Healthcare Improvement Scotland | SMC Advice on new medicines

Advice document
SMC2731

ublituximab concentrate for solution for infusion (Briumvi®)

Neuraxpharm UK Ltd

06 December 2024

The Scottish Medicines Consortium (SMC) has completed its assessment of the above product and, following review by the SMC executive, advises NHS Boards and Area Drug and Therapeutics Committees (ADTCs) on its use in NHSScotland. The advice is summarised as follows:

ADVICE: following an abbreviated submission

ublituximab (Briumvi®) is accepted for restricted use within NHSScotland.

Indication under review: treatment of adult patients with relapsing forms of multiple sclerosis (RMS) with active disease defined by clinical or imaging features.

SMC restriction: treatment of relapsing-remitting multiple sclerosis (RRMS) with active disease defined by clinical or imaging features.

Ublituximab offers an additional treatment choice in the therapeutic class of anti-CD20 monoclonal antibodies.

This advice applies only in the context of approved NHSScotland Patient Access Scheme (PAS) arrangements delivering the cost-effectiveness results upon which the decision was based, or PAS/ list prices that are equivalent or lower.

Chair
Scottish Medicines Consortium

1. Clinical Context

1.1. Medicine background

Ublituximab is a chimeric monoclonal antibody that targets the CD-20 surface antigen that is present at high levels on B-cells. Premedication must be administered before each infusion of ublituximab to reduce the frequency and severity of infusion-related reactions; refer to the Summary of Product Characteristics (SPC) for details. The recommended dose of ublituximab is 150 mg intravenous (IV) infusion (first infusion) followed by 450 mg IV infusion 2 weeks later. Subsequent doses are administered as 450 mg IV infusion every 24 weeks. The first subsequent dose of 450 mg should be administered 24 weeks after the first infusion. A minimal interval of 5 months should be maintained between each dose of ublituximab.
Refer to the SPC for further information. [1]

1.2. Relevant comparator(s)

The company compared ublituximab to ocrelizumab (Ocrevus®) (SMC2121) and ofatumumab (Kesimpta®) (SMC2357). Ocrelizumab and ofatumumab are anti-CD20 monoclonal antibodies that are accepted for restricted use within NHSScotland for the treatment of adult patients with relapsing forms of multiple sclerosis (RMS) with active disease defined by clinical or imaging features.

Ocrelizumab is restricted by SMC for the treatment of relapsing-remitting multiple sclerosis (RRMS) in adults with active disease defined by clinical or imaging features who are contra-indicated or otherwise unsuitable for alemtuzumab. [2] Ofatumumab is restricted by SMC for the treatment of relapsing-remitting multiple sclerosis (RRMS) with active disease defined by clinical or imaging features. [3]

2. Summary of Clinical Evidence

2.1. Evidence to support comparable efficacy with relevant comparators

Evidence to support the efficacy and safety of ublituximab is available from two randomised, double-blind studies, ULTIMATE I and ULTIMATE II. [1] There is no direct evidence comparing ublituximab with ocrelizumab or ofatumumab. [4, 5]

The submitting company conducted a network meta-analysis (NMA) to compare the efficacy and safety of ublituximab to six medicines used for the treatment of RMS, including ofatumumab, and ocrelizumab. The NMA found no statistically significant difference between ublituximab, ofatumumab and ocrelizumab for: annualised relapse rate (ARR), confirmed disability progression at 3 months (CDP-3m) and 6 months (CDP-6m), and all-cause treatment discontinuation. [4]

The findings were supported by the results of published Bayesian NMAs, which compared the efficacy of 18 treatments for RMS, including ublituximab, ocrelizumab, and ofatumumab. The

results showed no statistically significant differences between ublituximab, ocrelizumab and ofatumumab for ARR, CDP-3m, and CDP-6m. [5]

3. Company Estimate of Eligible Population, Uptake and Budget Impact

3.1. Company's number of patients assumed to be eligible for treatment

SMC is unable to publish the estimated patient numbers as the company considered that these were commercial in confidence.

3.2. Budget Impact assumption

Medicines reviewed under the abbreviated submissions process are estimated to have a limited net budget impact and resource allocation across NHS Scotland.

*Other data were also assessed but remain confidential.**

References

1. Neuraxpharm UK Ltd. Ublituximab (Briumvi®) Summary of Product Characteristics. Electronic Medicines Compendium www.medicines.org.uk/emc/product/100167/smpc. Last updated 20 September 2024.
2. Roche Products Limited. Ocrevus (ocrelizumab) Summary of Product Characteristics. Electronic Medicines Compendium www.medicines.org.uk/emc/product/8898/smpc. Last updated 10 July 2024
3. Novartis Pharmaceuticals UK Ltd. Ofatumumab (Kesimpta®) Summary of Product Characteristics. Electronic Medicines Compendium www.medicines.org.uk/emc/product/12433/smpc. Last updated 16 May 2024.
4. Moloney E. A systematic literature review and network meta-analysis of clinical evidence: Ublituximab for the Treatment of Patients with Relapsing Multiple Sclerosis (RMS). Data on File: 2024.
5. Samjoo IA, Drudge C, Walsh S, Tiwari S, Brennan R, Boer I*, et al.* Comparative efficacy of therapies for relapsing multiple sclerosis: a systematic review and network meta-analysis. J Comp Eff Res. 2023;12(7):e230016. Epub 20230602. 10.57264/cer-2023-0016

This assessment is based on data submitted by the applicant company up to and including 25 November 2024.

**Agreement between the Association of the British Pharmaceutical Industry (ABPI) and the SMC on guidelines for the release of company data into the public domain during a health technology appraisal:*https://www.scottishmedicines.org.uk/about-us/policies-publications/

Medicine prices are those available at the time the papers were issued to SMC for consideration. SMC is aware that for some hospital-only products national or local contracts may be in place for comparator products that can significantly reduce the acquisition cost to Health Boards. These contract prices are commercial in confidence and cannot be put in the public domain, including via the SMC Detailed Advice Document. Area Drug and Therapeutics Committees and NHS Boards are therefore asked to consider contract pricing when reviewing advice on medicines accepted by SMC.

Patient access schemes: A patient access scheme is a scheme proposed by a pharmaceutical company in order to improve the cost-effectiveness of a medicine and enable patients to receive access to cost-effective innovative medicines. A Patient Access Scheme Assessment Group (PASAG), established under the auspices of NHS National Services Scotland reviews and advises NHSScotland on the feasibility of proposed schemes for implementation. The PASAG operates separately from SMC in order to maintain the integrity and independence of the assessment process of the SMC. When SMC accepts a medicine for use in NHSScotland on the basis of a patient access scheme that has been considered feasible by PASAG, a set of guidance notes on the operation of the scheme will be circulated to Area Drug and Therapeutics Committees and NHS Boards prior to publication of SMC advice.

Advice context:

No part of this advice may be used without the whole of the advice being quoted in full.

This advice is based on the estimation of at least similar comparative efficacy and limited net budget impact compared with other medicinal products, within the same therapeutic class, that are in routine use within NHSScotland.

This advice represents the view of the Scottish Medicines Consortium and was arrived at after evaluation of the evidence submitted by the company. It is provided to inform the considerations of Area Drug & Therapeutics Committees and NHS Boards in Scotland in determining medicines for local use or local formulary inclusion. This advice does not override the individual responsibility of health professionals to make decisions in the exercise of their clinical judgement in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.