

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health Technology Appraisal

Mepolizumab for previously treated severe chronic rhinosinusitis with nasal polyps

Draft scope

Draft remit/appraisal objective

To appraise the clinical and cost effectiveness of mepolizumab within its marketing authorisation for treating severe chronic rhinosinusitis with nasal polyps.

Background

Nasal polyps, also referred to as nasal polyposis, are growths inside the nasal passages and sinuses, which usually only cause problems if they are large or grow in clusters, causing an obstruction. They often occur as a result of chronic rhinosinusitis. This is a condition in which the lining of the sinuses (air-filled spaces behind the nose, eyes and cheeks) becomes inflamed. It is characterised by symptoms including nasal congestion, discharge, decreased or lost sense of smell, facial pain and headache, which may last many years¹. Additional symptoms of nasal polyps include a blocked nose, snoring and obstructive sleep apnoea (which can disturb sleep)^{1,2}. Chronic rhinosinusitis is defined as persistence of symptoms for more than 12 weeks³. In severe cases, quality of life can be significantly affected³. Sinus or nasal inflammation and polyps on a CT scan or nasal endoscopy are diagnostic of chronic rhinosinusitis with nasal polyps¹.

The cause of nasal polyposis is unknown, but multiple factors are thought to contribute. These include the presence of fungus in the sinuses, likelihood of allergic response and aspirin sensitivity⁴. Chronic rhinosinusitis is common, affecting around 10% of the UK population³. Among all people with chronic rhinosinusitis, around 25% to 30% have nasal polyps¹. Up to 40% of people with nasal polyps have asthma of varying severity⁵.

The goal of treatment is to control inflammation and reduce the size of polyps or eliminate them. Drug treatments are usually the first approach and include intranasal corticosteroids. If this is not effective, an oral corticosteroid, such as prednisolone, either alone or with a nasal spray may be tried. Injectable corticosteroids may be used if the nasal polyps are severe. Surgery is frequently needed, but it does not always provide a permanent solution because polyps tend to recur⁵. There is no published NICE guidance for treating nasal polyps.

The technology

Mepolizumab (Nucala, GlaxoSmithKline) is an anti-interleukin-5 humanised monoclonal antibody. By reducing the effects of interleukin-5, mepolizumab causes a reduction in circulating eosinophils, a type of white blood cell involved in allergic response and tissue inflammation. Mepolizumab is administered subcutaneously.

Mepolizumab does not currently have a marketing authorisation in the UK for treating severe chronic rhinosinusitis with nasal polyps. It does have a marketing authorisation in the UK for treating people aged 6 years and above with previously

treated severe eosinophilic asthma. Mepolizumab has been studied in clinical trials in comparison with placebo in adults with severe bilateral nasal polyps, as an add on to mometasone furoate with best standard care for nasal polyps.

Intervention(s)	Mepolizumab as an add-on to maintenance treatment
Population(s)	People with previously treated chronic rhinosinusitis with nasal polyps
Comparators	Established clinical management without mepolizumab, including surgery.
Outcomes	<p>The outcome measures to be considered include:</p> <ul style="list-style-type: none"> • nasal congestion/obstruction • sense of smell • polyp size • need for surgery/ corticosteroids/ antibiotics • adverse effects of treatment • health-related quality of life.
Economic analysis	<p>The reference case stipulates that the cost effectiveness of treatments should be expressed in terms of incremental cost per quality-adjusted life year.</p> <p>The reference case stipulates that the time horizon for estimating clinical and cost effectiveness should be sufficiently long to reflect any differences in costs or outcomes between the technologies being compared.</p> <p>Costs will be considered from an NHS and Personal Social Services perspective.</p> <p>The availability of any commercial arrangements for the intervention, comparator and subsequent treatment technologies will be taken into account.</p>

<p>Other considerations</p>	<p>If the evidence allows, the following subgroups will be considered. These include:</p> <ul style="list-style-type: none"> • People who have type 2 inflammation co-morbidities (such as asthma and atopic dermatitis) • People who have had more than 1 previous surgery for chronic rhinosinusitis with nasal polyps • People with aspirin or steroid sensitivity/intolerance <p>Guidance will only be issued in accordance with the marketing authorisation. Where the wording of the therapeutic indication does not include specific treatment combinations, guidance will be issued only in the context of the evidence that has underpinned the marketing authorisation granted by the regulator.</p>
<p>Related NICE recommendations and NICE Pathways</p>	<p>Related Technology Appraisals:</p> <p>Mepolizumab for treating severe refractory eosinophilic asthma (2017) NICE technology appraisal guidance 431. Reviewed January 2020.</p> <p>Appraisals in development (including suspended appraisals)</p> <p>Omalizumab for treating chronic rhinosinusitis with nasal polyps [ID1650] NICE technology appraisal guidance. Publication date to be confirmed</p> <p>Dupilumab for treating chronic rhinosinusitis with nasal polyps [ID1179]. NICE technology appraisal guidance. Suspended.</p> <p>Mepolizumab for treating severe eosinophilic asthma [ID3750] NICE technology appraisal guidance. Publication expected Feb 2021</p> <p>Related Guidelines:</p> <p>Corticosteroid-eluting bioabsorbable stent or spacer insertion during endoscopic sinus surgery to treat chronic rhinosinusitis (2016) NICE interventional procedures guidance 551. Review date March 2019.</p> <p>XprESS multi sinus dilation system for treating chronic sinusitis (2016) NICE Medical technologies guidance 30. Review date 2023.</p> <p>Balloon catheter dilation of paranasal sinus ostia for chronic sinusitis (2008) NICE Interventional procedures guidance 273. Review date unknown.</p> <p>Related NICE Pathways:</p> <p>Ear, nose and throat conditions (2013, updated 2018) NICE</p>

	pathway.
Related National Policy	<p>The NHS Long Term Plan, 2019. NHS Long Term Plan</p> <p>NHS England (2018/2019) NHS manual for prescribed specialist services (2018/2019). Chapter 59. Highly specialist allergy services (adults and children)</p> <p>Department of Health and Social Care, NHS Outcomes Framework 2016-2017: Domains 2 and 3. https://www.gov.uk/government/publications/nhs-outcomes-framework-2016-to-2017</p> <p>NHS England (2013) B09/S/b 2013/14 NHS standard contract for specialised allergy services (all ages)</p>

Questions for consultation

What treatments would be given before maintenance therapy in the NHS for chronic rhinosinusitis with nasal polyps?

What maintenance treatments are currently used in clinical practice?

Would mepolizumab always be used with mometasone furoate? If not, what else would it be used with?

Have all relevant comparators for mepolizumab been included in the scope?

Does mepolizumab have the potential to be an alternative to surgery in this population?

Would mepolizumab be used in people for whom surgery is unsuitable?

What is current maintenance therapy in people for whom surgery is unsuitable?

Would maintenance treatment differ depending on the number of previous surgeries?

Are the outcomes listed appropriate?

Are the subgroups suggested in 'other considerations' appropriate? Are there any other subgroups of people in whom mepolizumab is expected to be more clinically effective and cost effective or other groups that should be examined separately?

Where do you consider mepolizumab will fit into the existing NICE pathway, [ear, nose and throat conditions](#)?

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. Please let us know if you think that the proposed remit and scope may need changing in order to meet these aims. In particular, please tell us if the proposed remit and scope:

- could exclude from full consideration any people protected by the equality legislation who fall within the patient population for which mepolizumab will be licensed;
- could lead to recommendations that have a different impact on people protected by the equality legislation than on the wider population, e.g. by making it more difficult in practice for a specific group to access the technology;
- could have any adverse impact on people with a particular disability or disabilities.

Please tell us what evidence should be obtained to enable the Committee to identify and consider such impacts.

Do you consider mepolizumab to be innovative in its potential to make a significant and substantial impact on health-related benefits and how it might improve the way that current need is met (is this a 'step-change' in the management of the condition)?

Do you consider that the use of mepolizumab can result in any potential significant and substantial health-related benefits that are unlikely to be included in the QALY calculation?

Please identify the nature of the data which you understand to be available to enable the Appraisal Committee to take account of these benefits.

To help NICE prioritise topics for additional adoption support, do you consider that there will be any barriers to adoption of this technology into practice? If yes, please describe briefly.

NICE intends to appraise this technology through its Single Technology Appraisal (STA) Process. We welcome comments on the appropriateness of appraising this topic through this process. (Information on the Institute's Technology Appraisal processes is available at <http://www.nice.org.uk/article/pmq19/chapter/1-Introduction>).

References

1. Stevens W, Schleimer R, and Kern R. Chronic Rhinosinusitis with Nasal Polyps. *J Allergy Clin Immunol Pract*. 2016 Jul-Aug; 4(4): 565–572.
2. NHS [Nasal Polyps](#). Accessed 08 September 2020
3. Ear Nose and Throat (ENT) UK [Chronic Rhinosinusitis](#). Accessed 12 August 2020.
4. Chaaban M, Walsh E, and Woodworth B. Epidemiology and differential diagnosis of nasal polyps. *Am J Rhinol Allergy*. 2013 Nov-Dec; 27(6): 473–478.
5. Ear Nose and Throat (ENT) UK [Nasal Polyps](#). Accessed 12 August 2020.