NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health Technology Evaluation

Upadacitinib for treating giant cell arteritis ID6299

Draft scope

Draft 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 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).

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 3 times more common in women than in men.[2]

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. Some people may have methotrexate in addition to corticosteroids.[3] 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 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)	People with giant cell arteritis
Comparators	• Tapering course of corticosteroids • Tocilizumab (in people with relapsing or refractory disease)
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 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)

Questions for consultation

Where do you consider upadacitinib will fit into the existing care pathway giant cell arteritis?

Please select from the following, will upadacitinib be:

A. Prescribed in primary care with routine follow-up in primary care
B. Prescribed in secondary care with routine follow-up in primary care
C. Prescribed in secondary care with routine follow-up in secondary care
D. Other (please give details):

For comparators and subsequent treatments, please detail if the setting for prescribing and routine follow-up differs from the intervention. Would upadacitinib be used alongside a tapering course of corticosteroids?

Would updadacitinib be used in newly diagnosed and/or relapsed or refractory giant cell arteritis?

Do you consider that the use of upadacitinib can result in any potential 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 committee to take account of these benefits.

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 with upadactinib 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.

NICE intends to evaluate this technology through its Single Technology Appraisal process. (Information on NICE's health technology evaluation processes is available at https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-technology-appraisal-guidance/changes-to-health-technology-evaluation).

References

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