pennsylvania
DEPARTMENT OF HUMAN SERVICES

MEDICAL ASSISTANCE BULLETIN

ISSUE DATE	EFFECTIVE DATE	NUMBER
January 18, 2019	January 28, 2019	*See below

SUBJECT

Prior Authorization of Multiple Sclerosis Agents – Pharmacy Services

BY

Sally A. Kozak, Deputy Secretary
Office of Medical Assistance Programs

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.

PURPOSE:

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

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 delivery system. Providers rendering services in the MA managed care delivery system should address any questions related to Multiple Sclerosis Agents to the appropriate managed care organization.

BACKGROUND:

The Department of Human Services' (DHS) Pharmacy and Therapeutics (P&T) Committee meets semi-annually to review published peer-reviewed clinical literature and recommends preferred or non-preferred status for new drugs in therapeutic classes already included on the Preferred Drug List (PDL), changes in the status of drugs on the PDL from

*01-19-10	09-19-10	27-19-10	33-19-10
02-19-09	11-19-09	30-19-09	
03-19-09	14-19-09	31-19-10	
08-19-12	24-19-09	32-19-09	

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

preferred to non-preferred and non-preferred to preferred, new quantity limits, and classes of drugs to be added to or deleted from the PDL. The P&T Committee also recommends new guidelines or modifications to existing guidelines to evaluate requests for prior authorization of prescriptions for medical necessity.

DISCUSSION:

During the November 27, 2018, meeting, the P&T Committee reviewed the Multiple Sclerosis Agents PDL class and recommended changing Aubagio from non-preferred to preferred status. In response to the PDL status change, DHS recommended adding Aubagio to the list of prescriptions that require prior authorization. DHS also recommended deleting the prior authorization guidelines for Zinbryta because Zinbryta has been discontinued by the manufacturer. The proposed changes to the medical necessity guidelines were subject to public review and comment and subsequently approved for implementation by DHS.

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. 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

I. Requirements for Prior Authorization of Multiple Sclerosis Agents

A. Prescriptions That Require Prior Authorization

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

1. 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. Ampyra (dalfampridine), Aubagio (teriflunomide), Gilenya (fingolimod), Tysabri (natalizumab), or Tecfidera (dimethyl fumarate), regardless of the quantity prescribed.

3. A Multiple Sclerosis Agent with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: http://www.dhs.pa.gov/provider/pharmacyservices/quantitylimitslist/index.htm.

GRANDFATHER PROVISION – The Department of Human Services (DHS) will grandfather prescriptions for a non-preferred Multiple Sclerosis Agent for those beneficiaries currently being prescribed the same non-preferred Multiple Sclerosis Agent if the Point-Of-Sale On-Line Claims Adjudication System verifies that the beneficiary has a record of a paid claim for the same non-preferred Multiple Sclerosis Agent within the past 90 days from the date of service of the new claim. If the beneficiary has a record of a paid claim for the same non-preferred Multiple Sclerosis Agent, a prescription or a refill for the same non-preferred 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:

   a. Is being treated for a condition that is U.S. Food and Drug

Administration (FDA) approved or a medically accepted indication,

AND

b. Has a history of therapeutic failure, contraindication, or intolerance to the preferred Multiple Sclerosis Agents approved for the beneficiary's diagnosis,

OR

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

OR

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

AND

3. Whether the beneficiary is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed literature.

AND

4. For Lemtrada (alemtuzumab), whether the beneficiary:

a. Is being prescribed Lemtrada (alemtuzumab) by a multiple sclerosis specialist,

AND

b. Does not have a contraindication to Lemtrada (alemtuzumab),

AND

c. Has no evidence of active or chronic infection,

AND

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

AND

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

AND

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

AND

g. Did not receive a VZV vaccination in the previous six weeks,

AND

h. Will not receive live vaccination while on therapy,

AND

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

    i. Complete blood count (CBC) 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

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

AND

k. Has documentation of a recent negative purified protein derivative (PPD) test or blood test for tuberculosis,

AND

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

AND

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

AND

n. 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

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 CBC 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

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

AND

5. For Ampyra (dalfampridine), whether the beneficiary:

a. Has a diagnosis of multiple sclerosis,

AND

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

AND

c. 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

d. Does not have a history of seizure,

AND

e. 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.

AND

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

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

AND

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

AND

c. Had a 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.

AND

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

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

AND

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

AND

c. Is being prescribed Aubagio (teriflunomide) by a neurologist,

AND

d. Has no evidence of active infection,

AND

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

AND

f. Had a CBC with differential within the 6 months prior to initiating therapy,

AND

g. Had transaminase and bilirubin levels with ALT ≤2 times the upper limit of normal within the 6 months prior to initiating therapy,

AND

h. Has a documented baseline blood pressure measurement,

AND

i. Was evaluated for active or latent tuberculosis infection by documented test results (PPD testing) or blood testing,

AND

j. If female and of child bearing potential, has documentation of a recent negative pregnancy test.

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 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 ≤3 times the upper limit of normal,

AND

f. If female and of child bearing potential, has documentation of a recent negative pregnancy test,

AND

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

AND

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

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

AND

b. Is being prescribed Gilenya (fingolimod) by a neurologist,

AND

c. Has no evidence of active infection,

AND

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

AND

e. Has documented positive antibodies for VZV,

AND

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

AND

g. Has a recent (previous 6 months) CBC with differential,

AND

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

AND

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

AND

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

AND

k. 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

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

AND

m. 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 CBC with differential and LFTs,

AND

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

AND

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

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

AND

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

AND

c. Does not have a contraindication to Ocrevus (ocrelizumab),

AND

d. Does not have evidence of significant active infection,

AND

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

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 and of childbearing potential, has documentation of a recent negative pregnancy test,

AND

i. If female and 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),

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 and of childbearing potential, has documentation of a recent negative pregnancy test,

AND

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

AND

10. 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.

    NOTE: If the beneficiary 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, the request for prior authorization will be approved.

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 a prescription for a Multiple Sclerosis Agent. 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 beneficiary.

D. Dose and Duration of Therapy

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

1. Up to 3 months of therapy for an initial approval of Ampyra (dalfampridine) or Aubagio (teriflunomide).

2. For Lemtrada (alemtuzumab):
   a. Up to 5 days of therapy for an initial treatment course.
   b. Up to 3 days of therapy for a second treatment course.
   c. Up to 1 renewal for a second treatment course.

E. 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.
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.
10. Disease-modifying treatment of relapsing-remitting multiple sclerosis in adults. Up To Date. Accessed January 24, 2017.
11. Disease-modifying treatment of relapsing-remitting multiple sclerosis in adults. Up To Date. Accessed August 3, 2017.
12. Hauser SL, Bar-Or A,Comi G, et al. Ocrelizumab versus Interferon Beta-1a in Relapsing Multiple Sclerosis. New England Journal of Medicine. January 19, 2017; 376:221-234.
13. 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.
14. Ocrevus (ocrelizumab) Package Insert. South San Francisco, CA: Genetech, Inc.; March 2017. Treatment of progressive multiple sclerosis in adults. Up To Date. Accessed August 4, 2017.