

# Putting NICE guidance into practice

## Resource impact report: Dupilumab for treating severe asthma with type 2 inflammation (TA751)

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## Summary

NICE has recommended <u>dupilumab</u> as an option as an add-on maintenance therapy for treating severe asthma with type 2 inflammation that is inadequately controlled in people 12 years and over, despite maintenance therapy with high-dose inhaled corticosteroids and another maintenance treatment in line with recommendation wording. See the guidance and section 1.1 of this report for further information.

#### We estimate that:

- Around 7,360 people with severe asthma and type 2 inflammation are eligible for treatment with dupilumab
- Around 515 people will start dupilumab in year 2025/26 once market share has reached 20% as shown in table 1. Around a further 960 people will be receiving subsequent years treatment with dupilumab by 2025/26.

Table 1 Estimated number of people in England receiving dupilumab

	2021/22	2022/23	2023/24	2024/25	2025/26
Cumulative market share for dupilumab (%)	1.0	2.5	7.0	13.0	20.0
People starting dupilumab each year	74	110	331	442	515
People receiving dupilumab in subsequent years 2-5	0	74	184	515	957
Total number of people receiving dupilumab	74	184	515	957	1,472

This report is supported by a local resource impact template because the list prices of dupilumab has a discount that is commercial-in-confidence. The discounted prices of dupilumab can be put into the template and other variables may be amended.

This technology is commissioned by NHS England. Providers are NHS Hospital trusts.

## 1 Dupilumab

- 1.1 NICE has recommended <u>dupilumab</u> as an option as an add-on maintenance therapy for treating severe asthma with type 2 inflammation that is inadequately controlled in people 12 years and over, despite maintenance therapy with high-dose inhaled corticosteroids and another maintenance treatment, only if:
  - the dosage used is 400 mg initially and then 200 mg subcutaneously every other week
  - the person has agreed to and follows an optimised standard treatment plan
  - the person has a blood eosinophil count of 150 cells per microlitre or more and fractional exhaled nitric oxide of 25 parts per billion or more, and has had at least 4 or more exacerbations in the previous 12 months
  - the person is not eligible for mepolizumab, reslizumab or benralizumab or has asthma that has not responded adequately to these biological therapies
  - the company provides dupilumab with the discount agreed in the patient access scheme.
- 1.2 Currently, severe asthma is usually treated with inhaled corticosteroids plus another drug, such as a long-acting beta-agonist. Oral corticosteroids may also be needed to prevent exacerbations (asthma attacks), but they can cause long-term adverse effects. Also, these treatments may not work well enough for severe asthma with type 2 inflammation, which can be difficult to control.
- Dupilumab is positioned for a population with an unmet need, that is, those ineligible to or not responding to biological treatment.
   Dupilumab could prevent or slow the move to treatment with oral corticosteroids, and the added complications.

## 2 Resource impact of the guidance

#### 2.1 We estimate that:

- Around 7,360 people with severe asthma and type 2 inflammation are eligible for treatment with dupilumab
- Around 515 people will start dupilumab in year 2025/26 once market share has reached 20% as shown in table 1. Around a further 960 people will be receiving subsequent years treatment with dupilumab by 2025/26.
- 2.2 The cumulative market share figures are shown in the resource impact template. Table 2 shows the number of people in England who are estimated to have dupilumab by financial year.

Table 2 Estimated number of people receiving dupilumab using NICE assumptions

	2021/22	2022/23	2023/24	2024/25	2025/26
Cumulative market share for dupilumab (%)	1.0	2.5	7.0	13.0	20.0
People starting dupilumab each year	74	110	331	442	515
People receiving dupilumab in subsequent years 2-5	0	74	184	515	957
Total number of people receiving dupilumab	74	184	515	957	1,472

2.3 This report is supported by a local resource impact template because the list prices of dupilumab has a discount that is commercial-in-confidence. The discounted prices of dupilumab can be put into the template and other variables may be amended.

#### Savings and benefits

- 2.4 The eligible population for dupilumab have had 4 or more exacerbations in the previous 12 months. Treatment with dupilumab could reduce the number of exacerbations people experience, improve quality of life and reduce resource expenditure in secondary care.
- 2.5 Dupilumab is the only licensed treatment for severe asthma with type 2 inflammation. Although asthma can respond to systemic corticosteroids, the treatment can be associated with long-term complications (such as diabetes mellitus, weight gain, bone loss, immunosuppression and a negative effect on mental health).

## 3 Implications for commissioners

- 3.1 This technology is commissioned by NHS England. Providers are NHS hospital trusts.
- 3.2 Dupilumab falls within the programme budgeting category 11B: Asthma.

## 4 How we estimated the resource impact

## The population

Around 6.38% of people in England have asthma (QoF 2020-21, NHS Digital), equivalent to around 3.1 million people aged 12 and over in England. Of these around 168,000 have severe asthma (Asthma UK). Around 54% of people with severe asthma have type 2 inflammation (UK Severe Asthma Registry 2020) and 78% of these people, equivalent to around 70,800 people, are expected to have a blood eosinophil count of 150 cells per microlitre or more and a fractional exhaled nitric oxide of 25 parts per billion or more. Experts estimate around 25% of these people will have 4 or more exacerbations in the last 12 months. The Liberty Asthma QUEST: Phase 3 Randomized, Double-Blind, Placebo-Controlled, Parallel-

Group Study to Evaluate Dupilumab Efficacy/Safety in Patients with Uncontrolled, Moderate-to-Severe Asthma and clinical experts estimated 27% of people will be ineligible for treatment with mepolizumab, reslizumab or benralizumab whilst also estimating that 20% of people that are eligible for existing biological treatment will not respond adequately and therefore be eligible for treatment with dupliumab.

- This gives a total eligible population for dupilumab of around 7,360 people.
- 4.3 Table 3 shows the total number of people with severe asthma and type 2 inflammation who are eligible for treatment with dupilumab.

Table 3 Number of people eligible for treatment in England

Population	Proportion of previous row (%)	Number of people
Total population <sup>1</sup>		56,286,961
Population aged 12 and over <sup>1</sup>		48,063,632
Prevalence of asthma <sup>2</sup>	6.38%	3,066,460
Prevalence of severe asthma <sup>3</sup>	5.48%	167,999
Number of people with severe asthma and type 2 inflammation <sup>4</sup>	54%	90,719
Number of people with blood eosinophil (EOS) ≥ 150 and Fractional Exhaled nitric oxide (FENO) ≥25 <sup>5</sup>	78%	70,761
People with 4 or more exacerbations in the last 12 months <sup>6</sup>	25%	17,690
People who are ineligible for treatment with mepolizumab, reslizumab or benralizumab <sup>7</sup>	27%	4,776
People who are eligible for treatment with mepolizumab, reslizumab or benralizumab <sup>7</sup>	73%	12,914
Of whom, people who have had mepolizumab, reslizumab or benralizumab but whose asthma had not responded adequately <sup>8</sup>	20%	2,583
Total number of people eligible for dupilumab		7,360

<sup>&</sup>lt;sup>1</sup> Office for National Statistics

<sup>&</sup>lt;sup>2</sup> Quality and Outcomes Framework (QOF) - 2020-21.

<sup>&</sup>lt;sup>3</sup> Asthma facts and statistics | Asthma UK

<sup>&</sup>lt;sup>4</sup> Characterisation of patients with severe asthma in the UK Severe Asthma Registry in the biologic era - PubMed (nih.gov)

<sup>&</sup>lt;sup>5</sup> Company submission

<sup>&</sup>lt;sup>6</sup> TA479 Clinical opinion

<sup>&</sup>lt;sup>7</sup> <u>Liberty Asthma QUEST: Phase 3 Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study to Evaluate Dupilumab Efficacy/Safety in Patients with Uncontrolled, Moderate-to-Severe Asthma - PubMed (nih.gov) and expert opinion</u>

<sup>&</sup>lt;sup>8</sup> Clinical expert opinion

#### **Assumptions**

- 4.4 The resource impact template assumes that:
  - People with severe asthma are currently treated with inhaled corticosteroids plus another drug, such as a long-acting betaagonist and will continue to receive this therapy in addition to dupilumab if prescribed.
  - No cost is included in the resource impact template for inhaled corticosteroids or long-acting beta-agonist drugs because it is assumed that people will continue to receive that therapy regardless of whether they are prescribed dupilumab as an addon.
  - Oral corticosteroids may also be used to prevent exacerbations
    (asthma attacks), but they can cause long-term adverse effects.
    Also, these treatments may not work well enough for severe
    asthma with type 2 inflammation, which can be difficult to
    control.
  - Market share of dupilumab will increase year on year until reaching 20% of the eligible population by year 5.
  - Dupilumab is administered by subcutaneous injection. The first three doses of dupilumab are administered in a hospital clinic and patients would be monitored for 15 minutes following administration.
  - Administration costs in clinic are based on 2021/22 National Tariff Payment System.
  - It is assumed that dupilumab is delivered via homecare after the first three doses and the administration cost for homecare is estimated to be £50 per month.
  - The dosage for dupilumab is 400 mg initially and then 200 mg subcutaneously every other week.
  - It is assumed patients will have continual treatment and maximum adherence due to patient support and homecare. A

- discontinuation rate is not included in the resource impact template.
- A reduction in healthcare resource use is expected in patients
  who are treated with dupilumab as they are likely to suffer from
  fewer severe exacerbations requiring hospitalisation.
- The template includes the option for users to amend assumptions on savings from a reduction in exacerbations. On the assumption sheet users will need to estimate the proportion of patients who will experience at least one exacerbation (moderate/severe) for both patients receiving dupilumab and those not receiving dupilumab. Users will then need to use the unit cost sheet to estimate the exacerbation annual cost per patient by inputting the average number of exacerbations per person per year and the average cost of an exacerbation.

## **About this resource impact report**

This resource impact report accompanies the NICE guidance on <u>Dupilumab</u> <u>for treating severe asthma with type 2 inflammation</u> and should be read with it. See <u>terms and conditions</u> on the NICE website.

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