NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health Technology Evaluation

Dupilumab for treating severe chronic rhinosinusitis with nasal polyposis

Final scope

Remit/evaluation objective

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

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. Rhinosinusitis is considered chronic when symptoms persist for more than 12 weeks. 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 factors. Chronic rhinosinusitis is common, affecting around 10% of the UK population. Among all people with chronic rhinosinusitis, around 25% to 30% have CRSwNP. It is estimated that there were 476 cases of CRSwNP per 100,000 people in England in 2018, with prevalence highest in men aged 65 to 84 years.

The goal of treatment is to control inflammation and reduce the size of polyps or eliminate them. CRSwNP may present as a distinct entity or alongside comorbidities such as asthma, non-steroidal anti-inflammatory drug-exacerbated respiratory disease and fungal allergy. Each case may have a slightly different treatment pathway but generally treatments can include saline irrigation as well as intranasal, oral or injectable corticosteroids. Surgery is frequently needed, but it does not always provide a permanent solution because polyps tend to recur.⁵

The technology

Dupilumab (Dupixent) is indicated as an add-on therapy with intranasal corticosteroids for the treatment of adults with severe CRSwNP for whom therapy with systemic corticosteroids and/or surgery do not provide adequate disease control.

Intervention(s)	Dupilumab as add on to maintenance treatment
Population(s)	People with previously treated severe chronic rhinosinusitis with nasal polyps
Subgroups	If the evidence allows, the following subgroups will be considered:
	People who have asthma
	People who are ineligible for surgery
	People who are ineligible for systemic corticosteroids
	 People with non-steroidal anti-inflammatory drug- exacerbated respiratory disease
Comparators	Established clinical management without dupilumab, including surgery
Outcomes	The outcome measures to be considered include:
	nasal congestion and/orobstruction
	sense of smell
	sinus opacifications
	need for surgery
	need for systemic corticosteroids
	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.
	The availability of any commercial arrangements for the intervention, comparator and subsequent treatment technologies will be taken into account.

Other considerations

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

Related technology appraisals:

Mepolizumab for treating severe chronic rhinosinusitis with nasal polyps (terminated appraisal) (2022) NICE technology appraisal guidance 847. Review date not stated

Omalizumab for treating chronic rhinosinusitis with nasal polyps (terminated appraisal) (2021) NICE technology appraisal guidance 678. Review date not stated

<u>Dupilumab for treating chronic rhinosinusitis with nasal polyps</u> (terminated appraisal) (2020) NICE technology appraisal guidance 648. Review date not stated

Related technology appraisals in development:

Corticosteroid-releasing bioabsorbable stent or spacer insertion during endoscopic sinus surgery to treat chronic rhinosinusitis. NICE interventional procedures guidance. Publication expected February 2025

Related NICE guidelines:

Sinusitis (acute): antimicrobial prescribing (2017) NICE guideline NG79. Review date not stated

Related interventional procedures:

<u>Cryotherapy for chronic rhinitis</u> (2023) NICE interventional procedures guidance 771

Corticosteroid-eluting bioabsorbable stent or spacer insertion during endoscopic sinus surgery to treat chronic rhinosinusitis (2016) NICE interventional procedures guidance 551

Combined endoscopic and laparoscopic removal of colonic polyps (2014) NICE interventional procedures guidance 503

<u>Balloon catheter dilation of paranasal sinus ostia for chronic sinusitis</u> (2008) NICE interventional procedures guidance 273

<u>XprESS multi sinus dilation system for treating chronic sinusitis</u> (2016) NICE medical technologies guidance 30

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Related National	The NHS Long Term Plan (2019) NHS Long Term Plan
Policy	NHS England (2023) Manual for prescribed specialist services (2023/2024) Chapter 59: specialist allergy services (adults and children).

References

- 1. Chaaban M, Walsh E, and Woodworth B (2013). Epidemiology and differential diagnosis of nasal polyps. Am J Rhinol Allergy 27(6): 473–478
- 2. Ear Nose and Throat (ENT) UK (2016) <u>Commissioning guide: Chronic Rhinosinusitis</u>
- 3. Stevens W, Schleimer R, and Kern R (2016). Chronic Rhinosinusitis with Nasal Polyps. J Allergy Clin Immunol Pract. 4(4): 565–572.
- 4. Benson V, Fu Q, Yang S, et al. (2023) Real-world characterisation of patients with chronic rhinosinusitis with nasal polyps with and without surgery in England. Clinical Otolaryngology 48(4): 680–88.
- 5. Bachert C, Mannent L, Naclerio RM et al 2016. 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 315(5): 469-479.