NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Proposed Health Technology Appraisal

Omalizumab for treating chronic rhinosinusitis with nasal polyps

Draft scope (pre-referral)

Draft remit/appraisal objective

To appraise the clinical and cost effectiveness of omalizumab 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, 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). In severe cases, quality of life can be significantly affected.

The cause of chronic rhinosinusitis with nasal polyposis is unknown, but multiple factors are thought to contribute[1]. Among all people with chronic rhinosinusitis, around 25% to 30% have chronic rhinosinusitis with nasal polyps[2] of which up to 60% may also have asthma of varying severity[3].

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 recur[4].

The technology

Omalizumab (Xolair) is a recombinant DNA-derived humanised monoclonal antibody that selectively binds to human immunoglobulin E (IgE). It is administered by subcutaneous injection.

Omalizumab does not currently have a marketing authorisation in the UK for treating chronic rhinosinusitis with nasal polyps. It does have a marketing authorisation for treating allergic asthma in adults, and children above 6 years

of age. It has been studied in clinical trials in adults with chronic rhinosinusitis with nasal polyps who have had previous treatment with nasal mometasone spray. In these trials, omalizumab was compared with a placebo subcutaneous injection. Omalizumab, and the placebo subcutaneous injection, were administered in addition to background treatments in the trials.

Intervention(s)	omalizumab
Population(s)	People with previously treated chronic rhinosinusitis with nasal polyps
Comparators	Established clinical management without omalizumab, including surgery.
Outcomes	The outcome measures to be considered include: • nasal congestion/obstruction • sense of smell • polyp size • need for surgery/ corticosteroids/ antibiotics • adverse effects of treatment • health-related quality of life.
Economic analysis	The reference case stipulates that the cost effectiveness of treatments should be expressed in terms of incremental cost per quality-adjusted life year. 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. Costs will be considered from an NHS and Personal Social Services perspective.

Other considerations	If the evidence allows, the following subgroups will be considered: • People who have type 2 inflammation co-morbidities (such as asthma and atopic dermatitis) • People who have had more than 1 previous surgery for CRSwNP 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.
Related NICE recommendations and NICE Pathways	Related Technology Appraisals: Omalizumab for previously treated chronic spontaneous urticaria (2015) NICE technology appraisal guidance 339 Omalizumab for treating severe persistent allergic asthma (2013) NICE technology appraisal guidance 278 Appraisals in development (including suspended appraisals) Dupilumab for treating chronic rhinosinusitis with nasal polyps ID1179. NICE technology appraisal guidance. Publication date to be confirmed Related Guidelines: Sinusitis (acute): antimicrobial prescribing (2017). NICE guideline [NG79] Review date October 2020. Related Interventional Procedures: Intranasal phototherapy for allergic rhinitis (2018). NICE interventional procedures guidance [IPG616]. XprESS multi sinus dilation system for treating chronic sinusitis (2016) NICE Medical technologies guidance [MTG30] Corticosteroid-eluting bioabsorbable stent or spacer insertion during endoscopic sinus surgery to treat chronic rhinosinusitis (2016) NICE Interventional

	procedures guidance [IPG551] Balloon catheter dilation of paranasal sinus ostia for chronic sinusitis (2008) NICE Interventional procedures guidance [IPG273] Related NICE Pathways: Ear, nose and throat conditions (2013, updated 2018) NICE pathway http://pathways.nice.org.uk/
Related National Policy	The NHS Long Term Plan, 2019. NHS Long Term Plan NHS England (2018/2019) NHS manual for prescribed specialist services (2018/2019). Chapter 59. Highly specialist allergy services (adults and children) 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 NHS England (2013) B09/S/b 2013/14 NHS standard contract for specialised allergy services (all ages)

Questions for consultation

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

Which treatments would omalizumab be used in combination with?

What is established clinical management for people who have had previous treatment for chronic rhinosinusitis with nasal polyps?

Are the outcomes listed appropriate?

Does omalizumab 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 omalizumab is expected to be more clinically effective and cost effective or other groups that should be examined separately?

Where do you consider omalizumab 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 omalizumab 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 omalizumab 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 omalizumab 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).

NICE has published an addendum to its guide to the methods of technology appraisal (available at https://www.nice.org.uk/Media/Default/About/what-we-do/NICE-guidance/NICE-technology-appraisals/methods-guide-addendum-cost-comparison.pdf), which states the methods to be used where a cost comparison case is made.

- Would it be appropriate to use the cost comparison methodology for this topic?

- Is the new technology likely to be similar in its clinical efficacy and resource use to any of the comparators?

- Is the primary outcome that was measured in the trial or used to drive the model for the comparator(s) still clinically relevant?

- Is there any substantial new evidence for the comparator technology/ies that has not been considered? Are there any important ongoing trials reporting in the next year?

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. Stevens W, Schleimer R, and Kern R. Chronic Rhinosinusitis with Nasal Polyps. J Allergy Clin Immunol Pract. 2016 Jul-Aug; 4(4): 565–572.

3. Ear Nose and Throat (ENT) UK Nasal Polyps. Accessed 27 September 2019

4. 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.