Commonwealth of Massachusetts
Executive Office of Health and Human Services
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MASSHEALTH
TRANSMITTAL LETTER POD-52
June 2006

TO: Podiatrists Participating in MassHealth

FROM: Beth Waldman, Medicaid Director BW

RE: *Podiatrist Manual* (Revised Regulations About New Tobacco Cessation Services)

Beginning July 1, 2006, MassHealth will cover individual and group tobacco cessation counseling and pharmacotherapy through the MassHealth tobacco cessation benefit. Those members eligible to receive physician services, community health center services, acute outpatient hospital services, and pharmacy services are covered for tobacco cessation services, based on their MassHealth coverage type as described at 130 CMR 450.105.

Podiatrist Regulation Changes

The podiatrist regulations (130 CMR 424.000) have been changed by removing the blanket restriction on coverage of drugs indicated for use as aids to tobacco cessation treatment. This permits reimbursement to pharmacies for the dispensing of these drugs to eligible members. MassHealth recommends that tobacco cessation pharmacotherapy be provided in conjunction with counseling to support the best possible treatment outcomes for members attempting to quit. MassHealth encourages podiatrists to refer members to their primary care clinician, community health center, or acute outpatient hospital department for tobacco cessation services.

This transmittal letter also transmits a revised Appendix F, Acute Inpatient Hospital Admission Guidelines. This revision updates terminology.

These regulations are effective July 1, 2006.

If you have any questions about the information in this transmittal letter please contact MassHealth Customer Service at 1-800-841-2900, e-mail your inquiry to providersupport@mahealth.net, or fax your inquiry to 617-988-8974.

NEW MATERIAL

(The pages listed here contain new or revised language.)

Podiatrist Manual

Pages 4-11 through 4-14, and F-1 through F-4

OBSOLETE MATERIAL

(The pages listed here are no longer in effect.)

Podiatrist Manual

Pages 4-11 and 4-12 — transmitted by Transmittal Letter POD-50

Pages 4-13 and 4-14 — transmitted by Transmittal Letter POD-51

Pages F-1 through F-4 — transmitted by Transmittal Letter POD-36

(B) Emergencies. When the pharmacist determines that an emergency exists, the MassHealth agency will pay a pharmacy for at least a 72-hour, nonrefillable supply of the drug in compliance with state and federal regulations. Emergency dispensing to a MassHealth member who is enrolled in the Controlled Substance Management Program (CSMP) must comply with 130 CMR 406.442(C)(2).

(C) Refills.

(1) The MassHealth agency does not pay for prescription refills that exceed the specific number authorized by the prescriber.

(2) The MassHealth agency pays for a maximum of 11 monthly refills, except in circumstances described at 130 CMR 424.417(C)(3).

(3) The MassHealth agency pays for more than 11 refills within a 12-month period if such refills are for less than a 30-day supply and have been prescribed and dispensed in accordance with 130 CMR 424.417(D).

(4) The MassHealth agency does not pay for any refill dispensed after one year from the date of the original prescription.

(5) The absence of an indication to refill by the prescriber renders the prescription nonrefillable.

(6) The MassHealth agency does not pay for any refill without an explicit request from a member or caregiver for each filling event. The possession by a provider of a prescription with remaining refills authorized does not in itself constitute a request to refill the prescription.

(D) Quantities.

(1) Days' Supply Limitations. The MassHealth agency requires that all drugs be prescribed in a 30-day supply, unless the drug is available only in a larger minimum package size, except as specified in 130 CMR 424.417(D)(2).

(2) Exceptions to Days' Supply Limitations. The MassHealth agency allows exceptions to the limitations described in 130 CMR 424.417(D)(1) for the following products:

(a) drugs in therapeutic classes that are commonly prescribed for less than a 30-day supply, including but not limited to antibiotics and analgesics;

(b) drugs that, in the prescriber's professional judgement, are not clinically appropriate for the member in a 30-day supply;

(c) drugs that are new to the member, and are being prescribed for a limited trial amount, sufficient to determine if there is an allergic or adverse reaction or lack of effectiveness. The initial trial amount and the member's reaction or lack of effectiveness must be documented in the member's medical record;

(d) drugs packed in such a way that the smallest quantity that may be dispensed is larger than a 30-day supply (for example, inhalers, ampules, vials, eye drops, and other sealed containers not intended by the manufacturer to be opened by any person other than the end user of the product);

(e) drugs in topical dosage forms that do not allow the pharmacist to accurately predict the rate of the product's usage (for example, lotions or ointments);

(f) products generally dispensed in the original manufacturer's packaging (for example, fluoride preparations, prenatal vitamins, and over-the-counter drugs); and

(g) methylphenidate and amphetamine prescribed in 60-day supplies.

(E) Prescription-Splitting. Providers must not split prescriptions by filling them for a period or quantity less than that specified by the provider. For example, a prescription written for a single 30-day supply may not be split into three 10-day supplies. The MassHealth agency considers prescription-splitting to be fraudulent. (See 130 CMR 450.238(B)(6).)

(F) Excluded, Suspended, or Terminated Clinicians. The MassHealth agency does not pay for prescriptions written by clinicians who:

(1) have been excluded from participation based on a notice by the U.S. Department of Health and Human Services Office of Inspector General; or

(2) the MassHealth agency has suspended, terminated, or denied admission into its program for any other reason.

424.418: Pharmacy Services: Covered Drugs

The MassHealth Drug List specifies the drugs that are payable under MassHealth. In addition, the MassHealth agency pays only for legend drugs that are approved by the U.S. Food and Drug Administration and manufactured by companies that have signed rebate agreements with the U.S. Secretary of Health and Human Services pursuant to 42 U.S.C. 1396r-8.

424.419: Pharmacy Services: Limitations on Coverage of Drugs

(A) Interchangeable Drug Products. The MassHealth agency pays no more for a brand-name interchangeable drug product than its generic equivalent, unless:

(1) the prescriber has requested and received prior authorization from the MassHealth agency for a nongeneric multiple-source drug (see 130 CMR 424.420); and

(2) the prescriber has written on the face of the prescription in the prescriber's own handwriting the words "brand name medically necessary" under the words "no substitution" in a manner consistent with applicable state law. These words must be written out in full and may not be abbreviated.

(B) Drug Exclusions. The MassHealth agency does not pay for the following types of drugs or drug therapy:

(1) Cosmetic. The MassHealth agency does not pay for legend or nonlegend preparations for cosmetic purposes or for hair growth.

(2) Cough and Cold. The MassHealth agency does not pay for legend or nonlegend drugs used solely for the symptomatic relief of coughs and colds, including but not limited to, those that contain an antitussive or expectorant as a major ingredient, unless they are dispensed to an institutionalized member.

(3) Fertility. The MassHealth agency does not pay for any drug used to promote male or female fertility.

(4) Obesity Management. The MassHealth agency does not pay for any drug used for the treatment of obesity.

(5) Less-Than-Effective Drugs. The MassHealth agency does not pay for drug products (including identical, similar, or related drug products) that the U.S. Food and Drug Administration has proposed, in a Notice of Opportunity for Hearing (NOOH), to withdraw from the market because they lack substantial evidence of effectiveness for all labeled indications.

(6) Experimental and Investigational Drugs. The MassHealth agency does not pay for any drug that is experimental, medically unproven, or investigational in nature.

(7) Drugs for Sexual Dysfunction. The MassHealth agency does not pay for drugs when used for the treatment of male or female sexual dysfunction.

(C) Service Limitations.

(1) MassHealth covers drugs that are not explicitly excluded under 130 CMR 424.419(B). The limitations and exclusions in 130 CMR 424.419(B)(1) through (5) do not apply to medically necessary drug therapy for MassHealth Standard enrollees under age 21. The MassHealth Drug List specifies the drugs that are payable under MassHealth. Any drug that does not appear on the MassHealth Drug List requires prior authorization, as set forth in 130 CMR 424.000. The MassHealth Drug List can be viewed online at www.mass.gov/druglist, and copies may be obtained upon request. The MassHealth agency will evaluate the prior-authorization status of drugs on an ongoing basis, and update the MassHealth Drug List accordingly. See 130 CMR 450.303.

(2) The MassHealth agency does not pay for the following types of drugs or drug therapy without prior authorization:

(a) immunizing biologicals and tubercular (TB) drugs that are available free of charge through local boards of public health or through the Massachusetts Department of Public Health (DPH);

(b) nongeneric multiple-source drugs; and

(c) drugs related to sex-reassignment surgery, specifically including but not limited to, presurgery and postsurgery hormone therapy. The MassHealth agency, however, will continue to pay for post sex-reassignment surgery hormone therapy for which it had been paying immediately prior to May 15, 1993.

(3) The MassHealth agency does not pay any additional fees for dispensing drugs in a unit-dose distribution system.

(4) The MassHealth agency does not pay for any drug prescribed for other than the FDA-approved indications as listed in the package insert, except as the MassHealth agency determines to be consistent with current medical evidence.

(5) The MassHealth agency does not pay for any drugs that are provided as a component of a more comprehensive service for which a single rate of pay is established in accordance with 130 CMR 450.307.

424.420: Pharmacy Services: Insurance Coverage

(A) Managed Care Organizations. The MassHealth agency does not pay pharmacy claims for services to MassHealth members enrolled in a MassHealth managed care organization (MCO) that provides pharmacy coverage through a pharmacy network or otherwise, except for family planning pharmacy services provided by a non-network provider to a MassHealth Standard MCO enrollee (where such provider otherwise meets all prerequisites for payment for such services). A pharmacy that does not participate in the MassHealth member's MCO must instruct the MassHealth member to take his or her prescription to a pharmacy that does participate in such MCO. To determine whether the MassHealth member belongs to an MCO, pharmacies must verify member eligibility and scope of services through POPS before providing service in accordance with 130 CMR 450.107 and 450.117.

(B) Other Health Insurance. When the member's primary carrier has a preferred drug list, the prescriber must follow the rules of the primary carrier first. The provider may bill the MassHealth

agency for the primary insurer's member copayment for the primary carrier's preferred drug without regard to whether the MassHealth agency generally requires prior authorization, except in cases where the drug is subject to a pharmacy service limitation pursuant to 130 CMR 424.419(C)(2)(a) and (c). In such cases, the prescriber must obtain prior authorization from the MassHealth agency in order for the pharmacy to bill the MassHealth agency for the primary insurer's member copayment. For additional information about third party liability, see 130 CMR 450.101 et seq.

(C) Medicare Part D. Except as otherwise required in 130 CMR 406.414(C)(2) and (3), for MassHealth members who have Medicare, the MassHealth agency does not pay for any Medicare Part D drugs, or for any cost-sharing obligations (including premiums, copayments, and deductibles) for Medicare Part D drugs, whether or not the member has actually enrolled in a Medicare Part D drug plan. Medications excluded from the Medicare Part D drug program continue to be covered for MassHealth members eligible for Medicare, if they are MassHealth-covered medications.

424.421: Pharmacy Services: Prior Authorization

(A) Prescribers must obtain prior authorization from the MassHealth agency for drugs identified by the MassHealth agency in accordance with 130 CMR 450.303. If the limitations on covered drugs specified in 130 CMR 424.418 and 424.419(A) and (C) would result in inadequate treatment for a diagnosed medical condition, the prescriber may submit a written request, including written documentation of medical necessity, to the MassHealth agency for prior authorization for an otherwise noncovered drug.

(B) All prior-authorization requests must be submitted in accordance with the instructions for requesting prior authorization in Subchapter 5 of the *Podiatrist Manual*. If the MassHealth agency approves the request, it will notify both the podiatrist and the member.

(C) The MassHealth agency will authorize at least a 72-hour emergency supply of a prescription drug to the extent required by federal law. (See 42 U.S.C. 1396r-8(d)(5).) The MassHealth agency acts on requests for prior authorization for a prescribed drug within a time period consistent with federal regulations.

(D) Prior authorization does not waive any other prerequisites to payment such as, but not limited to, member eligibility or requirements of other health insurers.

(E) The MassHealth Drug List specifies the drugs that are payable under MassHealth. Any drug that does not appear on the MassHealth Drug List requires prior authorization, as set forth in 130 CMR 424.417 through 424.421. The MassHealth agency will evaluate the prior-authorization status of drugs on an ongoing basis, and update the MassHealth Drug List.

424.422: Pharmacy Services: Member Copayments

The MassHealth agency requires under certain conditions that members make a copayment to the dispensing pharmacy for each original prescription and for each refill for all drugs (whether legend or nonlegend) covered by MassHealth. The copayment requirements are detailed in 130 CMR 450.130.

Acute Inpatient Hospital Admission Guidelines

A. Introduction

This appendix is intended to help providers make appropriate decisions about the medical necessity of acute inpatient hospital admissions. These guidelines have been approved by physicians from several medical specialties who have active practices in Massachusetts. Providers making decisions on whether to admit a member as an inpatient should use their medical judgment and these guidelines. Services that meet the medical-necessity criteria at 130 CMR 450.204 and the rules governing reimbursement of inpatient, outpatient, and observation services in 130 CMR 410.414 (see section E of this appendix) or 415.414 (see section C of this appendix) are reimbursable by MassHealth.

B. Definitions

The reimbursability of services defined below is not determined by these definitions, but by application of MassHealth regulations referenced in 130 CMR 450.000 and in section A above.

Inpatient Services — medical services provided to a member admitted to an acute inpatient hospital.

Observation Services — outpatient hospital services provided anywhere in an acute inpatient hospital, to evaluate a member's condition and determine the need for admission to an acute inpatient hospital. Observation services are provided under the order of a physician, consist of the use of a bed and intermittent monitoring by professional licensed clinical staff, and may be provided for more than 24 hours.

Outpatient Hospital Services — medical services provided to a member in a hospital outpatient department. Such services include, but are not limited to, emergency services, primary-care services, observation services, ancillary services, day-surgery services, and recovery-room services.

Outpatient Services — medical services provided to a member in an outpatient setting including but not limited to hospital outpatient departments, hospital-licensed health centers, physicians' offices, nurse practitioners' offices, freestanding ambulatory surgery centers, day treatment centers, or the member's home.

C. Medical Determination

[excerpted from MassHealth acute inpatient hospital regulations at 130 CMR 415.414]

To support the medical necessity of an inpatient admission, the provider must adequately document in the member's medical record that a provider with applicable expertise expressly determined that the member required services involving a greater intensity of care than could be provided safely and effectively in an outpatient setting. Such a determination may take into account the amount of time the member is expected to require inpatient services, but must not be based solely on this factor. The decision to admit is a medical determination that is based on factors, including but not limited to the:

(1) member's medical history;
(2) member's current medical needs;
(3) severity of the signs and symptoms exhibited by the member;
(4) medical predictability of an adverse clinical event occurring with the member;
(5) results of outpatient diagnostic studies;
(6) types of facilities available to inpatients and outpatients; and
(7) MassHealth Acute Inpatient Hospital Admission Guidelines (in section D of this appendix).

D. Acute Inpatient Hospital Admission Guidelines

The following guidelines describe admissions that generally are not medically necessary. This is not an all-inclusive list. MassHealth or its agent may also determine that other admissions not characterized in this list are medically unnecessary and nonreimbursable on an inpatient basis.

1. The admission occurs following observation services, and the admitting provider has not documented at least one of the following in the medical record at the time the decision to admit is made:
   - Failure to respond to outpatient treatment and a clear deterioration of the patient's clinical status;
   - a significant probability that the treatment plan will continue to need frequent clinical modifications and what specific modifications are necessary;
   - instability of the patient that is a deviation from either normal clinical parameters or the patient's baseline; or
   - a requirement for more intensive services than were already being delivered while the patient was on observation status, and a physician's order for each specific new service.

2. The admission occurs when the member's condition had improved significantly in response to outpatient treatment with a progression toward either normal clinical parameters or the member's baseline.

3. The admission is for further monitoring or observing for potential complications when the member undergoes a procedure that is appropriately performed in an outpatient setting according to the current standards of care, the procedure is performed without complications, and the member's clinical status is approaching either normal clinical parameters or his or her baseline.

4. The admission is primarily for providing or monitoring the services and treatment of a member with multiple or complex medical needs whose needs were adequately being met in a setting other than an acute inpatient hospital prior to that admission.

5. The admission of a member whose baseline clinical status is outside of the normal clinical parameters and whose condition has been managed successfully on an outpatient basis, when the admission is based primarily on the member's abnormal status, unless that status has significantly deteriorated.

6. The admission is primarily to observe for the possible progression of labor when examination and monitoring does not indicate definite progression of active labor leading to delivery.

7. The admission is primarily for education, teaching, minor medication changes and/or monitoring, or adjustment of therapies associated with a medically stable condition(s).

8. The admission is primarily because the member requires sedation or anesthesia in order to conduct diagnostic tests that are appropriately performed in an outpatient setting according to the current standards of care, when there are no serious complications requiring inpatient services.

9. The admission of a member whose baseline condition requires the use of complex medical technology, when the admission is primarily due to the need for such technology or other maintenance services related to the pre-existing medical condition(s), unless the member's condition is significantly deteriorating.

10. The admission is primarily for a continuation of treatment or monitoring that has already been delivered effectively in the home, hospital outpatient department, or other institutional setting.

11. The admission of a member who is a patient or resident in another institutional setting, and is admitted primarily for diagnostic or treatment services that could have been provided in the member's current institutional setting or by using outpatient services.

12. The admission of a member who has simple, uncomplicated, outpatient surgery and is being admitted primarily because of the time of day or the need for postoperative observation.

13. The admission is primarily due to the:
    - amount of time a member has spent as an outpatient in a hospital or other outpatient setting;
    - time of day a member recovers from outpatient surgery;
    - need for education of the member, parent, or primary caretaker;
    - need for diagnostic testing or obtaining consultations;
    - need to obtain medical devices or equipment or arrange home care or other noninstitutional services;
    - age of the member;
    - convenience of the physician, hospital, member, family, or other medical provider;
    - type of unit within the hospital in which the member is placed; or
    - need for respite care.

E. Observation Services

[excerpted from MassHealth outpatient hospital regulations at 130 CMR 410.414]

Reimbursable Services. MassHealth covers medically necessary observation services provided by acute inpatient hospitals. Reimbursable observation services may exceed 24 hours, and do not need to be provided in a distinct observation unit. To qualify for reimbursement of observation services, the medical record must specifically document when those services began and ended, the purpose of observation, and the name of the physician who ordered it. Acute inpatient hospitals will be reimbursed for these observation services on an outpatient basis in accordance with the signed provider agreement with the MassHealth agency.

Nonreimbursable Services.

(1) Nonreimbursable observation services include but are not limited to:
    (a) services that are not reasonable or necessary for the diagnosis or treatment of the member; and
    (b) routine preparation and recovery services associated with diagnostic testing or outpatient surgery.

(2) The following services are not reimbursable as a separate service:
    (a) postoperative monitoring during a standard recovery period that should be characterized as recovery-room services; and
    (b) observation services provided concurrently with therapeutic services such as chemotherapy.

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