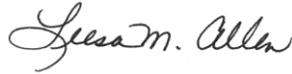


<b>ISSUE DATE</b> May 11, 2015	<b>EFFECTIVE DATE</b> May 18, 2015	<b>NUMBER</b> *See below
<b>SUBJECT</b> Prior Authorization of Multiple Sclerosis Agents – Pharmacy Service		<b>BY</b>  Leesa M. Allen, Deputy Secretary Office of Medical Assistance Programs

**PURPOSE:**

The purpose of this bulletin is to:

1. Inform providers about new requirements for prior authorization of Lemtrada (alemtuzumab).
2. Issue handbook pages that include instructions on how to request prior authorization of Multiple Sclerosis Agents, including the type of medical information needed to evaluate requests for medical necessity.

**SCOPE:**

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

**BACKGROUND:**

The Department of Human Services' (Department) 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 Department's Prospective Drug Use Review (ProDUR) and Retrospective Drug Use Review (RetroDUR) programs.

*01-15-09	09-15-08	27-15-07	33-15-08
02-15-07	11-15-07	30-15-07	
03-15-07	14-15-07	31-15-08	
08-15-09	24-15-07	32-15-07	

**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.state.pa.us/provider/healthcaremedicalassistance/index.htm>

**DISCUSSION:**

During the March 18, 2015 meeting, the DUR Board recommended guidelines to determine medical necessity of Lemtrada (alemtuzumab), a new medication in the Preferred Drug List (PDL) class of Multiple Sclerosis Agents that is designated as non-preferred. The proposed guidelines to determine medical necessity address health and safety concerns associated with Lemtrada (alemtuzumab) and appropriate patient selection and drug utilization. The guidelines to determine medical necessity, as recommended by the DUR Board, were subject to public review and comment, and subsequently approved for implementation by the Department. The requirements for prior authorization and clinical review guidelines to determine the medical necessity of Lemtrada (alemtuzumab) are included in the attached updated provider handbook pages.

**PROCEDURE:**

The procedures for prescribers to request prior authorization of Multiple Sclerosis Agents are located in SECTION I of the Prior Authorization of Pharmaceutical Services Handbook. The Department will take into account the elements specified in the clinical review guidelines (which are included in the provider handbook pages in the SECTION II chapters 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  
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

**I. 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 [www.providersynergies.com/services/documents/PAM\\_PDL.pdf](http://www.providersynergies.com/services/documents/PAM_PDL.pdf)
2. A prescription for Ampyra (dalfampridine), Gilenya (fingolimod), Aubagio (teriflunomide), 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.dpw.state.pa.us/provider/doingbusinesswithdpw/pharmacyservices/quantitylimitslist/index.htm>

GRANDFATHER PROVISION – The Department will grandfather prescriptions for Multiple Sclerosis Agents for those recipients 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 the Department 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 a non-preferred Multiple Sclerosis Agent, whether the recipient:
  - a. Has a diagnosis of a relapsing form of Multiple Sclerosis

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**AND**

- b. Has a documented history of therapeutic failure of the preferred Multiple Sclerosis Agents

**OR**

- c. Has a documented history of contraindication or intolerance of the preferred Multiple Sclerosis Agents

**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**

- 2. For Lemtrada (alemtuzumab), whether the recipient:
  - 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

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**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**

- 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 recipient:

- 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)

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**AND**

- f. Does not have active or chronic infection

**AND**

- 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**

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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

**OR**

3. For Ampyra (dalfampridine), whether the recipient:

a. Is 18 years of age or older

**AND**

b. Has a diagnosis of Multiple Sclerosis

**AND**

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

**AND**

5. 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**

6. Does not have a history of seizure

**AND**

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7. 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 recipient:

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

**AND**

- b. Has a documented improvement in motor function

**OR**

4. For Tecfidera (dimethyl fumarate), whether the recipient:

- 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 recipient:

- 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

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**OR**

5. For Aubagio (teriflunomide), whether the recipient:

- 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

**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**

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- 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 recipient has a history of a surgical sterilization

**FOR RENEWALS OF PRESCRIPTIONS FOR AUBAGIO (teriflunomide):** Requests for prior authorization of renewals of prescriptions for Aubagio (teriflunomide) that were previously approved will take into account whether the recipient:

- 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**

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- 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 recipient has a history of a surgical sterilization

**AND**

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

**OR**

- 6. For Gilenya (fingolimod), whether the recipient:

- a. Has documented history of contraindication, intolerance or therapeutic failure of the preferred Multiple Sclerosis agents

**AND**

- b. Is 18 years of age or older

**AND**

- c. Has a diagnosis of Relapsing Multiple Sclerosis

**AND**

- d. Is being prescribed Gilenya (fingolimod) by a neurologist

**AND**

- e. Has no evidence of active infection

**AND**

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

**AND**

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

**AND**

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

**AND**

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

**AND**

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

**AND**

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

**AND**

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

**AND**

- m. 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

**AND**

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

**AND**

- o. Does not have a contraindication to Gilenya (fingolimod)

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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 recipient:

- a. Has had improvement or stabilization of their Multiple Sclerosis as documented by the prescriber.

**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 recipients 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**

- 7. 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 recipient.

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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 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 recipient.

D. Dose and Duration of Therapy

The Department will limit authorization of prescriptions for Multiple Sclerosis Agents as follows:

1. 3 months of therapy for an initial approval of Ampyra (dalfampridine) or Aubagio (teriflunomide)
2. 6 months of therapy for an initial approval of Gilenya (fingolimod) or Tecfidera (dimethyl fumarate)
3. Up to 12 months of therapy for a renewal of Ampyra (dalfampridine), Aubagio (teriflunomide), Gilenya (fingolimod), or Tecfidera (dimethyl fumarate)
4. 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:

1. Ampyra Package Insert, Acorda Therapeutics, Inc. January 2010
2. Gilenya package insert. Novartis Pharmaceuticals Corporation East Hanover, New Jersey, May 2012
3. MedWatch FDA Safety Information and Adverse Event Reporting Program, Gilenya (fingolimod): Drug Safety Communication - Safety Review of a Reported Death After the First Dose, May 2012
4. Aubagio prescribing information, September 2012

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5. Multiple Sclerosis, The Pharmacists Letter.
6. Tecfidera Package Insert, Biogen Idec Inc. March 2013.
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