NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Single Technology Appraisal

Omalizumab for previously treated chronic spontaneous urticaria

Final scope

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. The lifetime prevalence of chronic urticaria in the UK is 0.5–1%, but approximately 15% of people experience urticaria at some time in their lives. For many 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. Angioedema (swelling of lips, hands and feet) may also be present. When symptoms are present for more than 6 weeks, the condition is considered to be chronic. Symptoms may persist for 3–5 years in approximately 50% of people, and 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, mycophenolate mofetil and methotrexate) and tetrahydrofolate dehydrogenase inhibitors (such as dapsone). Oral corticosteroid pulses may be used to treat exacerbations.

The technology

Omalizumab (Xolair, Novartis) is a monoclonal antibody that binds to soluble IgE, reducing the amount of free IgE circulating in the blood. It is administered by subcutaneous injection.

Omalizumab has a UK marketing authorisation as an add-on therapy for chronic spontaneous urticaria that has inadequately responded to H_1-antihistamine treatment in people aged 12 years and older.

Intervention(s)	Omalizumab
Population(s)	People aged 12 years and older with chronic spontaneous urticaria with an inadequate response to H_1-antihistamine treatment
Comparators	Established clinical management without omalizumab including: • leukotriene receptor antagonists • H_2-antagonists • immunosuppressant drugs (for example, ciclosporin, mycophenolate mofetil or methotrexate) • no further pharmacological treatment.
Outcomes	The outcome measures to be considered include: • symptoms (including number of hives on body, itch severity, angioedema and lack of sleep) • reducing or discontinuing corticosteroid use • 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	If the evidence allows, subgroups according to previous treatment received will be considered. Guidance will only be issued in accordance with the marketing authorisation.
Related NICE recommendations and NICE Pathways	None
Related national policy	None