Commonwealth of Massachusetts
Executive Office of Health and Human Services
Office of Medicaid
www.mass.gov/masshealth

MassHealth
Transmittal Letter POD-65
March 2011

TO: Podiatrists Participating in MassHealth

FROM: Terence G. Dougherty, Medicaid Director

RE: *Podiatrist Manual* (Amendments to Regulations about Payment for Surgery Services)

MassHealth has revised its regulations related to payment for multiple surgeries performed on the same day and has developed new rules for global surgery periods.

Under the new policy, payment for a surgical procedure includes a standard package of preoperative, intraoperative, and postoperative services. The services included within the global surgical package are not payable separately, regardless of the setting in which those services were performed.

In addition to a description of the global surgical package, the provisions in 130 CMR 424.413 and 424.414 describe payment for multiple surgeries and endoscopies, add-on surgical procedures, bilateral procedures, surgical assistants, team surgery, and co-surgery (two surgeons). The modifiers MassHealth has adopted are listed in Section 605 of Subchapter 6 of the MassHealth *Podiatrist Manual*.

These amendments are effective for dates of service on or after **April 1, 2011**.

MassHealth Web Site

This transmittal letter and attached pages are available on the MassHealth Web site at www.mass.gov/masshealth.

Questions

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 iv, vi, vii, and 4-7 through 4-18

OBSOLETE MATERIAL

(The pages listed here are no longer in effect.)

Podiatrist Manual

Pages iv, 4-15, and 4-16 — transmitted by Transmittal Letter POD-60

Page vi — transmitted by Transmittal Letter POD-55

Page vii — transmitted by Transmittal Letter POD-53

Pages 4-7 and 4-8 — transmitted by Transmittal Letter POD-39

Pages 4-9 through 4-14 — transmitted by Transmittal Letter POD-59

4. Program Regulations

424.401: Introduction 4-1
424.402: Definitions 4-1
424.403: Eligible Members 4-3
424.404: Provider Eligibility 4-3
424.405: Noncovered Services 4-4
424.406: Maximum Allowable Fees 4-5
424.407: Individual Consideration 4-5
424.408: Referral 4-5
424.409: Recordkeeping (Medical Records) Requirements 4-6
424.410: Report Requirements 4-6
424.411: Office Visits 4-7
424.412: Out-of-Office Visits 4-7
424.413: Surgical Services: Introduction 4-8
424.414: Surgery Services: Payment 4-9
424.415: Radiology Services 4-12
424.416: Clinical Laboratory Services 4-12
424.417: Pharmacy Services: Prescription Requirements 4-13
424.418: Pharmacy Services: Covered Drugs 4-14
424.419: Pharmacy Services: Limitations on Coverage of Drugs 4-15
424.420: Pharmacy Services: Insurance Coverage 4-16
424.421: Pharmacy Services: Prior Authorization 4-17
424.422: Pharmacy Services: Member Copayments 4-18
424.423: Drugs Dispensed in Provider's Office 4-18
424.424: Shoes and Corrective Devices 4-18
410.425: Early and Periodic Screening, Diagnosis and Treatment (EPSDT) Services 4-18

6. Service Codes and Descriptions

Introduction 6-1
Payable CPT Codes 6-1
Payable HCPCS Level II Service Codes for Injectable and Infusable Drugs Administered in the Office 6-3
Payable HCPCS Level II Service Codes for Diabetic Shoes and Orthotic Services 6-3
Modifiers 6-6

Appendix A. Directory A-1

Appendix B. Enrollment Centers B-1

Appendix C. Third-Party-Liability Codes C-1

Appendix D. (Reserved)

Appendix E. Utilization Management Program E-1

Appendix F. Admission Guidelines F-1

Appendix W. EPSDT Services: Medical and Dental Protocol and Periodicity Schedules W-1

Appendix X. Family Assistance Copayments and Deductibles X-1

Appendix Y. EVS Codes/Messages Y-1

Appendix Z. EPSDT/PPHSD Screening Services Codes Z-1

The regulations and instructions governing provider participation in MassHealth are published in the Provider Manual Series. MassHealth publishes a separate manual for each provider type.

Manuals in the series contain administrative regulations, billing regulations, program regulations, service codes, administrative and billing instructions, and general information. MassHealth regulations are incorporated into the Code of Massachusetts Regulations (CMR), a collection of regulations promulgated by state agencies within the Commonwealth and by the Secretary of State. MassHealth regulations are assigned Title 130 of the Code. Pages that contain regulatory material have a CMR chapter number in the banner beneath the subchapter number and title.

Administrative regulations and billing regulations apply to all providers and are contained in 130 CMR Chapter 450.000. These regulations are reproduced as Subchapters 1, 2, and 3 in this and all other manuals.

Program regulations cover matters that apply specifically to the type of provider for which the manual was prepared. For podiatrists, those matters are covered in 130 CMR Chapter 424.000, reproduced as Subchapter 4 in the *Podiatrist Manual*.

Revisions and additions to the manual are made as needed by means of transmittal letters, which furnish instructions for substituting, adding, or removing pages. Some transmittal letters will be directed to all providers; others will be addressed to providers in specific provider types. In this way, a provider will receive all those transmittal letters that affect its manual, but no others.

The Provider Manual Series is intended for the convenience of providers. Neither this nor any other manual can or should contain every federal and state law and regulation that might affect a provider's participation in MassHealth. The provider manuals represent instead MassHealth’s effort to give each provider a single convenient source for the essential information providers need in their routine interaction with MassHealth and its members.

424.411: Office Visits

The MasssHealth agency pays for four types of office visits: initial, limited, extended, and follow-up. The fees vary depending on the type of visit.

(A) The MassHealth agency pays for one initial visit (the member's first visit to a podiatrist) per member. This visit must include an initial comprehensive history, results of laboratory tests or other findings, whether positive or negative, and identification of both podiatric and general medical problems through vascular, orthopedic, neurological, dermatological, and musculoskeletal examination. The fee for an initial visit includes necessary treatment for relief of symptoms.

(B) The MassHealth agency pays for one limited visit per member within a 30-day period. A limited visit must include an interval history and examination and treatment of the foot, which may include removal of excrescences; palliative and prophylactic onychial care; treatment of hypertrophied toenails; and electroburring when the record documents that the member has a localized illness, injury, or symptoms involving the foot, including diabetes or peripheral vascular disease.

(C) The MassHealth agency pays for one extended visit per member within a 30-day period. An extended visit must include the application of flexible adhesive casting, minor modification to shoes, or electric modality physiotherapy. An extended visit may also include the removal of excrescences, palliative and prophylactic onychial care, treatment of hypertrophied or ingrown nails (or both), and other comparable procedures.

(D) The MassHealth agency pays for one follow-up visit per member per week. A follow-up visit is a return visit for a specific diagnosis (such as warts or an ulcer) in which a brief procedure, such as a dressing change, debridement, or removal of sutures, is performed.

(E) Payment for the removal of an ulcerated keratosis is included in the fees for any type of visit and must not be billed for separately.

(F) The MassHealth agency pays for either an office visit or a treatment or surgical procedure for the same member on the same date of service but not both.

424.412: Out-of-Office Visits

The MassHealth agency pays for podiatric care provided in a hospital, a member's home, or a long-term-care facility only when the following conditions are met.

(A) Podiatric care provided in any of the above settings is designed to treat a diagnosed condition, to minimize bed confinement, and to increase the member's activity.

(B) The podiatrist performs and documents a complete evaluation and all necessary treatment for relief of the member's symptoms or for the diagnosed condition.

(C) If further treatment is required, the podiatrist formulates a treatment plan and includes it in the member's medical record. This plan must justify any further diagnostic procedures, additional treatment, return visits, or referrals and must include the following information:

(1) a diagnosis of the member's podiatric condition;
(2) results of X rays and other diagnostic tests, if performed; and
(3) a description of treatment provided and recommendations for additional treatment.

(D) The treatment plan is updated after each visit and details the member's progress.

(E) Documentation of all out-of-office visits, including the member's evaluation, progress, and treatment plan, must be kept either in the podiatrist's office or at the appropriate facility where the service is provided.

(F) Payment is limited to one out-of-office visit per member in a 30-day period in a long-term-care facility or the member's home and two visits in a 30-day period for a member in a hospital setting.

(G) The MassHealth agency pays for either a visit or a treatment procedure. The MassHealth agency does not pay for both a visit and a treatment or surgical procedure provided to a member on the same day in the same location.

424.413: Surgery Services: Introduction

Surgical procedures must be performed in a podiatrist's office, in a hospital, or in a freestanding ambulatory surgical center.

(A) Provider Eligibility. The MassHealth agency pays a podiatrist for surgery only if the podiatrist is scrubbed and present in the operating room during the major portion of the operation.

(B) Nonpayable Services. The MassHealth agency does not pay for

(1) any experimental, unproven, cosmetic, or otherwise medically unnecessary procedure or treatment;
(2) reconstructive surgery, unless the MassHealth agency determines, pursuant to a request for prior authorization, the service is medically necessary to correct, repair, or ameliorate the physical effects of physical disease or defect, or traumatic injury;
(3) services billed under codes listed in Subchapter 6 of the *Podiatrist Manual* as not payable;
(4) services otherwise identified in MassHealth regulations at 130 CMR 424.000 or 450.000 as not payable; and
(5) services billed with otherwise-covered service codes when such codes are used to bill for nonpayable services as described in 130 CMR 424.405.

(C) Definitions. The following terms have the meanings given for purposes of 130 CMR 424.413 and 424.414, unless otherwise indicated.

(1) Complications Following Surgery – all additional medical or surgical services required of the surgeon during the postoperative period of the surgery because of complications that do not require additional trips to the operating room.

(2) Evaluation and Management (E/M) Services – visits and consultations furnished by physicians in various settings and of various complexities as defined in the Evaluation and Management section of the American Medical Association's *Current Procedural Terminology (CPT)* code book.
(3) Intraoperative Services – intraoperative services that are normally a usual and necessary part of a surgical procedure.
(4) Major Surgery – a surgery for which the Centers for Medicare & Medicaid Services (CMS) determines that the preoperative period is one day and the postoperative period is 90 days.
(5) Minor Surgery – a surgery for which CMS determines the preoperative period is zero days and the postoperative period is zero or 10 days.
(6) Postoperative Period –
(a) The postoperative period for major surgery is 90 days.
(b) The postoperative period for minor surgery and endoscopies is zero or 10 days.
(7) Postoperative Visits – follow-up visits during the postoperative period of the surgery that are related to recovery from the surgery.
(8) Postsurgical Pain Management – postsurgical pain management by the surgeon, including supplies.
(9) Preoperative Period –
(a) The preoperative period for major surgery is one day.
(b) The preoperative period for minor surgery is zero days.
(10) Preoperative Visits – preoperative visits after the decision is made to operate, beginning with the day before the day of surgery for major procedures and the day of surgery for minor procedures.

424.414: Surgery Services: Payment

Surgical services and other invasive procedures are listed in the surgery and medicine section of the American Medical Association's *Current Procedural Terminology (CPT)* code book. The MassHealth agency pays for all medicine and surgery CPT codes in effect at the time of service, except for those codes listed in Section 602 of Subchapter 6 of the *Podiatrist Manual*, subject to all conditions and limitations described in MassHealth regulations at 130 CMR 424.000 and 450.000.

(A) Visit and Treatment/Procedure on Same Day in Same Location. The MassHealth agency pays a podiatrist for either a visit or a treatment/procedure, whichever fee is greater. The MassHealth agency does not pay for both a preoperative evaluation and management visit, and a treatment/procedure provided to a member on the same day when they are performed in the same location. For minor surgeries and endoscopies, the MassHealth agency does not pay separately for an evaluation and management service on the same day as the surgery or endoscopy.

(B) Payment for Global Surgical Package. The payment for a surgical procedure includes a standard package of preoperative, intraoperative, and postoperative services. The services are included in the global surgical package regardless of setting, including but not limited to hospitals, ambulatory surgical centers, and podiatrists' offices.
(1) The following services are included in the payment for a global surgery when furnished by the podiatrist who performs the surgery:
(a) preoperative visits;
(b) intraoperative visits;
(c) complications following surgery;
(d) postoperative visits;

(e) postsurgical pain management;
(f) miscellaneous services related to surgery, including but not limited to dressing changes; local incisional care; removal of operative pack, cutaneous sutures and staples, lines, wires, tubes, drains, casts, and splints; insertion, irrigation, and removal of urinary catheters, routine peripheral intravenous lines, nasogastric tubes, and rectal tubes; and changes and removal of tracheostomy tubes; and
(g) visits related to the surgery to a patient in an intensive care or critical care unit, if made by the podiatrist. Intensive or critical care visits unrelated to surgery are not included in the global surgical package.

(2) The following services are not included in the payment for a global surgery:
(a) the initial consultation or evaluation of the problem by the podiatrist to determine the need for surgery;
(b) services of other podiatrists except where the surgeon and the other podiatrist or podiatrists agree on the transfer of care during the global period. Such transfer agreement must be in writing and a copy of the written transfer agreement must be kept in the member's medical record;
(c) visits unrelated to the diagnosis for which the surgical procedure is performed;
(d) treatment for the underlying condition or an added course of treatment that is not part of the normal recovery from the surgery;
(e) diagnostic tests and procedures, including diagnostic radiological procedures;
(f) clearly distinct surgical procedures during the postoperative period that are not reoperations or treatment for complications resulting from the surgery. A new postoperative period begins with the subsequent surgical procedure. This exception includes procedures done in two or more parts for which the decision to stage the procedure is made prospectively or a the time of the first procedure;
(g) treatment for postoperative complications that require a return trip to the operating room (OR). An OR for this purpose is defined as a place of service specifically equipped and staffed for the sole purpose of performing procedures. The term includes a cardiac catheterization suite, a laser suite, and an endoscopy suite. It does not include a patient's room, a minor treatment room, a recovery room, or an intensive care unit (unless the patient's condition was so critical that there would be insufficient time for transportation to an OR); and
(h) a second, more extensive procedure required because the initial, less extensive procedure did not produce the desired outcome.

(C) Payment for Multiple Surgeries. Multiple surgeries are separate procedures performed by a podiatrist on the same patient at the same operative session or on the same day. Multiple surgeries are distinguished from intraoperative services and surgeries that are incidental to or components of a primary surgery (that is, bundled services). Bundled services are not paid separately. When two or more related procedures are performed on a patient during a single session or visit, the MassHealth agency pays the provider for the comprehensive code and denies or adjusts the component, incidental, or mutually exclusive procedure performed during the same session. The bundling guidelines that MassHealth applies are based upon generally accepted industry guidelines including, but not limited to the Correct Coding Initiative administered through the Centers for Medicare & Medicaid Services (CMS) and the American Medical Association's *Current Procedural Terminology (CPT)* code book. To receive payment for multiple surgeries, the surgeon must bill with the multiple surgery modifier.

(D) Payment for Multiple Endoscopy Procedures. When multiple procedures are performed through the same endoscope, payment is made for the highest valued endoscopy procedure plus the difference between the next highest valued endoscopy procedure and the base endoscopy procedure. The base endoscopy procedure is included in the code for each of the multiple procedures. When two related endoscopies and an unrelated endoscopy are performed, the endoscopic payment rule stated above applies to the related endoscopies. Unrelated endoscopic procedures are treated as separate surgeries and paid as multiple surgeries pursuant to 130 CMR 424.414(C).

(E) Payment for Add-on Surgical Procedures. The Centers for Medicare & Medicaid Services (CMS) has identified certain procedures as add-on procedures that are always billed with another procedure. Add-on codes are identified in the CPT code book. By definition, these services do not stand alone and must be provided in conjunction with a primary surgical procedure or qualifying service. Both the service code for the primary procedure and add-on code are paid separately. The global surgery package provisions at 130 CMR 424.413 and 424.414 apply to the service code for the primary procedure.

(F) Payment for Bilateral Procedures. Bilateral surgeries are defined as procedures performed on both sides of the body during the same operative session or on the same day. To receive payment, the podiatrist must use the bilateral surgery modifier with the appropriate service code. The provider must not use the bilateral surgery modifier with service codes containing the terms "bilateral" or "unilateral or bilateral" in their definitions, since the terminology of the code identifies the service as one whose payment accounts for any additional work required for bilateral surgery.

(G) Surgical Assistants. Some surgical procedures require a primary surgeon and an assistant surgeon. A surgical assistant must meet the requirements for provider eligibility specified in 130 CMR 424.404. To receive payment, the assistant surgeon must use the appropriate modifier. Surgical codes that accept the surgical assistant modifiers are indicated in the *Correct Coding Initiative Guide*. In addition, the MassHealth agency does not pay for a surgical assistant if

(1) any component of the surgery is billed using a team surgery modifier pursuant to 130 CMR 424.414(H) or a two-surgeon modifier pursuant to 130 CMR 424.414(I);

(2) 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 and a qualified resident available to perform the services. If no qualified resident is available to perform the services, the MassHealth agency pays for a surgical assistant if the member's medical record documents that a qualified resident was unavailable at the time of the surgery; or

(3) the surgical procedure does not require the services of more than one surgeon.

(H) Team Surgery. Under some circumstances, the MassHealth agency pays for highly complex surgical procedures requiring the concomitant services of more than two surgeons as "team surgery." The MassHealth agency pays a single consolidated payment for team surgery to the director of the surgical team. To receive payment, the director of the team must use the team surgery modifier. Payment includes all surgical assistant fees. The director of the surgical team is expected to distribute the MassHealth payment to the other members of the surgical team.

(I) Two Surgeons (Co-Surgery). The MassHealth agency pays for co-surgery when two surgeons work together as primary surgeons performing distinct parts of a reportable procedure. To receive payment, each surgeon must use the two surgeons modifier. Payment includes all surgical assistant fees.

424.415: Radiology Services

(A) The MassHealth agency 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 MassHealth agency 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 MassHealth agency 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 MassHealth agency 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 MassHealth agency pays a certified independent clinical laboratory or hospital-licensed clinical laboratory if the laboratory tests are performed at the clinical laboratory.

(B) The MassHealth agency 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 MassHealth agency pays for prescription drugs and over-the-counter drugs and items on the Non-Drug Product List 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 for drugs in Schedule II through V must contain the prescriber's unique DEA number. For Schedule VI drugs, if the prescriber has no DEA registration number, the prescriber's Massachusetts Controlled Substance Registration number must appear 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 424.417(C)(3), or where the MassHealth Drug List specifically limits the number of refills, duration of the prescription, or both.

(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.

(a) The MassHealth agency allows exceptions to the limitations described in 130 CMR 424.417(D)(1) for the following products:

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

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

(iii) 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;

(iv) 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);

(v) 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);

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

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

(b) Drugs paid for by a member's primary insurance carrier that are dispensed in up to a 90-day supply when the MassHealth agency pays any portion of the claim, including the copayment portion or deductible, may be dispensed in up to a 90-day supply.

(c) Drugs used for family planning may be dispensed in up to a 90-day supply.

(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:

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

424.418: Pharmacy Services: Covered Drugs

(A) Drugs. The MassHealth Drug List specifies the drugs that are payable under MassHealth. In addition, the following rules apply.

(1) Prescription Drugs. The MassHealth agency pays only for prescription 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. Payment is calculated in accordance with DHCFP regulations at 114.3 CMR 31.00: Prescribed Drugs.

(2) Over-the-Counter Drugs. Payment by the MassHealth agency for over-the-counter drugs is calculated in accordance with DHCFP regulations at 114.3 CMR 31.00: Prescribed Drugs.

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 prescription or over-the-counter drugs or drug therapy:

(1) Cosmetic. The MassHealth agency does not pay for any drug used for cosmetic purposes or for hair growth.

(2) Cough and Cold. The MassHealth agency does not pay for any drug 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 a member who is a resident of a nursing facility or an intermediate care facility for the mentally retarded (ICF/MR).

(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 any 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 any drug 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) do not apply to medically necessary drugs 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. 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.

(1) Overview. 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.

(2) Medicare Part D One-Time Supplies. The MassHealth agency pays for one-time supplies of prescribed medications, as described in 130 CMR 406.414(C)(2)(a) and (b), if the medication is a MassHealth-covered medication and the MassHealth member would otherwise be entitled to MassHealth pharmacy benefits but for being eligible for Medicare prescription drug coverage. MassHealth prior authorization does not apply to such one-time supplies. The MassHealth agency pays for the one-time supplies in all instances in which the pharmacist cannot bill a Medicare Part D prescription drug plan at the time the prescription is presented.The MassHealth agency pays for a one-time 72-hour supply of prescribed medications.

(3) Cost-Sharing Assistance for MassHealth Members Enrolled in a Medicare Part D Prescription Drug Plan. For the purpose of 130 CMR 424.420(C)(3)(a) and (b), the "applicable MassHealth copayment" is the copayment the MassHealth member would pay for prescription drugs if the drugs were covered by MassHealth and not covered by Medicare Part D. MassHealth members who are enrolled in a Medicare Part D prescription drug plan and are charged a copayment or deductible in excess of the member's applicable MassHealth copayment for a drug that MassHealth would otherwise cover, must pay the applicable MassHealth copayment and the MassHealth agency pays the difference between the applicable MassHealth copayment and the amount charged by the Medicare Part D prescription drug plan.

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 prescription or nonprescription) 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) The MassHealth agency 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 applicable completed MassHealth Orthotic and Prosthetic Prescription and Medical Necessity Review Form.

(C) The MassHealth agency 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.

424.425: Early and Periodic Screening, Diagnosis and Treatment (EPSDT) Services

The MassHealth agency pays for all medically necessary podiatry services for EPSDT-eligible members in accordance with 130 CMR 450.140 et seq., without regard to service limitations described in 130 CMR 424.000, and with prior authorization.

REGULATORY AUTHORITY

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