

If a person fulfils the criteria for the Use of the Exogen Ultrasound Bone Healing System, it is important to have a partnership approach between the person and the clinician.

Shared Decision Making (SDM) is the meeting of minds of two types of experts:



It puts people at the centre of decisions about their own treatment and care and respects what is unique about them. This includes their preferences and values. It means that people receiving care and clinicians delivering care can understand what is important to the other person.

The person and their clinician may find it helpful to use 'Ask 3 Questions':

1. What are my options?
2. What are the pros and cons of each option for **me**?
3. How do I get support to help me make a decision that is right for **me**?

Exogen Ultrasound Bone Healing System – Plain Language Summary

Exogen delivers low-intensity pulsed ultrasound waves to stimulate bone healing. Healing is promoted by stimulating the production of growth factors and proteins that help to remove old bone and increase the production of new bone.

The Exogen system is a hand-held device with a visual treatment-tracking calendar and history log that can help patients manage their treatment schedule.

This policy has been developed with the aid of the following references:

1. National Health Service (2010) Health A to Z: Ultrasound boosts fracture healing [online] www.nhs.uk/news
2. NICE (2019) EXOGEN ultrasound bone healing system [MTG12] (Clinical Guidance) www.nice.org.uk/
3. Reddich and Bromsgrove CCG (2014, July). *Exogen Policy* www.redditchandbromsgroveccg.nhs.uk/
4. NCBI Resources (2014) ultrasound bone healing system PMC4175405 <https://www.ncbi.nlm.nih.gov/>

Due regard

In carrying out their functions, the Bristol, North Somerset and South Gloucestershire Commissioning Policy Review Group (CPRG) are committed to having due regard to the Public Sector Equality Duty (PSED). This applies to all the activities for which the ICBs are responsible, including policy development and review.

Document Control

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Governance

Commissioning policies are assessed for their likely level of impact on BNSSG ICB and the population for which it is responsible. This determines the appropriate level of sign off. The below described the approval route for each score category.

Policy Category	Approval By
Level 1	Commissioning Policy Review Group.
Level 2	Chief Medical Officer, or Chief Nursing Officer, or System Executive Group Chair
Level 3	ICB Board

OPCS Procedure codes

Must have any of (primary only):

N/A

Support

If you would like further copies of this policy or need it in another format, such as Braille or another language, please contact the Customer Services Team on: **0117 900 2655** or **0800 073 0907** or email them on BNSSG.customerservice@nhs.net