NICE National Institute for Health and Care Excellence

Putting NICE guidance into practice

Resource impact report:
Omalizumab for previously treated chronic spontaneous urticaria (TA339)

Published: February 2016

Summary

Omalizumab is recommended as an additional third- or fourth-line treatment option for the treatment of severe chronic spontaneous urticaria in adults and young people aged 12 and over. Implementing the guidance will lead to increased drug costs, but will decrease demand on a range of secondary care services because omalizumab treatment needs less monitoring and fewer tests than the main alternative treatment.

The company has agreed a patient access scheme with the Department of Health. This scheme provides a simple discount to the list price of omalizumab across all indications, with the discount applied at the point of purchase or invoice. The level of the discount is commercial in confidence. The Department of Health considered that this patient access scheme does not constitute an excessive administrative burden on the NHS. Enquiries from NHS organisations about the patient access scheme should be directed to the Commercial Operations Team at Novartis Pharmaceuticals UK on 01276 698717 or via email to commercial.team@novartis.com.

For the population of England, it is estimated that around 8,700 people aged 12 and over are eligible for third-line treatment for severe chronic spontaneous urticaria.

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

This technology is commissioned by clinical commissioning groups. Providers are secondary and tertiary hospitals.

1 Introduction

1.1 This report looks at the resource impact of implementing the NICE guidance on omalizumab in England.

1.2 The guidance states that:

- Omalizumab is recommended as an option as add-on therapy for treating severe chronic spontaneous urticaria in adults and young people aged 12 years and over only if:
  - the severity of the condition is assessed objectively, for example, using a weekly urticaria activity score of 28 or more
  - the person's condition has not responded to standard treatment with H_1-antihistamines and leukotriene receptor antagonists
  - omalizumab is stopped at or before the fourth dose if the condition has not responded
  - omalizumab is stopped at the end of a course of treatment (6 doses) if the condition has responded, to establish whether the condition has gone into spontaneous remission, and is restarted only if the condition relapses
  - omalizumab is administered under the management of a secondary care specialist in dermatology, immunology or allergy
  - the company provides omalizumab with the discount agreed in the patient access scheme.

1.3 The Department of Health and Novartis Pharmaceuticals UK have agreed that omalizumab will be available to the NHS with a patient access scheme which makes it available with a discount. The size of the discount is commercial in confidence. It is the responsibility of the company to communicate details of the discount to the relevant NHS organisations. Any enquiries from NHS organisations about the patient access scheme should be directed to the

Commercial Operations Team at Novartis Pharmaceuticals UK on 01276 698717 or via email to commercial.team@novartis.com.

1.4 The committee developing the guidance agreed that the immunosuppressant most commonly used for this population – ciclosporin – was a suitable comparator. However, it was not included in the initial cost analysis used to inform the development of the guidance, because of the limited availability of trial data. To form an estimate of the cost to commissioners, ciclosporin has been included as a comparator.

1.5 This report is supported by a resource impact template. The template aims to help organisations in England, Wales and Northern Ireland plan for the financial implications of implementing the NICE guidance by amending the variables.

1.6 This technology is commissioned by clinical commissioning groups. Providers are secondary and tertiary hospitals.

2 Background and epidemiology of chronic spontaneous urticaria

2.1 Urticaria is a dermatological disease, characterised by a red, raised, itchy rash (weals). It is estimated that in 60% of cases of chronic urticaria, there is no identifiable trigger and the condition is termed chronic spontaneous urticaria.

2.2 In England approximately 8,700 people are eligible for third-line treatment for severe chronic spontaneous urticaria. The guidance recommends that omalizumab be used as a third- or fourth-line treatment option for this indication, as a possible alternative to immunosuppressants. It is estimated that around 4,500 people will have omalizumab from year 6 onwards. See table 1 and for more detail see the resource impact template.

Table 1 number of people having treatment with omalizumab

	Current year	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6
Total number of people treated with omalizumab	600	1,700	2,800	3,300	4,000	4,900	4,500

3 Assumptions made

3.1 The resource impact template makes the following assumptions:

- **Discounted price of omalizumab**. The list price of omalizumab has been included in the costing template; users should include the discount in the assumption input sheet of the costing template.
- **Doses of omalizumab per year**. It is assumed that non-response to treatment would be identified at 16 weeks after 4 doses, and that people whose condition responds to treatment would have a total of 8 doses per year. This is based on the company's submission, and verified by expert opinion.
- **Average period to remission**. The average duration of symptoms is uncertain, but an average of 5 years was used in the revised economic model that informed the development of the guidance.
- **Progression to other treatments**: Following identification of non-response to omalizumab, it is assumed that people will proceed to 1 of the 2 other treatment categories in the same proportion to their initial treatment. For ciclosporin, it is assumed that non-response would only lead to the 'alternative treatment' category. This is because future treatment with ciclosporin is assumed to mean that a person cannot take omalizumab because it is contraindicated or they cannot tolerate it.

4 Resource impact

4.1 The list price of omalizumab has a discount that is commercial in confidence. The discounted price of omalizumab should be included in the assumptions input sheet of the template to calculate the resource impact of the guidance.

4.2 The current treatment and future uptake figure assumptions are based on the company's submission and expert clinical opinion and are shown in the resource impact template.

5 Other considerations

5.1 Omalizumab is typically administered every 4 weeks in an outpatient setting. Ciclosporin can be self-administered orally, but needs considerable monitoring. The annual administration costs for ongoing treatment are estimated to be £590 and £750 respectively (based on one 8-month cycle of ciclosporin per year).

5.2 Ciclosporin is associated with more severe adverse events than omalizumab, including: renal dysfunction; hypertension; and malignancy. The use of omalizumab as an alternative to ciclosporin is expected to reduce the costs associated with treating adverse events.

6 Implications for commissioners

6.1 The commissioner for this topic is clinical commissioning groups.

6.2 Omalizumab falls within programme budgeting category 14X 'Problems of the skin – other'.

About this resource impact report

This resource impact report accompanies the NICE technology appraisal guidance on omalizumab and should be read in conjunction with it. See terms and conditions on the NICE website.

This report is written in the following context

This report represents the view of NICE, which was arrived at after careful consideration of the available data and through consulting healthcare professionals. The report is an implementation tool and focuses on the recommendations that were considered to have a significant impact on national resource use.

Assumptions used in the report are based on assessment of the national average. Local practice may be different from this, and the impact should be estimated locally.

Implementation of the guidance is the responsibility of local commissioners and providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity and foster good relations. Nothing in this costing tool should be interpreted in a way that would be inconsistent with compliance with those duties.

© National Institute for Health and Care Excellence, 2016. All rights reserved. This material may be freely reproduced for educational and not-for-profit purposes. No reproduction by or for commercial organisations, or for commercial purposes, is allowed without the express written permission of NICE.