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MASSHEALTH
TRANSMITTAL LETTER POD-48
December 2004

TO: Podiatrists Participating in MassHealth

FROM: Beth Waldman, Medicaid Director

RE: *Podiatrist Manual* (Revised Pharmacy Services Regulations)

This letter transmits revisions to the podiatrist regulations about prescription drugs. These revisions allow refills of prescriptions for up to one year, prohibit pharmacies from automatically refilling prescriptions without a request from the member or caregiver, and make other clarifying changes.

MassHealth is removing Appendix G from the *Podiatrist Manual*. Appendix G listed the nonlegend drugs that are covered by MassHealth. An up-to-date list of nonlegend drugs can be found at www.mass.gov/druglist.

These regulations are effective January 1, 2005.

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

Podiatrist Manual

Pages vi and 4-9 through 4-14

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(The pages listed here are no longer in effect.)

Podiatrist Manual

Page vi — transmitted by Transmittal Letter POD-46

Pages 4-9 through 4-12 — transmitted by Transmittal Letter POD-43

Pages 4-13 and 4-14 — transmitted by Transmittal Letter POD-45

Pages G-1 and G-2 — transmitted by Transmittal Letter POD-47

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(B) Separate Procedures. A separate procedure (denoted by "S.P." after the service description in Subchapter 6 of the *Podiatrist Manual*) is reimbursable only when no other procedure is performed during the same operative session, unless one of the exceptions in 130 CMR 424.413(B)(1) through (3) applies.

(1) When, during the same operative session, an additional surgical procedure performed by the same podiatrist is designated "S.P." and requires an unrelated operative incision, the full maximum allowable fee is paid for the procedure with the largest fee and 50 percent of the maximum allowable fee is paid for each additional procedure, unless otherwise provided herein. In the event that two or more procedures are performed during the same operative session, the full maximum allowable fee is paid for only the procedure with the largest fee and 50 percent of the maximum allowable fee is paid for each additional procedure, unless otherwise provided herein.

(2) When, during the same operative session, one or more of the surgery procedures performed by the same podiatrist are designated "S.P." and do not require an unrelated operative incision, the maximum allowable fee is paid for the procedure commanding the largest fee and no payment is made for any other procedure.

(3) When, during the same operative session, all of the surgery procedures performed by the same podiatrist are designated "S.P." and one or more procedures require an unrelated operative incision, payment is determined by individual consideration.

424.414: Surgical Assistants

(A) MassHealth pays a surgical assistant at 15 percent of the allowable fee for the surgical procedure. MassHealth will not pay for a surgical assistant if a surgical assistant is used in less than five percent of the cases for that procedure nationally. In addition, MassHealth will not pay for a surgical assistant if the surgery services were provided in a teaching hospital that has an approved training program related to the medical specialty required for the surgical procedure(s) and a qualified resident available to perform the services. If no qualified resident is available to perform the services, MassHealth will pay for a surgical assistant if the member's medical record documents that a qualified resident was unavailable at the time of the surgery.

(B) A surgical assistant must meet the requirements for provider eligibility specified in 130 CMR 424.404.

424.415: Radiology Services

(A) MassHealth pays for radiology services when the services are needed to confirm the diagnosis of a bony or calcific disorder, to detect soft-tissue disorders, or to detect foreign bodies.

(B) Payment for radiology services is not included in the fees for visits and should be claimed separately.

(C) All radiology equipment used in providing these services must be inspected and approved by the Massachusetts Department of Public Health.

(D) MassHealth pays a podiatrist for radiology services only when the service is provided in the podiatrist's office and only when the films are developed and read in the podiatrist's office.

(E) All X rays must be labeled with the member's name, the date of examination, and the nature of the examination in addition to the information required in 130 CMR 424.409.

(F) MassHealth pays one maximum allowable fee for a routine study of a particular section of an extremity regardless of the number of X-ray views. An additional fee may be claimed only when a comparison study is necessary.

424.416: Clinical Laboratory Services

(A) MassHealth pays the podiatrist only for laboratory tests listed in the *Podiatrist Manual* and only when the tests are administered and analyzed in the podiatrist's office. MassHealth pays a certified independent clinical laboratory or hospital-licensed clinical laboratory if the laboratory tests are performed at the clinical laboratory.

(B) MassHealth pays for clinical laboratory tests that are necessary for the diagnosis or treatment of conditions of the foot only.

(C) Only the following laboratory tests may be administered without prior authorization:
(1) complete blood count or any of the separate components of such an analysis, including red cell count, white cell count, or hemoglobin;
(2) hematocrit;
(3) fungus culture;
(4) sensitivity, culture, and colony count;
(5) fasting blood sugar;
(6) platelet count;
(7) uric acid;
(8) complete urinalysis; and
(9) combination urinary dip stick (pH, blood, ketones, glucose, nitrites).

(D) The podiatrist must include the following information with any specimen submitted to a certified independent clinical laboratory or hospital-licensed clinical laboratory:
(1) a signed request for the laboratory services to be performed;
(2) the member's identification number, which appears on the member's MassHealth card; and
(3) the podiatrist's name, address, and provider number.

424.417: Pharmacy Services: Prescription Requirements

(A) Legal Prescription Requirements. MassHealth pays for legend drugs and nonlegend drugs 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, MassHealth 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) MassHealth does not pay for prescription refills that exceed the specific number authorized by the prescriber.
(2) MassHealth pays for a maximum of 11 monthly refills, except in circumstances described at 130 CMR 424.417(C)(3).
(3) MassHealth 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) MassHealth 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) MassHealth 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. MassHealth requires that all drugs be prescribed and dispensed in at least a 30-day supply, but no more than a 90-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. MassHealth 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 90-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); and
(f) products generally dispensed in the original manufacturer's packaging (for example, fluoride preparations, prenatal vitamins, and over-the-counter drugs).

(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. MassHealth considers prescription-splitting to be fraudulent. (See 130 CMR 450.238(B)(6).)

424.418: Pharmacy Services: Covered Drugs

The MassHealth Drug List specifies the drugs that are payable under MassHealth. In addition, MassHealth 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. MassHealth 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 MassHealth 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. MassHealth does not pay for the following types of drugs or drug therapy:

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

(2) Cough and Cold. MassHealth 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. MassHealth does not pay for any drug used to promote male or female fertility.

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

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

(6) Less-Than-Effective Drugs. MassHealth 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. MassHealth does not pay for any drug that is experimental, medically unproven, or investigational in nature.

(C) Service Limitations.

(1) MassHealth covers drugs that are not explicitly excluded under 130 CMR 424.419(B). 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. MassHealth 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) MassHealth 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;
(c) drugs used for the treatment of male or female sexual dysfunction;
(d) drugs related to sex-reassignment surgery, specifically including but not limited to, presurgery and postsurgery hormone therapy. MassHealth, however, will continue to pay for post sex-reassignment surgery hormone therapy for which it had been paying immediately prior to May 15, 1993; and
(e) topical acne products for members aged 21 or older. MassHealthpays for topical acne products for members under age 21, and all other topical acne products for members of all ages who have cases of acne Grade II or higher, without prior authorization.

(3) MassHealth does not pay any additional fees for dispensing drugs in a unit-dose distribution system.
(4) MassHealth does not pay for any drug prescribed for other than the FDA-approved indications as listed in the package insert, except as MassHealth determines to be consistent with current medical evidence.
(5) MassHealth 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. MassHealth 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 MassHealth for the primary insurer's member copayment for the primary carrier's preferred drug without regard to whether MassHealth 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), (c), (d), and (e). In such cases, the prescriber must obtain prior authorization from MassHealth in order for the pharmacy to bill MassHealth for the primary insurer's member copayment. For additional information about third party liability, see 130 CMR 450.101 et seq.

424.421: Pharmacy Services: Prior Authorization

(A) Prescribers must obtain prior authorization from MassHealth for drugs identified by MassHealth 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 MassHealth 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 MassHealth approves the request, it will notify both the podiatrist and the member.

(C) MassHealth authorizes 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).) MassHealth 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. MassHealth will evaluate the prior-authorization status of drugs on an ongoing basis, and update the MassHealth Drug List.

424.422: Pharmacy Services: Member Copayments

MassHealth 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.

424.423: Drugs Dispensed in Provider's Office

Drugs dispensed in the office are payable at the podiatrist's actual acquisition cost if this cost is more than $1.00. Claims for dispensing drugs must include the name of the drug or biological, the strength, and the dosage. A copy of the invoice showing the actual acquisition cost must be attached to the claim form, and must include the National Drug Code (NDC). Claims without this information will be denied.

424.424: Shoes and Corrective Devices

(A) MassHealth pays for only those shoes listed in Subchapter 6 of the *Podiatrist Manual*.

(B) For shoes, providers must submit with their claim a copy of the completed MassHealth Shoe Medical Necessity Form and a copy of the Life and Safety Certification from the primary care physician. (See 130 CMR 424.405.)

(C) MassHealth does not pay for casting materials used in the molding of orthotic shoes or corrective devices. The cost of these materials is included in the fee for prescribing and providing the shoe or corrective device.

REGULATORY AUTHORITY

130 CMR 424.000: M.G.L. c. 118E, §§7 and 12.