

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
2. A prescription for Ampyra (dalfampridine) or Gilenya (fingolimod), 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

AND

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

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

- 2. For Ampyra (dalfampridine), whether the recipient:

- 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

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(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

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

- a. Has 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 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

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

AND

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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)

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

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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

4. 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)

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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 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:

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- 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 recipient has a history of a surgical sterilization

AND

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

OR

- 5. 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.

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

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

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
5. Multiple Sclerosis, The Pharmacists Letter.