NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Single Technology Appraisal

Ocrelizumab for treating primary progressive multiple sclerosis

Final scope

Remit/appraisal objective

To appraise the clinical and cost effectiveness of ocrelizumab within its marketing authorisation for treating primary progressive multiple sclerosis.

Background

Multiple sclerosis is a chronic, neurodegenerative disorder 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 with variable severity and 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.

Approximately 90,000 people in England have multiple sclerosis, and about 4,200 people are diagnosed each year.[1] Most people have relapsing-remitting multiple sclerosis, which is characterised by periods of remission (when symptoms are mild or disappear altogether) followed by relapses (which may or may not result in residual disability). Approximately 10% of people are diagnosed with primary progressive multiple sclerosis,[2-4] in which symptoms develop and worsen over time without periods of remission.

There are currently no licensed treatments that slow down or stop disease progression in primary progressive multiple sclerosis. NICE clinical guideline 186 recommends ways to manage the symptoms of multiple sclerosis, including pharmacological treatments, physiotherapy and exercise programmes, occupational therapy, cognitive behavioural therapy, fatigue management, and speech therapy.

The technology

Ocrelizumab (Ocrevus, Roche) is a monoclonal antibody that selectively targets the CD20 surface antigen on B cells (a type of white blood cell). It promotes the destruction of B cells by the body's immune system. Ocrelizumab is administered by intravenous infusion.

Ocrelizumab does not currently have a marketing authorisation in the UK for treating multiple sclerosis. It has been studied in a clinical trial, compared with placebo, in people with primary progressive multiple sclerosis.

Intervention(s)	Ocrelizumab

Population(s)	People with primary progressive multiple sclerosis
Comparators	Established clinical management without ocrelizumab
Outcomes	The outcome measures to be considered include: • disability (for example, expanded disability status scale [EDSS], or time to walk 25 feet) • disease activity • patient-reported outcomes including fatigue, cognition and visual disturbance • 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.
Other considerations	If the evidence allows subgroups of people with or without inflammation will be considered. 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 and NICE Pathways	**Appraisals in development (including suspended appraisals)** Biotin for the first line treatment of primary or secondary progressive multiple sclerosis. NICE technology appraisal guidance [ID919]. Publication expected August 2018. Multiple sclerosis (primary-progressive) - fingolimod [ID62]. NICE technology appraisal (suspended). **Related Guidelines:**

	Multiple sclerosis in adults (2014). NICE guideline 186. Review date to be confirmed. **Related Interventional Procedures:** Percutaneous venoplasty for chronic cerebrospinal venous insufficiency for multiple sclerosis (2012). NICE interventional procedure guidance 420. **Related Quality Standards:** Multiple sclerosis (2016) NICE quality standard QS108. **Related NICE Pathways:** Multiple sclerosis (2014) NICE pathway.
Related National Policy	Department of Health (2016) NHS outcomes framework 2016 to 2017: Domains 1–5. NHS England (2016) Manual for Prescribed Specialised Services 2016/17. Chapter 11. Adult specialist neurosciences services NHS England (2014) Disease Modifying Therapies for Patients with multiple sclerosis (MS). Clinical commissioning policy reference D04/P/b.

References

1 Multiple Sclerosis Society (January 2016) MS in the UK [accessed February 2016]

2 Multiple Sclerosis Society (January 2016) Types of MS [accessed February 2016]

3 Murray T (2006) Diagnosis and treatment of multiple sclerosis. British Medical Journal 332: 525–7

4 Scolding N, Barnes D, Cader S et al. (2015). Association of British Neurologists: revised (2015) guidelines for prescribing disease-modifying treatments in multiple sclerosis Practical Neurology 0: 1–7

