Commonwealth of Massachusetts
Executive Office of Health and Human Services
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MASSHEALTH
TRANSMITTAL LETTER POD-43
March 2003

TO: Podiatrists Participating in MassHealth

FROM: Douglas S. Brown, Acting Commissioner

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

This letter transmits revised podiatrist regulations. The pharmacy-related provisions have been revised to:

- remove the definitions of financial terms that apply only to pharmacies;
- modify the definition of interchangeable drug product;
- define the MassHealth Drug List;
- reduce the number of allowable refills from 11 to five;
- clarify specific drug limitations and prior-authorization requirements; and
- clarify the impact of managed-care enrollment and insurance coverage on MassHealth pharmacy claims.

These regulations are effective April 1, 2003.

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

Podiatrist Manual

Pages iv, 4-1 through 4-4, and 4-9 through 4-14

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(The pages listed here are no longer in effect.)

Podiatrist Manual

Pages iv and 4-9 through 4-12 — transmitted by Transmittal Letter POD-39

Pages 4-1 through 4-4, 4-13, and 4-14 — transmitted by Transmittal Letter POD-41

4. PROGRAM REGULATIONS

424.401: Introduction

All podiatrists participating in MassHealth must comply with the regulations of the Division governing MassHealth, including but not limited to Division regulations set forth in 130 CMR 424.000 and 450.000.

424.402: Definitions

The following terms used in 130 CMR 424.000 have the meanings given in 130 CMR 424.402, unless the context clearly requires a different meaning. The reimbursability of services defined in 130 CMR 424.000 is not determined by these definitions, but by application of regulations elsewhere in 130 CMR 424.000 and in 130 CMR 450.000.

Controlled Substance – a drug listed in Schedule II, III, IV, V, or VI of the Massachusetts Controlled Substances Act (M.G.L. c. 94C).

Corrective Devices – orthotics, splints, inlays, appliances, and braces that support or accommodate part or all of the foot and serve to restore or improve functions of the foot.

Custom-Molded Shoe – an individually patterned shoe fabricated to meet the specific needs of an individual. A custom-molded shoe is not off-the-shelf, stock, or prefabricated. The shoe is individually constructed by a molded process over a modified positive model of the individual's foot. It is made of leather or other suitable material of equal quality, has removable customized inserts that can be replaced if necessary according to the individual's condition, and has some form of shoe closure.

Drug – a substance containing one or more active ingredients in a specified dosage form and strength. Each dosage form and strength is a separate drug.

Emergency – a sudden or unexpected illness or injury or traumatic injury or infection other than athlete's foot or chronic mycosis infecting the nail bed that must be treated promptly to prevent severe pain to the member.

Flexible Adhesive Casting – the application of adhesive tape to orthopedically support or stabilize the foot, or to exert beneficial stress for a structural instability.

Hygienic Foot Care – the trimming of nonpathogenic nails; the cleansing or soaking of the feet; the use of skin creams to maintain skin tone of both ambulatory and bedridden patients; or such other foot care that can be performed by the member or by the nursing facility staff if the member resides in a nursing facility.

Interchangeable Drug Product – a product containing a drug in the same amounts of the same active ingredients in the same dosage form as another product with the same generic or chemical name that has been determined to be therapeutically equivalent (that is, "A"-rated) by the Food and Drug Administration for Drug Evaluation and Research (FDA CDER), or by the Massachusetts Drug Formulary Commission.

Last – a model that approximates the shape and size of the foot and over which a shoe is made. A last is usually made of wood, plastic, or plaster.

Legend Drug – any drug for which a prescription is required by applicable federal or state law or regulation.

MassHealth Drug List – a list of commonly prescribed drugs and therapeutic class tables published by the Division. The MassHealth Drug List specifies the drugs that are payable under MassHealth. The list also specifies which drugs require prior authorization. Except for drugs and drug therapies described in 130 CMR 424.419(B), any drug that does not appear on the MassHealth Drug List requires prior authorization, as otherwise set forth in 130 CMR 424.000.

Moldable Shoes – off-the shelf, ready-made shoes formed from heat-activated materials. The shoes are molded by a thermo-forming process that first heats the material, then forms it over an individual's foot or a positive model of the individual's foot.

Molded Shoe – a shoe made from a plaster cast of an individual foot and molded to the foot to accommodate an anatomical deformity that cannot be accommodated by an orthopedic or modified standard shoe.

Multiple-Source Drug – a drug marketed or sold by two or more manufacturers or labelers, or a drug marketed or sold by the same manufacturer or labeler under two or more different names.

Nonlegend Drug – any drug for which no prescription is required by federal or state law.

Nonstandard Size (Width or Length) – a shoe size made on a standard last pattern, but which is not part of a manufacturer's regular inventory.

Orthopedic Shoes – shoes that are specially constructed to aid in the correction of a deformity of the musculoskeletal structure of the foot and to preserve or restore the function of the musculoskeletal system of the foot.

Orthotist – one who is skilled in the straightening or correction of a deformity or disability by use of a brace or orthopedic device.

Pharmacy On-Line Processing System (POPS) – the on-line, real-time computer network that adjudicates pharmacy claims, incorporating prospective drug utilization review, prior authorization, and member eligibility verification.

Split-Size Charge – an additional charge for dispensing an off-the-shelf, medical-grade pair of orthopedic shoes, where one shoe in the pair is a different size or width than the other shoe in the pair.

Unit-Dose Distribution System – a means of packaging or distributing drugs, or both, devised by the manufacturer, packager, wholesaler, or retail pharmacist. A unit dose contains an exact dosage of medication and may also indicate the total daily dosage or the times when the medication should be taken.

424.403: Eligible Members

(A) (1) MassHealth Members. The Division covers podiatry services only when provided to eligible MassHealth members, subject to the restrictions and limitations described in the Division's regulations. The Division's regulations at 130 CMR 450.105 specifically state, for each MassHealth coverage type, which services are covered and which members are eligible to receive those services.

(2) Age Limitations. In addition to any other restrictions and limitations set forth in 130 CMR 424.00 and 450.000, the Division covers shoes only when provided to eligible MassHealth members under age 21. This age restriction does not apply to therapeutic, moldable, or custom-molded shoes and shoe inserts for members who have severe diabetic foot disease.

(3) Recipients of the Emergency Aid to the Elderly, Disabled and Children Program. For information on covered services for recipients of the Emergency Aid to the Elderly, Disabled and Children Program, see 130 CMR 450.106.

(B) Member Eligibility and Coverage Type. For information on verifying member eligibility and coverage type, see 130 CMR 450.107.

424.404: Provider Eligibility

Payment for services described in 130 CMR 424.000 will be made only to providers who are participating in MassHealth on the date the service was provided or who are otherwise eligible for such payment pursuant to 130 CMR 450.000 and who meet the following requirements.

(A) In State. A podiatrist practicing in Massachusetts must be licensed by the Massachusetts Board of Registration in Podiatry.

(B) Out of State. An out-of-state podiatrist must be licensed by that state's board of registration for podiatrists. The Division pays an out-of-state podiatrist only when services are provided to an eligible Massachusetts member under the following circumstances:

(1) the podiatrist practices outside the border of Massachusetts and provides emergency services to a member;

(2) the podiatrist practices in a community of Connecticut, Maine, New Hampshire, New York, Rhode Island, or Vermont that is within 50 miles of the Massachusetts border and provides services to a member who resides in a Massachusetts community near the border of that state; or

(3) the podiatrist provides services to a member who is authorized to reside out of state by the Massachusetts Department of Social Services.

424.405: Service Limitations and Noncovered Services

(A) Services Limited to Life and Safety. The Division pays only for podiatry services that are certified to be necessary for the life and safety of the member. The Division reimburses for podiatry services as long as the provider's claim has attached to it a written certification on letterhead from the member's primary care physician that attests that such services are medically necessary for the life and safety of the member and that contains a substantiating medical explanation.

(B) Noncovered Services. The Division does not pay for the following:

(1) hygienic foot care as a separate procedure, except when the member's medical record documents that the member cannot perform the care or risks harming himself or herself by performing it. The preceding sentence notwithstanding, payment for hygienic foot care performed on a resident of a nursing facility is included in the nursing facility's per diem rate and is not reimbursable in any case as a separate procedure;

(2) canceled or missed appointments;

(3) services provided by a podiatrist whose contractual arrangements with a state institution, acute, chronic, or rehabilitation hospital, medical school, or other medical institution involve a salary, compensation in kind, teaching, research, or payment from any other sources, if such payment would result in dual compensation for professional, supervisory, or administrative services related to member care;

(4) telephone consultations;

(5) standard or stock shoes unless they are attached to braces;

(6) in-service education;

(7) research or experimental treatment;

(8) cosmetic services or devices;

(9) sneakers or athletic shoes;

(10) an additional charge for nonstandard size (width or length) in custom-molded shoes; or

(11) shoes when there is no diagnosis of associated foot deformities.

(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) The Division pays a surgical assistant at 15 percent of the allowable fee for the surgical procedure. The Division 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, the Division 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, the Division 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) The Division 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) The Division 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) The Division 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) The Division 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. The Division pays a certified independent clinical laboratory or hospital-licensed clinical laboratory if the laboratory tests are performed at the clinical laboratory.

(B) The Division 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. The Division 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, the Division will authorize a pharmacy to dispense at least a 72-hour, nonrefillable supply of the drug in compliance with state and federal regulations.

(C) Refills.

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

(2) The Division pays for a maximum of five monthly refills.

(3) The Division pays for more than five refills within a six-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 Division does not pay for any refill dispensed after six months from the date of the original prescription.

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

(D) Quantities.

(1) Days' Supply Limitations. The Division 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. The Division 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. The Division 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.

(A) Legend Drugs. The Division 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) Nonlegend Drugs. The Division pays only for the nonlegend drugs listed in Appendix G of the *Podiatrist Manual* (Nonlegend Drug List).

424.419: Pharmacy Services: Limitations on Coverage of Drugs

(A) Interchangeable Drug Products. The Division 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 Division 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 Division does not pay for the following types of drugs or drug therapy:

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

(2) Cough and Cold. The Division does not pay for legend or nonlegend preparations that contain an antitussive or expectorant as a major ingredient, or any drug used solely for the symptomatic relief of coughs and colds, when they are dispensed to a noninstitutionalized member.

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

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

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

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

(C) Service Limitations.

(1) The Division 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 on the Division's Web site, and copies may be obtained upon request. The Division 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 Division 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. The Division, 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) retinoids for members aged 26 or older. The Division pays for retinoids for members under age 26, and all other topical acne products for members of all ages who have cases of acne Grade II or higher, without prior authorization.

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

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

424.420: Pharmacy Services: Insurance Coverage

(A) Managed Care Organizations. The Division 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 Division for the primary insurer's copayment for the primary carrier's preferred drug without regard to whether the Division 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 the Division in order for the pharmacy to bill the Division for the primary insurer's copayment.

424.421: Pharmacy Services: Prior Authorization

(A) Prescribers must obtain prior authorization from the Division for drugs identified by the Division in accordance with 130 CMR 450.303. If the limitations on covered drugs specified in 130 CMR 424.418(A)(1) 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 Division 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 *Podiatry Manual*. If the Division approves the request, the Division will notify both the podiatrist and the member.

(C) The Division 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 Division 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 Division 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 Division 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 the Division's administrative and billing regulations at 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) The Division 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.

(C) The Division 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.

(D) The Division does not pay a podiatrist for stock items prescribed or ordered.

REGULATORY AUTHORITY

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