



Cedar

Healthcare Technology Research Centre

Review report of MTG12:

EXOGEN ultrasound bone healing system for delayed-union and non-union

Cost updates: September 2018 & April 2019

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1. Background

Medical technology guidance for EXOGEN was published in January 2013. All medical technology guidance is reviewed 3 years after publication. As part of their review process, NICE requested an update on the cost analysis of the original assessment, focusing on two of the cost models developed, one for non-unions and one for delayed unions. The cost update for the non-union model was carried out by Cedar as requested by NICE in September 2018. The cost update for the delayed union model was carried out by Cedar in April 2019. For the purposes of these cost updates, no review of clinical effectiveness have taken place.

2. The technology

The EXOGEN ultrasound bone healing system, delivers low-intensity pulsed ultrasound waves with the aim of stimulating bone healing. It is thought that healing is promoted by stimulating the production of growth factors and proteins that increase the removal of old bone, increase the production of new bone and increase the rate at which fibrous matrix at a fracture site is converted to mineralised bone. Long bone fractures are suitable for treatment if the fracture is stable and well-aligned. EXOGEN is not indicated for use in fractures of the skull or vertebrae, or in children or adolescents because of their skeletal immaturity ([NICE MTG 12](#)).

3. Original objective of guidance

To assess the clinical and cost effectiveness of EXOGEN ultrasound bone healing system for long bone fractures with non-union or delayed union.

4. Current guidance recommendations

1.1 The case for adopting the EXOGEN ultrasound bone healing system to treat long bone fractures with **non-union** (failure to heal after 9 months) is supported by the clinical evidence, which shows high rates of fracture healing.

1.2 The EXOGEN ultrasound bone healing system to treat long bone fractures with **non-union** is associated with an estimated cost saving of £1164 per patient compared with current management, through avoiding surgery.

1.3 There is some radiological evidence of improved healing when the EXOGEN ultrasound bone healing system is used for long bone fractures with **delayed healing** (defined as no radiological evidence of healing after approximately 3 months). There are substantial uncertainties about the rate at which bone healing progresses without adjunctive treatment between 3 and 9 months after fracture, and about whether or not surgery would be necessary. These uncertainties result in a range of cost consequences, some cost-saving and others that are more costly than current management.

4.1. Relevant cost evidence (from the current Guidance)

5.14 For the non-union model, the External Assessment Centre's additional analysis showed average costs per patient for the EXOGEN 4000+ of £5688 and for surgery of £6852. The EXOGEN 4000+ was therefore associated with a cost saving of £1164 compared with immediate surgery for non-union. Sensitivity analysis showed that the model is relatively insensitive to changes in assumptions about the relative effectiveness of surgery compared with EXOGEN. The External Assessment Centre considered that the EXOGEN 4000+ is significantly cheaper than surgery.

5.19 The External Assessment Centre's preferred scenario for the treatment of long bone fractures with delayed healing showed a total cost for the EXOGEN Express of £3033 and a total cost for current management of £2529. The EXOGEN Express was therefore associated with a cost increase of £504 per patient compared with observation followed by surgery at non-union if necessary.

5. New evidence

5.1. Changes in technology

EXOGEN 4000+ and EXOGEN Express are no longer sold in the UK but have been replaced by a single hand held device called EXOGEN. This single unit has two different treatment options: EXOGEN 150 and EXOGEN 250. EXOGEN 150 is equivalent to EXOGEN Express and EXOGEN 250 is equivalent to EXOGEN 4000+. The new version uses an SD card to control the number of treatments performed by the device. It also has new treatment compliance capabilities such as treatment tracking calendar and treatment history log. Other changes are the inclusion of a battery with less lithium, addition of a battery door and charger. However, the manufacturer has advised that the mechanism of action of the device has not changed. The CE mark for the device remains unchanged.

The device also has a new smartphone application “EXOGEN Connects” to facilitate adherence to the treatment regime by providing information such as treatment reminders.

5.2. New studies

The EAC has not carried out a review of the literature for this report, however, the manufacturer has submitted information on a number of studies which have been published since the publication of the original guidance. This information has been submitted to NICE by the company. Additionally a number of expert advisors have provided information on published and unpublished studies directly to NICE. As these are related to the clinical evidence and not identified as being related to the cost evidence they have not been considered for this cost update.

5.3. Ongoing trials

Two ongoing trials on EXOGEN were identified:

[NCT03382483](#) Observational, Non-interventional Use of LIPUS to Mitigate Fracture Non-union in Patients at Risk (BONES). This trial is enrolling by invitation. It is expected to complete in December 2019.

[NCT02383160](#) Scaphoid Non-union and Low-intensity Pulsed Ultrasound.

This trial status is unknown and was expected to complete in December 2018.

5.4. Changes in costs in the models

In their original submission, the company provided a de novo cost analysis for EXOGEN. Two cost models were submitted, 1 for non-union and 1 for delayed healing. For the non-union model, additional analyses were undertaken and the model updated to reflect this. For the delayed union model Birmingham Brunel EAC made several corrections and changes to the model and estimated results for 8 scenarios that reflected different rates of healing, relative risk and persistent benefits of EXOGEN. Of these a preferred scenario (known as model 1A) was identified and used in the NICE cost evidence. All of the models developed are detailed together with the inputs for the final model in the Assessment Report which was used as part of the development for [MTG12](#).

As part of the NICE review process, the costs for both the non-union model and the preferred delayed union model as included in the economic assessment of EXOGEN require updating. **Table 1** provides the costs that were used in the **non-union model** for the original cost assessment, together with updated costs which have been included in a model updated in September 2018. **Table 2** provides the costs used in the **delayed-union model** for the original cost assessment, together with updated costs which have been included in a model updated in April 2019.

Table 1. Non-Union Model inputs

Input	Original source	Original figure	Updated source	Updated figure
EXOGEN				
EXOGEN 250 (replaces EXOGEN 4000+)	Personal Communication Smith & Nephew (2012)	£2,562.50	Personal Communication Bioventus (2018)	£2,562.50
Surgery				
Bed stay	HES Main procedures & characteristics 2013-2014 W28.1 Application of internal fixation to bone. Mean length of stay 4.9 days	£1,184.28	HES Main procedures & characteristics 2017-2014 W28.1 Application of internal fixation to bone. Mean length of stay 7 days	£1,691.83
3 hours surgery	Source not stated	£957	As original inflated to 2016 prices (last available) using the Hospital & Community Health Services Pay & Prices Index (pay & prices).	£1,057.86
1 pre-op prophylaxis antibiotic	BNF	£14.50	BNF (updated September 2018)	£11.25
Long IM nail	NICE CG124	£1,175.40	As original inflated to 2017 prices using the Hospital & Community Health Services Pay & Prices Index (prices).	£1,432.68
Iliac bone graft	Additional 20 mins theatre time St John (2003). Cost of surgery source not stated	£106.33	As original inflated to 2016 prices (last available) using the Hospital & Community Health Services Pay & Prices Index (pay & prices).	£117.54
Total cost for surgery used in Model		£3,437	Total updated surgery costs	£4,311.16
GP visit				
	Curtis L (2010). Unit Costs of Health and Social Care 2010. Personal Social Services Research Unit. Table 10.8b: General Practitioner - unit costs. Per clinic consultation lasting 17.2 minutes, excluding direct care staff costs, without qualification costs.	£41	Curtis L (2017). Unit Costs of Health and Social Care 2017. Personal Social Services Research Unit. Table 10.3b: General Practitioner - unit costs. Per clinic consultation lasting 9.22 minutes, excluding direct care staff costs, without qualification costs.	£37
Outpatient visit				
Outpatient visit	NHS Reference Costs 2012-2013 NHS Trust Outpatient Attendance 110T Trauma and Orthopaedic: Trauma	£137	NHS Reference Costs 2016-2017 NHS Trust Outpatient Attendance 110 Trauma and Orthopaedic: Trauma	£119.19
Cost of infection (major) staged revision)				

Removal of implant & debridement	(3 hours surgery - Expert opinion) NICE CG124 Cost of surgery source not stated.	£957	As original inflated to 2016 prices (last available) using the Hospital & Community Health Services Pay & Prices Index (pay & prices).	£1,057.86
Temporary fixator	Personal communication Smith & Nephew	£1,050	As original inflated to 2017 prices using the Hospital & Community Health Services Pay & Prices Index (prices).	£1,279.83
Min 21 days bed stay	NICE CG124: NHS trust communication infection control guidelines	£5,075.49	As original.	£5,075.49
IV antibiotics Flucloxacillin 1g powder £4.90/vial, 8g/day)	NHS prescription services May 2012	£823.00	BNF (updated September 2018) (10 vials at £34.50 = £3.45 each)	£579.60
3 hours surgery	Expert opinion	£957	As original inflated to 2016 prices (last available) using the Hospital & Community Health Services Pay & Prices Index (pay & prices).	£1,057.86
Antibiotic prophylaxis		£14.50	BNF (updated September 2018)	£11.25
Synthetic bone graft and/or DBM	Data on file idata Orthopaedic biomaterials report	£448	As original inflated to 2016 prices (last available) using the Hospital & Community Health Services Pay & Prices Index (pay & prices).	£495.21
Simple external ring fixator	Personal communication Smith & Nephew	£2,520	As original inflated to 2017 prices using the Hospital & Community Health Services Pay & Prices Index (prices).	£3,071.59
Average days bed stay	HES Main procedures & characteristics. W30.4 application of external ring fixation to bone NEC, mean LoS = 11.1 bed days. Cost of bed days from NICE CG124	£2,682.76	HES Main procedures & characteristics 2017-2018. W30.4 application of external ring fixation to bone NEC mean LoS = 10 bed days. Cost of bed days from NICE CG124	£2,416.90
Total of the costs for staged revision		£14,527	Total of updated costs for staged revision	£15,045.59
Cost of superficial infection	Stated as HRG code HD23 – unable to verify	£3,108.68	As original inflated to 2017 prices using the Hospital & Community Health Services Pay & Prices Index (prices).	£3,789.52
Input for above	(14527x0.51)+(3108.68x0.49)	£8,932.02	(15,045.59x0.51)+(3,789.52x0.49)	£9,530.12
Drugs (for infection)	Expert opinion	£50	As original inflated to 2017 prices using the Hospital & Community Health Services Pay & Prices Index (prices).	£60.94
Cost of non-union surgery				
Bed stay	HES Main procedures & characteristics 2013-2014 W28.1 Application of internal fixation to bone. Mean length of stay 4.9 days	£1,184.28	As original	£1,691.83

3 hours surgery	Source not stated	£957	As original inflated to 2016 prices (last available) using the Hospital & Community Health Services Pay & Prices Index (pay & prices).	£1,057.86
1 pre-op prophylaxis antibiotic	BNF	£14.50	BNF (updated September 2018)	£11.25
Long IM nail	NICE CG124	£1,175.40	As original inflated to 2017 prices using the Hospital & Community Health Services Pay & Prices Index (prices).	£1,432.68
Iliac bone graft	Additional 20 mins theatre time St John (2003). Cost of surgery source not stated	£106.33	As original inflated to 2016 prices (last available) using the Hospital & Community Health Services Pay & Prices Index (pay & prices).	£117.54
Total cost for surgery used in Model		£3,437	Total updated surgery costs	£4,311.16
Cost of X-ray	Expert opinion	£70	As original inflated to 2017 prices using the Hospital & Community Health Services Pay & Prices Index (prices).	£85.32
Wheelchair (month)	Curtis L (2010). Unit Costs of Health and Social Care 2010. Personal Social Services Research Unit: Table 7.2: NHS Wheelchairs Unit cost per active user per chair per year.	£14	Curtis L (2017) Unit costs of Health & Social Care 2017. Personal Social Services Research Unit	£16.25
Crutches (month)	Based on expert opinion from 2005, inflated to 2010 prices	£35	As original inflated to 2017 prices using the Hospital & Community Health Services Pay & Prices Index (prices).	£37.22
Physio (month)	NICE guideline 124 Combination of Physiotherapy and Occupational therapy Health Economics report - Appendix H table 98 8.5 hours per patient p. 572 Band 5 Physio 2007 PSSRU costs	£200	Cost of Physiotherapist and Occupational Therapist updated from: Curtis L (2017) Unit costs of Health & Social Care 2017. Personal Social Services Research Unit	£280.50
Table 2. Delayed-Union Model inputs				
Input	Original source	Original figure	Updated source	Updated figure
EXOGEN				
EXOGEN 150 (replaces EXOGEN Express)	Personal Communication Smith & Nephew (2012)	£999.00	Personal Communication Bioventus (2018), confirmed as correct April 219.	£1,250.00
GP visit				
	Curtis L (2010). Unit Costs of Health and Social Care 2010. Personal Social Services Research Unit.	£41	Curtis L (2018). Unit Costs of Health and Social Care 2018. Personal Social Services Research Unit.	£28

Table 10.8b: General Practitioner - unit costs. Per clinic consultation lasting 17.2 minutes, excluding direct care staff costs, without qualification costs.		Table 10.3b: General Practitioner - unit costs. Per clinic consultation lasting 9.22 minutes, excluding direct care staff costs, without qualification costs.	
Outpatient visit			
Outpatient visit	NHS Reference Costs 2012-2013 NHS Trust Outpatient Attendance 110T Trauma and Orthopaedic: Trauma	£137	Department of Health. NHS Reference Costs 2017-18 NHS Trust Outpatient Attendance 110 Trauma and Orthopaedic: Trauma
Cost of infection (major) staged revision			
Removal of implant & debridement	(3 hours surgery - Expert opinion) NICE CG124 Cost of surgery source not stated.	£957	As original inflated to 2018 Curtis L (2018). Unit Costs of Health and Social Care 2018. (pay & prices).
Temporary fixator	Personal communication Smith & Nephew	£1,050	As original inflated to 2018 prices using Curtis L (2018). Unit Costs of Health and Social Care 2018 (prices).
Min 21 days bed stay	NICE CG124: NHS trust communication infection control guidelines	£5,075.49	As original.
IV antibiotics Flucloxacillin 1g powder £4.90/vial, 8g/day)	NHS prescription services May 2012	£823.00	BNF (updated March 2019) (10 vials at £34.50 = £3.45 each)
3 hours surgery	Expert opinion	£957	As original inflated to 2018 prices using Curtis L (2018). Unit Costs of Health and Social Care 2018 (pay & prices).
Antibiotic prophylaxis (Vancomycin 1g)		£14.50	BNF (updated March 2019)
Synthetic bone graft and/or DBM	Data on file idata Orthopaedic biomaterials report	£448	As original inflated to 2018 prices using Curtis L (2018). Unit Costs of Health and Social Care 2018 (pay & prices).
Simple external ring fixator	Personal communication Smith & Nephew	£2,520	As original inflated to 2018 prices using Curtis L (2018). Unit Costs of Health and Social Care 2018 (prices).
Average days bed stay	HES Main procedures & characteristics. W30.4 application of external ring fixation to bone NEC, mean LoS = 11.1 bed days. Cost of bed days from NICE CG124	£2,682.76	HES Main procedures & characteristics 2017-2018. W30.4 application of external ring fixation to bone NEC mean length of stay = 10 bed days. Cost of bed days from NICE CG124
Total of the costs for staged revision		£14,527	Total of updated costs for staged revision
Cost of superficial infection	Stated as HRG code HD23 – unable to verify	£3,108.68	As original inflated to 2018 prices using Curtis L (2018). Unit Costs of Health and Social Care 2018. (prices).
Input for above	(14527x0.51)+(3108.68x0.49)	£8,932.02	(15,239.82x.51)+(3,883.85x0.49)

Drugs (for infection)	Expert opinion	£50	As original inflated to 2018 prices using Curtis L (2018). Unit Costs of Health and Social Care 2018 (prices).	£62.47
Cost of non-union surgery				
Bed stay	HES Main procedures & interventions 2013-2014 W28.1 Application of internal fixation to bone. Mean length of stay 4.9 days	£1,184.28	HES Main procedures & interventions 2017-2018 W28.1 Application of internal fixation to bone. Mean length of stay 7 days. Cost of bed days from NICE CG124	£1,691.83
3 hours surgery	Source not stated	£957	As original inflated to 2018 using Curtis L (2018). Unit Costs of Health and Social Care 2018 (pay & prices).	£1,091.97
1 pre-op prophylaxis antibiotic (Vancomycin 1g)	BNF	£14.50	BNF (updated March 2019)	£12.50
Long IM nail	NICE CG124	£1,175.40	As original inflated to 2018 prices using Curtis L (2018). Unit Costs of Health and Social Care 2018 (prices).	£1,468.50
Iliac bone graft	Additional 20 mins theatre time St John (2003). Cost of surgery source not stated	£106.33	As original inflated to 2018 prices using Curtis L (2018). Unit Costs of Health and Social Care 2018 (pay & prices).	£121.33
Total cost for surgery used in Model		£3,437	Total updated surgery costs	£4,386.13
Cost of X-ray	Expert opinion	£70	As original inflated to 2018 prices using Curtis L (2018). Unit Costs of Health and Social Care 2018 (prices).	£87.46
Wheelchair (month)	Curtis L (2010). Unit Costs of Health and Social Care 2010. Personal Social Services Research Unit: Table 7.2: NHS Wheelchairs Unit cost per active user per chair per year.	£14	Curtis L (2018) Unit costs of Health & Social Care 2018. Personal Social Services Research Unit: Table 7.2: NHS Wheelchairs Unit cost per active user per chair per year (£202/12)	£16.83
Crutches (month)	Based on expert opinion from 2005, inflated to 2010 prices	£35	As original inflated to 2018 prices using Curtis L (2018). Unit Costs of Health and Social Care 2018 (prices).	£43.73
Physio (month)	NICE guideline 124. Combination of Physiotherapy and Occupational therapy. Health Economics report - Appendix H table 98. 8.5 hours per patient p. 572 Band 5 Physio 2007 PSSRU costs	£200	Cost of Physiotherapist and Occupational Therapist updated from: Curtis L (2018) Unit costs of Health & Social Care 2018. Personal Social Services Research Unit. Table 12 PT/OT hourly cost £35 x 8.5 hours	£297.50

5.5. Notes on model inputs

The EAC which carried out this update (Cedar) was not the EAC which carried out the work on the original Assessment Report (Birmingham Brunel EAC). As such Cedar does not have access to some background knowledge and information regarding decisions made on the chosen inputs in the original model. Where there is a lack of clarity regarding the source or choice of the original inputs, rather than provide inappropriate alternatives, inputs have been inflated using Hospital & Community Health Services Pay & Prices Index.

Cost of surgery: this has been used throughout the model using a cost of £319/hour. It is unclear where this cost originated and it has therefore been inflated as above.

Length of surgery: Expert opinion was used to illicit length of surgery for some inputs. This has been assumed to remain accurate.

Temporary fixator: The original cost for this was £1,050 and originated via a personal communication with the company. The current company has been unable to provide an updated cost, and [REDACTED]. As it is unclear from the EAC report or cost model why the original price was used and not taken from NHS reference costs the current EAC has inflated the original rather than risk using an unsuitable input.

Cost per bed day: The original model used a cost of £241.69 per bed day taken from NICE CG124. A length of stay of 21 days is used for one input, however the EAC has been unable to identify the source used for this estimate. Therefore Cedar have assumed this data remains accurate and have used the original inputs.

Synthetic bone graft – Data on file idata Orthopaedic biomaterials report. The current EAC do not have access to this data to verify it or access updates and have assumed it remains accurate.

Simple external ring fixator: The original cost for this was £2,520 and originated via a personal communication with the company. The current manufacturer has been unable to provide an updated costs and therefore the current EAC has inflated the original input.

Cost of superficial infection: This is stated as HRG code HD23 in the original model inputs. There are 3 codes under HD23 and the current EAC was unable to identify how the cost used in the model was calculated from the data in NHS reference costs. The current EAC therefore inflated the original input.

Drugs: Expert opinion was used to determine this cost in the original model but no details were provided. The current EAC have therefore inflated the original cost.

Cost of X-ray: Expert opinion was used to determine this cost in the original model but no details were provided. The current EAC have therefore inflated the original cost.

Crutches: This was based on expert opinion from 2005 and inflated to 2010 prices in the original model. The current EAC further inflated these costs in the updated model.

5.6. Additional economic information

For the April 2019 cost update on delayed-union, one of the expert advisors provided economic data from a local audit. These data suggested a shorter length of stay than is used in the updated delayed-union model. The patients included were described as patients treated for non-union so are likely to be outside the scope of the model being updated at that stage. However, the definition of non-union in the audit is unclear and it is therefore not possible to determine if they are the same used in the NICE Guidance. In order to see if they would affect the costs of EXOGEN for delayed-union they were considered in the updated model. If the inputs suggested (operating time 3 hours (same as current) and total length of stay = 4.49 days (currently 7 days)) are applied to the current model, the cost of EXOGEN would be

associated with a cost increase of £668 per patient compared with current management as the changes would be applied to both the EXOGEN plus surgery and surgery groups. Therefore even if the costs suggested in the audit are included EXOGEN is still cost incurring in the group of patients treated for delayed union.

The audit results suggest that the financial benefit for that institution in using EXOGEN is £1164.00 per patient. However no cost model is provided and as noted above, the patient group may be different than that included in the models considered here.

The audit data was not available at the time of the cost update for non-union and were therefore not considered.

Additionally, one economic evaluation was identified by the expert advisors (Tarride et al 2017), however this included patients with fresh tibial fractures and so is outside the scope of this review.

5.7. Results from updated changes

Using the updated costs detailed above Cedar re-ran the models used in the economic assessment as part of the development of the Guidance on EXOGEN.

Non-union

In the original Guidance, the use of EXOGEN ultrasound bone healing system to treat long bone fractures with **non-union** was associated with an estimated cost saving of £1,164 per patient compared with current management, through avoiding surgery. Using the updated inputs the use of the EXOGEN ultrasound bone healing system to treat long bone fractures with **non-union** is associated with an increased cost saving of £2,407 per patient compared with current management, through avoiding surgery. The change in cost from £1,164 to £2,407 is primarily due to the increase in length of stay following surgery from 4.9 days to 7 days (W28.1 Application of internal fixation to bone). It is unclear why this increase in bed days has occurred.

Delayed-union

The original Guidance found the use of EXOGEN ultrasound bone healing system to treat long bone fractures with **delayed-union** was associated with an estimated cost increase of £504 per patient compared with current management. Using the updated inputs the use of the EXOGEN ultrasound bone healing system to treat long bone fractures with delayed-union is associated with a cost increase of £628 per patient compared with current management. The increase in incremental cost from £504 to £628 per patient is due to the increase in cost of the EXOGEN 150 device. If all other cost parameters are updated as detailed but the original cost of the EXOGEN Express of £999 is used, the EXOGEN ultrasound bone healing system to treat long bone fractures with **delayed-union** would be associated with a cost increase of £377 per patient compared with current management.

6. Conclusion

Using updated costs in the original model as detailed above, the use of the EXOGEN ultrasound bone healing system to treat long bone fractures with **non-union** is associated with a cost saving of £2,407 per patient compared with current management, through avoiding surgery. The use of the EXOGEN ultrasound bone healing system to treat long bone fractures with **delayed-union** is associated with a cost increase of £628 per patient compared with current management.

7. References

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