NICE National Institute for Health and Care Excellence

Dupilumab: local formulary information

Implementation support
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Contents

Purpose

Medicines recommended in NICE technology appraisals should be adopted into a local formulary if clinically appropriate and relevant to the services provided by the organisation (see NICE's medicines practice guideline on developing and updating local formularies). This template supports that process by summarising information that local formulary decision-making groups are likely to need.

Local groups have their own format of a multi-criteria decision tool, reflecting their needs. This local formulary template does not mandate any change or variation from those decision tools. Local groups can adapt this template for their own circumstances and use it to help them complete their local documents.

Medicine name and product details

Dupilumab (Dupixent, Sanofi) is a recombinant human IgG4 monoclonal antibody that inhibits interleukin-4 and interleukin-13 signalling. It is licensed as add-on maintenance treatment for uncontrolled chronic obstructive pulmonary disease (COPD) characterised by raised blood eosinophils in adults who are taking an inhaled corticosteroid plus a long-acting beta2-agonist (LABA) and a long-acting muscarinic antagonist (LAMA), or a LABA and a LAMA if inhaled corticosteroids are not appropriate. It is administered by subcutaneous injection. The details of the licensed indication and dosage schedule are available in the summary of product characteristics for dupilumab.

National guidance and priorities

NICE's technology appraisal guidance TA1142 states:

1.1 Dupilumab can be used as an add-on maintenance treatment option for uncontrolled chronic obstructive pulmonary disease (COPD) with raised blood eosinophils in adults if:

- they are having:
  - triple therapy including an inhaled corticosteroid, a long-acting beta2-agonist (LABA) and a long-acting muscarinic antagonist (LAMA), or
  - double therapy including a LABA and a LAMA if inhaled corticosteroids are not appropriate, and
- the company provides dupilumab according to the commercial arrangement.

Uncontrolled COPD is defined as 1 or more severe exacerbations or 2 or more moderate exacerbations in the previous 12 months. Raised blood eosinophils is defined as a blood eosinophil count of 0.3 x 10^9 cells per litre or more (300 cells per microlitre or more).

1.2 Assess response to dupilumab at 12 months. Stop dupilumab if, compared with the 12 months before starting it, the number of severe exacerbations:

- is higher, or
- is the same, and the number of moderate exacerbations is higher.

1.3 These recommendations are not intended to affect treatment with dupilumab that was started in the NHS before this guidance was published. People having treatment outside this recommendation may continue without change to the funding arrangements in place for them before this guidance was published, until they and their NHS healthcare professional consider it appropriate to stop.

NICE also recommends dupilumab for treating severe asthma with type 2 inflammation that is inadequately controlled in people 12 years and over.

NHS England's business case guidance for COPD biologics provides integrated care board commissioners, clinical and service leads with the evidence base, alongside cost and health benefit information to support the case for change. This can be used to develop local business cases.

NHS England's commissioning strategies for the treatment of COPD provides strategies that optimise COPD care across the pathway.

Clinical effectiveness

Evidence for the effectiveness of dupilumab in COPD comes from 2 double-blind, placebo controlled, randomised phase 3 trials: BOREAS (n=939) and NOTUS (n=935). The studies had similar designs and the same primary outcome (annualised rate of moderate or severe exacerbations of COPD). Moderate exacerbations were defined as those that resulted in treatment with a systemic glucocorticoid, an antibiotic agent, or both. Severe exacerbations were defined as those that led to hospitalisation or an emergency medical care visit or that resulted in death.

Secondary endpoints were assessed at up to 52 weeks. St. George's Respiratory Questionnaire (SGRQ) scores range from 0 to 100, with lower scores indicating a better quality of life, with the minimum clinically important difference being 4 points. Evaluating Respiratory Symptoms in COPD (E-RS-COPD) scores range from 0 to 40, with lower scores representing less severe respiratory symptoms.

BOREAS included an additional 12-week safety follow-up period. NOTUS was stopped early because it met its primary end point at a planned interim analysis.

The intervention in both studies was dupilumab (as add-on) 300 mg given subcutaneously once every 2 weeks, compared with matched placebo. The populations of the studies were very similar, that is, people with moderate to severe COPD with an eosinophil count of at least 0.3 x 10^9 cells per litre who had at least 2 moderate exacerbations, or 1 severe exacerbation, within the past year. People had to have been taking an inhaled corticosteroid plus a LABA and a LAMA (triple therapy), or a LABA and a LAMA if inhaled corticosteroids were not appropriate. Enrolment of people who currently smoke was capped at 30% in both studies.

For TA1142, data from the trials was pooled to increase statistical power. The results of the analysis are summarised in table 1. Dupilumab reduced the adjusted annualised exacerbation rate compared with placebo by a mean 0.37 events per year (37 events per 100 patients), from 116 events to 79 events per 100 patients.

Table 1 Effects of dupilumab on the primary and secondary outcomes in BOREAS, NOTUS and the pooled analysis

Outcome compared with placebo	BOREAS	NOTUS	Pooled analysis
Primary outcome	–	–	–
Adjusted annualised rate of moderate or severe exacerbations per year (Rate ratio [95% CI])	0.70 (0.58 to 0.86, p=0.0005)	0.66 (0.54 to 0.82, p=0.0002)	0.69 (0.60 to 0.79, p<0.0001)
Secondary outcomes	–	–	–
Change from baseline in prebronchodilator FEV_1 at week 12. (Least-Squares mean difference [95% CI])	+83 ml (42 to 125, p<0.0001)	+82 ml (40 to 124, p=0.0001)	+83 ml (53 to 112, p<0.0001)
Change from baseline in prebronchodilator FEV_1 at week 52. (Least-Squares mean difference [95% CI])	+83 ml (38 to 128, p=0.0003)	+62 ml (11 to 113, p=0.0182)	+73 ml (40 to 107, p<0.0001)
Change from baseline to week 52 in SGRQ total score. (Least-Squares mean difference [95% CI])	−3.4 (-5.5 to −1.3, p=0.0017)	−3.4 (-5.8 to -0.9, p=0.0068)	−3.4 (−5.0 to −1.8, p<0.0001)
Percentage of patients with a change of at least 4 points in the SGRQ total score at week 52. (OR [95% CI])	51.5 with dupilumab; 43.1 with placebo (OR 1.4 [1.1 to 1.9, p=0.0089])	51.4 with dupilumab; 46.5 with placebo (OR 1.2 [0.9 to 1.6, p=0.3329])	51.4 with dupilumab; 44.6 with placebo (OR 1.3 [1.1 to 1.6, p=0.0089])
Change in Evaluating Respiratory Symptoms in COPD (E-RS–COPD) total score from baseline to week 52. (Least-squares mean difference [95% CI])	−1.1 (−1.8 to −0.4, p=0.001)	−0.6 (−1.4 to 0.2, no p value reported)	−0.9 (−1.4 to −0.4, p=0.0006)

Abbreviations: CI, confidence interval; E-RS–COPD, evaluating respiratory symptoms in

chronic obstructive pulmonary disease; FEV_1,forced expiratory volume in 1 second; OR, odds ratio; SGRQ, St. George's Respiratory Questionnaire.

Safety

See the summary of product characteristics for dupilumab for contraindications, warnings, precautions for use and reported adverse effects.

Treatment-emergent adverse events

Treatment-emergent adverse events are safety events arising after starting treatment. In BOREAS and NOTUS combined, 938 people had dupilumab and 934 people had placebo. Table 2 shows all treatment-emergent adverse events experienced by 5% or more of participants in either group, or by at least 2% in the dupilumab group with an incidence of at least 1% higher than the placebo group, by preferred term.

Table 2 Pooled analysis of treatment-emergent adverse events

System organ class	preferred term	Dupilumab (n=938)	Placebo (n=934)
All	any	676 (72.1)	663 (71.0)
Infections and infestations	any	402 (42.9)	406 (43.5)
Infections and infestations	nasopharyngitis	73 (7.8)	69 (7.4)
Infections and infestations	COVID-19	65 (6.9)	66 (7.1)
Infections and infestation	upper respiratory tract infection	50 (5.3)	57 (6.1)
Infections and infestations	urinary tract infection	28 (3.0)	18 (1.9)
Nervous system disorders	any	108 (11.5)	108 (11.6)
Nervous system disorders	headache	73 (7.8)	62 (6.6)
Vascular disorders	any	54 (5.8)	73 (7.8)
Respiratory, thoracic and mediastinal disorders	any	123 (13.1)	133 (14.2)

System organ class	preferred term	Dupilumab (n=938)	Placebo (n=934)
Respiratory, thoracic and mediastinal disorders	chronic obstructive pulmonary disease	50 (5.3)	64 (6.9)
Gastrointestinal disorder	any	135 (14.4)	130 (13.9)
Gastrointestinal disorder	gastritis	19 (2.0)	7 (0.7)
Musculoskeletal and connective tissue disorders	any	126 (13.4)	121 (13.0)
Musculoskeletal and connective tissue disorders	back pain	42 (4.5)	29 (3.1)
Injury, poisoning and procedural complications	any	122 (13.0)	139 (14.9)
Injury, poisoning and procedural complications	accidental overdose	57 (6.1)	62 (6.6)
Cardiac disorders	any	56 (6.0)	62 (6.6)

The summary of product characteristics for dupilumab reports injection site reactions in people with COPD. Anaphylactic reaction, angioedema, serum sickness and serum sickness-like reactions have also been reported after administration of dupilumab.

Ocular reactions have been reported in people having dupilumab for conditions other than COPD, predominantly atopic dermatitis. These include conjunctivitis, allergic conjunctivitis, eye pruritus, blepharitis, dry eye, keratitis and ulcerative keratitis. See the MHRA drug safety update on dupilumab (Dupixent): risk of ocular adverse reactions and need for prompt management for further information.

Place in the treatment pathway

The following fundamentals of COPD care should be addressed, if relevant, at each review and before referring to a specialist or considering biological treatment:

- offer treatment and support to stop smoking – see the NICE guideline on tobacco: preventing uptake, promoting quitting and treating independence
- offer pneumococcal vaccination and an annual influenza vaccination – see the UKHSA Green Book
- offer pulmonary rehabilitation if indicated. See NICE's early value assessment on digital technologies to deliver pulmonary rehabilitation programmes for adults with COPD for technologies that can be used in the NHS while more evidence is generated. These can be used to deliver pulmonary rehabilitation programmes for adults who cannot have or do not want face-to-face pulmonary rehabilitation
- co-develop a personalised self-management plan. See NICE's early value assessment on digital technologies to support self-management of COPD for technologies that can be used in the NHS while more evidence is generated. These provide components of self-management such as education, symptom tracking, exercise and remote monitoring
- optimise treatment for comorbidities – see NICE's guideline on multimorbidity
- assess inhaler technique and provide support to improve technique. This may include considering alternative devices if the person finds them easier to use.

See the COPD checklist for a summary of the actions to take after a confirmed diagnosis of COPD. NICE's guidance on chronic obstructive pulmonary disease in over 16s: diagnosis and management and the visual summary: treatment algorithm provide an overview of the treatment pathway.

Consider dupilumab as an option for people having optimised inhaled therapy when all the fundamentals of COPD care have been addressed. As per the technology appraisal, this is people who:

- are already taking an inhaled corticosteroid plus a LABA and a LAMA (triple therapy), or a LABA and a LAMA (double therapy) if inhaled corticosteroids are not appropriate

- have uncontrolled COPD defined as 1 or more severe exacerbations, or 2 or more moderate exacerbations in the previous 12 months. NICE's guideline on COPD defines a moderate exacerbation as one that requires treatment with systemic corticosteroids or antibiotics, and a severe exacerbation as one that requires admission to hospital
- have a raised blood eosinophil level defined as a blood eosinophil count of 0.3 x 10^9 cells per litre or more.

NICE recommends other treatment options for people on optimised inhaled therapy:

- azithromycin for people who do not smoke, are having optimised non-pharmacological and inhaled therapies, are vaccinated, have been referred to pulmonary rehabilitation (if appropriate) and continue to have frequent, prolonged or severe exacerbations (see recommendation 1.2.45 in NICE's guideline on COPD). In February 2026, this was an off-label use of azithromycin (see NICE's information on prescribing medicines)
- roflumilast for people with COPD with chronic bronchitis if it is severe, the person had 2 or more exacerbations in the previous 12 months despite triple inhaled therapy, and treatment is started by a specialist (see NICE's technology appraisal guidance on roflumilast for treating COPD).

Treatment with dupilumab should be started by a healthcare professional experienced in diagnosing and treating COPD. The local formulary decision-making group will need to agree on arrangements for ongoing prescription. A person may self-inject dupilumab or a person's carer may administer dupilumab if their healthcare professional determines that this is appropriate. Ongoing supply of dupilumab could be facilitated via homecare medicines services.

Equality impact assessment

See NICE's equality impact assessment for dupilumab for treating COPD.

Resource impact

See NICE's resource impact assessment tool for dupilumab for treating COPD.

References

Bhatt SP, Rabe KF, Hanania NA et al. (2023) Dupilumab for COPD with Type 2 Inflammation Indicated by Eosinophil Counts (BOREAS). New England Journal of Medicine 389(3): 205-214

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