NICE National Institute for Health and Care Excellence

Resource impact summary report

Resource impact

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This summary report is based on the NICE assumptions used in the resource impact template. Users can amend the 'Population and uptake' and 'Unit costs' worksheets in the template to reflect local data and assumptions.

Guidance recommendations

See NICE's recommendations on natalizumab (originator and biosimilar) for treating highly active relapsing–remitting multiple sclerosis after disease-modifying therapy (from here, TA1126).

Financial and capacity resource impact

The companies that make the natalizumab originator and the natalizumab biosimilar have agreed a nationally available price reduction for natalizumab with the Medicines Procurement and Supply Chain. The prices agreed through the framework are commercial in confidence.

Users can input the price of natalizumab (originator and biosimilar) and amend other variables in the resource impact template.

The payment mechanism for the technology is determined by the responsible commissioner and depends on the technology being classified as high cost.

Evidence shows that natalizumab (subcutaneous originator and intravenous biosimilar) provides benefits and value for money. So, it can be used routinely across the NHS for the condition and population in the recommendations in TA1126. Evidence does not suggest that natalizumab (intravenous originator) is value for money for the condition and population in the recommendations.

The committee noted that several disease-modifying therapies used in highly active relapsing–remitting multiple sclerosis (RRMS), including natalizumab, are associated with an increased risk of progressive multifocal leukoencephalopathy (PML). The clinical

experts explained that anti-John Cunningham human polyomavirus (JCV) antibody level tests are mandatory for people considering treatment with natalizumab (originator or biosimilar) to understand the risk of developing PML. They also confirmed that there is no NHS-funded anti-JCV antibody test available. So, the companies' tests are always used in clinical practice.

The clinical experts stated that subcutaneous natalizumab is normally administered in secondary care because of concerns about the continuity of funding for the home administration service. They highlighted that regular clinical contact is also important in mitigating the risk of PML, and they were concerned that this would be lost with home administration. But the committee considered that uptake of the home administration service is likely to differ throughout the NHS. Users can amend the split between secondary care and home administrations on the unit cost tab of the resource impact template.

For further analysis, or to calculate the financial and capacity impact from a commissioner and provider perspective, see the resource impact template.

Eligible population for intravenous natalizumab biosimilar and subcutaneous natalizumab originator

For this evaluation, the committee only evaluated natalizumab (originator and biosimilar) for people with highly active RRMS. This was because NICE's technology appraisal guidance for the treatment of adults with highly active RRMS (from here, TA127) already recommends natalizumab originator for people with rapidly evolving severe RRMS, but not for all people with highly active RRMS.

The resource impact template includes all comparator options for RRMS, not just those in TA1126. Natalizumab intravenous originator should not be used for the condition and population in the recommendations in TA1126. But it can be used in the rapidly evolving severe RRMS as recommended in TA127.

The following assumptions have been used to calculate the eligible population:

- The MS Trust webpage on how common is MS states that there are around 123,000 people living with MS in England.

- The MS Society webpage on RRMS states that 85% of people with MS are diagnosed with RRMS.
- In about 50% of people with RRMS, their condition will have progressed to secondary progressive MS (SPMS) 20 years after diagnosis. Assuming that, in about half of all people in the prevalent population, their condition was diagnosed 20 years ago, means that RRMS will have progressed to SPMS in about 25% (50% x 50%) of people.
- This results in 75% of people with RRMS at any one time. This is based on a Professor of Clinical Neurology opinion.
- The MS Society's My MS My Needs 2022 report states that 56% of people with RRMS have treatment with a DMT.

Users can update the uptake for all treatment options in the resource impact template.

Treatment options for the eligible population

Usual treatment for highly active RRMS after at least 1 disease-modifying therapy includes ocrelizumab, ofatumumab, ublituximab or cladribine.

Natalizumab (subcutaneous originator or intravenous biosimilar) is only a treatment option for highly active RRMS when characteristics of the person and the activity of their MS mean that cladribine is not suitable.

The dosing schedule for natalizumab is 300 mg every 4 weeks. Users can amend the resource impact template to reflect interval dosing and so a reduction in annual dosages. The average number of annual dosages from the economic modelling is confidential. But the clinical experts stated that, in their clinical practice, around 60% to 70% of people having natalizumab for rapidly evolving severe RRMS currently have 6-weekly dosing.

For more information about the treatments, such as dose and average treatment duration, see the resource impact template.

Key information

Table 1 Key information

Time from publication to routine commissioning funding	90 days

Programme budgeting category	07X Neurological, Neurological
Commissioner	NHS England
Provider	NHS Hospital trusts
Pathway position	Relapsing-remitting multiple sclerosis

About this resource impact summary report

This resource impact summary report accompanies the NICE technology appraisal guidance on natalizumab (originator and biosimilar) for treating highly active relapsing–remitting multiple sclerosis after disease-modifying therapy and should be read with it.

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