Northern Treatment Advisory Group

Northern (NHS) Treatment Advisory Group

Treatment Appraisal: Decision Summary

Date	8th December 2020 (updated June 2021)
Appraisal & Details	**Dupilumab and Omalizumab for chronic rhinosinusitis with nasal polyps.** The Northern (NHS) Treatment Advisory Group considered an appraisal of Dupilumab and Omalizumab for chronic rhinosinitis with nasal polyps in adults.
Recommendation	**The Northern (NHS) Treatment Advisory Group <u>does not</u> recommend the use of Dupilumab or Omalizumab for chronic rhinosinusitis with nasal polyps (CRSwNP).** The effectiveness of omalizumab and dupilumab in preventing or reducing the need for surgery is yet to be clearly established. Additional, large-scale studies are needed to confirm whether biologics represent a valid alternative to primary or revision sinus surgery. NTAG noted that NICE TA648 - Dupilumab for treating chronic rhinosinusitis with nasal polyps was a terminated appraisal. NICE was unable to make a recommendation about the use in the NHS of dupilumab for treating chronic rhinosinusitis with nasal polyps because Sanofi did not provide an evidence submission. The company confirmed that it does not intend to make a submission for the appraisal because there is unlikely to be sufficient evidence that the technology is a cost-effective use of NHS resources in this population. NTAG noted that NICE TA678 - Omalizumab for treating chronic rhinosinusitis with nasal polyps was a terminated appraisal. NICE is unable to make a recommendation about the use in the NHS of omalizumab for treating chronic rhinosinusitis with nasal polyps because Novartis Pharmaceuticals did not provide an evidence submission. The company has confirmed that it does not intend to make a submission for the appraisal because the technology will not be launched in the UK for treating this indication. Also no published economic analyses on the use of omalizumab or dupilumab in the treatment of CRSwNP were identified.
Clinical evidence summary	The efficacy of omalizumab in the treatment of CRSwNP was evaluated in two identical randomised, controlled trials (POLYP 1 and POLYP 2. In both studies, omalizumab was superior to placebo for the co-primary outcomes of improvements from baseline in NPS and weekly average NCS at Week 24. Similar results were found for the secondary outcomes, NSS, SNOT-22 and UPSIT. Although the proportion of patients requiring rescue medication or sinonasal surgery was lower in omalizumab groups the overall numbers in the pooled population were too low to draw meaningful conclusions about the benefit of omalizumab in these areas. The efficacy of dupilumab was evaluated in two randomised, controlled trials (SINUS-24 and SINUS-52. In both studies, dupilumab was superior to placebo for the co-primary outcomes of improvements from baseline in NPS and NC at

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	Week 24. In key secondary outcomes, TSS, SNOT-22, and UPSIT showed significantly greater improvement with dupilumab compared to placebo. Subjects continuing dupilumab through to week 52, showed continued improvement for almost all outcomes, with a significant reduction of SCS use and need for sinonasal surgery versus placebo.
Safety	The overall safety profile of omalizumab is well established, and in patients with CRSwNP omalizumab was well tolerated with no new or unexpected safety concerns identified. The overall safety profile of dupilumab is well established, and dupilumab was well tolerated in patients with CRSwNP with no significant new or unexpected safety concerns identified.
Patient Perspective	Long-term treatment options are limited for patients with CRSwNP not responding to standard treatment and/or surgery. Recently, two biologics (omalizumab (Xolair®) and dupilumab (Dupixent®▼)) have been approved as an add-on therapy with inhaled nasal corticosteroids for the treatment of adults with sever CRSwNP. However the effectiveness of omalizumab and dupilumab in preventing or reducing the need for surgery is yet to be clearly established. Additional, large-scale studies are needed to confirm whether biologics represent a valid alternative to primary or revision sinus surgery.
Cost analysis summary	Omalizumab and dupilumab are high cost compared to conventional treatment with inhaled nasal corticosteroids, systemic corticosteroids or surgery, and patients are likely to require ongoing treatment with them. There is no robust, published information on how many patients would be eligible for treatment with omalizumab or dupilumab in the NTAG region. Chronic rhinosinusitis (CRS) affects around 10% of the UK adult population, and up to 30% of these have CRS with nasal polyps (CRSwNP; 2,325 per 100,000 people in England). In 2018/19, there were ~18,000 admissions for CRSwNP (~30 per 100,000). If omalizumab or dupilumab were reserved for use in 15% of severely affected patients who remain uncontrolled after surgery this would equate to 2,700 patients (5 per 100,000). Based on the list price, the annual cost of omalizumab per patient would be between £1,665 and £26,642, and for dupilumab the cost per patient would be £16,445. Based on the list price and an NTAG adult population of 2.6 million the total annual cost for 130 patients would be between £216,000 and £3,464,000 for omalizumab depending on the dose, and £2,138,000 for dupilumab.
Financial impact PbR: Tariff excluded	Nil expected as not recommended by NTAG. Omalizumab and dupilumab are CCG-commissioned specified High Cost Drugs (PBR-excluded).