CONSULTATION

PHARMAC
Pharmaceutical Management Agency

7 August 2014

Multiple Sclerosis treatments funding proposal

PHARMAC is seeking feedback on a funding proposal involving five treatments for multiple sclerosis (MS), including two new treatments that are not currently funded – natalizumab and fingolimod.

In summary, this proposal would result, from 1 November 2014, in:

- natalizumab (Tysabri), supplied by Biogen, and fingolimod (Gilenya), supplied by Novartis, being funded in the community and in DHB hospitals subject to restrictions; and
- changes to the restrictions for funded access, in the community and in DHB hospitals, for interferon beta-1-alpha (Avonex), interferon beta-1-beta (Betaferon) and glatiramer acetate (Copaxone).

Details of the proposal, including proposed funding access criteria, and some background information can be found on the following pages.

The fingolimod component of this proposal is dependent on a multi-product provisional agreement with Novartis, for a number of other products including fingolimod, being approved. We are consulting on the Novartis multiproduct proposal separately, see our website at: www.pharmac.health.nz/news/consultation-2014-08-07-multiproduct.

Feedback sought

PHARMAC welcomes feedback on this proposal. To provide feedback, please submit it in writing by **Friday, 29 August 2014** to:

Adrienne Martin,
Therapeutic Group Manager,
PHARMAC
PO Box 10-254
Wellington 6143

Email: mstreatments@pharmac.govt.nz

Fax: 04 460 4995

All feedback received before the closing date will be considered by PHARMAC's Board (or its delegate) prior to making a decision on this proposal.

Feedback we receive is subject to the Official Information Act 1982 (OIA) and we will consider any request to have information withheld in accordance with our obligations under the OIA. Anyone providing feedback, whether on their own account or on behalf of an organisation, and whether in a personal or professional capacity, should be aware that the content of their feedback and their identity may need to be disclosed in response to an OIA request.

We are not able to treat any part of your feedback as confidential unless you specifically request that we do, and then only to the extent permissible under the OIA and other relevant laws and requirements. If you would like us to withhold any commercially sensitive, confidential proprietary, or personal information included in your submission, please clearly state this in your submission and identify the relevant sections of your submission that you would like it withheld. PHARMAC will give due consideration to any such request.

Level 9, 40 Mercer Street, PO Box 10-254, Wellington 6143, New Zealand
Phone: 64 4 460 4990 - Fax: 64 4 460 4995 - www.pharmac.govt.nz

Details of the proposal

Natalizumab

From 1 November 2014:

- Natalizumab (Tysabri) would be listed in Section B and in Part II of Section H (the Hospital Medicines List, or HML) of the Pharmaceutical Schedule, as a result of a provisional agreement with Biogen Idec, at the following price and subsidy (ex-manufacturer, excluding GST).

Chemical	Presentation	Brand	Pack size	Price and subsidy
Natalizumab	Inj 20 mg per ml, 15 ml vial	Tysabri	1	$1,750.00

- Natalizumab would be subject to the following access criteria in Section B of the Pharmaceutical Schedule:

Special Authority for subsidy
Special Authority approved by the Multiple Sclerosis Treatment Assessment Committee (MSTAC). Applications will be considered by MSTAC at its regular meetings and approved subject to eligibility according to the Entry and Stopping criteria (below)

Entry Criteria

1) Diagnosis of multiple sclerosis (MS) must be confirmed by a neurologist. Diagnosis should as a rule include MRI confirmation. For patients diagnosed before MRI was widely utilised in New Zealand, confirmation of diagnosis via clinical assessment and laboratory/ancillary data must be provided; and
2) patients must have Clinically Definite Relapsing Remitting MS (confirmed by MR scan where necessary) with or without underlying progression; and
3) patients must have:
    a) EDSS score 0 – 4 at least 4 weeks after the start of the episode and:
        - Evidence of MRI activity (either a contrast enhancing lesion on the baseline scan or with new T2 or enhancing lesion(s) on a scan subsequent to the baseline; and
        - Experienced at least 1 significant relapse (an attack sufficient to increase the EDSS or one Functional System Score by at least one point) of MS in the previous 12 months or 2 significant relapses in the past 24 months
4) Each relapse must:
    a) be confirmed by a neurologist or general physician (the patient may not necessarily have been seen during the relapse but the neurologist/physician must be satisfied that the clinical features were characteristic and met the specified criteria);
    b) be associated with characteristic new symptom(s)/sign(s) or substantial worsening of previously experienced symptom(s)/sign(s);
    c) last at least one week;
    d) follow a period of stability of at least one month;
    e) be severe enough to change either the EDSS or at least one of the Kurtzke functional systems scores by at least 1 point;
    f) be distinguishable from the effects of general fatigue; and
    g) not be associated with a fever (T>37.5°C); and

5) applications must be made by the patient's neurologist; and
6) the patient's neurologist must be registered in the Tysabri Australasian Prescribing Programme operated by the supplier; and
7) applications must be made at least four weeks after the date of the onset of the last known relapse; and
8) patients must have no previous history of lack of response to natalizumab; and

9) patients must have not previously been contraindicated or had an intolerance to natalizumab (i.e. to meet the access criteria for beta-interferon or glatiramer acetate), where
    a) Patient is JC virus negative, or
    b) Patient is JC virus positive and has given explicit written informed consent regarding the risks versus benefits associated with natalizumab
10) patient will not be co-prescribed interferon beta interferon or glatiramer acetate

Stopping Criteria

Any of the following:

1) Confirmed progression of disability that is sustained for six months during a minimum of one year of treatment. Progression of disability is defined as progress by any of the following EDSS points:
    a) from starting at EDSS 0 to increasing to (i.e. stopping on reaching) 3.0,
    b) 1.0 to 3.0,
    c) 1.5 to 3.5,
    d) 2.0 to 4.0,
    e) 2.5 to 4.5,
    f) 3.0 to 4.5,
    g) 3.5 to 4.5,
    h) 4.0 to 4.5
2) increasing relapse rate over 12 months of treatment (compared with the relapse rate on starting treatment) (see note);
3) intolerance to natalizumab; or
4) non-compliance with treatment, including refusal to undergo annual assessment

Note:

Natalizumab can only be dispensed from a pharmacy registered in the Tysabri Australasian Prescribing Programme operated by the supplier

Switching between natalizumab and fingolimod is permitted provided the stopping criteria are not met. For the avoidance of doubt, switching to interferon or glatiramer acetate is only permitted provided the stopping criteria are not met and both fingolimod and natalizumab are contraindicated or not tolerated.

Continued relapses on treatment would be expected to lead to a switch of treatment provided the stopping criteria are not met

If a relapse has resulted in an increased EDSS score that potentially may lead to discontinuation of treatment according to stopping criteria, a period of 6 months is allowed from the start of the relapse in order for recovery to occur.

For the avoidance of doubt, anti-JCV antibody negative status is not a prerequisite for funding. Natalizumab applications for patients who are anti-JCV antibody positive will be considered, however it is expected that the patient will have given explicit written informed consent regarding the risks versus benefits associated with natalizumab.

- Natalizumab would be subject to the following restrictions in the HML:

Restricted
Only for use in patients with approval by the Multiple Sclerosis Treatment Assessment Committee (MSTAC). Applications will be considered by MSTAC at its regular meetings and approved subject to eligibility according to the Entry and Stopping criteria (set out in Section B of the Pharmaceutical Schedule).

Natalizumab can only be dispensed from a pharmacy registered in the Tysabri Australasian Prescribing Programme operated by the supplier.

Details of the Tysabri Australasian Prescriber Programme, operated by the supplier (Biogen Idec), are provided in the background section in this consultation (page 9).

Fingolimod

From 1 November 2014:

- Fingolimod (Gilenya) would be listed in Section B, and in Part II of Section H (the Hospital Medicines List, or HML) of the Pharmaceutical Schedule, subject to a provisional agreement with Novartis New Zealand Ltd, at the following price and subsidy (ex-manufacturer, excluding GST).

Chemical	Presentation	Brand	Pack size	Price and subsidy
Fingolimod	Cap 0.5 mg	Gilenya	28	$2,650.00

- A confidential rebate would apply to Gilenya, reducing its net price.

- Gilenya would have subsidy and delisting protection until 31 October 2017.

- Fingolimod would be subject to the following access criteria in Section B of the Pharmaceutical Schedule:

Special Authority for Subsidy
Special Authority approved by the Multiple Sclerosis Treatment Assessment Committee (MSTAC). Applications will be considered by MSTAC at its regular meetings and approved subject to eligibility according to the Entry and Stopping criteria (below).

Entry Criteria

1) Diagnosis of multiple sclerosis (MS) must be confirmed by a neurologist. Diagnosis should as a rule include MRI confirmation. For patients diagnosed before MRI was widely utilised in New Zealand, confirmation of diagnosis via clinical assessment and laboratory/ancillary data must be provided; and
2) patients must have Clinically Definite Relapsing Remitting MS (confirmed by MR scan where necessary) with or without underlying progression; and
3) patients must have:
    a) EDSS score 0 – 4 at least 4 weeks after the start of the episode and:
        - Evidence of MRI activity (either a contrast enhancing lesion on the baseline scan or with new T2 or enhancing lesion(s) on a scan subsequent to the baseline; and
        - Experienced at least 1 significant relapse (an attack sufficient to increase the EDSS or one Functional System Score by at least one point) of MS in the previous 12 months or 2 significant relapses in the past 24 months
4) Each relapse must:
    a) be confirmed by a neurologist or general physician (the patient may not necessarily have been seen during the relapse but the neurologist/physician must be satisfied that the clinical features were characteristic and met the specified criteria);
    b) be associated with characteristic new symptom(s)/sign(s) or substantial worsening of previously experienced symptom(s)/sign(s);
    c) last at least one week;
    d) follow a period of stability of at least one month;
    e) be severe enough to change either the EDSS or at least one of the Kurtzke functional systems scores by at least 1 point;

f) be distinguishable from the effects of general fatigue; and
g) not be associated with a fever (T>37.5°C); and

5) applications must be made by the patient's neurologist; and
6) applications must be made no less than four weeks after the date of the onset of the last known relapse; and
7) patients must have no previous history of lack of response to fingolimod; and
8) patients must have not previously been contraindicated or had an intolerance to fingolimod (i.e. to meet the access criteria for beta-interferon or glatiramer acetate); and
9) patient must not be co-prescribed interferon beta interferon or glatiramer acetate.

Stopping Criteria

Any of the following:

1) Confirmed progression of disability that is sustained for six months during a minimum of one year of treatment. Progression of disability is defined as progress by any of the following EDSS points:
   a) from starting at EDSS 0 to increasing to (i.e. stopping on reaching) EDSS 3.0,
   b) 1.0 to 3.0,
   c) 1.5 to 3.5,
   d) 2.0 to 4.0,
   e) 2.5 to 4.5,
   f) 3.0 to 4.5,
   g) 3.5 to 4.5,
   h) 4.0 to 4.5
2) increasing relapse rate over 12 months of treatment (compared with the relapse rate on starting treatment)(see note);
3) intolerance to fingolimod; or
4) non-compliance with treatment, including refusal to undergo annual assessment.

Note:
Switching between natalizumab and fingolimod is permitted provided the stopping criteria are not met. For the avoidance of doubt, switching to interferon or glatiramer acetate is only permitted provided the stopping criteria are not met and both fingolimod and natalizumab are contraindicated or not tolerated.

Continued relapses on treatment would be expected to lead to a switch of treatment provided the stopping criteria are not met

If a relapse has resulted in an increased EDSS score that potentially may lead to discontinuation of treatment according to stopping criteria, a period of 6 months is allowed from the start of the relapse in order for recovery to occur

- Fingolimod would be subject to the following access criteria in the HML from 1 November 2014:

Restricted
Only for use in patients with approval by the Multiple Sclerosis Treatment Assessment Committee (MSTAC). Applications will be considered by MSTAC at its regular meetings and approved subject to eligibility according to the Entry and Stopping criteria (set out in Section B of the Pharmaceutical Schedule).

Interferon beta 1 alpha, interferon beta 1 beta and glatiramer acetate

From 1 November 2014:

For new patients

- Interferon beta-1-alpha (Avonex) would be listed in Section B and Part II of Section H of the Pharmaceutical Schedule at the following prices and subsidies (ex-manufacturer, excluding GST):

Chemical	Presentation	Brand	Pack size	Price and subsidy
Interferon beta-1-alpha	Inj 6 million iu prefilled syringe	Avonex	4	$1170.00
Interferon beta-1-alpha	Injection 6 million iu per 0.5 ml pen injector	Avonex Pen	4	$1170.00
Interferon beta-1-alpha	Inj 6 million iu per vial	Avonex	4	$1170.00

- There would be no change to the price or subsidy of interferon beta-1-beta (Betaferon) or glatiramer acetate (Copaxone).

- Interferon beta-1-alpha, interferon beta-1-beta and glatiramer acetate would be subject to new access criteria in Section B of the Pharmaceutical Schedule, for new patients only[1], as outlined below. For purposes of comparison the current access criteria can be found on pages 149-150 of the Pharmaceutical Schedule, available from the following link: http://www.pharmac.govt.nz/2014/08/01/Schedule.pdf

Special Authority for Subsidy
Special Authority approved by the Multiple Sclerosis Treatment Assessment Committee (MSTAC). Applications will be considered by MSTAC at its regular meetings and approved subject to eligibility according to the Entry and Stopping criteria (below)

Entry Criteria

1) Diagnosis of multiple sclerosis (MS) must be confirmed by a neurologist. Diagnosis should as a rule include MRI confirmation. For patients diagnosed before MRI was widely utilised in New Zealand, confirmation of diagnosis via clinical assessment and laboratory/ancillary data must be provided; and
2) patients must have Clinically Definite Relapsing Remitting MS (confirmed by MR scan where necessary) with or without underlying progression; and
3) patients must have:
    a) EDSS score 0 – 4 at least 4 weeks after the start of the episode and:
        - Evidence of MRI activity (either a contrast enhancing lesion on the baseline scan or with new T2 or enhancing lesion(s) on a scan subsequent to the baseline; and
        - Experienced at least 1 significant relapse (an attack sufficient to increase the EDSS or one Functional System Score by at least one point) of MS in the previous 12 months or 2 significant relapses in the past 24 months
4) Each relapse must:
    a) be confirmed by a neurologist or general physician (the patient may not necessarily have been seen during the relapse but the neurologist/physician must be satisfied that the clinical features were characteristic and met the specified criteria);
    b) be associated with characteristic new symptom(s)/sign(s) or substantial worsening of previously experienced symptom(s)/sign(s);

[1] For existing patients see page 9 of this Consultation

c) last at least one week;
d) follow a period of stability of at least one month;
e) be severe enough to change either the EDSS or at least one of the Kurtzke functional systems scores by at least 1 point;
f) be distinguishable from the effects of general fatigue; and
g) not be associated with a fever (T>37.5°C); and

5) applications must be made by the patient's neurologist; and
6) applications must be made at least four weeks after the date of the onset of the last known relapse; and
7) patients must have no previous history of lack of response to beta-interferon or glatiramer acetate; and
8) patients must have either intolerance or contraindication to **both**
    a) natalizumab; **and**
    b) fingolimod
9) patient will not be co-prescribed natalizumab or fingolimod

Stopping Criteria

Any of the following:

1) Confirmed progression of disability that is sustained for six months during a minimum of one year of treatment. Progression of disability is defined as progress by any of the following EDSS points:
    a) from starting at EDSS 0 to increasing to (i.e. stopping on reaching) EDSS 3.0,
    b) 1.0 to 3.0,
    c) 1.5 to 3.5,
    d) 2.0 to 4.0,
    e) 2.5 to 4.5,
    f) 3.0 to 4.5,
    g) 3.5 to 4.5,
    h) 4.0 to 4.5
2) increasing relapse rate over 12 months of treatment (compared with the relapse rate on starting treatment)(see note);
3) intolerance to interferon beta-1-alpha, and/or interferon beta-1-beta and/or glatiramer acetate; or
4) non-compliance with treatment, including refusal to undergo annual assessment

Note:

Treatment with interferon beta -1-beta, interferon beta-1-alpha and glatiramer acetate, providing the stopping criteria are not met, is only permitted if treatment with both natalizumab and fingolimod is not tolerated or contraindicated, rather than disease progression. Beta-interferon or glatiramer acetate will not be funded as second line treatments if disease progression has occurred with natalizumab or fingolimod.

Patients who have an increasing relapse rate over 12 months of treatment (compared with the relapse rate on starting treatment) and who do not meet any of the other Stopping Criteria at annual review may switch to from either of the beta-interferon's [interferon beta-1-beta or interferon beta-1-alpha] to glatiramer acetate or vice versa. Patients may switch between either of the beta-interferon's [interferon beta-1-beta or interferon beta-1-alpha] to glatiramer acetate or vice versa for this reason only once, after which they will be required to stop funded treatment if the meet any of the Stopping Criteria at annual review (including the criterion relating to increasing relapse rate over 12 months of treatment).

If a relapse has resulted in an increased EDSS score that potentially may lead to discontinuation of treatment according to stopping criteria, a period of 6 months is allowed from the start of the relapse in order for recovery to occur.

For the avoidance of doubt, in this funding setting anti-JCV antibody positive status can be considered as an absolute contraindication to treatment to natalizumab, should the patient and their treating physician (considering the risks versus benefits) associated with natalizumab decide that treatment with natalizumab is not indicated for them in particular.

- Interferon beta-1-alpha, interferon beta-1-beta and glatiramer acetate would be subject to the following access criteria in Part II of Section H of the Pharmaceutical Schedule (the HML):

> **Restricted**
> Only for use in patients with approval by the Multiple Sclerosis Treatment Assessment Committee (MSTAC). Applications will be considered by MSTAC at its regular meetings and approved subject to eligibility according to the Entry and Stopping criteria (set out in Section B of the Pharmaceutical Schedule).

Currently funded patients[2]

- Provided the stopping criteria (under the criteria that applied when the patient was granted their approval) are not met, the patient could continue funded treatment with interferon beta-1-alpha, interferon beta-1-beta or glatiramer acetate until they met the stopping criteria that existed at the time they received the approval.

- Currently funded patients who meet the proposed entry criteria for fingolimod & natalizumab would be able to switch treatments. If they choose to change treatment, the proposed new stopping criteria (see pages 3 & 5 above) would then apply.

- The current stopping criteria for interferon beta-1-beta, interferon beta-1-alpha and glatiramer acetate, which are on pages 149-150 of the Pharmaceutical Schedule, available from the link below, would apply to any currently funded patient who chooses not to switch to one of the newly funded treatments:

  http://www.pharmac.govt.nz/2014/08/01/Schedule.pdf

- For the avoidance of doubt, if a currently funded patient met the stopping criteria for interferon beta-1-beta, interferon beta-1-alpha and glatiramer acetate after 1 November 2014, they would likely not meet the proposed entry criteria for fingolimod or natalizumab.

[2] i.e. patients with Special Authority approvals issued prior to 1 November 2014.

Background

About 600 people currently receive funded treatment for MS and we estimate, should this proposal be approved, around 87% of these people would be eligible to change to the new treatments. The other 13% could continue receiving their existing funded treatment.

In addition, should this proposal be accepted, we estimate that about 400 more people with MS would become eligible for funded treatments during the next five years.

Currently funded treatments

There are currently three funded MS treatments: the beta interferons (interferon beta-1-beta, interferon beta-1-alpha) and glatiramer acetate. There are funding criteria in place for these treatments; patients' eligibility for funded treatment is determined by a panel of clinicians contracted by PHARMAC, the Multiple Sclerosis Treatment Assessment Committee (MSTAC).

New treatments

Fingolimod is a sphingosine-1-phosphate receptor modulator indicated for the treatment of relapsing remitting multiple sclerosis (RRMS) to reduce the frequency of relapses and to delay the progression of disease. Fingolimod is an oral capsule taken once daily.

Natalizumab is a humanised monoclonal antibody administered once monthly by intravenous infusion, over approximately one hour.

Natalizumab is registered for the treatment of patients with RRMS to delay the progression of physical disability and to reduce the frequency of relapses. Natalizumab is associated with an increased risk of progressive multifocal leucoencephalopathy (PML), which is an opportunistic viral infection of the brain that usually leads to death or severe disability.

Due to the risk of PML associated with natalizumab, and related to the registration of natalizumab, the supplier (Biogen Idec) requires that any practitioner prescribing natalizumab, or pharmacy dispensing natalizumab, has taken part in a training program (the Tysabri Australasian Prescribing Programme, which is operated by the supplier) and is aware of the monitoring requirements for the drug. Should the proposal be accepted then a website and a toll free phone number would be provided by Biogen detailing information about the training programme.

Clinical Advice

Funding applications for both natalizumab and fingolimod have undergone extensive review by PHARMAC's clinical advisory groups, including the Pharmacology and Therapeutics Advisory Committee (PTAC) and the Neurological Subcommittee of PTAC. In addition, PTAC and PHARMAC have sought input from the Multiple Sclerosis Treatment Advisory Committee (MSTAC).

The most recent review of these applications was by PTAC at its February 2014 meeting. PTAC recommended that natalizumab and fingolimod be funded as first-line agents for MS patients with an Expanded Disability Status Scale (EDSS, a measure of disease severity) score of 0–4 with a medium priority.

PTAC also recommended that the beta-interferons and glatiramer acetate not be funded as second-line agents following first-line treatment failure (i.e. disease progression); rather, PTAC recommended that they should be funded, for patients with RRMS and an EDSS score of 0–4, if treatment with both of the recommended first-line agents (natalizumab and fingolimod) are not tolerated or are contraindicated.

PTAC recommended a treatment algorithm (treatment path) that involves first-line treatment with either fingolimod or natalizumab and amended access to the currently funded treatments.

Natalizumab minutes can be found here:
http://www.pharmac.govt.nz/patients/ApplicationTracker?ProposalId=613

Fingolimod minutes can be found here:
http://www.pharmac.govt.nz/patients/ApplicationTracker?ProposalId=555

Current funding is restricted via EDSS score and relapse frequency. The proposed treatment algorithm would change the commencement of funding eligibility for MS treatments via a change to entry EDSS scores and a reduction in relapse frequency requirements. Patients would be able to access funding for new treatments (and switch between them) earlier in their disease, but also would be required to stop treatment earlier should their disease progress.

The proposed changes are in line with PTAC's clinical advice, which highlights that the newer treatments appear to have greater efficacy than currently funded treatments and are most likely more effective at preventing progression of disease if used at earlier stages of disease.

PHARMAC appreciates the complexity of a proposal involving a treatment algorithm with two new treatments and amended access for currently funded treatments. The key proposed changes, including a comparison with the current funding criteria, are further outlined on the following pages.

Further detail of the proposed changes to funding criteria (entry and stopping)

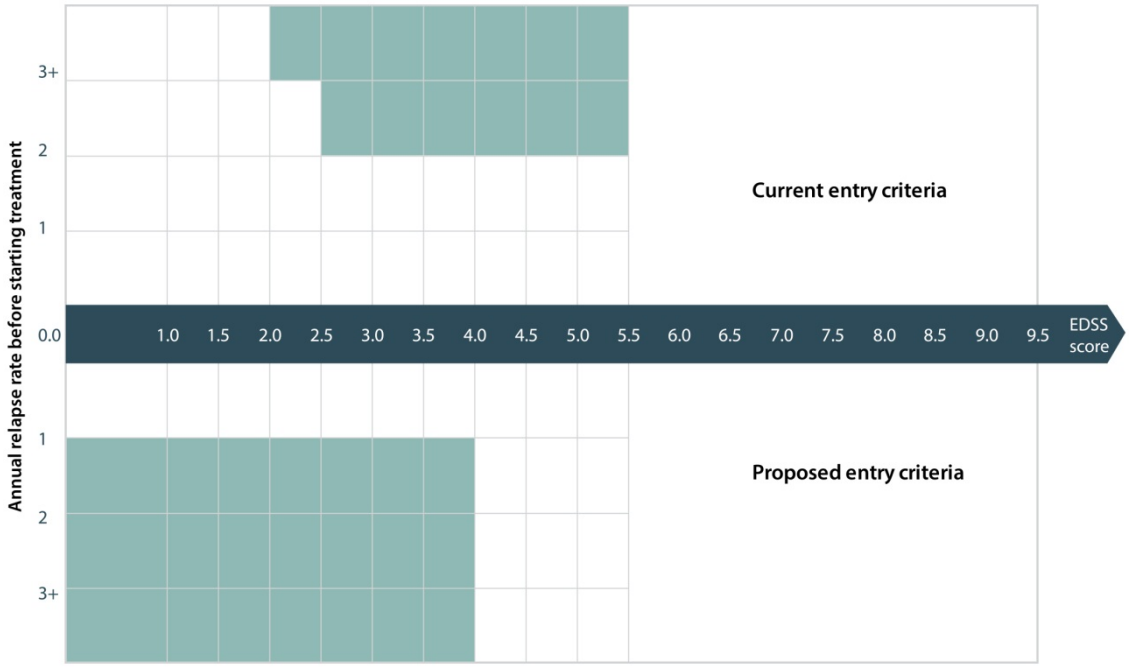
The beta-interferons and glatiramer acetate are currently funded for patients who meet specified entry criteria, in which patients must have:

- an EDSS score of at least 2.0 and have had at least three significant relapses of MS in the previous 12 months; or
- an EDSS of at least 2.5 and have had at least two significant relapses of MS in the previous 12 months.

Under the proposed funding criteria, natalizumab and fingolimod (and the beta-interferons and glatiramer acetate if treatment with both natalizumab and fingolimod is not tolerated or is contraindicated) would be funded for patients who have:

- an EDSS score of 0–4 and have had at least one significant relapse in the previous 12 months

Below is a diagram showing the proposed changes to key features of the entry criteria for MS treatments, namely those involving changes to both EDSS disability states and relapse frequency before treatment:



Current criteria mean that funded treatment ceases for patients if they have a stable or increasing relapse rate. In addition, funded treatment ceases if a patient's disability progresses by any of the following EDSS points (the first point is the EDSS at treatment entry):

- 2.0–4.0
- 2.5–4.0
- 3.0–4.5
- 3.5–4.5
- 4.0–5.0
- 4.5–5.5
- 5.0–6.0
- 5.5–6.0

Under the proposed criteria funded treatment would stop if patients' have an increasing relapse rate. In addition, funding would cease if there is progression of disability by any of the following EDSS points (the first point is the EDSS at treatment entry, the second when treatment stops):

- 0–3.0
- 1.0–3.0
- 1.5–3.5
- 2.0–4.0
- 2.5–4.5
- 3.0–4.5
- 3.5–4.5
- 4.0–4.5

PHARMAC notes that this is a brief explanation of the main proposed changes. It is important to note that the proposed funding criteria for interferon beta-1-alpha, interferon beta-1-beta and glatiramer acetate differ from the current criteria. Full details of the current entry and stopping criteria are on pages 149-150 of the Pharmaceutical Schedule, available from the link below, and can be used to compare against the criteria in this proposal for further understanding: http://www.pharmac.govt.nz/2014/08/01/Schedule.pdf

Applications, distribution and administration

Applications (including for those patients switching treatments) for funding of natalizumab and fingolimod would be considered and determined by MSTAC, as is currently the case for interferon beta-1-alpha, interferon beta-1-beta and glatiramer acetate.

Due to the complexities and monitoring requirements of the new treatments it is proposed that only neurologists would be able to make an application. We would appreciate feedback on whether:

- only neurologists being able to apply for funding for interferon beta-1-alpha, interferon beta-1-beta and glatiramer acetate, given that these would only be funded if both the new treatments are contraindicated or not tolerated, or
- the prescriber type applicant restriction for these three treatments should also include general physicians with a special interest in MS.

No changes are proposed to the method of distribution of interferon beta-1-alpha, interferon beta-1-beta and glatiramer acetate. Prescriptions and delivery of these pharmaceuticals would continue to be managed by PHARMAC.

Fingolimod is an oral capsule which would be dispensed through community pharmacy on receipt of a prescription, in the same way that other pharmaceuticals listed on the Pharmaceutical Schedule are dispensed.

As explained above, the supplier of natalizumab requires any practitioner prescribing natalizumab, and any pharmacy dispensing natalizumab, must have taken part in a training program (the Tysabri Australasian Prescribing Programme). Should the proposal be approved then a website and a toll free phone number would be provided by the supplier (Biogen Idec) detailing information about the training programme.

Costs to the Health Sector

For the avoidance of doubt, when calculating the cost and cost effectiveness of a treatment PHARMAC takes into account any costs to the total health sector. For example, PHARMAC's assessment of costs for natalizumab has factored in the costs associated with monitoring and infusing the treatment as well as the health gains associated with the treatment (i.e. reduced admissions, delayed onset of disability, reduced GP visits etc). More information about how PHARMAC calculates cost effectiveness of treatments can be found in the Prescription for Pharmacoeconomic Analysis at: http://www.pharmac.govt.nz/2012/06/26/PFPAFinal.pdf.