NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

SingleTechnology Appraisal

Tocilizumab for treating giant cell arteritis

Final scope

Remit/appraisal objective

To appraise the clinical and cost effectiveness of tocilizumab within its marketing authorisation for treating giant cell arteritis.

Background

Giant cell arteritis is a condition which causes inflammation in the walls of medium and large arteries, usually in the head and neck. This inflammation causes the arteries to narrow, which restricts blood flow. The condition is sometimes called temporal arteritis because it often affects the temporal arteries (on either side of the head). The cause of giant cell arteritis is unknown, but it could be linked to genetic factors, infection, or a history of cardiovascular disease. The most common symptom is headache. Other common symptoms include tenderness over one or both sides of the forehead, visual disturbances, jaw muscle pain, tiredness, loss of appetite, and fever. Complications of giant cell arteritis include permanent vision loss, stroke and aortic aneurysm (a swelling in the largest blood vessel in the body, which can be fatal if it bursts).

Around 1 in every 4,500 people aged 40 years and over develop giant cell arteritis each year in the UK[1]. The condition is rare in people aged below 50 years.

Giant cell arteritis is initially treated with high-dose corticosteroids, such as prednisolone. Prolonged corticosteroid treatment is usually required, but side effects of treatment are common. The dose of corticosteroids is gradually reduced ('tapered'), over a period of 18 to 24 months. Drugs that suppress the immune system (including methotrexate, azathioprine and leflunomide) may also be used to reduce the risk of symptoms returning and complications developing.

The technology

Tocilizumab (RoActemra, Roche Products) is a humanised monoclonal antibody that inhibits interleukin-6, a cytokine that is partly responsible for inflammation of the arteries in giant cell arteritis. It is administered by subcutaneous injection.

Tocilizumab does not currently have a marketing authorisation in the UK for giant cell arteritis. It has been studied in clinical trials in combination with corticosteroids, compared with placebo in combination with corticosteroids, in people aged 50 years or older with active giant cell arteritis. The clinical trials

included people with active relapsed or refractory disease (that is, disease that has not responded to corticosteroids), or newly diagnosed disease.

Intervention(s)	Tocilizumab
Population(s)	People with giant cell arteritis
Comparators	Established clinical management without tocilizumab
Outcomes	The outcome measures to be considered include: • disease remission • time to relapse after disease remission • adverse effects of long term corticosteroid treatment (including weight gain, osteoporotic fractures and diabetes mellitus) • morbidity (including vision loss, stroke and aortic aneurysm) • mortality • 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. The availability of any patient access schemes for the intervention or comparator technologies will be taken into account.

Other considerations	If evidence allows the following subgroups will be considered: • people with newly diagnosed giant cell arteritis • people with relapsed or refractory disease. Guidance will only be issued in accordance with the marketing authorisation. Where the wording of the therapeutic indication does not include specific treatment combinations, guidance will be issued only in the context of the evidence that has underpinned the marketing authorisation granted by the regulator.
Related NICE recommendations and NICE Pathways	None
Related National Policy	NHS England (2016) Clinical Commissioning Policy: Tocilizumab for Giant Cell Arteritis (adults) NHS England (2016) Manual for prescribed specialised services 2016/17 Chapter 5: Adult highly specialised rheumatology services NHS England (2016) IM3 Multi-system Auto-immune Rheumatic Diseases MDT Clinics, Data Collection and Policy Compliance NHS England (2013) 2013/14 NHS Standard Contract for Specialised Rheumatology Services (adult) Department of Health, NHS Outcomes Framework 2016-2017, April 2016. Domains 1–5.

References

1 NHS Choices website. Giant cell arteritis - overview [accessed September 2016]