

130 CMR: DIVISION OF MEDICAL ASSISTANCE

130 CMR 442.000: ORTHOTICS SERVICES

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442.401: Introduction

130 CMR 442.000 states the requirements and procedures for the purchase and repair of orthotic and pedorthic devices, customized equipment, and supplies under MassHealth. All providers of orthotic and pedorthic services participating in MassHealth must comply with the regulations of the Division governing MassHealth, including, but not limited to, regulations set forth in 130 CMR 442.000 and in 130 CMR 450.000.

442.402: Definitions

The following terms used in 130 CMR 442.000 have the meanings given in 130 CMR 442.402 unless the context clearly requires a different meaning. The reimbursability of services defined in 130 CMR 442.000 is not determined by these definitions, but by application of regulations elsewhere in 130 CMR 442.000 and in 130 CMR 450.000.

Accessory Equipment — equipment that is fabricated primarily and customarily to modify or enhance the usefulness or functional capability of another piece of orthotic or pedorthic equipment and that is generally not useful in the absence of such orthotic or pedorthic equipment.

Adjusted Acquisition Cost — except where the manufacturer is the provider, the price paid by the provider to the manufacturer or any other supplier for orthotic or pedorthic devices, customized equipment, or supplies, excluding all associated costs such as shipping, handling, and insurance costs in accordance with 130 CMR 442.422. Where the manufacturer is the provider, the adjusted acquisition cost is the actual cost of manufacturing such orthotic or pedorthic devices, customized equipment, or supplies.

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.

Date of Service — the date the orthotic or pedorthic device is delivered and fitted to the MassHealth member. If the orthotic or pedorthic service involves a series of fittings and adjustments, the date of service is the date on which the final adjustment is made. If the orthotic or pedorthic service involves only the provision of a service (for example, a repair), then the date of service is the date on which the service was completed.

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Diabetic Shoes — therapeutic footwear prescribed to prevent or alleviate painful or disabling conditions associated with diabetes by minimizing pressure on the foot.

Discount — any remuneration or reduction of payment of any kind, whether direct or indirect, received by the provider.

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.

Moldable Shoe — an off-the-shelf, ready-made shoe formed from heat-activated materials. The shoe is 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.

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.

Nursing Facility — a licensed facility that meets the provider-eligibility and certification requirements of 130 CMR 456.404 or 456.405 and whose members meet the medical eligibility criteria under 130 CMR 456.409. Nursing facilities do not include facilities such as rest homes, state schools, and state hospitals.

Nursing Facility Visit — a visit by a provider to a nursing facility for the purpose of providing orthotic and pedorthic services.

Off-the-shelf Shoe — a shoe that is made on a standard last and is a regular part of a manufacturer's or provider's 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.

Orthosis (or Orthotic Equipment) — a mechanical device that:

- (1) is fabricated primarily and customarily to support or correct a defect of form or function of the human body;
- (2) can withstand repeated use over time; and
- (3) is appropriate for home use.

Orthotic Service — the purchase, customization, fitting, repair, replacement, or adjustment of an orthosis or component part, or other activity performed or equipment provided in accordance with 130 CMR 442.000.

Orthotic Supplies — products that are:

- (1) fabricated primarily and customarily to fulfill a medical or surgical purpose;
- (2) used in conjunction with an orthosis or orthotic equipment;
- (3) generally not useful in the absence of an orthosis; and
- (4) non-reusable and disposable.

Orthotics — the design and application of external appliances to support a paralyzed muscle, promote a specific motion, or correct musculoskeletal deformities.

Pedorthic Service — the design, manufacture, modification, and fitting of orthopedic or diabetic shoes, including foot orthoses, prosthetic fillers, and orthotic or pedorthic appliances for use from the ankle and below, provided in accordance with 130 CMR 442.000.

Service Facility — The place of business physically accessible to MassHealth members where orthotic or pedorthic services, especially those involving fitting, adjustment, repair, and replacement of orthoses, are performed. A service facility does not include a MassHealth member's place of residence.

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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.

442.403: Eligible Members

(A) (1) MassHealth Members. The Division covers orthotic and pedorthic services only when provided to eligible MassHealth members, subject to the restrictions and limitations in the Division's regulations. 130 CMR 450.105 specifically states, for each 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 442.000 and 450.000, the Division covers orthotic and pedorthic services only when provided to eligible MassHealth members, subject to the age limitations set forth in Subchapter 6 of the *Orthotics Manual*. No age restriction applies 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) For information on verifying member eligibility and coverage type, see 130 CMR 450.107.

442.404: Provider Eligibility

For services described in 130 CMR 442.000 the Division pays only those providers of orthotic and pedorthic services who are participating in MassHealth as of the date of service.

(A) In State. To participate in MassHealth, a provider with a service facility in Massachusetts must:

- (1) (a) primarily engage in the business of providing orthotic, pedorthic, and repair services to the public; and
- (b) meet all state and local requirements for engaging in such business;
- (2) (a) for orthotic providers, be or employ an orthotist currently certified by the American Board for Certification in Orthotics and Prosthetics, Inc. or the Board for Orthotics/Prosthetics Certification; or
- (b) for pedorthic providers, be or employ a pedorthist currently certified by the Board for Certification in Pedorthics;
- (3) be a Medicare provider;
- (4) have a service facility that is physically accessible to MassHealth members during reasonable business hours;
- (5) maintain a visible sign identifying the business and hours of operation; and
- (6) maintain a primary business telephone listed under the name of the business in a local directory. The exclusive use of a pager, answering machine, or cell phone is prohibited.

(B) Out of State. A provider with no service facility in Massachusetts may participate in MassHealth only if the provider participates in the medical assistance program of the state in which the provider primarily conducts business and otherwise meets the requirements of 130 CMR 442.404(A). Such a provider may receive payment for MassHealth services only as set forth in 130 CMR 450.109.

442.405: Provider Responsibility

(A) The provider must ensure that all orthotic and pedorthic equipment and supplies are:

- (1) clean (sterilized when appropriate);
- (2) in proper working condition;
- (3) functional;
- (4) free from defects; and
- (5) new and unused at the time of purchase.

(B) The provider must ensure that all orthotic and pedorthic services are the most cost effective, given the medical need for which they are prescribed and the member's physical limitations.

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(C) The provider must make a reasonable effort to purchase the item from the least costly reliable source by comparing prices charged by different suppliers for comparable items.

442.406: Covered Services

The Division pays for only those orthotic and pedorthic services listed in, and subject to the service limitations set forth in, 130 CMR 442.407 and Subchapter 6 of the *Orthotics Manual*.

442.407: Service Limitations

(A) Nonstandard Size. A provider may bill an additional charge for a nonstandard size for off-the-shelf, medical-grade orthopedic shoes once per pair.

(B) Split-size Charge. A provider may bill a split-size charge for off-the-shelf, medical-grade orthopedic shoes once per pair.

(C) Shoe Maximum. A member is not entitled to more than one pair of shoes during a 12-month period, unless the attending physician or nurse practitioner submits documentation that the member's physical condition has changed. The shoe provider must make diligent efforts to ensure that the member has not already received a pair of shoes from another provider within the previous 12 months. Diligent efforts include but are not limited to:

- (1) asking the member and the prescriber if the member has received shoes from another shoe provider within the previous 12 months; and
- (2) reviewing the provider's own records to determine whether the member has already received a pair of shoes within the previous 12 months.

(D) Closure Modification. When a manufacturer offers an off-the-shelf shoe that comes standard with either lace or velcro closures, the provider must choose the appropriate shoe to meet the member's needs, and not bill separately for closure modification.

(E) Custom-shoe Inserts. When a manufacturer offers a customized shoe that includes the insert, the provider must not bill separately for the insert.

(F) Other Service Limitations. The service limitations set forth in Subchapter 6 of the *Orthotics Manual* apply, subject to the Early and Periodic Screening, Diagnosis, and Treatment provisions set forth in 130 CMR 450.144(A).

442.408: Noncovered Services

MassHealth does not pay for any of the following:

- (A) any orthotic or pedorthic services for which, under comparable circumstances, the provider does not customarily bill private patients who do not have health insurance;
- (B) nonmedical orthotic or pedorthic services. Equipment that is used primarily and customarily for a nonmedical purpose is not considered medical equipment, even if such equipment has a medically related use;
- (C) storage of orthotic or pedorthic equipment or associated items;
- (D) sneakers or athletic shoes;
- (E) an additional charge for nonstandard size (width or length) in custom-molded shoes;
- (F) shoes when there is no diagnosis of associated foot deformities; and
- (G) orthotic or pedorthic services that are not both medically necessary in accordance with 130 CMR 450.204 and reasonable for the treatment of a member's condition. This includes services that:

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- (1) cannot reasonably be expected to make a meaningful contribution to the treatment of a member's condition or the performance of the member's activities of daily living; and
- (2) are more costly than a medically comparable and suitable alternative or that serve essentially the same purpose as equipment already available to the member.

442.409: Prescription and Other Documentation Requirements

(A) The purchase of orthotic or pedorthic equipment requires a written prescription signed by a licensed physician, a licensed podiatrist, or an independent nurse practitioner.

(1) For orthotic equipment other than shoes, the prescriber must write the prescription on the prescriber's prescription form and must include the following information:

- (a) the member's name and address;
- (b) the member's MassHealth identification number;
- (c) specific identification of the prescribed item;
- (d) medical justification for the use of the item, including the member's diagnosis;
- (e) the prescriber's address and telephone number; and
- (f) the date on which the prescription was signed by the prescriber.

(2) For shoes, the provider must complete the shoe prescription form designated by MassHealth. A copy of the shoe prescription form must be submitted to MassHealth to support the provider's claim.

(B) MassHealth pays for podiatry services only when the member's primary care physician certifies on letterhead that such services are medically necessary for the life and safety of the member. Prescriptions from podiatrists for any orthotic or pedorthic equipment must be accompanied by a copy of such a letter from the member's primary care physician.

(C) The provider must keep the shoe prescription form and any accompanying letters, if required, on file for the period of time required by 130 CMR 450.205.

442.410: Orthotic and Pedorthic Services and Equipment Provided to Institutionalized Members

(A) Nursing Facilities. MassHealth pays orthotic and pedorthic providers for:

- (1) nursing facility visits;
- (2) the purchase and repair of orthotic and pedorthic equipment; and
- (3) orthotic and pedorthic supplies provided for the personal full-time use of a member residing in a nursing facility.

(B) Institutions Licensed as Hospitals, Chronic Disease Hospitals, and Rehabilitation Hospitals. MassHealth does not pay orthotic or pedorthic providers for the purchase or repair of orthotic or pedorthic equipment or for supplies provided to a hospitalized member, except for orthotic or pedorthic equipment that is prescribed for home use after discharge. The hospital record must document the member's discharge plan and that the date of discharge was before the purchase or repair of the prescribed item.

(C) Intermediate Care Facilities for the Mentally Retarded with 16 Beds or More (State Schools).

- (1) MassHealth pays orthotic and pedorthic providers for the purchase and repair of customized orthotic and pedorthic equipment provided for the personal full-time use of a member residing in an ICF/MR with 16 beds or more (a state school) only if the customization precludes the use of the equipment by subsequent residents in that institution.
- (2) MassHealth does not pay orthotic or pedorthic providers for noncustomized equipment or supplies provided to a member residing in a state school.

(D) Rest Homes. The Division pays orthotic and pedorthic providers for the purchase and repair of orthotic and pedorthic equipment and for associated supplies provided for the personal full-time use of a member residing in a rest home.

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442.411: Repairs of Orthotic and Pedorthic Equipment

- (A) The Division pays for all repair services on an individual-consideration basis as described in 130 CMR 442.422.
- (B) The provider of repair services is liable for the quality of the workmanship and parts, and for ensuring that repaired equipment is in proper working condition.
- (C) The provider of repair services must exhaust all manufacturer warranties before submitting claims for repairs to orthotic or pedorthic equipment to the Division.

442.412: Prior Authorization

- (A) Services that require prior authorization as a prerequisite for payment are identified in 130 CMR 442.000 or are listed in Subchapter 6 of the *Orthotics Manual* with the designation "(P.A.)" appearing after the service description. To determine if prior authorization is required, the provider should review both 130 CMR 442.000 and Subchapter 6. Prior authorization determines only the medical necessity of the prescribed item or service and does not waive any other prerequisites to payment such as member eligibility or resort to health-insurance payment.
- (B) The provider must request prior authorization in accordance with the billing instructions in Subchapter 5 of the *Orthotics Manual*. The Division may, at its discretion, require the prescriber to submit an assessment of the member's condition and the objectives of the requested service. The Division may also, at its discretion, require an evaluation by a licensed orthotist or pedorthist to determine whether the requested orthotic or pedorthic service is useful to the member, given the member's physical condition and physical environment.
- (C)(1) The Division will send notification to the member and the provider of the following prior-authorization decisions:
 - (a) approval;
 - (b) modification; or
 - (c) denial.
- (2) If the Division defers the prior-authorization decision because additional information is required to determine whether the requested service is medically necessary, the Division will notify the provider.
- (3) If the Division denies or modifies a request, the notification will include the reason for the Division's determination. The member may appeal the prior-authorization decision within 30 days after the date of the notice. Procedures for such an appeal are set forth in 130 CMR 610.000.
- (D) The Division will make a decision on the request within 15 days after the date of receipt of a fully completed prior-authorization request. The Division will confirm the date of receipt and the date of action upon written request.
- (E) The provider must keep the prior-authorization request on file for the period of time required by 130 CMR 450.205.

442.413: Procedure for Requesting Prior Authorization

- (A) The provider must obtain prior authorization from the Division before providing any service that requires prior authorization. The provider must submit the Request for Prior Authorization within 90 days of the date of service requested on the prescription.
- (B) The Request for Prior Authorization must document the adjusted acquisition cost (see 130 CMR 442.421) and the medical necessity of the requested service. The Request for Prior Authorization must contain the following documentation:
 - (1) a copy of the invoice or invoices from the manufacturer for the equipment, disclosing all discounts;
 - (2) a copy of the current prescription that must not be older than 90 days from the date of service (see 130 CMR 442.409 for information that must be included in the prescription);

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- (3) if requested by the Division, a current orthotic or pedorthic evaluation for the equipment, performed independently of the provider by a licensed physician, orthotist, or pedorthist;
- (4) the date or projected date of service;
- (5) the projected duration of need for the equipment; and
- (6) if replacing existing equipment, the date the existing equipment was purchased.

442.414: Medicare Coverage

- (A) For Medicare and third-party-liability coverage, see 130 CMR 450.316 through 450.318.
- (B) For Medicare-covered services that are provided to members who receive Medicare Part B benefits, the Division does not require prior authorization.
- (C) When Medicare denies a claim for orthotic or pedorthic services or considers the services uncovered, the Division requires prior authorization for those services that would require prior authorization for members without Medicare.

442.420: Payment for Orthotic or Pedorthic Services

- (A) Payment to a provider for orthotic or pedorthic equipment and supplies is subject to the conditions and limitations in 130 CMR 442.000 and 450.000, and will be the lower of:
 - (1) the provider's usual and customary charge to the general public; or
 - (2) the fee set forth in the schedule of maximum allowable fees established by the Massachusetts Division of Health Care Finance and Policy (DHCFP).
- (B) Payment for the following services is included in the provider payment under 130 CMR 442.420(A). No separate payment is allowed for:
 - (1) the fitting of the orthosis or pedorthic device;
 - (2) instructing the member in the use of the orthosis or pedorthic device;
 - (3) the cost of the component parts and accessory equipment;
 - (4) repairs due to normal wear and tear within 90 days of the date of delivery; and
 - (5) adjustments to the orthosis or pedorthic device and any orthotic or pedorthic component made when fitting the orthosis and for 90 days from the date of delivery, when the adjustments are not necessitated by changes in the member's functional abilities.

442.421: Individual Consideration

When the rate of payment for the purchase or repair of certain orthotic or pedorthic equipment has not been established by the Division of Health Care Finance and Policy, the Division pays for the service based on individual consideration, subject to all other conditions of payment. Such items are identified in Subchapter 6 of the *Orthotics Manual* by the designation "(I.C.)" next to the description of the item or service. The Division determines the rate of payment for an individual-consideration item or service based on the provider's report of services and a current invoice that indicates the provider's adjusted acquisition cost as defined in 130 CMR 442.421 and 442.422(B). Payment for the fitting of an orthosis or pedorthic device is included in the adjusted acquisition cost. The provider must maintain adequate records to document the individual consideration claim and must provide these documents to the Division and the Attorney General's Medicaid Fraud Control Unit upon demand (see 130 CMR 450.205). Payment to a provider for an individual consideration claim is the lower of:

- (A) the provider's usual and customary charge to the general public; or
- (B) the adjusted acquisition cost of the item plus a markup not to exceed:
 - (1) 70% for any item whose adjusted acquisition cost is less than \$100;
 - (2) 50% for any item whose adjusted acquisition cost is \$100 or greater and less than \$200;
 - (3) 45% for any item whose adjusted acquisition cost is \$200 or greater and less than \$300; or
 - (4) 40% for any item whose adjusted acquisition cost is \$300 or greater.

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442.422: Adjusted Acquisition Cost

- (A) The provider must disclose all discounts, as defined in 130 CMR 442.402, and must reflect such discounts in the provider's claim for payment pursuant to M.G.L. c. 118E, § 41, and U.S.C. § 1320a-7b(b)(3)(A). Any provider who fails to disclose and pass on any discounts to the Division may be subject to civil and criminal penalties, including imprisonment, in accordance with state and federal laws.
- (B) (1) Except where the manufacturer is the provider, the adjusted acquisition cost must not exceed the manufacturer's current wholesale price and must be evidenced by the purchase price of the equipment or goods listed on a copy of the supplier's invoice.
(2) Where the manufacturer is the provider, the adjusted acquisition cost must not exceed the actual cost of manufacturing the items.
- (C) Where the manufacturer is the provider of any item covered under 130 CMR 442.000, the manufacturer must submit documentation that demonstrates to the Division's satisfaction the actual cost of manufacturing the item, as set forth in 130 CMR 442.421(B).
- (D) If the provider has not purchased the equipment at the time of the prior-authorization request, the provider may substitute a price quotation reflecting the absolute lowest price of the item and the catalog (list) price. The quotation must be on the manufacturer's letterhead or form and be addressed to the provider.
- (E) The provider must maintain the actual receipted invoice in the member's record, and make it available to the Division and the Attorney General's Medicaid Fraud Control Unit pursuant to 130 CMR 442.423 and 450.205.
- (F) The provider may group together low-cost items (those with an adjusted acquisition cost of less than \$5 each) to equal \$5 or less, and bill the total adjusted acquisition cost plus the allowable markup listed in 130 CMR 442.422(B).

442.423: Recordkeeping Requirements

The provider must keep a record of all orthotic and pedorthic services, nursing facility visits, and the medical necessity of such services, provided to a member for the period of time required by 130 CMR 450.205. This record must include the following:

- (A) a prescription for all purchases;
- (B) a copy of the approved prior-authorization request for all orthotic and pedorthic services requiring prior authorization;
- (C) an acknowledgement of receipt, signed by the member or the member's representative, of prescribed equipment or supplies, including:
- (1) the date of receipt of equipment or supplies;
 - (2) the condition of the equipment or supplies (for example, whether it is in proper working order or is damaged);
 - (3) the manufacturer, brand name, model number, and serial number of the equipment or supplies;
 - (4) for repair services, a complete description of the service, including the manufacturer, brand name, model number, and serial number of the repaired item; and
 - (5) next to the signature, an explanation of the representative's relationship to the member by the individual acknowledging receipt. This individual cannot be associated with either the provider or the delivery service.
 - (a) For routine delivery of supplies, the member must acknowledge receipt at least monthly.
 - (b) A signature stamp may be used by or on behalf of a MassHealth member whose disability inhibits the member's ability to write. A signature stamp may only be used by a member or the member's representative, provided that the stamp is used by the member in his or her normal course of conducting business. A signature stamp cannot be used by anyone associated with either the provider or the delivery service;

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(D) the actual invoice showing the cost to the provider of the materials (if the provider is not the manufacturer of the materials);

(E) documentation demonstrating the cost of manufacturing the item provided (if the provider is the manufacturer);

(F) copies of written warranties; and

(G) documentation demonstrating efforts under 130 CMR 442.405(C) to purchase the item from the least costly reliable source.

REGULATORY AUTHORITY

130 CMR 442.000: M.G.L. c. 118E, §§ 7 and 12.

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