SHARP Health Plan

Clinical Policy

SUBJECT: CLINICAL POLICIES – HEARING AIDS - MEDICARE **POLICY NUMBER: HS-CP-MA-H1** **EFFECTIVE DATE: MARCH 27, 2024** **SERVICE/PRODUCT LINE: MEDICARE – MEDICAL**	Product Line (check all that apply): ☐ All ☐ Group HMO ☐ Individual HMO ☐ PPO ☐ POS ☒ Medicare ☐ N/A

These guidelines are used in conjunction with the independent judgment of a qualified licensed physician and do not constitute the practice of medicine or medical advice. This Clinical Policy is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care and are solely responsible for the medical advice and treatment of members. This Clinical Policy is not intended to recommend treatment for members. Members should consult with their treating provider in connection with diagnosis and treatment decisions.

When coverage criteria are not fully established by Medicare including but not limited to National Coverage Decisions (NCD), Local Coverage Decisions (LCD), Medicare Manuals and National Coverage Articles, Sharp Health Plan develops Clinical Policies that serve as recommendations for medical necessity decisions. Sharp Health Plan utilizes evidence-based guidelines from nationally recognized professional organizations, peer reviewed medical and scientific literature and evidence-based consensus statements, which are all based on generally accepted standards of care.

I. BENEFIT STATEMENT: Any service reviewed and approved by this Sharp Health Plan Clinical Policy must be a covered benefit according to the member's evidence of coverage (EOC). Since benefit plans vary in coverage and some plans may not provide coverage for certain services discussed in this clinical policy, decisions are subject to all terms and conditions of the applicable benefit plan. Benefit determinations should be based in all cases on the member's contract benefits in effect at the time of service.

A. All reviewers must first identify member eligibility and all decisions of this clinical policy are subject to current state and/or federal law. Clinical policy does not constitute plan authorization, nor is it an explanation of benefits. In the event of a conflict, a member's benefit plan, EOC, always supersedes the information in the Clinical Policies.

II. REGULATORY: Hearing Aids and examinations for hearing aids are not a Medicare covered benefit. Medicare Benefit Policy Manual Chapter 16 - General Exclusions from Coverage - 90 - Routine Services and Appliances (Rev. 186, Issued: 04-16-14, Effective: 01-01 01, Implementation: 05-12-14.05-12-14)

100- Hearing Aids and Auditory Implants (Rev. 39; Issued 11-20-05; Effective 11-10-05; Implementation: 12-12-05).

100 - Hearing Aids and Auditory Implants

(Rev. 39; Issued: 11-10-05; Effective: 11-10-05; Implementation: 12-12-05)

Section 1862(a)(7) of the Social Security Act states that no payment may be made under part A or part B for any expenses incurred for items or services "where such expenses are for . . . hearing aids or examinations therefore. . . ." This policy is further reiterated at 42 CFR 411.15(d) which specifically states that "hearing aids or examination for the purpose of prescribing, fitting, or changing hearing aids" are excluded from coverage.

Hearing aids are amplifying devices that compensate for impaired hearing. Hearing aids include air conduction devices that provide acoustic energy to the cochlea via stimulation of the tympanic membrane with amplified sound. They also include bone conduction devices that provide mechanical energy to the cochlea via stimulation of the scalp with amplified mechanical vibration or by direct contact with the tympanic membrane or middle ear ossicles.

Certain devices that produce perception of sound by replacing the function of the middle ear, cochlea or auditory nerve are payable by Medicare as prosthetic devices. These devices are indicated only when hearing aids are medically inappropriate or cannot be utilized due to congenital malformations, chronic disease, severe sensorineural hearing loss or surgery.

The following are prosthetic devices:

- Cochlear implants and auditory brainstem implants, i.e., devices that replace the function of cochlear structures or auditory nerve and provide electrical energy to auditory nerve fibers and other neural tissue via implanted electrode arrays.
- Osseointegrated implants, i.e., devices implanted in the skull that replace the function of the middle ear and provide mechanical energy to the cochlea via a mechanical transducer.

Medicare contractors deny payment for an item or service that is associated with any hearing aid as defined above. See §180 for policy for the medically necessary treatment of complications of implantable hearing aids, such as medically necessary removals of implantable hearing aids due to infection.

The Plan provides coverage for hearing aids, hearing aid evaluations and hearing aid examinations as a mandatory supplemental benefit for some of their Employer Group Waiver Plan (EGWP) Medicare Advantage members. Please see member's Evidence of Coverage for specific benefit.

III. DESCRIPTION

The following Clinical Policy – Hearing Aids, applies to the Medicare Advantage Prescription Drug Contract (MA-PD) administered by Sharp Health Plan (Plan) and / or delegates.

The purpose of this policy is to outline the Plan requirements for determination of medical necessity in order for Hearing Aids to be covered.

IV. DEFINITIONS

A. **Mandatory supplemental benefits** are benefits not covered under Part A, Part B, or Part D but are covered by the Medicare Advantage (MA) plan for every person enrolled in the MA plan.

B. **Hearing impairment** is the consequence of sensorineural and/or conductive malfunctions of the ear. Hearing loss may be congenital or secondary to trauma, use of ototoxic medication or disease. There are three basic types of hearing loss, which can be unilateral or bilateral:

1. Conductive hearing loss involves the outer and middle ear and is due to mechanical or physical blockage of sound. It can result from cerumen impaction, a punctured eardrum, middle ear fluid, or

ossicular chain fixation. Usually, a conductive hearing loss can be corrected medically or surgically.

2. Sensorineural or "nerve" hearing loss involves damage to the inner ear, cochlea, or the eighth cranial nerve (i.e., auditory nerve). It can be caused by aging, prenatal or birth-related problems, viral or bacterial infections, heredity, trauma, exposure to loud noises, the use of certain drugs, or a benign tumor in the inner ear or that involves the auditory nerve. Only rarely can sensorineural hearing loss be medically or surgically corrected. It is the type of hearing loss that is most commonly managed with a hearing aid.
3. Mixed hearing loss is conductive hearing loss coupled with sensorineural hearing loss.

C. **Hearing Loss Levels**: Normal speech and conversation occurs at 40–60 dB (decibels) within a frequency range of 500–3000 Hz (Hertz). Required hearing aid and hearing loss severity is classified as follows:

1. Mild 26–40 dBHL(decibels of hearing loss)
2. Moderate 41–70 dBHL
3. Severe 71–90 dBHL
4. Profound ≥ 91 dBHL

D. **Hearing Aids** are amplifying devices that compensate for impaired hearing. Hearing aids include air conduction devices that provide acoustic energy to the cochlea via stimulation of the tympanic membrane with amplified sound. They also include bone conduction devices that provide mechanical energy to the cochlea via stimulation of the scalp with amplified mechanical vibration or by direct contact with the tympanic membrane or middle ear ossicles.

1. The hearing aid consists of:
    a) A microphone which picks up sound waves and converts them into electrical signals;
    b) An amplifier which increases the strength of the signal;
    c) A battery which provides the energy to operate the hearing aid;
    d) A receiver which changes the electrical signals back to sound waves; and
    e) A specially fitted ear mold that connects the receiver to the ear canal.
2. Although hearing aids provide amplification of sound, the manner by which they process, or control incoming signals may differ. Presently, hearing aids fall into three categories:
    a) Analog hearing aids provide constant analysis and modification of the incoming signal.
    b) Digitally programmable hearing aids use analog processing and programming of the hearing aid response characteristics into digital memory, with digital control of the analog circuit.
    c) True digital devices use digital signal processing (DSP). DSP differs from traditional analog and digital/hybrid systems, in that the incoming acoustic signal is first converted to a string of digits, after which a DSP scheme (i.e., complex mathematical algorithm) is applied.

E. **Air conduction hearing aids** allow sound to travel through the external ear canal and middle ear. They are designed for placement in one of the following locations:

1. Behind the ear (BTE): This type of hearing aid fits behind the ear and carries sound to the ear through a custom ear mold. Hearing aids attached to eyeglasses are a type of behind-the-ear hearing aid. They are useful for mild-to-severe hearing loss.

2. In the ear (ITE): These hearing aids are custom-made to fit in the outer ear. Wires cannot be seen because they are inside the aid. They are useful for mild to moderate hearing loss.
3. In the ear, canal (ITC): This type of hearing aid is custom-made to fit in the ear canal. There are no wires or tubes. These hearing aids are almost impossible to see. They help people with all but the worst hearing loss.
4. Completely in the canal (CIC): This type of hearing aid fits almost entirely in the canal. Due to the small size, the number of output/response controls is limited. Deep placement precludes use of a directional microphone. Amount of gain is sufficient for no more than moderate hearing loss.

F. **Contralateral routing of signal (CROS):** This type of hearing aid is designed for persons with no usable hearing in one ear and normal hearing or minimal hearing loss in the other ear. A microphone is located on the impaired side and sound is transmitted to the good ear via an open ear mold. The microphone and receiver may be coupled by a wire that runs around the back of the neck (or through the glasses), or the signal may be transmitted wirelessly over a radio frequency.

G. **Bone Conduction Hearing Aid:** For some people, the use of a conventional air-conduction hearing device is precluded by medical conditions, such as chronic ear discharge. Under such circumstances, users must consider an alternative device, such as a bone conduction aid. With this system, a bone conduction receiver is placed on the mastoid and held in position by a headband and a small wire that connects the bone oscillator to a BTE hearing aid. Bone conduction devices stimulate the cochlea in the same way as during bone conduction threshold assessments.

H. **Percutaneous Bone Anchored Hearing Aid (BAHA):** BAHA devices are FDA-approved, bone-anchored, bone conduction hearing aids. The bone anchored hearing aid or hearing device consists of a titanium implant anchored in the mastoid, a skin-penetrating abutment, and a sound processor. The sound processor transforms sound into mechanical vibrations that are transmitted through the abutment and implant to the skull. This direct transmission of mechanical energy is 10 to 15 dB more efficient than sound transmission via skin and underlying tissues with conventional bone conduction. They are also referred to as auditory osseo-integrated implant systems. BAHA devices are considered prosthetic devices and not true hearing aids. They are covered as prosthetic devices. (see Medical Necessity below)

I. **Prosthetic Device:** A prosthetic device is an artificial device that replaces a missing body part, which may be lost through trauma, disease, or a condition present at birth (congenital disorder). Prostheses are intended to restore the normal functions of the missing body part, which in the case of hearing are devices that produce perception of sound by replacing the function of the middle ear, cochlea, or auditory nerve.

V. MEDICAL NECESSITY

A. The following are requirements for medical necessity:

1. Audiology evaluations, which should be performed within the Plan Medical Group (PMG), as part of the MA-PD coverage benefit. If the PMG is not able to perform a formal audiology assessment, it may refer the member to an external MA-PD contracted vendor for formal audiology testing. Services performed at this contracted vendor are SHP risk.
2. The Plan covers Benefit for new Hearing Aids if the evaluation and testing indicate a hearing loss that meets the terms of coverage below.
3. The Plan covers a hearing aid / replacement (under specific circumstances) as part of the supplemental benefit as medically necessary for appropriate candidates who have ANY of the

following:

a) Conductive hearing loss unresponsive to medical or surgical interventions

b) Sensorineural hearing loss

c) Mixed hearing loss

4. The Plan covers the following air conduction hearing aids for the treatment of mild to profound hearing loss, including advanced signal processing technologies (e.g., digital signal processing, directional microphones, multiple channels, multiple memories) when one of the medical necessity criteria for the hearing aid has been met:

a) Behind the ear (BTE): for cases of mild to profound hearing loss

b) In the ear (ITE): for cases of mild to moderate hearing loss

c) In the ear canal (ITC): for all but the most severe hearing loss

d) Completely in the canal (CIC): for mild to moderate hearing loss

B. Mild to profound hearing loss severity is classified by audiogram.

1. Hearing loss is classified as follows:

a) Mild 26–40 dBHL

b) Moderate 41–70 dBHL

c) Severe 71–90 dBHL

d) Profound ≥ 91 dBHL

2. Air conduction devices are the only hearing aids covered by this supplemental benefit of the Plan. They are the treatment of choice for sensorineural hearing loss, mixed hearing loss or conductive hearing loss not responsive to medical or surgical correction. The Plan does not provide coverage for all other hearing aids.

3. Bone Conduction and Bone Anchored devices (osseointegrated devices) are indicated for ALL of the following:

a) Age greater than 5 years or older, AND

b) Cortical thickness or 3 mm or more, AND

c) Middle or external ear pathology not amenable to surgical reconstruction, AND

d) Pure-tone average bone conduction hearing threshold (measured at 0.5,1, 2, and 3 kHz) less than or equal to level appropriate for model to be implanted by device, either with abutment or magnetic coupling. Examples but not limited to:

(1) 45 decibels for BAHA Attract, BAHA Divino, BAHA BP100;

(2) 55 decibels for BAHA 5Power, BAHA Intenso, Ponto Plus Power;

(3) 65 decibels (Cordelle II device), AND

e) Speech discrimination score greater than or equal to 60% in affected ear, AND

f) Trial of air conduction hearing aid failed or not appropriate as indicated by 1 or more of the following:

(1) Anatomy will not allow proper fitting,

(2) Lack of substantial audiologic improvement with air conduction hearing aid,

(3) Member develops significant otitis externa, suppurative otitis media, or recurrent ear infections that preclude long-term use.

g) Non-Osseointegrated hearing devices, transcutaneously worn, non-surgical application of a fully or partially implantable bone conduction (bone anchored) hearing-aid utilizing a headband or Softband is considered medically necessary as an alternative and bridge to an implantable BAHA for young children less than 5 years of age with conductive or mixed hearing loss who meet medical necessity of b-f above. As a bridge to osseointegrated hearing device (BAHA), these devices are considered as prosthetics.

h) Cochlear Implants are considered prosthetic devices and are reviewed per MCG Guideline ACG-A0177.

C. The Plan covers replacement of a medically necessary hearing aid as follows: Replacement is covered when the currently used device is no longer functioning adequately and has been determined to be non-repairable, as long as a minimum of 36 months have passed since the member's receipt of the hearing aid.

The Plan will cover Food and Drug Administration (FDA) approved hearing aids purchased over the counter or from non-contracted providers with a hearing exam by a Plan provider and prior authorization.

VI. NOT MEDICALLY NECESSARY

A. The Plan excludes or limits the services and supplies listed below:

1. Replacement of a hearing aid that is lost, broken or stolen within 36 months of receipt.
2. Repair of the hearing aid and related service.
3. Surgically implanted hearing devices.
4. Services or supplies for which a member is entitled to receive reimbursement under any applicable workers' compensation law.
5. Services or supplies, which are not necessary according to professionally accepted standards of practice.
6. An eyeglass-type hearing aid or additional charges for a hearing aid designed specifically for cosmetic purposes.
7. Coverage expenses relating to hearing aids are limited to the usual and customary charge of a basic hearing aid to provide functional improvement.
8. Repair, replacement parts or upgrades to an existing implantable bone-anchored hearing aid are not covered if:

a) The medical necessity criteria for the original implantable bone-anchored hearing aid were not met, or

b) The device is under warranty, or

c) Documentation of malfunction, such as repair log, is not provided or

d) The request is for convenience or to upgrade to a newer technology when the current

components are functional.

B. The Plan does not cover the following hearing aid devices because they are considered experimental, investigational or unproven:

1. Non-implantable, intraoral bone conduction hearing aid (e.g., SoundBite™ Hearing System).
2. Implantable and semi-implantable middle ear hearing aids.

C. Over the Counter FDA approved hearing aids or devices.

VII. CODES:

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all-inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Inclusion of a code in this section does not guarantee that it will be reimbursed. The member specific benefit plan document and applicable laws that may require coverage for a specific service determine benefit coverage for health services.

CPT Codes	**Description**
69710	Implantation or replacement of electromagnetic bone conduction hearing device in temporal bone
69714	Implantation, Osseo integrated implant, temporal bone, with percutaneous attachment to external speech processor/cochlear stimulator; without mastoidectomy (bone-anchored hearing aid (BAHA)
69799	Unlisted procedure, middle ear when specified as implantation of semi-implantable or fully implantable hearing aid
69930	Cochlear device implantation, with or without mastoidectomy
ICD-10 Codes	**Description**
H90.0-H90.2	Conductive hearing loss
H90.3	Sensorineural hearing loss, bilateral
H90.41-H90.42	Sensorineural hearing loss, unilateral, with unrestricted hearing on the contralateral side
H90.5	Unspecified sensorineural hearing loss
H90.6-H90.8	Mixed conductive and sensorineural hearing loss
H91.93	Unspecified hearing loss, bilateral
HCPCS Codes	**Description**
L8614	Cochlear device, includes all internal and external components
L8690	Auditory Osseo integrated device, includes all internal and external components

L8699	Prosthetic implant, not otherwise specified(when specified as hybrid cochlear device)
S2230	Implantation of magnetic component of semi-implantable hearing device on ossicles in middle ear
V5030	Hearing aid, monaural, body worn, air conduction
V5050	Hearing aid, monaural, in the ear
V5060	Hearing aid, monaural, behind the ear
V5070	Glasses, air conduction
V5095	Semi-implantable middle ear hearing prosthesis
V5100	Hearing aid, bilateral, body worn
V5130	Binaural, in the ear
V5140	Binaural, behind the ear
V5242	Hearing aid, analog, monaural, CIC (completely in ear canal)
V5243	Hearing aid, analog, monaural, ITC (in the ear canal)
V5244	Hearing aid, digitally programmable analog, monaural, CIC
V5245	Hearing aid, digitally programmable analog, monaural, ITC
V5246	Hearing aid, digitally programmable analog, monaural, ITE (in the ear)
V5247	Hearing aid, digitally programmable analog, monaural, BTE (behind the ear)
V5248	Hearing aid, analog, binaural, CIC
V5249	Hearing aid, analog, binaural, ITC
V5250	Hearing aid, digitally programmable analog, binaural, CIC
V5251	Hearing aid, digitally programmable analog, binaural, ITC
V5252	Hearing aid, digitally programmable, binaural, ITE
V5253	Hearing aid, digitally programmable, binaural, BTE
V5254	Hearing aid, digital, monaural, CIC
V5256	Hearing aid, digital, monaural, ITE
V5257	Hearing aid, digital, monaural, BTE
V5258	Hearing aid, digital, binaural, CIC
V5259	Hearing aid, digital, binaural, ITC
V5260	Hearing aid, digital, binaural, ITE
V5261	Hearing aid, digital, binaural, BTE
V5262	Hearing aid, disposable, any type, monaural
V5263	Hearing aid, disposable, any type, binaural

VIII. PROCESS/ATTACHMENTS

A. The member schedules a visit with their PCP to assess hearing loss.

B. PCP performs an office hearing evaluation, which may include a whispered voice test, a tone emitting otoscope or audiology test, use of tuning forks, physical examination of the ear, and/or pneumoscopy.

C. The PCP refers member for audiology consultation within the PMG, as appropriate, based on the history, physical exam findings, and results of the office hearing evaluation.

D. If hearing loss is verified by the formal audiologic assessment and it is determined a hearing aid may benefit the member, the audiologist recommends that the PCP refer the member for hearing aid assessment and fitting.

E. PCP shall submit an authorization request to the Plan for an Initial Hearing Aid Evaluation and Testing

Note: There is no provision in the law for Medicare to pay audiologists for therapeutic services. Audiological diagnostic tests are not covered under the benefit for services incident to a physician's service (described in Pub. 100-02, chapter 15, section 60), because they have their own benefit as "other diagnostic tests". See Pub. 100-04, chapter 13 for general outpatient diagnostic test policies.

1. When completing a prior authorization request, specifically address the MA-PD benefit, which initially includes "evaluation and testing".

F. The Plan Utilization Management (UM) staff shall follow current Plan Medical Policy to adjudicate requests based on medical necessity. The UM staff takes into consideration the severity of hearing loss, the type of hearing loss, and prior interventions.

G. If the PMG is not able to perform a formal audiology assessment, the member may be referred to an external vendor for formal audiology testing.

2. UM staff shall advise PMG of MA-PD contracted Hearing Aid Vendor: Referral is required for audiology services.

    a) Audiology tests are covered as "other diagnostic tests" under section 1861(s) (3) or 1861(s) (2) (C) of the Act in the physician's office or hospital outpatient settings, respectively, when a physician (or an NPP, as applicable) orders such testing for the purpose of obtaining information necessary for the physician's diagnostic medical evaluation or to determine the appropriate medical or surgical treatment of a hearing deficit or related medical problem.

H. If the findings indicate a need for a hearing aid, the PCP shall submit a prior authorization request to the Plan that includes the name of the preferred Hearing Aid vendor.

1. The request shall include:

    a) Evaluation and testing results

    b) Codes for specific hearing aid

    c) Justification for hearing aid type

I. The Plan Utilization Management (UM) staff shall adjudicate the request according to current Plan Prior Authorization process.

J. The UM staff shall process the determination according to the current Policy & Procedure:

1. SHP UM Medicare PP Organization Determinations (Referrals and Auths)
2. SHP PP Member and Practitioner UM Denial Letter Notification

IX. REFERENCES

A. Centers for Medicare and Medicaid (CMS). Medicare Benefit Policy Manual. Chapter 16 General Exclusions From Coverage. Rev. 198, 11/06/2014 100- Hearing aids and auditory implants. Rev.39; Issued: 11/10/05; Effective: 11/10/05; Implementation: 12/12/05. Accessed January 30, 2024https://www.cms.gov/media/125231

B. Medicare and You – Hearing Aid Coverage: Accessed January 30, 2024https://www.medicare.gov/coverage/hearing-and-balance-exam-and-hearing-aids.html

C. Audiology Services: Accessed January 16, 2021 https://www.cms.gov/Medicare/Medicare-Fee-for-Service Payment/PhysicianFeeSched/Audiology.html

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P. MCG Health Ambulatory Care 27th Edition Hearing Aids, Bone Anchored and Bone Conduction ACG: A-0564

Q. MCG Health Ambulatory Care 27th Edition Middle Ear Hearing Aids, Implantable and Semi-Implantable ACG: A-0404

R. MCG Health Ambulatory Care 27th Edition Cochlear Implant ACG: A-0177

S. 2024 UpToDate Peter Weber Hearing Amplification in Adults review current Dec 2023, last updated Aug 18, 2022

T. Bittencourt, Aline Gomes et al. Implantable and Semi-Implantable Hearing Aids: a Review of History and Indications, and Surgery. Int Arch Otorhinolaryngol. 2014 Jul; 18(3): 303-310

U. DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration Federal Register / Vol. 87, No. 158 / Wednesday, August 17, 2022 / Rules and Regulations

X. REVISION HISTORY

Date	Modification (Original, Reviewed or Revised)
11/18/15	Original
06/22/16	Revised to clarify process under Policy A.1.
12/06/17	Revised
02/22/18	Revised BAHA band section, identifying it as a prosthetic device; approved by MBPTAC
03/14/18	Sent to QMC and Approved
03/27/19	Reformatted and Updated
03/25/20	BAHA devices are covered under DME for prosthetic devices, Added section VII. Codes, Updated References
03/31/21	Updated align with Commercial and EOC
3/29/23	OTC to be updated, updated references
3/27/24	Updated References, OTC hearing aids added

Approved by: _____ Date: 3/27/2024

Cary Shames, DO, CMO/VP