Disease modifying therapies for multiple sclerosis (Interim Policy)

Disease modifying therapies (DMT) for multiple sclerosis (MS) WILL BE funded in line with their marketing authorisation and criteria included in National Institute of Health and Care Excellence (NICE) Technology Appraisals. This policy applies only to the following DMTs:

- Interferon beta
- Glatiramer acetate
- Natalizumab
- Fingolimid
- Teriflunomide
- Alemtuzumab
- Demethyl fumarate
- Daclizumab

The indications, starting and stopping criteria set out in Department of Health, Health Service Circular 2002/004 must be followed for interferon beta and glatiramer acetate. For the other DMTs listed above, the indications, starting and stopping criteria as set out in the relevant NICE TA (see links below) must be followed.

DHSC will only fund beta interferon, glatiramer acetate, fingolimid, teriflunomide, dimethyl fumarate and daclizumab if these can be acquired by the Isle of Man at the agreed NHS discounted prices.

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<th>Strength of evidence</th>
<th>Clinical Effectiveness</th>
<th>Cost Effectiveness</th>
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Comments

Interferon beta and glatiramer acetate: assessed not to be clinically and cost effective by NICE in 2002 (NICE TA32: https://www.nice.org.uk/guidance/ta32/chapter/1-Guidance). These drugs have been available on the NHS in England since that time as part of a risk sharing scheme that was intended to reduce the costs to within the accepted cost effectiveness thresholds (see Health Service Circular 2002/004).

Natalizumab: assessed by NICE as clinically and cost effective at the manufacturer’s list price (NICE TA127)

Fingolimid: clinically effective but only cost effective within the NHS discounted patient access scheme (NICE TA254)
### Summary of evidence

NHS England, Clinical Commissioning Policy, Disease Modifying Therapies for Patients with Multiple Sclerosis, May 2014, Ref: NHS England/DO4/P/b

Cost effective provision of disease modifying therapies for people with multiple sclerosis, Department of Health, Health Services Circular 2002/004

National Institute of Health and Care Excellence: Technology Appraisals:
TA127, Natalizumab, 2007
https://www.nice.org.uk/guidance/ta127

TA254, Fingolimod, 2012
https://www.nice.org.uk/guidance/ta254

TA303, Teriflunomide, 2014
https://www.nice.org.uk/guidance/ta303

TA312, Alemtuzumab, 2014
https://www.nice.org.uk/guidance/ta312

TA320, Dimethyl Fumarate, 2014
https://www.nice.org.uk/guidance/ta320

TA441, Daclizumab, 2017
https://www.nice.org.uk/guidance/ta441

National Institute of Health and Care Excellence, Clinical Guideline, Multiple Sclerosis in Adults: management, CG186, 2013
https://www.nice.org.uk/guidance/cg186

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**Comments**

- Teriflunomide: clinically effective but only cost effective within the NHS discounted patient access scheme (NICE TA303)
- Alemtuzumab: assessed by NICE as clinically and cost effective at the manufacturer’s list price (NICE TA312)
- Dimethyl fumarate: clinically effective but only cost effective within the NHS discounted patient access scheme (NICE TA320)
- Daclizumab: clinically effective but only cost effective within the NHS discounted patient access scheme (NICE TA441)
Reason for requesting a policy recommendation:

Replaces and extends CRC recommendation 06/13: Gilenya (fingolimid) for multiple sclerosis (2014).

To date, fingolimid has been the only DMT taken through the CRC process. Some DMTs have been included on the Nobles’ Formulary (but without CRC consideration or DHSC funding policy) and others, which have not been considered for the formulary, appear to have been funded for individual patients (but not through the individual funding requests process). The result is a somewhat ad hoc system which is not consistent. A clear policy approach to all DMTs is required.

The CRC acknowledges that the funding consequences of formalising policy are difficult to estimate. CRC considers that there is a high likelihood that a formal policy will be cost neutral or possibly offer a small cost saving, given that some of the DMTs included in the formulary are more expensive than options not currently included. Accordingly, CRC recommends that this policy should be interim, with review after one year to enable the cost impact to be assessed.

A further reason for agreeing an interim policy is that a number of new DMTs have recently received marketing authorisation from the European Medicines Agency and NICE is due to publish technology appraisal guidance during the coming year. Review of this policy after one year will enable use and costs of existing drugs to be considered alongside implications of including the newer drugs.

DMTs for which NICE guidance is awaited include:

- Cladribine for relapsing/remitting MS – NICE TA expected February 2018
- Ocrelizumab for primary progressive and relapsing MS – NICE TA expected July 2018
- Biotin for primary and secondary progressive MS – NICE TA expected August 2018

Where a patient is considered to have exceptional need for and capacity to benefit from a treatment that is not routinely funded, a request for individual funding may be made to the Individual Funding Requests Panel. The patient must be made aware that the Panel may not support the request and must not be given any expectation that they will be able to have the treatment until a decision to fund has been received in writing from the Panel.

For further information contact:

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Email: clinicalcommissioning.dhsc@gov.im
Website: www.gov.im/dhscclinicalcommissioning

Date for policy review: November 2018