NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health Technology Evaluation

Remibrutinib for treating chronic spontaneous urticaria inadequately controlled by H1-antihistamines ID6356

Draft scope

Draft remit/evaluation objective

To appraise the clinical and cost effectiveness of remibrutinib within its marketing authorisation for treating chronic spontaneous urticaria that is inadequately controlled by H1-antihistamines.

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%.[1] 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 the lips, hands and feet) may also present. When symptoms are present for more than 6 weeks, the condition is considered to be chronic. Symptoms may persist for 1-2 years in approximately 80% of people, and for more than 10 years in 20% of people.[1] Women are twice as likely than men to be diagnosed with chronic spontaneous urticaria.

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 (up to 4-fold) may be required if the standard dose is ineffective. NICE technology appraisal 339 recommends omalizumab as a second line treatment option for previously treated chronic spontaneous urticaria that has not responded to standard H_1-antihistamines and leukotriene receptor antagonists. Other subsequent treatment options for people whose condition does not respond to non-sedating antihistamines may include leukotriene receptor antagonists, H_2-receptor antagonists and immunosuppressant drugs (such as ciclosporin, mycophenolate mofetil and methotrexate). The British Association of Dermatologists guidelines includes tetrahydrofolate dehydrogenase inhibitors (such as dapsone) as a third line treatment option.[2] Oral corticosteroid may be used to treat exacerbations (such as prednisolone).

The technology

Remibrutinib (brand name unknown, Novartis Pharmaceuticals) does not currently have a marketing authorisation in the UK for treating chronic spontaneous urticaria that is inadequately controlled by H_1-antihistamines. It has been studied in

randomised controlled trials compared with placebo in adults with chronic spontaneous urticaria inadequately controlled by H_1-antihistamines.

Intervention(s)	Remibrutinib
Population(s)	People with chronic spontaneous urticaria that is inadequately controlled by H_1-antihistamines
Comparators	Established clinical management without remibrutinib including but not limited to: • omalizumab • H_2-antagonists • Immunosuppressant drugs (for example, ciclosporin, mycophenolate mofetil, tacrolimus or methotrexate) • leukotriene receptor antagonists (for example, montelukast) • oral corticosteroid (for example, prednisolone).
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. The availability of any commercial arrangements for the intervention, comparator and subsequent treatment technologies will be taken into account. 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:** Omalizumab for previously treated chronic spontaneous urticaria (2015) NICE technology appraisal guidance 339.

Questions for consultation

Where do you consider remibrutinib will fit into the existing care pathway for chronic spontaneous urticaria?

Please select from the following, will remibrutinib 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 remibrutinib be a candidate for managed access?

Do you consider that the use of remibrutinib 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.

Please indicate if any of the treatments in the scope are used in NHS practice differently than advised in their Summary of Product Characteristics. For example, if the dose or dosing schedule for a treatment is different in clinical practice. If so, please indicate the reasons for different usage of the treatment(s) in NHS practice. If stakeholders consider this a relevant issue, please provide references for data on the efficacy of any treatments in the pathway used differently than advised in the Summary of Product Characteristics.

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 remibrutinib 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. Allergy UK (2021). Chronic Spontaneous Urticaria (CSU). (Accessed May 2025)
2. Sabroe et al. (2021). British Association of Dermatologists guidelines for the management of people with chronic urticaria 2021*. Br J Dermatol. 2022 Mar;186(3):398-413.