



**Commonwealth of Massachusetts**  
**Executive Office of Health and Human Services**  
**Office of Medicaid**  
600 Washington Street  
Boston, MA 02111  
[www.mass.gov/masshealth](http://www.mass.gov/masshealth)



MASSHEALTH  
TRANSMITTAL LETTER POD-49  
May 2005

**TO:** Podiatrists Participating in MassHealth  
**FROM:** Beth Waldman, Medicaid Director *BW*  
**RE:** *Podiatrist Manual* (Revision to Service Limitations)

This letter transmits revisions to the podiatrist regulations about topical acne products. The revision removes language about service limitations for topical acne products. Service limitations to this type of drug therapy will be in the MassHealth Drug List.

The revisions also clarify service limitations and exclusions.

These regulations are effective May 15, 2005.

**NEW MATERIAL**

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

**Podiatrist Manual**

Pages iv and 4-11 through 4-16

**OBSOLETE MATERIAL**

(The pages listed here are no longer in effect.)

**Podiatrist Manual**

Pages iv — transmitted by Transmittal Letter POD-43

Pages 4-11 through 4-14 — transmitted by Transmittal Letter POD-48

<b>Commonwealth of Massachusetts</b> <b>Division of Medical Assistance</b> <b>Provider Manual Series</b>  PODIATRIST MANUAL	<b>SUBCHAPTER NUMBER AND TITLE</b> TABLE OF CONTENTS	<b>PAGE</b> iv
	<b>TRANSMITTAL LETTER</b> POD-49	<b>DATE</b> 05/15/05

#### 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: Service Limitations and 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 and Utilization Management Program Requirements .....	4-8
424.414: Surgical Assistants .....	4-9
424.415: Radiology Services.....	4-9
424.416: Clinical Laboratory Services.....	4-10
424.417: Pharmacy Services: Prescription Requirements .....	4-10
424.418: Pharmacy Services: Covered Drugs .....	4-12
424.419: Pharmacy Services: Limitations on Coverage of Drugs .....	4-12
424.420: Pharmacy Services: Insurance Coverage.....	4-13
424.421: Pharmacy Services: Prior Authorization .....	4-14
424.422: Pharmacy Services: Member Copayments .....	4-14
424.423: Pharmacy Services: Drugs Dispensed in Provider's Office .....	4-15
424.424: Shoes and Corrective Devices.....	4-15

<b>Commonwealth of Massachusetts Division of Medical Assistance Provider Manual Series</b>  PODIATRIST MANUAL	<b>SUBCHAPTER NUMBER AND TITLE</b> 4 PROGRAM REGULATIONS (130 CMR 424.000)	<b>PAGE</b> 4-11
	<b>TRANSMITTAL LETTER</b> POD-49	<b>DATE</b> 05/15/05

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

(C) Refills.

- (1) The MassHealth agency does not pay for prescription refills that exceed the specific number authorized by the prescriber.
- (2) The MassHealth agency pays for a maximum of 11 monthly refills, except in circumstances described at 130 CMR 424.417(C)(3).
- (3) The MassHealth agency pays for more than 11 refills within a 12-month period if such refills are for less than a 30-day supply and have been prescribed and dispensed in accordance with 130 CMR 424.417(D).
- (4) The MassHealth agency does not pay for any refill dispensed after one year from the date of the original prescription.
- (5) The absence of an indication to refill by the prescriber renders the prescription nonrefillable.
- (6) The MassHealth agency does not pay for any refill without an explicit request from a member or caregiver for each filling event. The possession by a provider of a prescription with remaining refills authorized does not in itself constitute a request to refill the prescription.

(D) Quantities.

- (1) Days' Supply Limitations. The MassHealth agency requires that all drugs be prescribed 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 MassHealth agency allows exceptions to the limitations described in 130 CMR 424.417(D)(1) for the following products:
  - (a) drugs in therapeutic classes that are commonly prescribed for less than a 30-day supply, including but not limited to antibiotics and analgesics;
  - (b) drugs that, in the prescriber's professional judgement, are not clinically appropriate for the member in a 30-day supply;
  - (c) drugs that are new to the member, and are being prescribed for a limited trial amount, sufficient to determine if there is an allergic or adverse reaction or lack of effectiveness. The initial trial amount and the member's reaction or lack of effectiveness must be documented in the member's medical record;
  - (d) drugs packed in such a way that the smallest quantity that may be dispensed is larger than a 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).

<b>Commonwealth of Massachusetts</b> <b>Division of Medical Assistance</b> <b>Provider Manual Series</b>  PODIATRIST MANUAL	<b>SUBCHAPTER NUMBER AND TITLE</b> 4 PROGRAM REGULATIONS (130 CMR 424.000)	<b>PAGE</b> 4-12
	<b>TRANSMITTAL LETTER</b> POD-49	<b>DATE</b> 05/15/05

(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).)

424.418: Pharmacy Services: Covered Drugs

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

424.419: Pharmacy Services: Limitations on Coverage of Drugs

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

- (1) the prescriber has requested and received prior authorization from the MassHealth agency for a nongeneric multiple-source drug (see 130 CMR 424.420); and
- (2) the prescriber has written on the face of the prescription in the prescriber's own handwriting the words "brand name medically necessary" under the words "no substitution" in a manner consistent with applicable state law. These words must be written out in full and may not be abbreviated.

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

- (1) Cosmetic. The MassHealth agency does not pay for legend or nonlegend preparations for cosmetic purposes or for hair growth.
- (2) Cough and Cold. The MassHealth agency does not pay for legend or nonlegend drugs used solely for the symptomatic relief of coughs and colds, including but not limited to, those that contain an antitussive or expectorant as a major ingredient, unless they are dispensed to an institutionalized member.
- (3) Fertility. The MassHealth agency does not pay for any drug used to promote male or female fertility.
- (4) Obesity Management. The MassHealth agency does not pay for any drug used for the treatment of obesity.
- (5) 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.

<b>Commonwealth of Massachusetts Division of Medical Assistance Provider Manual Series</b>  PODIATRIST MANUAL	<b>SUBCHAPTER NUMBER AND TITLE</b> 4 PROGRAM REGULATIONS (130 CMR 424.000)	<b>PAGE</b> 4-13
	<b>TRANSMITTAL LETTER</b> POD-49	<b>DATE</b> 05/15/05

(C) Service Limitations.

- (1) MassHealth covers drugs that are not explicitly excluded under 130 CMR 424.419(B). The limitations and exclusions in 130 CMR 424.419(B)(1) through (5) do not apply to medically necessary drug therapy for MassHealth Standard enrollees under age 21. The MassHealth Drug List specifies the drugs that are payable under MassHealth. Any drug that does not appear on the MassHealth Drug List requires prior authorization, as set forth in 130 CMR 424.000. The MassHealth Drug List can be viewed online at [www.mass.gov/druglist](http://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;
  - (c) drugs used for the treatment of male or female sexual dysfunction; and
  - (d) 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>Commonwealth of Massachusetts Division of Medical Assistance Provider Manual Series</b>  PODIATRIST MANUAL	<b>SUBCHAPTER NUMBER AND TITLE</b> 4 PROGRAM REGULATIONS (130 CMR 424.000)	<b>PAGE</b> 4-14
	<b>TRANSMITTAL LETTER</b> POD-49	<b>DATE</b> 05/15/05

(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), (c), and (d). 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.

424.421: Pharmacy Services: Prior Authorization

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

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

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

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

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

424.422: Pharmacy Services: Member Copayments

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

<b>Commonwealth of Massachusetts Division of Medical Assistance Provider Manual Series</b>  PODIATRIST MANUAL	<b>SUBCHAPTER NUMBER AND TITLE</b> 4 PROGRAM REGULATIONS (130 CMR 424.000)	<b>PAGE</b> 4-15
	<b>TRANSMITTAL LETTER</b> POD-49	<b>DATE</b> 05/15/05

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 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) 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.

REGULATORY AUTHORITY

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

<b>Commonwealth of Massachusetts</b> <b>Division of Medical Assistance</b> <b>Provider Manual Series</b>  PODIATRIST MANUAL	<b>SUBCHAPTER NUMBER AND TITLE</b> 4 PROGRAM REGULATIONS (130 CMR 424.000)	<b>PAGE</b> 4-16
	<b>TRANSMITTAL LETTER</b> POD-49	<b>DATE</b> 05/15/05

This page is reserved.