




<b>ISSUE DATE</b> December 27, 2017	<b>EFFECTIVE DATE</b> January 8, 2018	<b>NUMBER</b> *See Below
<b>SUBJECT</b> Prior Authorization of Multiple Sclerosis Agents - Pharmacy Services		<b>BY</b>  Leesa M. Allen, Deputy Secretary Office of Medical Assistance Programs

**New IMPORTANT REMINDER:** All providers must revalidate the Medical Assistance (MA) enrollment of each service location every 5 years. Providers should log into PROMISE to check the revalidation dates of each service location and submit revalidation applications at least 60 days prior to the revalidation dates. Enrollment (revalidation) applications may be found at:

[http://www.dhs.pa.gov/provider/promise/enrollmentinformation/S\\_001994](http://www.dhs.pa.gov/provider/promise/enrollmentinformation/S_001994).

**PURPOSE:**

The purpose of this bulletin is to issue updated handbook pages for Multiple Sclerosis Agents that include the requirements for prior authorization and the type of information needed to evaluate the medical necessity of prescriptions for Ocrevus (ocrelizumab) for prior authorization.

**SCOPE:**

This bulletin applies to all licensed pharmacies and prescribers enrolled in the Medical Assistance Program and providing services in the fee-for-service delivery system, including pharmacy services to residents of long-term care facilities.

**BACKGROUND:**

The Department of Human Services (DHS) Drug Utilization Review (DUR) Board meets semi-annually to review provider prescribing and dispensing practices for efficacy, safety, and quality and to recommend interventions for prescribers and pharmacists through the DHS Prospective Drug Use Review and Retrospective Drug Use Review programs.

*01-17-38	09-17-37	27-17-35	
02-17-33	11-17-33	30-17-34	
03-17-33	14-17-34	31-17-39	
08-17-40	24-17-34	32-17-33	33-17-38

**COMMENTS AND QUESTIONS REGARDING THIS BULLETIN SHOULD BE DIRECTED TO:**

The appropriate toll free number for your provider type

Visit the Office of Medical Assistance Programs Web site at  
<http://www.dhs.pa.gov/provider/healthcaremedicalassistance/index.htm>

**DISCUSSION:**

Ocrevus (ocrelizumab) is a new medication in the Multiple Sclerosis Agents class of drugs on the DHS Preferred Drug List (PDL) and is currently designated as non-preferred. During the September 20, 2017 DUR Board meeting, the DUR Board recommended guidelines to determine medical necessity of Ocrevus (ocrelizumab), which were subject to public review and comment, and subsequently approved for implementation by DHS. In addition, DHS added a cross reference to the handbook chapter for Tysabri (natalizumab) which is now included in this class of drugs on the DHS PDL.

**PROCEDURE:**

The procedures for prescribers to request prior authorization of Ocrevus (ocrelizumab) are located in SECTION I of the Prior Authorization of Pharmaceutical Services Handbook. DHS will take into account the elements specified in the clinical review guidelines (which are included in the provider handbook pages in the SECTION II chapter related to Multiple Sclerosis Agents) when reviewing the prior authorization request to determine medical necessity.

As set forth in 55 Pa. Code § 1101.67(a), the procedures described in the handbook pages must be followed to ensure appropriate and timely processing of prior authorization requests for drugs that require prior authorization.

**ATTACHMENTS:**

Prior Authorization of Pharmaceutical Services Handbook - Updated pages

SECTION II  
Multiple Sclerosis Agents

MEDICAL ASSISTANCE HANDBOOK  
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**Requirements for Prior Authorization of Multiple Sclerosis Agents**

A. Prescriptions That Require Prior Authorization

Prescriptions for Multiple Sclerosis Agents which meet any of the following conditions must be prior authorized:

1. A prescription for a non-preferred Multiple Sclerosis Agent. See the Preferred Drug List (PDL) for the list of preferred Multiple Sclerosis Agents at: <https://papdl.com/preferred-drug-list>
2. A prescription for Ampyra (dalfampridine), Gilenya (fingolimod), Tysabri (natalizumab), or Tecfidera (dimethyl fumarate), regardless of the quantity prescribed
3. A prescription for a preferred Multiple Sclerosis Agent with a prescribed quantity that exceeds the quantity limit. See Quantity Limits for the list of drugs with quantity limits at: [http://www.dhs.pa.gov/cs/groups/webcontent/documents/document/s\\_002077.pdf](http://www.dhs.pa.gov/cs/groups/webcontent/documents/document/s_002077.pdf)

GRANDFATHER PROVISION – The Department of Human Services (DHS) will grandfather prescriptions for Multiple Sclerosis Agents for those beneficiaries currently being prescribed a non-preferred Multiple Sclerosis Agent if the PROMISe Point-Of-Sale On-Line Claims Adjudication System verifies a record of payment by DHS for a prescription for a non-preferred Multiple Sclerosis Agent within the past 90 days from the date of service of the new claim. If there is a record of a prescription for a non-preferred Multiple Sclerosis Agent, a prescription or a refill for the same Multiple Sclerosis Agent will be automatically approved.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a Multiple Sclerosis Agent, the determination of whether the requested prescription is medically necessary will take into account the following:

1. For Tysabri (natalizumab), see the provider handbook pages in the SECTION II chapter related to Tysabri (natalizumab)

**OR**

2. For a non-preferred Multiple Sclerosis Agent, whether the beneficiary:

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- a. Is being treated for a condition that is a U.S. Food and Drug Administration (FDA) approved indication or is supported by nationally recognized compendia.

**AND**

- b. Has a documented history of therapeutic failure of the preferred Multiple Sclerosis Agents approved for the beneficiary's indication.

**OR**

- c. Has a documented history of contraindication or intolerance of the preferred Multiple Sclerosis Agents approved for the beneficiary's indication

**OR**

- d. Has a current prescription (within the past 90 days) for the same non-preferred Multiple Sclerosis Agent

**OR**

- e. For Lemtrada (alemtuzumab), received an initial treatment course at least 12 months prior to the current request

**AND**

- 3. For Lemtrada (alemtuzumab), whether the beneficiary:

- a. Is 17 years of age or older

**AND**

- b. Is being prescribed Lemtrada (alemtuzumab) by a Multiple Sclerosis specialist

**AND**

- c. Does not have a contraindication to Lemtrada (alemtuzumab)

**AND**

- d. Has no evidence of active or chronic infection

**AND**

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- e. Is not receiving concomitant therapy with antineoplastic, immunosuppressive or immune modulating therapies

**AND**

- f. Is up to date on immunizations at least 6 weeks prior to initiating therapy

**AND**

- g. Has documented positive antibodies for varicella zoster virus (VZV)

**AND**

- h. Did not receive a VZV vaccination in the previous six weeks

**AND**

- i. Will not receive live vaccination while on therapy

**AND**

- j. Has recent documentation of and will have follow-up monitoring of, all of the following, according to package labeling:

- i. Complete blood count with differential
- ii. Serum creatinine
- iii. Urinalysis with urine cell counts
- iv. Thyroid function tests such as TSH
- v. Skin exam
- vi. Human papilloma virus screening if female

**AND**

- k. If positive for human papilloma virus, has documentation of scheduled gynecologic follow-up

**AND**

- l. Has documentation of a recent negative purified protein derivative [PPD] test or blood test for tuberculosis

**AND**

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- m. Will receive antiviral agents for herpetic prophylaxis according to package labeling

**AND**

- n. Will receive pre-medication according to package labeling prior to infusions

**AND**

- o. Will be observed in a medical facility for at least 2 hours after each dose

FOR RENEWALS OF PRESCRIPTIONS FOR LEMTRADA (alemtuzumab): Requests for prior authorization of renewals of prescriptions for Lemtrada (alemtuzumab), that were previously approved will take into account whether the beneficiary:

- a. Is being prescribed Lemtrada (alemtuzumab) by a Multiple Sclerosis specialist

**AND**

- b. Had only one previous treatment course with Lemtrada (alemtuzumab)

**AND**

- c. Received the previous treatment course at least 12 months prior to the requested second treatment course with Lemtrada (alemtuzumab)

**AND**

- d. Has documented improvement or stabilization of the signs or symptoms of Multiple Sclerosis

**AND**

- e. Does not have a contraindication to Lemtrada (alemtuzumab)

**AND**

- f. Does not have active or chronic infection

**AND**

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g. Is not receiving concomitant therapy with antineoplastic, immunosuppressive or immune modulating therapies

**AND**

h. Will not receive live vaccination while on therapy

**AND**

i. Has documentation of the following for 48 weeks subsequent to the initial treatment course and which will be repeated subsequent to the second treatment course:

- i. Monthly complete blood count with differential
- ii. Monthly serum creatinine
- iii. Monthly urinalysis with urine cell counts
- iv. Thyroid function tests such as TSH every 3 months

**AND**

j. Has documentation of an annual:

- i. Skin exam
- ii. Human papilloma virus screening if female

**AND**

k. If positive for human papilloma virus, has documentation of scheduled gynecologic follow-up

**AND**

l. Has no signs of malignancy or autoimmune disorder

**AND**

m. Will receive antiviral agents for herpetic prophylaxis according to package labeling

**AND**

n. Will receive pre-medication according to package labeling prior to infusions

**AND**

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- o. Will be observed in a medical facility for at least 2 hours after each dose

**OR**

- 4. For Ampyra (dalfampridine), whether the beneficiary:
  - a. Is 18 years of age or older

**AND**

- b. Has a diagnosis of Multiple Sclerosis

**AND**

- c. Is being prescribed Ampyra (dalfampridine), by a neurologist or physical medicine and rehabilitation specialist (PM and R)

**AND**

- d. Has motor dysfunction on a continuous basis that impairs the ability to complete Instrumental Activities of Daily Living (IADL's) or Activities of Daily Living (ADL's) despite optimal treatment for Multiple Sclerosis

**AND**

- e. Does not have a history of seizure

**AND**

- f. Has a creatinine clearance of 50 ml/min or greater

FOR RENEWALS OF PRESCRIPTIONS FOR AMPYRA (dalfampridine): Requests for prior authorization of renewals of prescriptions for Ampyra (dalfampridine), that were previously approved will take into account whether the beneficiary:

- a. Has a creatinine clearance of 50 ml/min or greater

**AND**

- b. Has a documented improvement in motor function

**OR**



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5. For Tecfidera (dimethyl fumarate), whether the beneficiary:

a. Is 18 years of age or older

**AND**

b. Has a diagnosis of a relapsing form of Multiple Sclerosis

**AND**

c. Is being prescribed Tecfidera (dimethyl fumarate) by a neurologist

**AND**

d. Had a Complete Blood Count (CBC) with differential within the 6 months prior to initiating therapy

FOR RENEWALS OF PRESCRIPTIONS FOR TECFIDERA (dimethyl fumarate): Requests for prior authorization of renewals of prescriptions for Tecfidera (dimethyl fumarate) that were previously approved will take into account whether the beneficiary:

a. Has documented improvement or stabilization of the signs or symptoms of Multiple Sclerosis

**AND**

b. Had follow-up monitoring of CBC with differential 6 months after starting Tecfidera (dimethyl fumarate) and annually thereafter

**OR**

6. For Aubagio (teriflunomide), whether the beneficiary:

a. Has a documented history of contraindication, intolerance or therapeutic failure of MS agents such as Copaxone, Interferon, etc.

**AND**

b. Is 18 years of age or older

**AND**

c. Has a diagnosis of a relapsing form of Multiple Sclerosis

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**AND**

d. Does not have a contraindication to Aubagio (teriflunomide)

**AND**

e. Is being prescribed Aubagio (teriflunomide) by a neurologist

**AND**

f. Has no evidence of active infection

**AND**

g. Does not have a diagnosis of severe immunodeficiency or bone marrow disease

**AND**

h. Had a Complete Blood Count (CBC) with differential within the 6 months prior to initiating therapy

**AND**

i. Had transaminase and bilirubin levels with ALT  $\leq$  2 times the upper limit of normal within the 6 months prior to initiating therapy

**AND**

j. Has a documented baseline blood pressure

**AND**

k. Was evaluated for active or latent tuberculosis infection by documented test results (purified protein derivative [PPD] testing) or blood testing

**AND**

l. If female, recently tested negative for pregnancy unless the beneficiary has a history of a surgical sterilization

FOR RENEWALS OF PRESCRIPTIONS FOR AUBAGIO  
(teriflunomide): Requests for prior authorization of renewals of

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prescriptions for Aubagio (teriflunomide) that were previously approved will take into account whether the beneficiary:

- a. Has documented improvement or stabilization of the signs or symptoms of Multiple Sclerosis

**AND**

- b. Does not have a contraindication to Aubagio (teriflunomide)

**AND**

- c. Has no evidence of active infection

**AND**

- d. Does not have a diagnosis of severe immunodeficiency or bone marrow disease

**AND**

- e. Had monthly monitoring of their LFTs for the first 6 months after starting Aubagio (teriflunomide) with ALT  $\leq$  3 times the upper limit of normal

**AND**

- f. If female, recently tested negative for pregnancy unless the beneficiary has a history of a surgical sterilization

**AND**

- g. Had periodic assessment of his/her blood pressure

**OR**

7. For Gilenya (fingolimod), whether the beneficiary:

- a. Is 18 years of age or older

**AND**

- b. Has a diagnosis of Relapsing Multiple Sclerosis

**AND**

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c. Is being prescribed Gilenya (fingolimod) by a neurologist

**AND**

d. Has no evidence of active infection

**AND**

e. Is not receiving concomitant therapy with antineoplastic, immunosuppressive or immune modulating therapies

**AND**

f. Has documented positive antibodies for varicella zoster virus (VZV)

**AND**

g. Has not had a VZV vaccination in the previous one month

**AND**

h. Has a recent (previous 6 months) Complete Blood Count (CBC) with differential

**AND**

i. Has recent (previous 6 months) transaminase and bilirubin levels

**AND**

j. Has a recent (previous 3 months) EKG with no evidence of heart block or bradycardia

**AND**

k. Has a baseline (within previous 3 months) ophthalmologic exam of the macula

**AND**

l. Will be observed in a medical facility for at least 6 hours after the first dose for signs and symptoms of bradycardia, in accordance with package labeling

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**AND**

m. Will have a repeat EKG 6 hours after the first dose

**AND**

n. Does not have a contraindication to Gilenya (fingolimod)

FOR RENEWALS OF PRESCRIPTIONS FOR GILENYA (fingolimod): Requests for prior authorization of renewals of prescriptions for Gilenya (fingolimod) that were previously approved will take into account whether the beneficiary:

a. Has documented improvement or stabilization of the signs or symptoms of Multiple Sclerosis

**AND**

b. Does not have a contraindication to Gilenya (fingolimod)

**AND**

c. Has no evidence of active infection

**AND**

d. Is not receiving concomitant therapy with antineoplastic, immunosuppressive or immune modulating therapies

**AND**

e. Had appropriate monitoring of their Complete Blood Count (CBC) with differential and LFTs

**AND**

f. Had a 3-4 month follow-up ophthalmologic exam of the macula following initiation of therapy

**OR**

g. For beneficiaries with history of diabetes or uveitis, had a 3-4 month follow-up ophthalmologic exam of the macula following initiation of therapy and annually thereafter

**OR**

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8. For Zinbryta (daclizumab), whether the beneficiary:

a. Is 17 years of age or older

**AND**

b. Has a diagnosis of a relapsing form of multiple sclerosis

**AND**

c. Is being prescribed Zinbryta (daclizumab) by a neurologist who is certified through the Zinbryta Risk Evaluation and Mitigation Strategy (REMS) Program

**AND**

d. Does not have a contraindication to Zinbryta (daclizumab)

**AND**

e. Does not have evidence of active, severe infection

**AND**

f. Is not receiving concomitant therapy with antineoplastic, immunosuppressive, or immune modulating therapies

**AND**

g. Has documentation of baseline serum transaminases (ALT and AST) and bilirubin levels

**AND**

h. Will continue to have ALT, AST, and bilirubin tested monthly and assessed prior to the next dose

**AND**

i. Is up to date on recommended live vaccines

**AND**

j. Will not receive live vaccination while on therapy and for at least 4 months after discontinuing treatment

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**AND**

- k. Has documentation of a recent negative purified protein derivative [PPD] test or blood test for tuberculosis

**AND**

- l. Has documentation of a recent screen negative for Hepatitis B and C

**AND**

- m. Does not have suicidal ideations

**AND**

- n. Has documentation of a screening for depression and, if diagnosed with depression, has been referred for, or is receiving, treatment for that condition

**AND**

- o. Is enrolled in the Zinbryta REMS Program and will comply with ongoing monitoring requirements

FOR RENEWALS OF PRESCRIPTIONS FOR Zinbryta (daclizumab): Requests for prior authorization of renewals of prescriptions for Zinbryta (daclizumab), that were previously approved will take into account whether the beneficiary:

- a. Is being prescribed Zinbryta (daclizumab) by a neurologist, who is certified through the Zinbryta Risk Evaluation and Mitigation Strategy (REMS) Program

**AND**

- b. Has documented improvement or stabilization of the signs or symptoms of Multiple Sclerosis

**AND**

- c. Does not have a contraindication to Zinbryta (daclizumab)

**AND**

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d. Does not have evidence of active, severe infection

**AND**

e. Is not receiving concomitant therapy with antineoplastic, immunosuppressive, or immune modulating therapies

**AND**

f. Has documentation of monthly monitoring of ALT, AST, and bilirubin

**AND**

g. Will not receive live vaccination while on therapy and for at least 4 months after discontinuing treatment

**AND**

h. Does not have suicidal ideations

**AND**

i. If diagnosed with depression, continues to receive treatment

**OR**

9. For Ocrevus (ocrelizumab), whether the beneficiary:

a. Is 18 years of age or older

**AND**

b. Has a diagnosis of a relapsing or primary progressive form of multiple sclerosis

**AND**

c. Is being prescribed Ocrevus (ocrelizumab) by a neurologist

**AND**

d. Does not have a contraindication to Ocrevus (ocrelizumab)

**AND**



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e. Does not have evidence of significant active infection

**AND**

f. Is up to date on immunizations according to current guidelines at least 6 weeks prior to initiating therapy

**AND**

g. Will not receive live or live-attenuated vaccines while on therapy or after discontinuation until B-cell repletion

**AND**

h. Is not receiving concomitant therapy with antineoplastic, immunosuppressive, or immune modulating therapies

**AND**

i. If female of childbearing potential, has documentation of a recent negative pregnancy test

**AND**

j. If female of child bearing potential, will use adequate contraception to prevent pregnancy during treatment and for 6 months following the last infusion

FOR RENEWALS OF PRESCRIPTIONS FOR OCREVUS (OCRELIZUMAB): Requests for prior authorization of renewals of prescriptions for Ocrevus (ocrelizumab) that were previously approved will take into account whether the beneficiary:

a. Is being prescribed Ocrevus (ocrelizumab) by a neurologist

**AND**

b. Has documented improvement or stabilization of the multiple sclerosis disease course

**OR**

c. Based on the prescriber's professional judgement, continues to benefit from Ocrevus (ocrelizumab)

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**AND**

- d. Does not have a contraindication to Ocrevus (ocrelizumab)

**AND**

- e. Does not have evidence of significant active infection

**AND**

- f. Will not receive live or live–attenuated vaccines while on therapy or after discontinuation until B-cell repletion

**AND**

- g. Is not receiving concomitant therapy with antineoplastic, immunosuppressive, or immune modulating therapies

**AND**

- h. If female of childbearing potential, has documentation of a recent negative pregnancy test

**AND**

- i. If female of childbearing potential, will use adequate contraception to prevent pregnancy during treatment and for 6 months following last infusion

**OR**

- 10. Does not meet the clinical review guidelines listed above, but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

In addition, if a prescription for a Multiple Sclerosis Agent is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines that are set forth in the Quantity Limits Chapter.

**C. Clinical Review Process**

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above, to assess the medical necessity of the request. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer

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for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

D. Dose and Duration of Therapy

Requests for prior authorization of Multiple Sclerosis Agents will be approved as follows:

1. 3 months of therapy for an initial approval of Ampyra (dalfampridine) or Aubagio (teriflunomide)
2. For Lemtrada (alemtuzumab):
  - a. 5 days of therapy for an initial treatment course
  - b. 3 days of therapy for a second treatment course
  - c. 1 renewal for a second treatment course

References:

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4. Aubagio prescribing information, September 2012
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7. Treatment of relapsing-remitting multiple sclerosis in adults. Up To Date. Accessed May 19, 2014
8. Lemtrada prescribing information, Genzyme Corporation. November 2014
9. Treatment of relapsing-remitting multiple sclerosis in adults. Up To Date. Accessed February 5, 2015
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14. Montalban X, Hauser SL, Kappos L, et al. Ocrelizumab versus Placebo in Primary Progressive Multiple Sclerosis. New England Journal of Medicine. January 19, 2017. 376:209-220

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