NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Centre for Health Technology Evaluation

Review decision

Review of MTG30: XprESS multi-sinus dilation system for treating chronic sinusitis

This guidance was issued in December 2016.

1. Review decision

Transfer the guidance to the 'static guidance list.' The guidance remains valid and is designated as static guidance. Literature searches are carried out every 5 years to check whether any of the Medical Technologies Guidance on the static list should be flagged for review.

2. Original objective of guidance

To assess the case for adoption of XprESS multi-sinus dilation system for treating chronic sinusitis

3. Current guidance

1.1 The case for adopting the XprESS multi-sinus dilation system for treating uncomplicated chronic sinusitis after medical treatment has failed is supported by the evidence. Treatment with XprESS leads to a rapid and sustained improvement in chronic symptoms, fewer acute episodes and improved quality of life which is comparable to functional endoscopic sinus surgery (FESS).

1.2 XprESS should be considered in patients with uncomplicated chronic sinusitis who do not have severe nasal polyposis. In these patients, XprESS works as well as FESS, is associated with faster recovery times, and can more often be done under local anaesthesia.

1.3 Cost modelling indicates that XprESS is cost saving compared with FESS when treatment is done using local anaesthetic in an outpatient setting. The estimated saving per patient is £152, assuming that 80% of treatments are done this way, FESS takes 60 minutes and the device cost for XprESS is £820. By adopting this technology, the NHS in England may save around £7.4 million a year by 2020. Estimated savings are mainly achieved through the shift of treatment from operating theatre to outpatient setting.

4. Rationale

There is new clinical efficacy evidence for the technology that is supportive of the recommendations in MTG30. Costs are unchanged.

5. New evidence

The search strategy from the original assessment report was re-run. References from 2016 onwards were reviewed. Additional searches of clinical trials registries were also carried out and relevant guidance from NICE and other professional bodies was reviewed to determine whether there have been any changes to the care pathways. The company was asked to submit all new literature references relevant to their technology along with updated costs and details of any changes to the technology itself or the CE marked indication for use for their technology. The results of the literature search are discussed in the 'Summary of evidence and implications for review' section below. See Appendix 2 for further details of ongoing and unpublished studies.

5.1 Technology availability and changes

The technology is still available and has not undergone any changes. The technology has however changed its name to the XprESS LoProfile ENT dilation system to reflect its widened indications to include eustachian tube dilation. This indication was added to the company's CE mark in April 2017. The company have informed NICE that no changes have been made to the price of the technology.

5.2 Clinical practice

The NICE pathway is sinusitis

There have been no changes to the pathway since the guidance was published

Responses were received from 4 experts, 2 declared a financial interest. 3 had direct experience with the technology, the remaining expert managed patients who had received treatment using XprESS. None of the experts were aware of different versions of the technology, and all were aware of similar competing technologies. Those with barotrauma were identified as a group who had specifically benefitted from the use of the technology. 2 experts considered that the care pathway or evidence had not changed such that an update would result in a different recommendation. One considered the

evidence needs fresh consideration but that this was being addressed in the forthcoming EPOS2020 position paper.

5.3 NICE facilitated research

None.

5.4 New studies

Evidence searches conducted at NICE identified 1 study published since the guidance of potential relevance to the scope.

Jenks et al (2017) is a publication written by the EAC and NICE reporting on the findings from the MTG, so contained no new evidence.

The company submitted five new studies (4 published, 1 unpublished):

Levy et al (2016) is a systematic review and meta-analysis of paranasal sinus balloon dilation. This involved a qualitative and quantitative analysis of 17 and 11 studies respectively. The included studies used XprESS and other (reported and unreported) balloon catheter devices (BCD). The balloon catheter devices were used alone or in combination with endoscopic sinus surgery (ESS), in an office, operation room or combination of the 2 settings. Variously revision procedures and/or nasal polyposis were included. Due to this there was significant heterogeneity in the included studies meaning that the numbers included in the actual meta-analyses was a much-reduced subset. The results showed a post BCD improvement in SNOT and Lund-Mackay scores and a non-significant change in SNOT score in favour of BCD compared to ESS. The results showed significant heterogeneity as evident through high I2 scores. The study was considered by the EAC and not included in the original assessment report and so does not constitute new evidence.

Soler et al (2017) was seen previously by the EAC in abstract form and excluded on the basis that the information contained was limited making critical appraisal difficult, and on expert opinion that sinus surgery is rarely conducted in children. The study reports on 50 paediatric patients (2 to 21 years old), 33 of whom were aged 2 to 12 at 4 centres in the USA. The study is non-comparative and reports that all sinus dilations attempted (98 maxillary, 30 frontal, and 29 sphenoid sinuses) were successful with no complications. There was a significant improvement in sinus and nasal quality of life survey (SN-5) at 6 months compared to baseline overall and across all domains for all patients and those aged 2 to 12 years old ($p<0.0001$). When the SN5 was reported for the 11, 2 to 12 years olds who received balloon treatment only (60% of patients overall had adjunctive procedures most commonly adenoidectomy) the overall score remained significant ($p<0.0001$) and on all domains ($p<0.005$). Changes at 6 months for SNOT 22 and Rhinosinusitis Symptom Inventory (RSI) scores were also significant overall and across all

domains (p≤0.002). The study was funded by the company and the principal author was a consultant for the company.

Bhikhazi et al (ENR white paper, publication details unclear) involved XprESS used in a hybrid procedure alongside other office based sinonasal surgical procedures. The study involved 100 participants aged 18 or over enrolled from 7 clinical centres in the US between April 2016 and March 2017. Mean improvement in SNOT-22 score was determined using 1 sided hypothesis testing with a clinically meaningful difference of 8.9 ($p<0.025$, 90% power). Differences over time were determined using a saturated means model with SNOT-22 score as the dependent variable, a fixed effect for visit, and an unstructured covariate structure to account for multiple measurements per patient. Mean change in overall RSI and SNOT-22 scores from baseline at 1, 3, 6, and 12 months were all significant ($p<0.0001$). Changes in RSI scores at 12 months were all significant compared to baseline ($p<0.001$). Three of the study authors were consultants for the company and 1 was an employee.

Meyer et al (2018) looked at the effectiveness of the technology in treating Eustachian Tube Function, a different indication considered outside of scope.

Blissett et al., is an unpublished manuscript costing the adoption of XprESS in the NHS based on verbal responses from 3 NHS consultants in 3 hospitals alongside data from the NICE economic evaluation. The study estimates a cost saving of between £126 and £235 per patient.

5.5 Cost update

There have been no changes to the price of the technology. The EAC did a bottom up costing for FESS, the comparator, which consisted primarily of theatre and staff costs, with some minor consumable costs. It is very unlikely that these costs will have fallen, and certainly not of a magnitude to reverse the recommendation for XprESS.

Experts were largely of the opinion that the device would not save money, with one saying a successful business case was dependent on increased day case surgery and a move towards local anaesthesia in an ambulatory setting. This is consistent with the recommendations.

6. Summary of new information and implications for review

The new information supports the original guidance and does not alter the recommendations.

7. Implementation

The adoption and impact team did not develop any adoption support resources for this topic.

They did respond during internal consultation to inform us that they are not aware of any overlaps or conflicts with ongoing or published appraisals or guidance.

8. Equality issues

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others.

No equalities issues were identified in MTG30.

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Appendix 1 – explanation of options

If the published Medical Technologies Guidance needs updating NICE must select one of the options in the table below:

Options	**Consequences**	**Selected – 'Yes/No'**
Amend the guidance and consult on the review proposal	The guidance is amended but the factual changes proposed have no material effect on the recommendations.	No
Amend the guidance and do not consult on the review proposal	The guidance is amended but the factual changes proposed have no material effect on the recommendations.	No
Standard update of the guidance	A standard update of the Medical Technologies Guidance will be planned into NICE's work programme.	No
Update of the guidance within another piece of NICE guidance	The guidance is updated according to the processes and timetable of that programme.	No

If the published Medical Technologies Guidance does not need updating NICE must select one of the options in the table below:

Options	**Consequences**	**Selected – 'Yes/No'**
Transfer the guidance to the 'static guidance list'	The guidance remains valid and is designated as static guidance. Literature searches are carried out every 5 years to check whether any of the Medical Technologies Guidance on the static list should be flagged for review.	Yes
Defer the decision to review the guidance	NICE will reconsider whether a review is necessary at the specified date.	No
Withdraw the guidance	The Medical Technologies Guidance is no longer valid and is withdrawn.	No

Appendix 2 – supporting information

Relevant Institute work

None

References

Registered and unpublished trials

Trial name and registration number	Details
None	

References

Bikhazi N, et al. (2019) Office-based balloon sinus dilation and sinonasal procedures using local anesthesia: a prospective 100-patient observational registry. ENT J White Paper.

Jenks, M., Willits, I., Turner, E.E et al. (2017) The XprESS Multi-Sinus Dilation System for the Treatment of Chronic Sinusitis: A NICE Medical Technology Guidance. Appl Health Econ Health Policy 15: 567–582. https://doi.org/10.1007/s40258-017-0337-7

Levy, J. M., Marino, M. J., & McCoul, E. D. (2016). Paranasal Sinus Balloon Catheter Dilation for Treatment of Chronic Rhinosinusitis: A Systematic Review and Meta-analysis. Otolaryngology–Head and Neck Surgery, 154(1): 33–40. https://doi.org/10.1177/0194599815613087

Meyer, T., O'Malley, E., Schlosser, R et al. (2018). A Randomized Controlled Trial of Balloon Dilation as a Treatment for Persistent Eustachian Tube Dysfunction With 1-Year Follow-Up. Otology & Neurotology, 39 (7): 894-902.

Soler ZM, et al. (2017) Prospective, multicenter evaluation of balloon sinus dilation for treatment of pediatric chronic rhinosinusitis. Int Forum Allergy Rhinol.7:221–229.