NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health Technology Evaluation

Upadacitinib for treating giant cell arteritis [ID6299]

Final scope

Remit/evaluation objective

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

Background

Giant cell arteritis is a chronic 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 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 confusion, depression, deafness, encephalopathy, permanent vision loss, stroke and aortic aneurysm (a swelling in the largest blood vessel in the body, which can be fatal if it bursts), cardiovascular disease, lingual necrosis, scalp necrosis and peripheral neuropathy.[1]

The incidence of giant cell arteritis is estimated to be 2.2 per 10,000 in the UK.[1] Giant cell arteritis is very rare in people younger than 50 years and those who develop giant cell arteritis are usually over 60 years. It is 2-3 times more common in women than in men.[2,3] Relapses occur in around 50% of people.[1]

Giant cell arteritis is initially treated with high-dose corticosteroids, such as prednisolone. Prolonged corticosteroid treatment is usually required, but side effects such as infections, cataracts, glaucoma, hypertension, diabetes, osteoporosis, osteonecrosis, thromboses, mental health disturbance and sarcopenia are common and can pose a large burden. The dose of corticosteroids is gradually reduced ('tapered'), over a period of 18 to 24 months. Some people may have methotrexate in addition to tapered corticosteroids if they are at risk of corticosteroid toxicity.[4] NICE Technology appraisal 518 recommends tocilizumab when used with a tapering course of glucocorticoids (and when used alone after glucocorticoids) for treating giant cell arteritis in adults who have relapsing or refractory disease if they have not already had tocilizumab. The recommendations for tocilizumab state that tocilizumab must be stopped after 1 year of uninterrupted treatment. Methotrexate in addition to tapered corticosteroids may also be used for people with relapsed giant cell arteritis.[4]

The technology

Upadacitinib (Rinvoq, AbbVie) does not currently have a marketing authorisation in the UK for treating giant cell arteritis. It has been studied in a phase 3 randomised clinical trial in people with giant cell arteritis who had treatment with corticosteroids and whose condition was stable enough to start tapering corticosteroids. In the trial upadacitinib plus corticosteroids tapered over 26 weeks was compared with placebo

plus corticosteroids tapered over 52 weeks. In people who had disease remission the effect of continued upadacitinib on maintaining remission was assessed.

Intervention(s)	Upadacitinib
Population(s)	Adults with giant cell arteritis
Subgroups	If the evidence allows the following subgroups will be considered: • People with newly diagnosed giant cell arteritis • People with relapsing giant cell arteritis • People who have experienced previous corticosteroid toxicity or have pre-existing conditions likely to be exacerbated by corticosteroids • People who have had up to 12 months of tocilizumab • People for whom tocilizumab is unsuitable
Comparators	• Tapering course of corticosteroids • Tocilizumab in combination with a tapering course of corticosteroids, or alone if used after corticosteroids • Methotrexate in combination with a tapering course of corticosteroids
Outcomes	The outcome measures to be considered include: • disease remission • time to relapse after disease remission • cumulative dose of corticosteroids • adverse effects of long-term corticosteroid treatment (including weight gain, osteoporotic fractures, hypertension, cataracts, cardiovascular events, mood disturbance and diabetes mellitus) • morbidity (including vision loss, stroke and aortic aneurysm) • mortality • adverse effects of treatment (including thromboembolism) • 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 and cost of biosimilar and generic products should be taken into account.
Other considerations	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	**Related technology appraisals:** Tocilizumab for treating giant cell arteritis (2018). NICE technology appraisal 518 **Related technology appraisals in development** None **Related NICE guidelines:** None
Related National Policy	The NHS Long Term Plan (2019) NHS Long Term Plan. NHS England (2013) 2013/14 NHS Standard Contract for Specialised Rheumatology Services (adult)

Reference

1. NICE. Clinical Knowledge summaries. Giant cell arteritis. Accessed March 2025
2. Lazarewicz, K. and Watson, P. (2019) 'Giant cell arteritis', BMJ, p. 1964.
3. Cambridge University Hospitals. Information for people who have, or are under investigation as potentially having, giant cell arteritis (GCA). Accessed December 2024
4. British Society for Rheumatology (2020) British Society for Rheumatology guideline on diagnosis and treatment of giant cell arteritis