SECTION 2

Multiple Sclerosis (MS) Drug Coverage

MULTIPLE SCLEROSIS (MS) DRUG COVERAGE

Selected Drug Products used in the treatment of patients with relapsing remitting multiple sclerosis (MS) and secondary progressive MS with relapses may be considered for coverage for patients within Alberta government-sponsored drug plans. For further information regarding eligibility for Alberta government-sponsored drug plans refer to the Introduction section of the Alberta Health and Wellness Drug Benefit List (AHWDBL).

In order to be eligible for Multiple Sclerosis (MS) Drug Coverage, an individual must:

In order to be eligible for *MS Drug Coverage*, an individual must:

- Have valid Alberta government-sponsored drug plan coverage; and
- Meet specific clinical criteria according to *MS Drug Coverage* requirements; and
- Have an *MS Drug Coverage* Application submitted on their behalf to Alberta Blue Cross by an "MS Neurologist" identified by the Alberta Multiple Sclerosis (MS) Drug Review Panel (the MS Panel); and
- Have their *MS Drug Coverage* Application approved.

Alberta Multiple Sclerosis (MS) Drug Review Panel

The Alberta Multiple Sclerosis (MS) Drug Review Panel (the MS Panel) is an external panel comprised of neurologists and other health professionals with expertise in MS, appointed by the Minister of Health.

The MS Panel's functions include:

- Making recommendations on *MS Drug Coverage* requirements, including eligibility and coverage criteria;
- Identifying "MS Neurologists" for the purposes of *MS Drug Coverage*, and;
- Reviewing Applications for *MS Drug Coverage*.

Process for *Multiple Sclerosis (MS) Drug Coverage*

Participating "MS Neurologists" must complete an *MS Drug Coverage* Application form for each patient. Applications must be completed within 4 months of the Patient Assessment date (or if already on an MS disease modifying therapy (MS DMT), from the most recent Assessment).

A new *MS Drug Coverage* Application form must be completed by an "MS Neurologist" for each renewal request and also if coverage of a different MS disease modifying therapy (MS DMT) is being requested. (Refer to the Application form for additional completion details.) For clarity, MS DMTs are Drug Products for purposes of Section 2 and other applicable provisions in the AHWDBL.

Alberta Blue Cross, in providing administrative support to the MS Panel, receives and screens each Application for completeness, then forwards it to the MS Panel for review. After an Application is reviewed, Alberta Blue Cross will notify the "MS Neurologist" and the patient by letter of the coverage decision.

Approval of each Application must be granted before coverage occurs. Approval is granted for a specific period, to a maximum of 12 months. If continued treatment is necessary, it is the responsibility of the "MS

Neurologist" to re-apply on behalf of the patient for MS DMT renewal coverage prior to the expiry date of the approval period. Current information must be provided in each Application.

If the patient is approved for *MS Drug Coverage,* an MS Nurse (a nurse with extensive knowledge of MS and MS therapies) will provide the patient with education regarding: (i) potential benefits and limitations of therapy, (ii) side-effects, (iii) how MS DMT administration will be taught, (iv) how the patient will be followed, (v) how the patient can access help or information, (vi) how the treatment will be reimbursed and the requirements for reimbursement, (vii) indications that treatment should (possibly) be discontinued, and (viii) what should be reported and to whom. The MS Nurse will also inform the requesting "MS Neurologist" of the timelines for the necessary follow-up and monitoring to contribute to safe, appropriate, ongoing use and coverage of MS DMT.

To be eligible for *MS Drug Coverage*, prescriptions must be written by an "MS Neurologist".

Regular monitoring of patients during the first year of therapy is needed for best patient care and to minimize the potential for MS DMT wastage. Therefore, prescription quantities are limited to a one-month supply for the first year of therapy. This quantity limit also applies when one MS DMT is discontinued and a new MS DMT is started. Once the patient has been stabilized on a particular MS DMT (excluding Tysabri) and dosage for one year and received a renewal of their coverage authorization, up to 100 days' supply may be dispensed at a time.

Government will not be responsible for reimbursement of MS DMT costs associated with patient loss or wastage of the MS DMT (e.g., due to improper storage).

Grace Renewals

As a result of two Contraindications to Coverage changes effective September 1, 2012, some patients who would previously have been eligible for renewal of coverage will no longer meet coverage criteria.

A one-time grace renewal authorization may be approved for MS DMT coverage for patients who are now contraindicated to continued coverage based on either or both of the two Contraindications:

1. The development of Secondary Progressive MS (SPMS) or, for Betaseron or Extavia, the development of SPMS without relapses.

2. An EDSS score of 7 or above sustained for a minimum of 1 year. (Coverage of an MS DMT may be considered in a patient with a sustained EDSS score of 7 or above, for example, when the patient is wheelchair bound after an acute relapse without complete recovery. For MS DMT coverage to be considered, details must be provided in a letter from the "MS Neurologist" and accompany the Application.)

Those who may be eligible for a one-time Grace Renewal include patients who:

- otherwise meet criteria for renewal, except for either or both of the two Contraindications to Coverage noted above; and
- have an *MS Drug Coverage* Application for renewal of coverage with a Patient Assessment completed between September 1, 2012 and August 31, 2013; and
- are seeking renewal of the MS DMT they are currently and continuously using; and
- were already approved under a Government of Alberta drug plan for the MS DMT within the year prior to September 1, 2012; and
- have not already been granted a Grace Renewal.

A Grace Renewal:

- is a one-time coverage authorization of the patient's MS DMT for a 12 month period, based on the Patient Assessment date;
- allows time for the "MS Neurologist" and patient to make an informed decision about continuing the MS DMT if Government of Alberta drug plan coverage does not continue.

After the Grace Renewal ends, patients must meet criteria as published to continue under *MS Drug Coverage*.

Alberta Blue Cross will notify the "MS Neurologist" and the patient by letter of the coverage decision.

Refer to the *MS Drug Coverage* Application for completion requirements. Completed *MS Drug Coverage* Application should be directed by mail or FAX to:

Clinical Drug Services
Alberta Blue Cross
10009 108 Street NW
Edmonton, Alberta T5J 3C5
(780) 498-8384 in Edmonton and area
1-877-828-4106 toll-free for all other areas

ALBERTA BLUE CROSS®

AVONEX/BETASERON/COPAXONE/EXTAVIA/GILENYA/REBIF/TYSABRI
MS DRUG COVERAGE APPLICATION

Applicant must be covered on an Alberta Government sponsored drug program.

PATIENT INFORMATION

Surname	First Name	Middle Initial	Sex M / F	Date of Birth Year	Month	Day

Street Address	City	Province	Postal Code	Alberta Personal Health Number

Coverage Type: ☐ Alberta Blue Cross ☐ Alberta Human Services ☐ Other:

Identification/Client/Coverage No:

MS NEUROLOGIST INFORMATION

Surname First Name Initial	College of Physicians and Surgeons Registration No.	
Street Address	Telephone Number	Fax Number
City, Province	Date Form Completed	
Postal Code	MS Neurologist's Signature	

MS NURSE INFORMATION

Surname	First Name	MS Nurse Signature	Telephone Number	Fax Number

APPLICATION INFORMATION REQUIRED:

All Applications:	Pages 1-3	
Gilenya and **Tysabri:**	**New to MS Drug Coverage:**	Start MS DMT upon approval: Pages 1-4
		On requested MS DMT already: Pages 1-5
	Renewal:	Pages 1-3, and 5

MS DISEASE MODIFYING THERAPY (DMT) REQUESTED (Complete for each Application)

☐ **Avonex/Avonex PS** (interferon beta-1a)	☐ **Betaseron** (interferon beta-1b)	☐ **Copaxone** (glatiramer acetate)	☐ **Extavia** (interferon beta-1b)	☐ **Gilenya** (fingolimod)	☐ **Rebif** (interferon beta-1a)	☐ **Tysabri** (natalizumab)

Dosage and Frequency Requested	Planned Start Date

☐ New to MS Drug Coverage: Start MS DMT upon approval ☐ New to MS Drug Coverage: On requested MS DMT already ☐ MS DMT change ☐ Renewal

DIAGNOSIS (Complete all that apply. McDonald 2010[1(page 2)] criteria must be met and applicable MRI reports provided.)

Date of Onset[2 (page 2)]
(Consider onset as the time of first convincing MS symptoms)

Year	Month

For Avonex, Betaseron, Copaxone, Extavia, Gilenya, Rebif, Tysabri:

☐ Relapsing-remitting multiple sclerosis

☐ Ambulatory with or without aid

For Betaseron or Extavia only:

☐ Secondary-progressive multiple sclerosis with relapses

☐ EDSS ≤ 5.5

☐ Ambulatory to 100 m without an aid

Please mail this Application to:	Or fax to:	**Case Number**
Alberta Blue Cross, Clinical Drug Services **10009-108 Street NW, Edmonton, Alberta T5J 3C5**	**Alberta Blue Cross, Clinical Drug Services** **780-498-8384** in Edmonton • **1-877-828-4106** toll-free all other areas	

Notice to Applicant: The information on this form is being collected and pursuant to sections 20, 21 and 22 of the Health Information Act, and sections 33 and 34 of the Freedom of Information and Protection of Privacy Act, for the purposes of determining or verifying eligibility to participate in a program or receive a benefit, product or health service. If you have any questions regarding the collection or use of this information, please contact an Alberta Blue Cross privacy matters representative toll-free at 1-855-498-7302 or write to Privacy Matters, Alberta Blue Cross, 10009 - 108 Street, Edmonton AB T5J 3C5.

ALBERTA BLUE CROSS®

AVONEX/BETASERON/COPAXONE/EXTAVIA/GILENYA/REBIF/TYSABRI

MS DRUG COVERAGE APPLICATION

Patient's Alberta Personal Health Number (only) _____

PREVIOUS MS DMT (Complete for each Application)

MS DMT	DATE STARTED	DATE STOPPED	REASON FOR MS DMT STOPPAGE*

* Examples of reasons MS DMT may be stopped: lack of efficacy, intolerability, non-compliance, pregnancy, financial reasons, antibody positive

CONTRAINDICATIONS TO COVERAGE (Complete for each Application)

Does the patient have any of the following?	**Yes**	**No**
Concurrent significant illness likely to alter compliance or substantially reduce life expectancy.....	❑	❑
For patients who have been on an MS DMT for less than 6 months; active, severe, untreated depression.[3]……	❑	❑
Planned or current pregnancy or breastfeeding.....	❑	❑
Immuno-compromised due to treatment (e.g., immunosuppressant or antineoplastic) or disease (e.g., HIV, leukemia).....	❑	❑
Severe, chronic active infections (e.g., hepatitis, tuberculosis).....	❑	❑
Secondary progressive MS (SPMS); or for Betaseron or Extavia Applications, SPMS without relapses.....	❑	❑
EDSS score of 7 or above sustained for a minimum of 1 year[4].....	❑	❑
Any contraindication listed in the Health Canada approved MS DMT product monograph……..	❑	❑
In addition to the above:		
Gilenya Applications: Severe hepatic impairment ……	❑	❑
Tysabri Applications: Has or has had progressive multifocal leukoencephalopathy (PML)……	❑	❑

Pages 1, 2, and 3:

1. The 2010 McDonald diagnostic criteria (patients must meet one of the following conditions):
   a) 2 relapses confirmed by objective findings and evidence of 2 clinically objective lesions.
   b) 2 relapses confirmed by objective findings, and 1 clinically objective lesion, and dissemination in space by MRI.
   c) 1 relapse confirmed by objective findings, and 2 clinically objective lesions, and dissemination in time by MRI.
   d) 1 relapse confirmed by objective findings, and 1 clinically objective lesion, and dissemination in space by MRI and dissemination in time by MRI.
   Dissemination in space (DIS) by MRI:
   At least 2 of the following: i) ≥1 periventricular lesion; ii) ≥1 juxtacortical lesion; iii) ≥1 infratentorial lesion; iv) spinal cord lesion.
   Gadolinium enhancement of lesions is not required for DIS.
   Dissemination in time (DIT) by MRI:
   i)A new T2 and/or gadolinium-enhancing lesion(s) on follow-up MRI, with reference to a baseline scan, irrespective of the timing of the baseline MRI; or ii) Simultaneous presence of asymptomatic gadolinium-enhancing and non-enhancing lesions at any time.
2. This would include episodes such as transverse myelitis or optic neuritis, but not (in most cases) non-specific symptoms such as dizziness, visual blurring or fatigue.
3. A depression waiver completed by a psychologist or psychiatrist must accompany the MS Drug Coverage Application for such patients for coverage of an MS DMT to be considered.
4. Coverage of an MS DMT may still be considered in a patient with a sustained EDSS score of 7 or above, for example, when the patient is wheelchair bound after an acute relapse without complete recovery. For MS DMT coverage to be considered, details must be provided in a letter from the MS Neurologist and accompany the Application.

Case Number _____

QUALIFYING RELAPSES (Not required for renewals)

The patient must have had at least two relapses of MS during the previous two years or in the two years prior to starting an MS DMT. In RRMS, a relapse is defined as the appearance of new symptoms or worsening of old symptoms, lasting at least 48 hours in the absence of fever, not associated with withdrawal from steroids[5].

Relapses must be separated by a period of at least one month. At least one definite gadolinium-enhancing T1 MRI lesion (not questionable faint enhancement) at least 90 days before or after a relapse may substitute for one clinical relapse. McDonald 2010 criteria[1(Page 2)] must be met and applicable MRI reports provided.

DATE OF QUALIFYING CLINICAL AND/OR MRI RELAPSES			MRI RELAPSE (attach report)	SEVERITY[6]	RECOVERY	FUNCTIONAL SYSTEMS INVOLVED		OBJECTIVE CHANGES (SPMS[5] ONLY)
Year	Month	Day	❑ Yes	❑ Mild ❑ Moderate ❑ Severe ❑ Very Severe	❑ None ❑ Incomplete ❑ Complete	❑ Pyramidal ❑ Cerebellar ❑ Bowel/bladder ❑ Cognitive/cerebral	❑ Sensory ❑ Brain Stem ❑ Visual	❑ Yes ❑ No
Year	Month	Day	❑ Yes	❑ Mild ❑ Moderate ❑ Severe ❑ Very Severe	❑ None ❑ Incomplete ❑ Complete	❑ Pyramidal ❑ Cerebellar ❑ Bowel/bladder ❑ Cognitive/cerebral	❑ Sensory ❑ Brain Stem ❑ Visual	❑ Yes ❑ No

PATIENT ASSESSMENTS (Complete for each Application. Where available, at least two years' history must be provided.)

	PRE MS DMT YY/MM/DD	CURRENT if on MS DMT YY/MM/DD	YEAR 1 YY/MM/DD	YEAR 2 YY/MM/DD	YEAR 3 YY/MM/DD	YEAR 4 YY/MM/DD
Date[7] (Year / Month / Day)						
EDSS[8]						
Pyramidal						
Cerebellar						
Brain Stem						
Visual Score						
Sensory						
Bowel/Bladder						
Cognitive						
# of relapses during 2 yrs prior to baseline assessment						
# of relapses during the last 12 months						
Relapse at time of assessment (Yes or No)						
Secondary Progressive MS (Yes or No)						
Interferon antibodies (Yes, No, N/A, or Unknown)						

Page 3 and 4:

5. In SPMS, a relapse is defined as the appearance of new symptoms or worsening of old symptoms (documented by a physician), lasting at least 72 hours in the absence of fever, not associated with withdrawal from steroids, and preceded by stability for at least one month.
6. **Severity**: **Mild** - symptoms of MS are present but do not affect activities of daily living; **Moderate** - modification or more time is required to carry out activities of daily living; **Severe** – there is inability to carry out some activities of daily living; **Very Severe** – activities of daily living must be completed by others.
7. Date of patient assessment must be within 4 months preceding submission of this Application where the patient is not currently on the requested MS DMT. If the patient is currently on the requested MS DMT, the most recent annual assessment may be accepted.
8. An EDSS score of 7 or above sustained for a minimum of 1 year is a Contraindication to Coverage.

Case Number

ALBERTA BLUE CROSS®

GILENYA/TYSABRI

MS DRUG COVERAGE APPLICATION

Patient's Alberta Personal Health Number (only) _____

New Gilenya Applications: Please complete response to EITHER interferon beta OR glatiramer acetate
New Tysabri Applications: Please complete response to BOTH interferon beta AND glatiramer acetate

RESPONSE TO INTERFERON BETA (Avonex, Betaseron, Extavia, or Rebif):

I. NEUTRALIZING ANTIBODIES TO INTERFERON BETA — **Yes** ❑ **No** ❑

Does the patient have clinically significant titres of neutralizing antibodies to interferon beta? (report must be provided)

OR

II. INTOLERANT TO INTERFERON BETA

'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in the product monograph, or a persisting adverse event that is unresponsive to recommended management techniques and which is incompatible with further use of that class of MS DMT.

Describe the intolerance (or attach letter): _____

Have symptom management techniques been tried? ❑ Yes ❑ No

OR

III. REFRACTORY TO INTERFERON BETA

Within a consecutive 12-month period while on interferon beta taken at the recommended doses:

1. Has the patient been adherent to interferon beta, defined as greater than 80% of approved doses administered? ❑ Yes ❑ No

2. The patient must have experienced at least two clinical relapses* confirmed by the presence of neurologic deficits on examination.[9]

*At least one gadolinium-enhancing T1 MRI lesion (not questionable faint enhancement) obtained at least 90 days after initiation of the DMT and at least 90 days before or after a clinical relapse may substitute for one clinical relapse. McDonald 2010[1(page 2)] criteria must be met and applicable MRI reports provided.

DATE OF RELAPSES[9]			MRI RELAPSE*	SEVERITY[6 (page 3)]	RECOVERY
Year	Month	Day			
			❑ Yes	❑ Moderate ❑ Severe ❑ Very Severe	❑ None ❑ Incomplete ❑ Complete
Year	Month	Day			
			❑ Yes	❑ Moderate ❑ Severe ❑ Very Severe	❑ None ❑ Incomplete ❑ Complete

RESPONSE TO GLATIRAMER ACETATE (Copaxone):

I. INTOLERANT TO GLATIRAMER ACETATE — **Yes** ❑ **No** ❑

'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in the product monograph, or a persisting adverse event that is unresponsive to recommended management techniques and which is incompatible with further use of that class of MS DMT.

Describe the intolerance (or attach letter): _____

Have symptom management techniques been tried? ❑ Yes ❑ No

OR

II. REFRACTORY TO GLATIRAMER ACETATE

Within a consecutive 12-month period while on glatiramer acetate taken at the recommended doses:

1. Has the patient been adherent to glatiramer acetate, defined as greater than 80% of approved doses administered? ❑ Yes ❑ No

2. The patient must have experienced at least two clinical relapses* confirmed by the presence of neurologic deficits on examination.[9]

*At least one gadolinium-enhancing T1 MRI lesion (not questionable faint enhancement) obtained at least 90 days after initiation of the DMT and at least 90 days before or after a clinical relapse may substitute for one clinical relapse. McDonald 2010[1(page 2)] criteria must be met and applicable MRI reports provided.

DATE OF RELAPSES[9]			MRI RELAPSE*	SEVERITY[6 (page 3)]	RECOVERY
Year	Month	Day			
			❑ Yes	❑ Moderate ❑ Severe ❑ Very Severe	❑ None ❑ Incomplete ❑ Complete
Year	Month	Day			
			❑ Yes	❑ Moderate ❑ Severe ❑ Very Severe	❑ None ❑ Incomplete ❑ Complete

9. i. The first qualifying clinical relapse must have begun at least one month after treatment initiation.
ii. There must be at least one month between the onset of clinical relapses.
iii. Both qualifying relapses must be classified with a relapse severity of moderate, severe, or very severe[6 (page 3)].

Case Number _____

ALBERTA BLUE CROSS®

GILENYA/TYSABRI
MS DRUG COVERAGE APPLICATION

Patient's Alberta Personal Health Number (only) _____

GILENYA/TYSABRI RENEWALS, OR APPROVALS FOR PATIENTS PREVIOUSLY ON GILENYA/TYSABRI

Gilenya or Tysabri treatment start date (YYYY/MM/DD): _____

	Yes	No
Has the patient been adherent to the approved MS DMT? (The patient has not missed any doses, or delayed any doses by more than 2 weeks with the exception of medically authorized delays. Rationale for such delays must be justified in a narrative; only serious medical conditions may be acceptable)	❑	❑
Has the patient been assessed by an MS Neurologist and had an MRI with gadolinium at least every 12 months? (Attach reports. The MRI must be completed within **4 months** of the renewal date to qualify for up to a 12 month renewal.)	❑	❑

NEUTRALIZING ANTIBODIES TO TYSABRI (Complete for patients currently on Tysabri ONLY)

There must be evidence that neutralizing antibodies to Tysabri are absent (attach report):

Are neutralizing antibodies **absent** at 6 to 8 months after initiation of Tysabri?

Yes ❑ If Yes: further testing is not required

No ❑ If No: Are neutralizing antibodies **absent** on repeat testing? (attach report) Yes ❑ No ❑

RESPONSE TO GILENYA OR TYSABRI (Complete for **ALL** patients on Gilenya or Tysabri, update for each Application)

On assessment, the MS Neurologist must confirm that the patient is a 'responder':	Yes	No
Have there been less than two inflammatory events in the last year? (defined as either a clinical relapse or gadolinium-enhancing lesion on MRI)	❑	❑
OR		
If the patient had four or more relapses in the year prior to starting treatment, has there been at least a 50% reduction in relapse rate over the entire Gilenya or Tysabri treatment period?	❑	❑

PRIOR to Gilenya or Tysabri treatment:
Indicate confirmed inflammatory events over the 2 years prior to initiation of treatment with Gilenya or Tysabri (include all independent clinical relapses and MRI events):

MRI	Clinical relapse	Date of onset/MRI (YYYY/MM/DD)
❑	❑	
❑	❑	
❑	❑	
❑	❑	
❑	❑	
❑	❑	
❑	❑	
❑	❑	
❑	❑	
❑	❑	

WHILE ON Gilenya or Tysabri treatment:
Indicate all confirmed inflammatory events after initiation of treatment with Gilenya or Tysabri (include all independent clinical relapses and MRI events):

No inflammatory events ❑

MRI	Clinical relapse	Date of onset/MRI (YYYY/MM/DD)
❑	❑	
❑	❑	
❑	❑	
❑	❑	
❑	❑	
❑	❑	
❑	❑	
❑	❑	
❑	❑	
❑	❑	

Case Number _____

Drug Products Under *Multiple Sclerosis (MS) Drug Coverage* Program

FINGOLIMOD HYDROCHLORIDE

FINGOLIMOD

Relapsing Remitting Multiple Sclerosis:

Fingolimod coverage may be provided for the treatment of relapsing remitting multiple sclerosis (RRMS) to reduce the frequency of clinical relapses and to delay the progression of physical disability in adult patients (18 years of age or older) who are 'refractory' or 'intolerant' to either interferon beta (Avonex, Betaseron/Extavia or Rebif) or glatiramer acetate (Copaxone). Patients who develop neutralizing antibodies to interferon beta will be considered to be 'refractory' to interferon beta.

Neutralizing Antibodies to interferon beta

-If neutralizing antibodies are present, a report indicating clinically significant titres must be provided.

Refractory

-When the above MS disease modifying therapies (DMTs) are taken at the recommended doses for a full and adequate course of treatment 'refractory' is defined as, within a consecutive 12-month period while the patient was on the MS DMT, the patient has:

1) Been adherent to the MS DMT (greater than 80% of approved doses have been administered);

AND

2) Experienced at least two clinical relapses* confirmed by the presence of neurologic deficits on examination.
i. The first qualifying clinical relapse must have begun at least one month after treatment initiation.
ii. There must be at least one month between the onset of clinical relapses.
iii. Both qualifying relapses must be classified with a relaspse severity of moderate, severe or very severe**.

*At least one definite gadolinium-enhancing T1 MRI lesion (not questionable faint enhancement) obtained at least 90 days after initiation of the DMT and at least 90 days before or after a relapse may substitute for one clinical relapse. McDonald 2010 criteria must be met and applicable MRI reports provided.

**Relapse Severity: with moderate relapses modification or more time is required to carry out activities of daily living; with severe relapses there is inability to carry out some activities of daily living; with very severe relapses activities of daily living must be completed by others

Intolerant

'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in the product monograph, or a persisting adverse event that is unresponsive to recommended management techniques and which is incompatible with further use of that class of MS DMT.

Coverage

For coverage, fingolimod must be prescribed by a Specialist in Neurology ("MS Neurologist") who has been identified by the Alberta MS Drug Review Panel.

FINGOLIMOD HYDROCHLORIDE

Initial Coverage

A baseline MRI scan with gadolinium must be completed within 12 months of commencing therapy with fingolimod.

The patient must be ambulatory with or without aid.

To meet the active disease criterion, within the 2 years prior to the fingolimod Application, the patient must meet the same relapse criteria that are required for other MS DMTs (i.e., have had at least two relapses* of MS during the previous two years or in the two years prior to starting an MS DMT. In most cases this will be satisfied by the 'refractory' to treatment criterion but if a patient failed interferon beta and glatiramer acetate more than one year earlier, ongoing active disease must be confirmed).

*A relapse is defined as the appearance of new symptoms or worsening of old symptoms, lasting at least 48 hours in the absence of fever, not associated with withdrawal from steroids. Relapses must be separated by a period of at least one month. At least one definite gadolinium-enhancing T1 MRI lesion at least 90 days before or after a relapse may substitute for one clinical relapse in RRMS patients. McDonald 2010 Criteria must be met and applicable MRI reports provided.

None of the Contraindications to Coverage identified below exist.

Coverage will not be approved when any MS DMT or other immunosuppressive therapy is to be used in combination with fingolimod.

Coverage of fingolimod will not be approved if the patient was deemed to be 'refractory' to the fingolimod in the past, i.e., has not met the 'responder' criteria below in "Continued Coverage". Patients previously treated with natalizumab may be eligible for coverage of fingolimod. Coverage criteria for fingolimod must be met.

Following assessment of the Application, coverage may be approved for up to 12 months. Patients will be limited to receiving a one-month supply of fingolimod per prescription at their pharmacy for the first 12 months of coverage.

Continued Coverage

For continued coverage beyond 13 doses, the patient must meet the following criteria:

1) The patient must be assessed by an MS Neurologist and have an MRI with gadolinium at least every 12 months;

AND

2) On assessment, the MS Neurologist must confirm in writing that the patient is a 'responder' that meets all of the following criteria:

- There has been no more than one inflammatory event in the last year (defined as either a clinical relapse or gadolinium-enhancing lesion). In instances where a patient has had four or more clinical relapses in the year prior to starting treatment, there must be at least a 50% reduction in relapse rate over the entire treatment period.

- The patient has not missed any doses by more than 2 weeks with the exception of medically authorized delays. (Rationale for such delays must be justified in a narrative; only serious medical conditions are acceptable.)

- None of the coverage contraindications identified below exist.

Following assessment of the Application, continued coverage may be approved for maintenance

FINGOLIMOD HYDROCHLORIDE

therapy for up to 12 months. Patients may receive up to 100 days supply of fingolimod per prescription at their pharmacy.

Contraindications to Coverage

Coverage will not be approved if any of the following contraindications exist:

- concurrent significant illness likely to alter compliance or substantially reduce life expectancy;

- for patients who have been on an MS DMT less than 6 months; active, severe, untreated depression. (A depression waiver, completed by a psychologist or psychiatrist, must accompany the MS Drug Coverage Application for such patients for coverage of an MS DMT to be considered.);

- planned or current pregnancy or breastfeeding;

- immune compromised due to treatment (e.g., immunosuppressant or antineoplastic) or disease (e.g., immunodeficiency such as HIV, leukemia);

- severe chronic active infections (e.g., hepatitis, tuberculosis);

- Secondary progressive MS;

- EDSS score of 7 or above sustained for a minimum of 1 year. (Coverage of an MS DMT may be considered in a patient with a sustained EDSS score of 7 or above, for example, when the patient is wheelchair bound after an acute relapse without complete recovery. For MS DMT coverage to be considered, details must be provided in a letter from the MS Neurologist and accompany the Application.);

- severe hepatic impairment;

- any of the contraindications listed in the Health Canada approved Gilenya product monograph.

0.5 MG ORAL CAPSULE				
00002365480	GILENYA	NOV	$	85.1648

GLATIRAMER ACETATE

GLATIRAMER ACETATE

Relapsing Remitting Multiple Sclerosis:

"For the reduction of the frequency and severity of clinical relapses and reduction of the number and volume of active brain lesions identified on MRI scans, in ambulatory patients with relapsing remitting multiple sclerosis.

For coverage, this MS DMT must be prescribed by an 'MS Neurologist' who has been identified by the Alberta MS Drug Review Panel and the patient must:

1) Have had at least two relapses of MS during the previous two years or in the two years prior to starting an MS DMT. [A relapse is defined as the appearance of new symptoms or worsening of old symptoms, lasting at least 48 hours in the absence of fever, not associated with withdrawal from steroids. Relapses must be separated by a period of at least one month. At least one definite gadolinium-enhancing T1 MRI lesion (not questionable faint enhancement) at least 90 days before or after a relapse may substitute for one clinical relapse. McDonald 2010 criteria must be met and applicable MRI reports provided.]

2) Be ambulatory with or without aid.

3) Have none of the Contraindications to Coverage identified below.

Contraindications to Coverage

In addition to meeting the above clinical criteria, the patient must not have any of the contraindications listed below:

- Concurrent significant illness likely to alter compliance or substantially reduce life expectancy;

- For patients who have been on an MS DMT for less than 6 months; active, severe, untreated depression. (A depression waiver, completed by a psychologist or psychiatrist, must accompany the MS Drug Coverage Application for such patients for coverage of an MS DMT to be considered.);

- Planned or current pregnancy or breastfeeding;

- Immuno-compromised due to treatment (e.g., immunosuppressant or antineoplastic) or disease (e.g., immunodeficiency such as HIV, leukemia);

- Severe chronic active infections (e.g., hepatitis, tuberculosis);

- Secondary Progressive MS;

- EDSS score of 7 or above sustained for a minimum of 1 year. (Coverage of an MS DMT may be considered in a patient with a sustained EDSS score of 7 or above, for example, when the patient is wheelchair bound after an acute relapse without complete recovery. For MS DMT coverage to be considered, details must be provided in a letter from the MS Neurologist and accompany the Application.);

- any contraindication listed in the Health Canada approved Copaxone product monograph."

20 MG / SYR INJECTION SYRINGE				
00002245619	COPAXONE	TMP	$	43.2000

INTERFERON BETA-1A

Avonex

Relapsing Remitting Multiple Sclerosis:

"For the reduction of the frequency and severity of clinical relapses and reduction of the number and volume of active brain lesions identified on MRI scans, in ambulatory patients with relapsing remitting multiple sclerosis.

For coverage, this MS DMT must be prescribed by an 'MS Neurologist' who has been identified by the Alberta MS Drug Review Panel and the patient must:

1) Have had at least two relapses of MS during the previous two years or in the two years prior to starting an MS DMT. [A relapse is defined as the appearance of new symptoms or worsening of old symptoms, lasting at least 48 hours in the absence of fever, not associated with withdrawal from steroids. Relapses must be separated by a period of at least one month. At least one definite gadolinium-enhancing T1 MRI lesion (not questionable faint enhancement) at least 90 days before or after a relapse may substitute for one clinical relapse. McDonald 2010 criteria must be met and applicable MRI reports provided.]

2) Be ambulatory with or without aid.

3) Have none of the Contraindications to Coverage identified below.

Contraindications to Coverage

In addition to meeting the above clinical criteria, the patient must not have any of the contraindications listed below:

- Concurrent significant illness likely to alter compliance or substantially reduce life expectancy;

- For patients who have been on an MS DMT for less than 6 months; active, severe, untreated depression. (A depression waiver, completed by a psychologist or psychiatrist, must accompany the MS Drug Coverage Application for such patients for coverage of an MS DMT to be considered.);

- Planned or current pregnancy or breastfeeding;

- Immuno-compromised due to treatment (e.g., immunosuppressant or antineoplastic) or disease (e.g., immunodeficiency such as HIV, leukemia);

- Severe chronic active infections (e.g., hepatitis, tuberculosis);

- Secondary Progressive MS;

- EDSS score of 7 or above sustained for a minimum of 1 year. (Coverage of an MS DMT may be considered in a patient with a sustained EDSS score of 7 or above, for example, when the patient is wheelchair bound after an acute relapse without complete recovery. For MS DMT coverage to be considered, details must be provided in a letter from the MS Neurologist and accompany the Application.);

- any contraindication listed in the Health Canada approved Avonex product monograph."

Rebif

Relapsing Remitting Multiple Sclerosis:
"For the reduction of the frequency and severity of clinical relapses and reduction of the number and volume of active brain lesions identified on MRI scans, in ambulatory patients with relapsing remitting multiple sclerosis.

INTERFERON BETA-1A

For coverage, this MS DMT must be prescribed by an 'MS Neurologist' who has been identified by the Alberta MS Drug Review Panel and the patient must:

1) Have had at least two relapses of MS during the previous two years or in the two years prior to starting an MS DMT. [A relapse is defined as the appearance of new symptoms or worsening of old symptoms, lasting at least 48 hours in the absence of fever, not associated with withdrawal from steroids. Relapses must be separated by a period of at least one month. At least one definite gadolinium-enhancing T1 MRI lesion (not questionable faint enhancement) at least 90 days before or after a relapse may substitute for one clinical relapse. McDonald 2010 criteria must be met and applicable MRI reports provided.]

2) Be ambulatory with or without aid.

3) Have none of the Contraindications to Coverage identified below.

Contraindications to Coverage

In addition to meeting the above clinical criteria, the patient must not have any of the contraindications listed below:

- Concurrent significant illness likely to alter compliance or substantially reduce life expectancy;

- For patients who have been on an MS DMT for less than 6 months; active, severe depression. (A depression waiver, completed by a psychologist or psychiatrist, must accompany the MS Drug Coverage Application for such patients for coverage of an MS DMT to be considered.);

- Planned or current pregnancy or breastfeeding;

- Immuno-compromised due to treatment (e.g., immunosuppressant or antineoplastic) or disease (e.g., immunodeficiency such as HIV, leukemia);

- Severe chronic active infections (e.g., hepatitis, tuberculosis);

- Secondary progressive MS;

- EDSS score of 7 or above sustained for a minimum of 1 year. (Coverage of an MS DMT may be considered in a patient with a sustained EDSS score of 7 or above, for example, when the patient is wheelchair bound after an acute relapse without complete recovery. For MS DMT coverage to be considered, details must be provided in a letter from the MS Neurologist and accompany the Application.);

- any contraindication listed in the Health Canada approved Rebif product monograph

6 MIU / VIAL INJECTION			
00002237770	AVONEX (30 MCG)	BIO	$ 365.8568
44 MCG / ML INJECTION CARTRIDGE			
00002318253	REBIF (1.5 ML CARTRIDGE)	SRO	$ 240.9300
88 MCG / ML INJECTION CARTRIDGE			
00002318261	REBIF (1.5 ML CARTRIDGE)	SRO	$ 293.3061
6 MIU / SYR INJECTION SYRINGE			
00002269201	AVONEX PS/PEN (30 MCG/0.5 ML)	BIO	$ 381.0075
22 MCG / SYR INJECTION SYRINGE			
00002237319	REBIF (0.5 ML SYRINGE)	SRO	$ 120.4650
44 MCG / SYR INJECTION SYRINGE			
00002237320	REBIF (0.5 ML SYRINGE)	SRO	$ 146.6530

INTERFERON BETA-1B

Betaseron

Relapsing Remitting Multiple Sclerosis:

"For the reduction of the frequency and severity of clinical relapses and reduction of the number and volume of active brain lesions identified on MRI scans, in ambulatory patients with relapsing remitting multiple sclerosis.

For coverage, this MS DMT must be prescribed by an 'MS Neurologist' who has been identified by the Alberta MS Drug Review Panel and the patient must:

1) Have had at least two relapses of MS during the previous two years or in the two years prior to starting an MS DMT. [A relapse is defined as the appearance of new symptoms or worsening of old symptoms, lasting at least 48 hours in the absence of fever, not associated with withdrawal from steroids. Relapses must be separated by a period of at least one month. At least one definite gadolinium-enhancing T1 MRI lesion (not questionable faint enhancement) at least 90 days before or after a relapse may substitute for one clinical relapse. McDonald 2010 criteria must be met and applicable MRI reports provided.]

2) Be ambulatory with or without aid.

3) Have none of the Contraindications to Coverage identified below.

Contraindications to Coverage

In addition to meeting the above clinical criteria, the patient must not have any of the contraindications listed below:

- Concurrent significant illness likely to alter compliance or substantially reduce life expectancy;

- For patients who have been on an MS DMT for less than 6 months; active, severe, untreated depression. (A depression waiver, completed by a psychologist or psychiatrist, must accompany the MS Drug Coverage Application for such patients for coverage of an MS DMT to be considered.);

- Planned or current pregnancy or breastfeeding;

- Immuno-compromised due to treatment (e.g., immunosuppressant or antineoplastic) or disease (e.g., immunodeficiency such as HIV, leukemia);

- Severe chronic active infections (e.g., hepatitis, tuberculosis);

- Secondary Progressive MS without relapses;

- EDSS score of 7 or above sustained for a minimum of 1 year. (Coverage of an MS DMT may be considered in a patient with a sustained EDSS score of 7 or above, for example, when the patient is wheelchair bound after an acute relapse without complete recovery. For MS DMT coverage to be considered, details must be provided in a letter from the MS Neurologist and accompany the Application.);

-any contraindication listed in the Health Canada approved Betaseron product monograph."

Secondary Progressive Multiple Sclerosis with Relapses:

"For the slowing of progression in disability and the reduction of the frequency of clinical relapses in patients with secondary progressive multiple sclerosis with relapses.

Coverage

INTERFERON BETA-1B

For coverage, this MS DMT must be prescribed by an 'MS Neurologist' who has been identified by the Alberta MS Drug Review Panel.

Initial Coverage

The patient must:

1) Have had at least two relapses of MS during the previous two years. [A relapse is defined as the appearance of new symptoms or worsening of old symptoms (documented by a physician), lasting at least 72 hours in the absence of fever, not associated with withdrawal from steroids, and preceded by stability for at least one month. Relapses must be separated by a period of at least one month. At least one definite gadolinium-enhancing T1 MRI lesion (not questionable faint enhancement) at least 90 days before or after a relapse may substitute for one clinical relapse. McDonald 2010 criteria must be met and applicable MRI reports provided.]

2) Have an EDSS score of less than or equal to 5.5; and

3) Be ambulatory to 100m without an aid.

4) Have none of the Contraindications to Coverage identified below.

Continued Coverage

For continued coverage beyond 12 months, the patient must have none of the Contraindications to Coverage identified below.

Contraindications to Coverage

In addition to meeting the above clinical criteria, the patient must not have any of the contraindications listed below:

- Concurrent significant illness likely to alter compliance or substantially reduce life expectancy;

- For patients who have been on an MS DMT for less than 6 months; active, severe, untreated depression. (A depression waiver, completed by a psychologist or psychiatrist, must accompany the MS Drug Coverage Application for such patients for coverage of an MS DMT to be considered.);

- Planned or current pregnancy or breastfeeding;

- Immuno-compromised due to treatment (e.g., immunosuppressant or antineoplastic) or disease (e.g., immunodeficiency such as HIV, leukemia);

- Severe chronic active infections (e.g., hepatitis, tuberculosis);

- Secondary Progressive MS without relapses;

- EDSS score of 7 or above sustained for a minimum of 1 year. (Coverage of an MS DMT may be considered in a patient with a sustained EDSS score of 7 or above, for example, when the patient is wheelchair bound after an acute relapse without complete recovery. For MS DMT coverage to be considered, details must be provided in a letter from the MS Neurologist and accompany the Application.);

- any contraindication listed in the Health Canada approved Betaseron product monograph."

Extavia
Relapsing Remitting Multiple Sclerosis:

INTERFERON BETA-1B

"For the reduction of the frequency and severity of clinical relapses and reduction of the number and volume of active brain lesions identified on MRI scans, in ambulatory patients with relapsing remitting multiple sclerosis.

For coverage, this MS DMT must be prescribed by an 'MS Neurologist' who has been identified by the Alberta MS Drug Review Panel and the patient must:

1) Have had at least two relapses of MS during the previous two years or in the two years prior to starting an MS DMT. [A relapse is defined as the appearance of new symptoms or worsening of old symptoms, lasting at least 48 hours in the absence of fever, not associated with withdrawal from steroids. Relapses must be separated by a period of at least one month. At least one definite gadolinium-enhancing T1 MRI lesion (not questionable faint enhancment) at least 90 days before or after a relapse may substitute for one clinical relapse. McDonald 2010 criteria must be met and applicable MRI reports provided.]

2) Be ambulatory with or without aid.

3) Have none of the Contraindications to Coverage identified below.

Contraindications to Coverage

In addition to meeting the above clinical criteria, the patient must not have any of the contraindications listed below:

- Concurrent significant illness likely to alter compliance or substantially reduce life expectancy;

- For patients who have been on an MS DMT for less than 6 months; active, severe, untreated depression. (A depression waiver, completed by a psychologist or psychiatrist, must accompany the MS Drug Coverage Application for such patients for coverage of an MS DMT to be considered.);

- Planned or current pregnancy or breastfeeding;

- Immuno-compromised due to treatment (e.g., immunosuppressant or antineoplastic) or disease (e.g., immunodeficiency such as HIV, leukemia);

- Severe chronic active infections (e.g., hepatitis, tuberculosis);

- Secondary progressive MS without relapses;

- EDSS score of 7 or above sustained for a minimum of 1 year. (Coverage of an MS DMT may be considered in a patient with a sustained EDSS score of 7 or above, for example, when the patient is wheelchair bound after an acute relapse without complete recovery. For MS DMT coverage to be considered, details must be provided in a letter from the MS Neurologist and accompany the Application.);

- any contraindication listed in the Health Canada approved Extavia product monograph."

Secondary Progressive Multiple Sclerosis with Relapses:

"For the slowing of progression in disability and the reduction of the frequency of clinical relapses in patients with secondary progressive multiple sclerosis with relapses.

Coverage

For coverage, this MS DMT must be prescribed by an 'MS Neurologist' who has been identified by the Alberta MS Drug Review Panel.

Initial Coverage

INTERFERON BETA-1B

The patient must:

1) Have had at least two relapses of MS during the previous two years. [A relapse is defined as the appearance of new symptoms or worsening of old symptoms (documented by a physician), lasting at least 72 hours in the absence of fever, not associated with withdrawal from steroids, and preceded by stability for at least one month. Relapses must be separated by a period of at least one month. At least one definite gadolinium-enhancing T1 MRI lesion (not questionable faint enhancement) at least 90 days before or after a relapse may substitute for one clinical relapse. McDonald 2010 Criteria must be met and applicable MRI reports provided.]

2) Have an EDSS score of less than or equal to 5.5; and

3) Be ambulatory to 100m without an aid.

4) Have none of the Contraindications to Coverage identified below.

Continued Coverage

For continued coverage beyond 12 months, the patient must have none of the Contraindications to Coverage identified below.

Contraindications to Coverage

In addition to meeting the above clinical criteria, the patient must not have any of the contraindications listed below:

- Concurrent significant illness likely to alter compliance or substantially reduce life expectancy;

- For patients who have been on an MS DMT for less than 6 months; active, severe, untreated depression. (A depression waiver, completed by a psychologist or psychiatrist, must accompany the MS Drug Coverage Application for such patients for coverage of an MS DMT to be considered.);

- Planned or current pregnancy or breastfeeding;

- Immuno-compromised due to treatment (e.g., immunosuppressant or antineoplastic) or disease (e.g., immunodeficiency such as HIV, leukemia);

- Severe chronic active infections (e.g., hepatitis, tuberculosis);

- Secondary progressive MS without relapses;

- EDSS score of 7 or above sustained for a minimum of 1 year. (Coverage of an MS DMT may be considered in a patient with a sustained EDSS score of 7 or above, for example, when the patient is wheelchair bound after an acute relapse without complete recovery. For MS DMT coverage to be considered, details must be provided in a letter from the MS Neurologist and accompany the Application.);

- any contraindication listed in the Health Canada approved Extavia product monograph."

9.6 MIU / VIAL INJECTION

00002169649	**BETASERON (0.3 MG)**	**BHP**	$	**99.3593**
00002337819	**EXTAVIA (0.3 MG)**	**NOV**	$	**99.3593**

NATALIZUMAB

Natalizumab

Relapsing Remitting Multiple Sclerosis:

"Natalizumab coverage may be provided for the treatment of relapsing remitting multiple sclerosis (RRMS) to reduce the frequency of clinical relapses, to decrease the number and volume of active brain lesions identified on magnetic resonance imaging (MRI) scans and to delay the progression of physical disability, in adult patients (18 years of age or older) and who are 'refractory' or 'intolerant' to both interferon beta (Avonex, Betaseron/Extavia or Rebif) and glatiramer acetate (Copaxone). Patients who develop neutralizing antibodies to interferon beta will be considered to be 'refractory' to interferon beta.

Neutralizing Antibodies to interferon beta

-If neutralizing antibodies are present, a report indicating clinically significant titres must be provided.

Refractory

-When the above MS disease modifying therapies (DMTs) are taken at the recommended doses for a full and adequate course of treatment 'refractory' is defined as, within a consecutive 12-month period while the patient was on the MS DMT, the patient has:

1) Been adherent to the MS DMT (greater than 80% of approved doses have been administered);

AND

2) Experienced at least two clinical relapses* confirmed by the presence of neurologic deficits on examination.
i. The first qualifying clinical relapse must have begun at least one month after treatment initiation.
ii. There must be at least one month between the onset of clinical relapses.
iii. Both qualifying relapses must be of classified with a relas pse severity of moderate, severe or very severe**.

*At least one definite gadolinium-enhancing T1 MRI lesion (not questionable faint enhancement) obtained at least 90 days after initiation of the DMT and at least 90 days before or after a relapse may substitute for one clinical relapse. McDonald 2010 criteria must be met and applicable MRI reports provided.

**Relapse severity: with moderate relapses modification or more time is required to carry out activities of daily living; with severe relapses there is inability to carry out some activities of daily living; with very severe relapses activities of daily living must be completed by others

Intolerant

'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in the product monograph, or a persisting adverse event that is unresponsive to recommended management techniques and which is incompatible with further use of that class of MS DMT.

Coverage

For coverage, natalizumab must be prescribed by a Specialist in Neurology ("MS Neurologist") who has been identified by the Alberta MS Drug Review Panel.

Initial Coverage

NATALIZUMAB

A baseline MRI scan with gadolinium must be completed within 12 months of commencing therapy with natalizumab.

The patient must be ambulatory with or without aid.

To meet the active disease criterion, within the 2 years prior to the natalizumab Application, the patient must meet the same relapse criteria that are required for other MS DMTs (i.e., have had at least two relapses* of MS during the previous two years or in the two years prior to starting an MS DMT. In most cases this will be satisfied by the 'refractory' to treatment criterion but if a patient failed interferon beta and glatiramer acetate more than one year earlier, ongoing active disease must be confirmed).

*A relapse is defined as the appearance of new symptoms or worsening of old symptoms, lasting at least 48 hours in the absence of fever, not associated with withdrawal from steroids. Relapses must be separated by a period of at least one month. At least one definite gadolinium-enhancing T1 MRI lesion at least 90 days before or after a relapse may substitute for one clinical relapse in RRMS patients. McDonald 2010 Criteria must be met and applicable MRI reports provided.

None of the Contraindications to Coverage identified below exist.

Coverage will not be approved when any MS DMT or other immunosuppressive therapy is to be used in combination with natalizumab.

Coverage of natalizumab will not be approved if the patient was deemed to be 'refractory' to natalizumab in the past, i.e., has not met the 'responder' criteria below in "Continued Coverage". Patients previously treated with fingolimod may be eligible for coverage of natalizumab. Coverage criteria for natalizumab must be met.

Following assessment of the Application, coverage may be approved for 13 doses of 300 mg (i.e., one dose administered every 4 weeks for a period of 12 months). Patients will be limited to receiving 1 dose (4 weeks supply) of natalizumab per prescription at their pharmacy.

Continued Coverage

For continued coverage beyond 13 doses, the patient must meet the following criteria:
1) The patient must be assessed by an MS Neurologist and have an MRI with gadolinium at least every 12 months;

AND

2) At the first renewal there must be evidence that neutralizing antibodies to natalizumab are absent. This requires an initial test between 6 to 8 months of treatment. If neutralizing antibodies are absent, no further testing is required. If neutralizing antibodies are present, testing must be repeated prior to the renewal request.

AND

3) On assessment, the MS Neurologist must confirm in writing that the patient is a 'responder' that meets all of the following criteria:

- There has been no more than one inflammatory event in the last year (defined as either a clinical relapse or gadolinium-enhancing lesion). In instances where a patient has had four or more relapses in the year prior to starting treatment, there must be at least a 50% reduction in relapse rate over the entire natalizumab treatment period.

- The patient has not missed any doses, or delayed any doses by more than 2 weeks with the exception of medically authorized delays. (Rationale for such delays must be justified in a narrative; only serious medical conditions may be acceptable.)

NATALIZUMAB

- None of the coverage contraindications identified above exist.

Following assessment of the Application, continued coverage may be approved for maintenance therapy of 300 mg every 4 weeks for a period of 12 months. Patients will be limited to receiving 1 dose of natalizumab per prescription at their pharmacy."

Contraindications to Coverage

Coverage will not be approved if any of the following contraindications exist:

- concurrent significant illness likely to alter compliance or substantially reduce life expectancy;

- for patients who have been on an MS DMT less than 6 months; active, severe, untreated depression. (A depression waiver, completed by a psychologist or psychiatrist, must accompany the MS Drug Coverage Application for such patients for coverage of an MS DMT to be considered.);

- planned or current pregnancy or breastfeeding;

- immune compromised due to treatment (e.g., immunosuppressant or antineoplastic) or disease (e.g., immunodeficiency such as HIV, leukemia);

- severe chronic active infections (e.g., hepatitis, tuberculosis);

- Secondary progressive MS;

- EDSS score of 7 or above sustained for a minimum of 1 year. (Coverage of an MS DMT may be considered in a patient with a sustained EDSS score of 7 or above, for example, when the patient is wheelchair bound after an acute relapse without complete recovery. For MS DMT coverage to be considered, details must be provided in a letter from the MS Neurologist and accompany the Application.);

- patients who have or have had progressive multifocal leukoencephalopathy (PML);

- any contraindication listed in the Health Canada approved Tysabri product monograph."

20 MG / ML INJECTION

00002286386	TYSABRI	BIO	$ 166.2756