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416.401: Introduction

130 CMR 416.000 governs services provided by hearing instrument specialists under MassHealth. A hearing instrument specialist who complies with 130 CMR 416.404, dispenses hearing aids or instruments, and provides services related to the care and maintenance of hearing aids or instruments is eligible to become a MassHealth provider. All hearing instrument specialists participating in MassHealth must comply with MassHealth regulations, including but not limited to those set forth in 130 CMR 416.000 and 450.000: *Administrative and Billing Regulations*.

416.402: Definitions

The following terms used in 130 CMR 416.000 have the meanings given in 130 CMR 416.402 unless the context clearly requires a different meaning. The reimbursability of services defined in 130 CMR 416.402 is not determined by these definitions, but by application of regulations elsewhere in 130 CMR 416.000 and 450.000: *Administrative and Billing Regulations*.

Accessories — those essential items or options on a hearing aid purchased by a hearing instrument specialist that are not intrinsic components of the basic hearing aid unit. Accessories do not include nonessential items such as carrying cases.

Adjusted Acquisition Cost — the unit price paid to a manufacturer by a hearing instrument specialist for a hearing aid or accessories, excluding postal-insurance charges. The adjusted acquisition cost does not exceed the manufacturer's current catalog price and is verified by a copy of the manufacturer's invoice retained by the hearing instrument specialist in the member's medical record as described under 130 CMR 416.419.

Binaural — the type of fitting or hearing aid necessitated by varying degrees of hearing loss in both ears that requires unparalleled amplification via the use of two microphones and two receivers.

Binaural Fitting — the fitting of two hearing aids, one to each ear, by a hearing instrument specialist; the fitting to the second ear taking place no later than six months after the fitting to the first ear.

Complete Audiological Evaluation — an evaluation that includes a routine audiological examination (air and bone conduction, spondee thresholds, and word discrimination testing) as recommended by a physician.

Date of Service — the date on which the medical service is furnished to a member or, in the case of custom-made goods, the date on which the goods are delivered to a member.

Dispense — the prescription of a hearing aid, its modification, its fitting, orientation to its use, and any adjustments required within the manufacturer's trial warranty period.

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Dispensing Fee — a one-time-only fee for dispensing monaural or binaural hearing aids. The fee includes initial programming, fitting, orientation to its use, and any adjustments required during the manufacturer’s trial warranty period.

Hearing Aid — a hearing aid is a small electronic device consisting of a microphone, amplifier and a receiver.

Independent Hearing Instrument Specialist – a hearing instrument specialist who is licensed in accordance with 130 CMR 416.404 and who is engaged in the practice of hearing aid dispensing through a private practice or self-employment, or both.

Major Repair — a repair to a hearing aid that must be made at a repair facility other than the hearing instrument specialist’s place of business.

Minor Repair — a repair to a hearing aid performed at the hearing instrument specialist’s place of business, such as, but not limited to, the replacement or cleaning of tubing.

Monaural Fitting — the fitting of one hearing aid by a hearing instrument specialist.

416.403: Eligible Members

(A)(1) MassHealth Members. The MassHealth agency covers hearing-aid services only when provided to eligible MassHealth members, subject to the restrictions and limitations described in MassHealth regulations. MassHealth regulations at 130 CMR 450.105: *Coverage Types* specifically state, for each MassHealth coverage type, which services are covered and which members are eligible to receive those services.

(2) 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: *Emergency Aid to the Elderly, Disabled and Children Program*.

(B) For information on verifying member eligibility and coverage type, see 130 CMR 450.107: *Eligible Members and the MassHealth Card*.

416.404: Provider Eligibility

(A) In State. The following requirements apply when the practice is located in Massachusetts.

(1) Independent Hearing Instrument Specialist. An independent hearing instrument specialist engaged in private practice in Massachusetts is eligible to participate in MassHealth only if the individual is licensed by the Commonwealth of Massachusetts, Division of Professional Licensure, Board of Registration of Hearing Instrument Specialists.

(2) Acute Hospital Outpatient Department, Hospital-Licensed Health Center, or Other Satellite Clinic. An acute hospital’s outpatient department, hospital-licensed health center, or other satellite clinic that participates in MassHealth pursuant to the Executive Office of Health and Human Services (EOHHS) Acute Hospital Request for Applications (RFA) and contract is eligible to provide services designated as hearing aid services in Subchapter 6 of the MassHealth *Hearing Instrument Specialist Manual* for providers under 130 CMR 416.000.

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(B) Out of State. To participate in MassHealth, an independent hearing instrument specialist practicing outside of Massachusetts must:

- (1) be certified by the National Board for Certification in Hearing Instrument Sciences;
- (2) be licensed by the appropriate licensing agency in its own state (as applicable); and
- (3) participate in the medical assistance program in its own state.

416.405: Out-of-State Services

The MassHealth agency pays out-of-state hearing instrument specialists in accordance with 130 CMR 450.109: *Administrative and Billing Regulations*.

416.406: Maximum Allowable Fees

The MassHealth agency pays the lower of the following for hearing aids and related services:

- (A) the hearing instrument specialist's usual and customary fee; or
- (B) the maximum fee listed in the applicable fee schedule of the Massachusetts Division of Health Care Finance and Policy.

416.407: Individual Consideration

Services designated "I.C." in the list of service codes and descriptions in Subchapter 6 of the *Hearing Instrument Specialist Manual* are given individual consideration by the MassHealth agency to determine the amount of payment to be made to the hearing instrument specialist. The MassHealth agency determines the amount of payment using the following criteria:

- (A) the time required to perform the procedure;
- (B) the degree of skill required to perform the procedure;
- (C) the severity or complexity of the member's hearing disorder or disability;
- (D) the policies, procedures, and practices of other third-party purchasers of health care; and
- (E) the reasonable and customary practices of hearing instrument specialists.

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416.408: Prior Authorization

(A) Services designated "P.A." in the list of service codes and descriptions in Subchapter 6 of the *Hearing Instrument Specialist Manual* require prior authorization from the MassHealth agency.

The MassHealth agency requires prior authorization for:

- (1) any hearing aid that costs more than the amount indicated in the applicable service description in Subchapter 6 of the *Hearing Instrument Specialist Manual*;
- (2) the replacement of a hearing aid consistent with the provisions of 130 CMR 416.418, regardless of the cost of the hearing aid, due to:
 - (a) a medical change;
 - (b) loss of the hearing aid; or
 - (c) damage beyond repair to the hearing aid; and
- (3) certain hearing aid related services as specified in Subchapter 6 of the *Hearing Instrument Specialist Manual*.

(B) The MassHealth agency requires the following documents from the provider requesting prior authorization for replacement of hearing aids, or certain hearing aid related services, as applicable:

- (1) the audiological evaluation required under 130 CMR 416.414(A);
- (2) the previous audiological evaluation if the replacement hearing aid is needed because of a medical change;
- (3) a comprehensive report that justifies the medical necessity for the hearing aid;
- (4) a statement of the circumstances of the loss or destruction of the hearing aid (where applicable);
- (5) the medical clearance required under 130 CMR 416.414(B); and
- (6) an itemized estimate of the anticipated cost of the hearing aid.

(C) All prior-authorization requests must be submitted in accordance with the administrative and billing instructions in Subchapter 5 of the *Hearing Instrument Specialist Manual*. Prior authorization determines only the medical necessity of the authorized service and does not establish or waive any other prerequisites for payment such as member eligibility or resort to health insurance payment.

416.409: Separate Procedures

Some procedures are commonly carried out as an integral part of a total service, and as such do not warrant a separate identification. When, however, such a procedure is performed independently of, and is not immediately related to, other services, it is designated as a "separate procedure" or "S.P." in the list of service codes and descriptions in Subchapter 6 of the *Hearing Instrument Specialist Manual*. Thus, when a procedure is performed alone for a specific purpose, it must be considered a separate procedure.

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

The MassHealth agency pays for all medically necessary hearing instrument specialist services for EPSDT-eligible members in accordance with 130 CMR 450.140 *et seq.*, without regard to service limitations described in 130 CMR 416.000, and with prior authorization.

(130 CMR 416.411 through 416.413 Reserved)

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416.414: Dispensing Requirements

A hearing instrument specialist may dispense a hearing aid only after receiving the following documentation.

(A) Complete Audiological Evaluation. A complete audiological evaluation includes air and bone conduction, spondee thresholds, and word discrimination testing.

(1) The hearing instrument specialist must have received a complete audiological evaluation (air and bone conduction, spondee thresholds, and word discrimination testing) performed by one of the following:

- (a) an independent audiologist who personally performed and completed the audiological evaluation;
- (b) a licensed audiologist who is employed at a speech and hearing clinic and who personally performed and completed the audiological evaluation; or
- (c) a licensed audiologist who is employed by a physician, or by an acute hospital's outpatient department, hospital-licensed health center, or other satellite clinic.

(2) Audiological evaluations for members under age 18 must be performed by a licensed audiologist pursuant to M.G.L. c. 93 §§ 71 and 72. For members aged 18 or older, the audiological evaluation may also be performed by a licensed hearing instrument specialist. Hearing testing performed by a hearing instrument specialist must meet the requirements of the Massachusetts Rules and Regulations Governing Hearing Instrument Specialists of the Division of Professional Licensure at 265 CMR 2.00 through 10.00.

(3) This evaluation must contain the following information:

- (a) the date of the evaluation;
- (b) a written summary of findings and impressions, which must include a favorable prognosis for hearing aid use and an assurance that no physiological causes exist that would make the member unable to use a hearing aid;
- (c) the recommended hearing aid make and model;
- (d) whether or not the amplification should be monaural (and if so, for which ear) or binaural; and
- (e) the signature of the audiologist or hearing instrument specialist who performed the evaluation, including the individual's name and credentials printed clearly and legibly next to the signature.

(4) The evaluation must have been performed no more than six months before the dispensing date of the hearing aid.

(5) The make, model, and specifications such as maximum output, frequency response configuration, and any other special requirements of the hearing aid dispensed must be the same as or comparable to that recommended in the audiological evaluation.

(B) Medical Clearance. The hearing instrument specialist must have received and must maintain in the member's medical record pursuant to 130 CMR 416.419(B) a medical clearance from a physician that meets the following conditions:

- (1) the medical clearance must state that the member is a candidate for and has no medical conditions that would contraindicate the use of a hearing aid; and
- (2) the medical examination by the physician must have been performed no more than six months before the dispensing date of the hearing aid;

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(3) the medical clearance must be signed by the physician. If the medical clearance is not printed on the physician's letterhead, the physician's name and credentials must also be printed clearly and legibly on the medical clearance; and

(4) the medical clearance must include the date of the medical clearance, identify which ears are cleared, and indicate whether or not the member, at the time of the medical examination, currently owns or uses a hearing aid for the designated ear.

416.415: Conditions of Payment

All claims must be submitted in accordance with the administrative and billing instructions in Subchapter 5 of the *Hearing Instrument Specialist Manual*.

416.416: Reimbursable Services

(A) Audiological Evaluation/Testing Services. Payment for an audiological evaluation will be made only if the evaluation is recommended by a physician.

(B) Hearing Aid Purchase. Payment for a hearing-aid purchase includes the following:

(1) the hearing aid and standard accessories and options required for the proper operation of the hearing aid;

(2) the proper fitting and instruction in the use, care, and maintenance of the hearing aid;

(3) maintenance, minor repair, and servicing of the hearing aid that is furnished free of charge to non-MassHealth members;

(4) the initial manufacturer's warranty against loss or damage; and

(5) the loan of a hearing aid to the member by the hearing instrument specialist, when necessary.

(C) Earmold. The provider may not claim payment for an earmold until the earmold has actually been delivered to the member. The date of service for the earmold is the date on which the earmold was delivered to the member. An earmold is not reimbursable if it is included in the manufacturer's price of the hearing aid or if the member already has an appropriate earmold.

Payment for an earmold includes the following:

(1) the ear impression;

(2) the proper fitting of the earmold; and

(3) any adjustments that may be needed during the operational life of the earmold.

(D) Ear Impression.

(1) Ear Impression for an ITE/ITC Hearing Aid. Payment for an ear impression for a hearing aid includes one properly formed ear impression for each in-the-ear (ITE) or in-the-canal (ITC) hearing aid purchased. The provider may not claim payment for an ear impression for a hearing aid until the hearing aid has actually been delivered to the member.

(2) Ear Impression for an Earmold for a BTE Hearing Aid. Payment for an ear impression for a hearing aid includes one properly formed ear impression for each behind-the-ear (BTE) hearing aid.

(E) Batteries. Batteries must be new at the time of purchase.

(F) Accessories. Payment for accessories and hearing-aid options includes proper fitting and adjustment of the accessory as needed. Accessories must be billed separately from the basic hearing-aid unit.

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(G) Major Repairs. The provider of a repair service is responsible for the quality of the workmanship and parts, and for ensuring that the repaired hearing aid is in proper working condition. The hearing instrument specialist is responsible for ensuring that the repaired hearing aid is in proper working condition upon returning the aid to the member. Payment for a major repair to a hearing aid is limited to the following conditions.

- (1) All warranties and insurance must have expired.
- (2) The hearing aid must be sent directly to the repair facility or manufacturer that will perform the repair. (The handling charges of an intermediary are not reimbursable.)
- (3) The repair service must include a written warranty against all defects for a minimum of six months.
- (4) A copy of the invoice from the repair facility or manufacturer for the cost of the repair must be kept in the member's medical record.

(H) Office Visits for Evaluation and Management Services. The MassHealth agency pays for an office visit for evaluation and management services only when one or more of the following services is required and is provided as part of the visit:

- (1) minor adjustments to the hearing aid to assure a proper fitting, such as an earmold adjustment, when the provider is not the provider who initially fit the hearing aid, and the provider who initially fit the hearing aid is no longer a MassHealth provider;
- (2) minor office repairs for which the provider customarily charges non-MassHealth members;
- (3) cleaning of the hearing aid; or
- (4) replacement of parts such as, but not limited to, tubing, hooks, battery doors, and recasing.

(I) Refitting Services and Other Professional Services. The MassHealth agency pays for additional fitting or refitting services only where the hearing aid was dispensed more than one year prior to the date of service of the refitting services. These professional services include refitting of the aid, orientation, counseling with the member or member's family, contact with interpreters, fitting of a loaner aid, and similar services. Payment for these services must include a face-to-face encounter with the member.

416.417: Nonreimbursable Services

The MassHealth agency does not pay for any of the following services:

- (A) the rental of hearing aids;
- (B) hearing aids that are completely in the ear canal (CIC);
- (C) personal FM systems; or
- (D) assistive technology devices provided under 34 CFR 300.308, where such devices are maintained at the school facility for the general use of disabled students, and assistive technology services provided under 34 CFR 300.308 relating to the use of such devices.

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416.418: Service Limitations

(A) The MassHealth agency does not pay for more than one hearing aid per ear per member in a 60-month period without prior authorization in accordance with 130 CMR 416.408. One hearing aid per ear consists of either one binaural hearing-aid fitting, or two monaural hearing aids dispensed more than six months apart, with one aid dispensed for the left ear and the other dispensed for the right ear.

(B) Two monaural fittings dispensed within a six-month period, with one aid dispensed for the left ear and the other for the right ear, are defined as a single binaural fitting. The MassHealth agency does not pay two monaural dispensing fees for this service. MassHealth pays only one binaural dispensing fee for this service.

(C) The MassHealth agency will pay for the hearing tests listed in Subchapter 6 of the *Hearing Instrument Specialist Manual* only when provided for the sole purpose of hearing aid fitting and dispensing to an eligible member aged 18 or older. The MassHealth agency will not pay for services for which the provider does not customarily charge non-MassHealth members.

416.419: Recordkeeping Requirements

A hearing instrument specialist must maintain a medical record for each member for a period of at least as long as the minimum period required by 130 CMR 450.205(G). The MassHealth agency does not pay a provider for services if the provider does not have adequate documentation to substantiate the provision of services payable under MassHealth. The medical record must contain all pertinent information about the services provided, including the date of service and the dates on which materials were ordered and dispensed. In no instance does the completion of the appropriate MassHealth claim form, the maintenance of a copy of such a claim, or the simple notation of service codes constitute sufficient documentation for the purposes of 130 CMR 416.419. The recordkeeping requirements are specific to each type of service and are described as follows.

(A) Earmolds. The hearing instrument specialist must maintain the manufacturer's invoice in the member's medical record, indicating the actual acquisition cost for the earmold.

(B) Hearing Aids. The hearing instrument specialist must maintain the following information in the member's medical record:

- (1) a history of the member's hearing loss and use of hearing aids. The history must contain the following information:
 - (a) the etiology and chronology of the member's hearing loss, including the member's age at the onset of the loss and an indication of whether the hearing loss is progressive;
 - (b) the make, model number, type, and date of purchase of each hearing aid previously worn by the member;
 - (c) a description of any speech and hearing therapy received by the member; and
 - (d) a description of any medical condition that the member has that may impair vision or affect hearing aid use;
- (2) all audiological evaluations. The evaluations must have been performed no more than six months before the dispensing date of the hearing aid;
- (3) the medical clearance from a physician obtained in accordance with 130 CMR 416.414(B); and

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(4) the manufacturer's invoice indicating the actual acquisition cost of the hearing aid, including all discounts, and the warranty indicating the terms of repair or replacement in the event of loss of or damage to the hearing aid.

(C) Replacement Hearing Aids.

(1) If the member's hearing aid has been lost, the hearing instrument specialist must maintain in the member's medical record a statement from the member or someone acting on the member's behalf (for example, an immediate family member or other legal representative) that describes the circumstances of the loss of the hearing aid.

(2) If the member's hearing aid has been irreparably damaged, the hearing instrument specialist must maintain in the member's medical record a statement from the manufacturer documenting that the hearing aid cannot be repaired.

(D) Accessories/Options. The hearing instrument specialist must maintain in the member's medical record the manufacturer's invoice indicating the actual acquisition cost of all accessories/options.

(E) Audiological Evaluation. The results of all audiological evaluations must be fully documented in the member's medical record.

(F) Office Visits for Evaluation and Management Services. The hearing instrument specialist must maintain in the member's medical record documentation substantiating the necessity of the office visit and detailing the services provided.

(G) Refitting Services and Other Professional Services. The hearing instrument specialist must maintain in the member's medical record documentation substantiating the necessity of the office visit and detailing the services provided.

REGULATORY AUTHORITY

130 CMR 416.000: M.G.L. c. 118E, §§ 7 and 12.

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