

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Proposed Health Technology Appraisal

Dupilumab for treating chronic rhinosinusitis with nasal polyps

Draft scope (pre-referral)

Draft remit/appraisal objective

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

Background

Chronic rhinosinusitis 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 years. People with the condition may have nasal polyps, which is also referred to as nasal polyposis. If nasal polyps are also present, the condition is referred to as chronic rhinosinusitis with nasal polyps (CRSwNP). These are growths inside the nasal passages and sinuses, which usually only cause problems if they are large or grow in clusters, causing an obstruction. Additional symptoms of nasal polyps include a blocked nose, snoring and obstructive sleep apnoea (which can disturb sleep).

The cause of chronic rhinosinusitis with nasal polyposis is unknown, but multiple factors including allergies and fungal infection, are known to be contributory factors¹. Sinusitis is common, affecting around 15% of the UK population². Among all people with chronic rhinosinusitis, around 25% to 30% have chronic rhinosinusitis with nasal polyps³ of which 20 – 40% are likely to also have asthma⁴.

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 may sometimes be needed, but it does not always provide a permanent solution because polyps tend to recur⁵.

The technology

Dupilumab (Dupixent) is a fully human monoclonal antibody which blocks both interleukin-4 (IL-4) and interleukin-3 (IL-3) signalling. It is administered by subcutaneous injection. Dupilumab does not currently have a marketing authorisation in the UK for treating chronic rhinosinusitis with nasal polyps. It has been studied in clinical trials in adults with chronic rhinosinusitis with

nasal polyps who have had previous treatment with systemic corticosteroids and/or prior surgery. In these trials, dupilumab was administered in combination with mometasone furoate nasal spray and was compared with a placebo administered with mometasone furoate nasal spray.

Intervention(s)	Dupilumab
Population(s)	People with previously treated chronic rhinosinusitis with nasal polyps.
Comparators	<ul style="list-style-type: none"> Established clinical management without dupilumab, including surgery.
Outcomes	<p>The outcome measures to be considered include:</p> <ul style="list-style-type: none"> nasal congestion/obstruction sense of smell sinus opacifications need for surgery 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>
Other considerations	<p>If the evidence allows, the following subgroups will be considered:</p> <ul style="list-style-type: none"> People who have asthma <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>
Related NICE recommendations and NICE	<p>Related Technology Appraisals:</p> <p>Dupilumab for treating moderate to severe atopic</p>

Pathways	<p>dermatitis after topical treatments. NICE technology appraisal 534. Review date August 2021.</p> <p>Related Guidelines:</p> <p>Sinusitis (acute): antimicrobial prescribing (2017). NICE guideline [NG79] Review date October 2020.</p> <p>Related Interventional Procedures:</p> <p>Intranasal phototherapy for allergic rhinitis (2018). NICE interventional procedures guidance [IPG616].</p> <p>XprESS multi sinus dilation system for treating chronic sinusitis (2016) NICE Medical technologies guidance [MTG30]</p> <p>Corticosteroid-eluting bioabsorbable stent or spacer insertion during endoscopic sinus surgery to treat chronic rhinosinusitis (2016) NICE Interventional procedures guidance [IPG551]</p> <p>Balloon catheter dilation of paranasal sinus ostia for chronic sinusitis (2008) NICE Interventional procedures guidance [IPG273]</p> <p>Related NICE Pathways:</p> <p>Ear, nose and throat conditions (2013, updated 2018) NICE pathway</p>
Related National Policy	<p>NHS England (2018/2019) NHS manual for prescribed specialist services (2018/2019) Chapter 59. Highly specialist allergy services (adults and children)</p> <p>https://www.england.nhs.uk/wp-content/uploads/2017/10/prescribed-specialised-services-manual-2.pdf</p> <p>Department of Health and Social Care, NHS Outcomes Framework 2016-2017 (published 2016): Domains 2 and 3. https://www.gov.uk/government/publications/nhs-outcomes-framework-2016-to-2017</p>

Questions for consultation

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

Which treatments are considered to be established clinical practice in the NHS for chronic rhinosinusitis with nasal polyps?

What is established clinical management for people who have had previous treatment for chronic rhinosinusitis with nasal polyps?
Are the outcomes listed appropriate?

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

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

Where do you consider dupilumab will fit into the existing NICE pathway, "Nose conditions – [Nasal obstruction and Sinusitis](#)"?

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 dupilumab 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 dupilumab 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 dupilumab 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/pmg19/chapter/1-Introduction>).

References

1. 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.
2. Scadding GK, Durham SR, Mirakian NS *et al*. BSACI guidelines for the management of rhinosinusitis and nasal polyposis. *Clinical & Experimental Allergy* 2008;38(2):260–275
3. Stevens W, Schleimer R, and Kern R. Chronic Rhinosinusitis with Nasal Polyps. *J Allergy Clin Immunol Pract*. 2016 Jul-Aug; 4(4): 565–572.
4. Ear Nose and Throat (ENT) UK [Nasal Polyps](#). Accessed 23 November 2018
5. Bachert C, Mannent L, Naclerio RM *et al*. Effect of subcutaneous dupilumab on nasal polyp burden in patients with chronic sinusitis and nasal polyposis: a randomized clinical trial. *Journal of the American Medical Association* 2016 2;315(5):469-479.