

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health Technology Evaluation

Ublituximab for treating relapsing multiple sclerosis

Final scope

Remit/evaluation objective

To appraise the clinical and cost effectiveness of ublituximab within its marketing authorisation for treating relapsing multiple sclerosis.

Background

Multiple sclerosis is a chronic, neurological condition which affects the brain, optic nerves, and spinal cord. It often results in progressive neurological impairment and severe disability. Multiple sclerosis has an unpredictable course which varies in severity and rate of progression. Symptoms can include pain, disturbance to muscle tone including weakness or spasticity, chronic fatigue, unsteady gait, speech problems, incontinence, visual disturbance, and cognitive impairment. Relapsing–remitting multiple sclerosis is the most common clinical form of multiple sclerosis. It is characterised by periods of remission (where people may have no symptoms, or they may be relatively stable) followed by relapses (which may or may not result in residual disability). Relapsing–remitting multiple sclerosis can progress to secondary progressive multiple sclerosis. This is characterised by more persistent or gradually increasing disability; some people with secondary progressive disease continue to have relapses.

Over 130,000 people in the UK have multiple sclerosis, and about 7,000 people are diagnosed each year.¹ Multiple sclerosis is two to three times as common in females than males.² Approximately 85% of people are diagnosed with relapsing–remitting multiple sclerosis.³

Current pharmacological management of multiple sclerosis includes disease-modifying agents to reduce the frequency and severity of relapses and the rate of disease progression.

NICE recommends the following treatment options for relapsing multiple sclerosis:

- diroximel fumarate for treating active relapsing-remitting multiple sclerosis that is not highly active or rapidly evolving severe multiple sclerosis (NICE [TA794](#))
- ponesimod for treating active relapsing-remitting multiple sclerosis (NICE [TA767](#))
- ofatumumab for treating relapsing multiple sclerosis in adults with active disease defined by clinical or imaging features (NICE [TA699](#))
- peginterferon beta-1a for treating relapsing-remitting multiple sclerosis (NICE [TA624](#))
- cladribine tablets for treating highly active multiple sclerosis only for rapidly evolving severe relapsing–remitting disease or disease that has responded inadequately to treatment with disease-modifying therapy (NICE [TA616](#))
- ocrelizumab for active relapsing–remitting multiple sclerosis only if alemtuzumab is contraindicated or otherwise unsuitable (NICE [TA533](#))

- interferon beta-1a and glatiramer acetate for relapsing–remitting multiple sclerosis and interferon beta-1b for relapsing–remitting multiple sclerosis with 2 or more relapses within the last 2 years and secondary progressive multiple sclerosis (NICE [TA527](#))
- teriflunomide and dimethyl fumarate for active relapsing–remitting multiple sclerosis, only if people do not have highly active or rapidly evolving severe relapsing–remitting multiple sclerosis (NICE [TA303](#) and [TA320](#) respectively)
- alemtuzumab for highly active and rapidly evolving severe relapsing–remitting multiple sclerosis (NICE [TA312](#))
- fingolimod for highly active relapsing–remitting multiple sclerosis in adults who have an unchanged or increased relapse rate or ongoing severe relapses compared with the previous year despite treatment with beta interferon (NICE [TA254](#))
- natalizumab for rapidly evolving severe relapsing–remitting multiple sclerosis (NICE [TA127](#))
- siponimod for active secondary progressive multiple sclerosis (NICE [TA656](#))

The technology

Ublituximab (Brimuvi, Neuraxpharm) has a marketing authorisation in the UK for the treatment of adult patients with relapsing forms of multiple sclerosis (RMS) with active disease defined by clinical or imaging features.

Intervention(s)	Ublituximab
Population(s)	Adults with active relapsing forms of multiple sclerosis.
Subgroups	<p>If the evidence allows, the following subgroup of people will be considered:</p> <ul style="list-style-type: none"> • People with active and highly active relapsing-remitting multiple sclerosis • People with rapidly evolving severe relapsing-remitting multiple sclerosis
Comparators	<ul style="list-style-type: none"> • ocrelizumab (only if alemtuzumab is contraindicated or otherwise unsuitable) • ofatumumab

<p>Outcomes</p>	<p>The outcome measures to be considered include:</p> <ul style="list-style-type: none"> • relapse rate • severity of relapse • disability (for example, expanded disability status scale [EDSS]) • disease progression • symptoms of multiple sclerosis (such as fatigue, cognition or visual disturbance) • freedom from disease activity (for example lesions on MRI scans) • mortality • adverse effects of treatment • health-related quality of life.
<p>Economic analysis</p>	<p>The reference case stipulates that the cost effectiveness of treatments should be expressed in terms of incremental cost per quality-adjusted life year.</p> <p>If the technology is likely to provide similar or greater health benefits at similar or greater health benefits at similar or lower cost than technologies recommended in published NICE technology guidance for the same indication, a cost-comparison may be carried out.</p> <p>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.</p> <p>Costs will be considered from an NHS and Personal Social Services perspective.</p>
<p>Other considerations</p>	<p>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.</p>
<p>Related NICE recommendations</p>	<p>Related technology appraisals:</p> <p>Diroximel fumarate for treating relapsing-remitting multiple sclerosis (2022). NICE technology appraisals guidance 767.</p> <p>Ponesimod for treating relapsing multiple sclerosis (2022). NICE technology appraisals guidance 767.</p> <p>Ofatumumab for treating relapsing multiple sclerosis (2021). NICE technology appraisals guidance 699.</p> <p>Ozanimod for treating relapsing multiple sclerosis (2021). NICE technology appraisals guidance TA706.</p>

	<p>Peginterferon beta-1a for treating relapsing–remitting multiple sclerosis (2020). NICE technology appraisal guidance 624.</p> <p>Cladribine tablets for treating relapsing–remitting multiple sclerosis (2017). NICE technology appraisal guidance 616.</p> <p>Ocrelizumab for treating relapsing–remitting multiple sclerosis (2018). NICE technology appraisal guidance 533.</p> <p>Beta interferons and glatiramer acetate for treating multiple sclerosis (2018). NICE technology appraisal guidance 527.</p> <p>Dimethyl fumarate for treating relapsing-remitting multiple sclerosis (2014). NICE technology appraisal guidance 320.</p> <p>Alemtuzumab for treating relapsing–remitting multiple sclerosis (2014). NICE technology appraisal guidance 312.</p> <p>Teriflunomide for treating relapsing–remitting multiple sclerosis (2014). NICE technology appraisal guidance 303.</p> <p>Natalizumab for the treatment of adults with highly active relapsing–remitting multiple sclerosis (2007). NICE technology appraisal guidance 127.</p> <p>Related technology appraisals in development:</p> <p>Evobrutinib for treating relapsing multiple sclerosis [ID6313] Publication date to be confirmed</p> <p>Cladribine for treating relapsing multiple sclerosis [ID6263] Publication date to be confirmed</p> <p>Related NICE guidelines:</p> <p>Multiple sclerosis in adults: management. (2022) NICE guideline [NG220]</p> <p>Related quality standards:</p> <p>Multiple sclerosis (2016). NICE quality standard 108.</p>
<p>Related National Policy</p>	<p>NHS England (2023) Treatment Algorithm for Multiple Sclerosis: Disease-Modifying Therapies</p> <p>The NHS Long Term Plan (2019) NHS Long Term Plan</p> <p>NHS England (2018) NHS manual for prescribed specialist services (2018/2019)</p>

References

1. Multiple Sclerosis Society [MS in the UK](#) [accessed January 2024].
2. MS International Federation (2022) [Who gets MS?](#) [accessed January 2024].
3. Multiple Sclerosis Society (2019) [Relapsing remitting MS \(RRMS\)](#) [accessed January 2024].