pennsylvania
DEPARTMENT OF HUMAN SERVICES

MEDICAL ASSISTANCE BULLETIN

ISSUE DATE	EFFECTIVE DATE	NUMBER
August 13, 2018	August 13, 2018	*See below

SUBJECT

Prior Authorization of Multiple Sclerosis Agents - Pharmacy Services

BY

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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 under the MA managed care delivery system should address any questions related to Multiple Sclerosis Agents to the appropriate managed care organization.

BACKGROUND/DISCUSSION:

The current guidelines to determine medical necessity of Multiple Sclerosis Agents include U. S. Food and Drug Administration (FDA) approved age limits for specific Agents within this class. The FDA recently announced approval of Gilenya (fingolimod) to treat

*01-18-24	09-18-25	27-18-23	33-18-24
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03-18-19	14-18-20	31-18-25	
08-18-26	24-18-20	32-18-19	

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

relapsing multiple sclerosis in children and adolescents age 10 years and older. In lieu of updates to handbook pages each time the FDA approves a new age limit for a specific Multiple Sclerosis Agent, DHS proposed to replace drug-specific age limits with a general guideline reflecting age-specific FDA approved package labeling, nationally recognized compendia, or peer-reviewed literature. The proposed change to the medical necessity guidelines was 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. 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 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

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), 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. The list of drugs that are subject to quantity limits with accompanying quantity limits, is available at: 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:

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. 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 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 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

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

OR

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 specialist (PM and R)

   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

OR

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 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

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

AND

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

AND

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

AND

e. Has no evidence of active infection

AND

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

AND

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

AND

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

AND

i. Has a documented baseline blood pressure

AND

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

AND

k. 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

OR

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

a. Has a diagnosis of Relapsing 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 varicella zoster virus (VZV)

AND

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

AND

g. Has a recent (previous 6 months) Complete Blood Count (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 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

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

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

AND

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

AND

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

AND

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 baseline serum transaminases (ALT and AST) and bilirubin levels

AND

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

AND

h. Is up to date on recommended live vaccines

AND

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

AND

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

AND

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

AND

l. Does not have suicidal ideations

AND

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

AND

n. 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

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

10. 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

11. 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: As described in Section C, if the beneficiary does not meet the clinical review guidelines and/or the quantity limit 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 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 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:

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. Zinbryta Package Insert, Biogen Inc. May 2016
12. Disease-modifying treatment of relapsing-remitting multiple sclerosis in adults. Up To Date. Accessed August 3, 2017.
13. 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
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
15. 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.