



Commonwealth of Massachusetts
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MASSHEALTH
TRANSMITTAL LETTER PHY-107
November 2005

TO: Physicians Participating in MassHealth
FROM: Beth Waldman, Medicaid Director *BW*
RE: *Physician Manual* (Revised Pharmacy Services Regulations)

This letter transmits revisions to the physician regulations about prescription drugs. The changes clarify that MassHealth does not pay for prescriptions if the prescribing clinician has been suspended or terminated by MassHealth. In addition, MassHealth does not pay for prescriptions written by out-of-state clinicians, unless the circumstances described at 130 CMR 450.109 are met.

The revisions also include the following:

- limiting the days' supply to 30 days;
- adding methylphenidate and amphetamine to the exceptions to the days' supply limitations; and
- excluding drugs for the treatment of sexual dysfunction.

In addition, the revisions eliminate specific language about Norplant, although implantable contraceptives, such as Norplant, remain covered services.

These regulations are effective December 1, 2005.

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.)

Physician Manual

Pages iv-a, 4-29 through 4-32, and 4-41 through 4-44

OBSOLETE MATERIAL

(The pages listed here are no longer in effect.)

Physician Manual

Pages iv-a, 4-31, and 4-32 — transmitted by Transmittal Letter PHY-104

Pages 4-29 and 4-30 — transmitted by Transmittal Letter PHY-103

Pages 4-41 through 4-44 — transmitted by Transmittal Letter PHY-92

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433.441: Pharmacy Services: Prescription Requirements

(A) Legal Prescription Requirements. The MassHealth agency pays for legend drugs, nonlegend drugs, and those medical supplies listed at 130 CMR 433.442(C) only if the pharmacy has in its possession a prescription that meets all requirements for a legal prescription under all applicable federal and state laws and regulations. Each prescription, regardless of drug schedule, must contain the prescriber's unique DEA number. For Schedule VI drugs, if the prescriber has no DEA registration number, the prescriber must provide the state registration number on the prescription.

(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 433.441(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 433.441(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 433.441(D)(2).

(2) Exceptions to Days' Supply Limitations. The MassHealth agency allows exceptions to the limitations described in 130 CMR 433.441(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);

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- (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.

433.442: Pharmacy Services: Covered Drugs and Medical Supplies

(A) 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.

(B) Medical Supplies. The MassHealth agency pays only for the medical supplies listed in 130 CMR 433.442(B)(1) through (6):

- (1) blood and urine testing reagent strips used for the management of diabetes;
- (2) disposable insulin syringe and needle units;
- (3) insulin cartridge delivery devices and needles or other devices for injection of medication (for example, Epipens);
- (4) lancets;
- (5) drug delivery systems for use with metered dose inhalers (for example, aerochambers); and
- (6) alcohol swabs.

433.443: 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 433.444); 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.

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(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 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) Smoking Cessation. The MassHealth agency does not pay for any drug used for smoking cessation.

(6) 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.

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

(8) 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 433.443(B). The limitations and exclusions in 130 CMR 433.443(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 433.000. 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.

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433.444: 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 433.443(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.

433.445: 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 433.442(A) and 433.443(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 *Physician Manual*. If the MassHealth agency approves the request, it will notify the pharmacy 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.

433.446: Pharmacy Services: Member Copayments

Under certain conditions, the MassHealth agency requires 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.

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433.459: Hysterectomy Services

(A) Nonpayable Services. The MassHealth agency does not pay for a hysterectomy provided to a member under the following conditions.

- (1) The hysterectomy was performed solely for the purpose of sterilizing the member.
- (2) If there was more than one purpose for the procedure, the hysterectomy would not have been performed but for the purpose of sterilizing the member.

(B) Hysterectomy Information Form. The MassHealth agency pays for a hysterectomy only when the appropriate section of the Hysterectomy Information (HI-1) form is completed, signed, and dated as specified below.

- (1) Prior Acknowledgment. Except under the circumstances specified below, the member and her representative, if any, must be informed orally and in writing before the hysterectomy operation that the hysterectomy will make her permanently incapable of reproducing. (Delivery in hand of the Hysterectomy Information (HI-1) form will fulfill the written requirement, but not the oral requirement.) Section (B) of the Hysterectomy Information (HI-1) form must be signed and dated by the member or her representative before the operation is performed, as acknowledgment of receipt of this information. Whenever any surgery that includes the possibility of a hysterectomy is scheduled, the member must be informed of the consequences of a hysterectomy, and must sign and date section (B) of the Hysterectomy Information (HI-1) form before surgery.
- (2) Prior Sterility. If the member is sterile prior to the hysterectomy operation, the physician who performs the operation must so certify, describe the cause of sterility, and sign and date section (C)(1) of the Hysterectomy Information (HI-1) form.
- (3) Emergency Surgery. If the hysterectomy is performed in an emergency, under circumstances that immediately threaten the member's life, and if the physician determines that obtaining the member's prior acknowledgment is not possible, the physician who performs the hysterectomy must so certify, describe the nature of the emergency, and sign and date section (C)(2) of the Hysterectomy Information (HI-1) form.

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(4) Retroactive Eligibility. If the hysterectomy was performed during the period of a member's retroactive eligibility, the physician who performed the hysterectomy must certify that one of the following circumstances existed at the time of the operation:

- (a) the woman was informed before the operation that the hysterectomy would make her sterile (the physician must sign and date section (D)(1) of the HI-1 form);
- (b) the woman was sterile before the hysterectomy was performed (the physician must sign, date, and describe the cause of sterility in section (D)(2) of the HI-1 form); or
- (c) the hysterectomy was performed in an emergency that immediately threatened the woman's life and the physician determined that it was not possible to obtain her prior acknowledgment (the physician must sign, date, and describe the nature of the emergency in section (D)(3) of the HI-1 form).

(C) Submission of the Hysterectomy Information Form. Each provider must attach a copy of the completed Hysterectomy Information (HI-1) form to each claim form submitted to the MassHealth agency for hysterectomy services. When more than one provider is billing the MassHealth agency for the same hysterectomy, each provider must submit a copy of the completed HI-1 form.

(130 CMR 433.460 through 433.465 Reserved)

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PART 4. OTHER SERVICES

433.466: Durable Medical Equipment and Medical/Surgical Supplies: Introduction

(A) Covered Equipment. Durable medical equipment consists of products that are fabricated primarily and customarily to fulfill a medical purpose, are generally not useful in the absence of illness or injury, can withstand repeated use over an extended period of time, and are appropriate for home use. Payment for durable medical equipment and medical/surgical supplies is considered by the MassHealth agency on an individual basis.

(B) Nonpayable Services

- (1) The MassHealth agency does not pay for durable medical equipment or medical/surgical supplies that are experimental in nature, unless prior authorization has been obtained.
- (2) The MassHealth agency does not pay for nonmedical equipment or supplies. Equipment that is used primarily and customarily for a nonmedical purpose is not considered medical equipment, even if such equipment has a medically related use. For example, equipment whose primary function is environmental control, comfort, or convenience, or that is provided primarily for the comfort or convenience of a person caring for the member, or that is customarily used to promote physical fitness is not covered.
- (3) The MassHealth agency does not pay for durable medical equipment or medical/surgical supplies that are not both necessary and reasonable for the treatment of a member's medical condition. This includes:
 - (a) items that cannot reasonably be expected to make a meaningful contribution to the treatment of a member's illness or injury or to the improved functioning of a member's malformed body member; and
 - (b) items that are substantially more costly than a medically appropriate and feasible alternative piece of equipment or that serve essentially the same purpose as equipment already available to the member.
- (4) The MassHealth agency does not pay for standard medical and surgical treatment products, goods, and health-related items provided to members who reside in hospitals, nursing facilities, or rehabilitation facilities.

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433.467: Durable Medical Equipment and Medical/Surgical Supplies: Prescription Requirements

The purchase or rental of durable medical equipment and the purchase of medical/surgical supplies are payable only when prescribed in writing by a licensed physician. The equipment and repair services must be furnished by a participating MassHealth provider. The prescription must include the following information:

- (A) the member's name, address, and member identification number;
- (B) the specific identification of the prescribed equipment or supplies;
- (C) the medical justification for use of the equipment or supplies;
- (D) the estimated length of time that the equipment or supplies will be used by the member;