NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Proposed Health Technology Appraisal

Omalizumab for previously treated chronic spontaneous urticaria

Draft scope (pre-referral)

Draft remit/appraisal objective

To appraise the clinical and cost effectiveness of omalizumab within its licensed indication for previously treated chronic spontaneous urticaria.

Background

Urticaria (also known as hives, welts or nettle rash) is a vascular reaction characterised by the transient appearance of raised, itchy lesions ('wheals') on the skin. It occurs when histamine and other chemicals are released from under the surface of the skin, causing tissues to swell. In the UK, approximately 15% of people experience urticaria at some time in their lives and the lifetime prevalence of chronic urticaria is 0.5–1%. For around 40–50% of people with urticaria, the cause of their condition is unknown.

Individual wheals can change size rapidly and move around the skin, disappearing in one place and then reappearing somewhere else on the body. They generally appear on the skin for no longer than 24 hours, however the condition may persist for several months. Approximately 20–30% of people with chronic spontaneous urticaria may also have angioedema (swelling of lips, hands and feet). When symptoms are present for more than 6 weeks, the condition is considered to be chronic. In approximately 50% of people symptoms may persist for 3–5 years, or for more than 10 years in 20% of people.

Initial treatment of chronic spontaneous urticaria is a non-sedating H_1-antihistamine (for example, cetirizine, levocetirizine, fexofenadine, loratadine, bilastine, desloratadine). Dose escalation of the antihistamine (2-fold and then 4-fold) may be required if the standard dose is ineffective. Subsequent treatment options for people whose condition does not respond to non-sedating antihistamines include leukotriene receptor antagonists, H_2-receptor antagonists, immunosuppressant drugs (such as ciclosporin, sulfasalazine and methotrexate) and tetrahydrofolate dehydrogenase inhibitors (such as dapsone).

The technology

Omalizumab (Xolair, Novartis) is a monoclonal antibody that binds to IgE, which stops it from binding to the IgE receptor and triggering an allergic response. It is administered by subcutaneous injection.

Omalizumab does not currently have a UK marketing authorisation for treating chronic spontaneous urticaria. It has been compared with placebo in clinical

trials in people aged 12 years and over receiving concomitant antihistamines and/or leukotriene receptor antagonists for the treatment of chronic spontaneous urticaria that is refractory to standard-dosed H_1-antihistamines.

Intervention(s)	Omalizumab
Population(s)	People aged 12 years and older with chronic spontaneous urticaria refractory to antihistamine treatment
Comparators	Immunosuppressant drugs (for example, ciclosporin, sulfasalazine or methotrexate)
Outcomes	The outcome measures to be considered include: • symptoms (including number of hives on body and itch severity) • 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.
Other considerations	Guidance will only be issued in accordance with the marketing authorisation. If evidence allows, subgroups according to severity of disease will be considered.
Related NICE recommendations and NICE Pathways	None
Related NHS England Policy	None

Questions for consultation

Have all relevant comparators for omalizumab been included in the scope?

- Are there any drug combinations that should be included?
- Which treatments are considered to be established clinical practice in the NHS for chronic spontaneous urticaria?

Are there any specific symptoms that should be included as outcomes?

Is omalizumab likely to only be used in clinical practice to treat people with severe disease?

Is the subgroup in 'other considerations' appropriate? Are there any other subgroups of people in whom the technology is expected to be more clinically effective and cost effective or other groups that should be examined separately?

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. Please let us know if you think that the proposed remit and scope may need changing in order to meet these aims. In particular, please tell us if the proposed remit and scope:

- could exclude from full consideration any people protected by the equality legislation who fall within the patient population for which omalizumab will be licensed;
- could lead to recommendations that have a different impact on people protected by the equality legislation than on the wider population, e.g. by making it more difficult in practice for a specific group to access the technology;
- could have any adverse impact on people with a particular disability or disabilities.

Please tell us what evidence should be obtained to enable the Committee to identify and consider such impacts.

Do you consider the technology to be innovative in its potential to make a significant and substantial impact on health-related benefits and how it might improve the way that current need is met (is this a 'step-change' in the management of the condition)?

Do you consider that the use of the technology can result in any potential significant and substantial health-related benefits that are unlikely to be included in the QALY calculation?

Please identify the nature of the data which you understand to be available to enable the Appraisal Committee to take account of these benefits.

NICE intends to appraise this technology through its Single Technology Appraisal (STA) Process. We welcome comments on the appropriateness of appraising this topic through this process. (Information on the Institute's Technology Appraisal processes is available at http://www.nice.org.uk/aboutnice/howwework/devnicetech/technologyappraisalprocessguides/technology_appraisal_process_guides.jsp)