

Medical Policy



Hearing Aids

Policy Number: PG0141
Last Review: 09/01/2024

HMO AND PPO
ELITE (MEDICARE ADVANTAGE)
MARKETPLACE

GUIDELINES:

- This policy does not certify benefits or authorization of benefits, which is designated by each individual policyholder terms, conditions, exclusions, and limitations contract. It does not constitute a contract or guarantee regarding coverage or reimbursement/payment. Self-Insured group specific policy will supersede this general policy when group supplementary plan document or individual plan decision directs otherwise.
- Paramount applies coding edits to all medical claims through coding logic software to evaluate the accuracy and adherence to accepted national standards.
- This medical policy is solely for guiding medical necessity and explaining correct procedure reporting used to assist in making coverage decisions and administering benefits.
- Durable Medical Equipment (DME) frequency limitations are calculated based on The Center for Medicare and Medicaid Services (CMS) criteria and guidelines, National Coverage Determinations (NCD), and Local Coverage Determinations (LCD) rules and regulations.

SCOPE:

☒ Professional
☐ Facility

DESCRIPTION:

Hearing Aids are devices that amplify and deliver speech and other sounds at levels equivalent to that of normal speech and conversation and are used by individuals with hearing loss. Their function is to bring sound more effectively into the ear of a person with a hearing impairment. The hearing impairment may range from slight to complete deafness.

Air conduction hearing aids allow sound to travel along the normal physiologically route through the external ear canal and middle ear. There are many styles of air conduction hearing aids designed for placement in one of several locations:

- In-the-Ear (ITE) units are probably the most comfortable, the least expensive and the easiest to operate.
- In-the-Canal (ITC) units are a little more expensive than ITEs. They require good dexterity to control the volume wheels and other controls on the faceplate, and they are smaller than ITEs.
- Mini-Canals (MC) are the size between ITC and CIC. A mini canal is a good choice when a small hearing aid is desired while still having manual control over the volume wheel and possibly other controls.
- Completely-in-the-Canal (CIC) units are the tiniest hearing aids made. CICs do not usually have manual controls attached to them because they are too small.
- Behind-the-Ear (BTE) hearing aids are the largest and most reliable hearing aids. BTEs have the most circuit options and can typically have much more power than any of the custom made in the ear units. BTEs are the units that "sit" on the back of the ear. They are connected to the ear canal via custom-made plastic tubing. The tubing is part of the earmold. The earmold is custom made from an ear impression to perfectly replicate the size and shape of the ear.

Programmable Hearing Aids utilize analog technology that is controlled by modifying the frequency and output characteristics using a computer. It may contain multiple microphones, multiple memories, and multiple channels, and may operate with a remote control.

Digital Hearing Aids analyze incoming sound, transforms it by converting the sound into digital bits and manipulates the frequency and output characteristics of the sound before the sound is amplified. Digital hearing

aids are programmed with a computer and contain multiple memories, microphones, and channels. The digital processor permits the hearing aid to change its parameters, to reduce background noise, and/or manage feedback without adversely affecting the benefits for the user.

Conventional Hearing Aids have a microphone that gathers sound, an amplifier that increases the volume of sound, and a receiver that transmits this amplified sound to the ear. These instruments may have a manual volume control for the user. These devices have screw-set controls mounted onto the hearing aids for the licensed provider to adjust.

Middle Ear Implants (MEIs) are hearing aids that can be either very implantable or partially implantable and use either a piezoelectric, electromechanical, or electromechanical-based vibration transducer that directly moves inner or middle ear structures.

POLICY:

Paramount Commercial Insurance Plans and Elite (Medicare Advantage) Plans

- **Covered hearing aids do not require prior authorization.**
- **See terms of Benefit coverage/non-coverage for hearing aids below.**

Non-participating providers are required to obtain prior authorization BEFORE any services are rendered.

COVERAGE CRITERIA:

Paramount Commercial Insurance Plans

The hearing aid products, dispensing fees, and repairs are covered under the hearing aid benefit. These are covered based on the member's benefit coverage for a specific product line or provider group. The following coverage criteria applies only to members with a Hearing Aid Benefit. Auditory evaluations are considered medical and do not fall under the hearing benefit.

A hearing aid device is considered medically necessary for ANY of the following:

- conductive hearing loss unresponsive to medical or surgical interventions
- sensorineural hearing loss
- mixed hearing loss

One of the following hearing loss qualification criteria are met:

- In adult patient (18 years of age or older), pure-tone average loss of 40 decibels (dB) hearing level or greater; or
- In pediatric patients (less than 18 years of age), pure-tone average loss of 25 dB hearing level or greater.

The hearing aid is prescribed, fitted, and dispensed by a licensed audiologist, hearing aid/instrument specialist, or other Qualified Practitioner

ANY of the following air conduction hearing aid devices is considered medically necessary for the treatment of mild to profound hearing loss:

- behind the ear (BTE) device
- in the ear (ITE) device
- in the ear canal (ITC) device
- completely in the canal (CIC) device
- contralateral routing of sound (CROS) device, for single-sided hearing loss (i.e., bone conduction on the hearing side is normal)
- Binaural CROS (BiCROS)

Adjustment of hearing aids is included in the fitting and dispensing fee and is not reimbursable separately.

Aural rehabilitation therapy is included in the fitting and dispensing fee and is not reimbursable separately.

Requests for two hearing aids on the same date of service will be reimbursed using binaural (for two ears) codes only.

Reimbursement for all covered hearing aids includes all the following:

- Hearing aid, cleaning kit, ear mold inserts when required for behind the ear style hearing aids, and a one-month supply of batteries
- Shipping and handling
- All required warranty costs
- Hearing tests and fitting and dispensing of hearing aid

Payment for any hearing aid dispensing fee includes all the following, not all-inclusive:

- Ear mold impression(s)
- Hearing aid selection and fitting(s)
- Up to three hours of counseling
- All visits necessary for the dispensing and fitting of the aid (regardless of place of service)
- All service calls and follow-up during the warranty period
- Charges for travel to dispense the hearing aid

Hearing Aid Replacements

- Conventional (analog) hearing aids can be replaced every four years.
- Digital hearing aids can be replaced every five years.
- Requests for replacements any sooner can be made through the prior authorization process.
- Replacement requests can be denied in instances of malicious damage, neglect, culpable irresponsibility, or wrongful disposition.
- Paramount is not responsible for any replacement charges, including deductibles, upon the loss of a hearing aid still covered under warranty.
- No hearing aid will be approved for replacement until it is determined that replacement is not covered by the manufacturer's warranty or insurance.
- A request for replacement hearing aids outside of the warranty period must be evaluated.
- No hearing aid will be approved for replacement if repair or reconditioning is more cost-effective.

Hearing Aid Repairs

- The medical necessity of the hearing aid has been established
- The repair is not covered by warranty or insurance
- No more than one major repair is covered in any 365-day period, and prior authorization is required for all major repairs.
- Minor repairs are covered every 120 days without prior authorization; however, if minor repair is needed more frequently than 120 days, a prior authorization is required.
- Routine maintenance and cleaning of the hearing aid is not covered and is the responsibility of the recipient.

Elite (Medicare Advantage) Plans

Hearing services

Diagnostic hearing and balance evaluations performed to determine if medical treatment is covered as outpatient care when furnished by a physician, audiologist, or other qualified provider.

Supplemental routine hearing exam, up to one exam every year.

Hearing Aids

Are covered for up to two TruHearing-branded hearing aids (one per ear) every year.

TruHearing provider is required to use this benefit.

Call **1-866-929-8812** to schedule an appointment (TTY,dial 711).

Hearing aid purchase includes:

- Hearing Aid Fitting/Evaluation - Unlimited follow-up provider visits within first year of hearing aid purchase. These visits are available for 12 months following hearing aid purchase and only with the purchase of a hearing aid from a TruHearing provider.
- 60-day trial period
- 3-year extended warranty
- 80 batteries per hearing aid for non-rechargeable models

Benefit does not include or cover any of the following:

- Additional cost for optional hearing aid rechargeability
- Ear molds
- Hearing aid accessories
- Additional provider visits
- Additional batteries
- Batteries when a rechargeable hearing aid is purchased
- Hearing aids that are not TruHearing-branded hearing aids
- Costs associated with loss and damage warranty claims
- Costs associated with excluded items are the responsibility of the member and are not covered by the plan.

Auditory evaluations are considered medical and do not fall under the hearing benefit.

Paramount Commercial Insurance Plans and Elite (Medicare Advantage) Plans

The following types of hearing aids are not covered:

- All types of “in the canal” and “completely in the canal” hearing aids
- All types of disposable hearing aids
- Used or reconditioned hearing aids, which are defined as hearing aids that have been previously utilized by another individual

Limitations, not all-inclusive:

- Malformations of the external or middle ear (e.g., microtic ears, congenital atresia, small ear canals, tumor)
- Conditions involving chronic middle ear drainage (e.g., dermatitis, severe chronic otitis media)
- Documentation of chronic ear infection/inflammation
- Digital, computerized, programmable, or other non-conventional hearing aids, as well as added features for cosmetic purposes are not a covered benefit.
- Replacement or repair from misuse or abuse.
- Replacement for a lost hearing aid, unless 48 months have passed since receipt of the device
- Hearing aid spectacles
- Assistive listening devices
- Laser or light-based Hearing Aids, unproven and not medically necessary for treating hearing loss due to insufficient evidence of efficacy
- Any hearing aid that is not FDA approved

CODING/BILLING INFORMATION:

The appearance of a code in this section does not necessarily indicate coverage. Codes that are covered may have selection criteria that must be met. Payment for supplies may be included in payment for other services rendered.

HCPCS CODES	
S2230	Implantation of magnetic component of semi-implantable hearing device on ossicles in middle ear
V5011	Fitting/orientation/checking of hearing aid
V5014	Repair/modification of a hearing aid
V5030	Hearing aid, monaural, body worn, air conduction
V5040	Hearing aid, monaural, body worn, bone conduction
V5050	Hearing aid, monaural, in the ear
V5060	Hearing aid, monaural, behind the ear
V5070	Hearing Aid, glasses air conduction
V5080	Hearing aid, glasses bone conduction
V5090	Dispensing fee, unspecified hearing aid
V5095	Semi-implantable middle ear hearing prosthesis
V5100	Hearing aid, bilateral, body worn
V5110	Dispensing fee, bilateral
V5120	Binaural, body
V5130	In ear binaural hearing aid
V5140	Behind ear binaural hearing aid
V5150	Binaural, glasses
V5160	Dispensing fee, binaural
V5170	Within ear CROS (Contralateral Routing of Sound) hearing aid (Deleted Code)
V5171	Hearing aid, contralateral routing device, monaural, in the ear (ITE)
V5172	Hearing aid, contralateral routing device, monaural, in the canal (ITC)
V5180	Behind ear CROS hearing aid (Deleted Code)
V5181	Hearing aid, contralateral routing device, monaural, behind the ear (BTE)
V5190	Glasses cross hearing aid
V5200	Dispensing fee, CROS
V5210	In ear BICROS (Bilateral Contralateral Routing of Sound) hearing aid (Deleted Code)
V5211	Hearing aid, contralateral routing system binaural, ITE/ITE
V5212	Hearing aid, contralateral routing system binaural, ITE/ITC
V5213	Hearing aid, contralateral routing system binaural, ITE/BTE
V5214	Hearing aid, contralateral routing system binaural, ITC/ITC
V5215	Hearing aid, contralateral routing system binaural, ITC/BTE
V5220	Behind ear BICROS hearing aid (Deleted Code)
V5221	Hearing aid, contralateral routing system binaural, BTE/BTE
V5230	Hearing aid, BiCROS, glasses
V5240	Dispensing fee, BICROS
V5241	Dispensing fee, monaural hearing aid, any type
V5242	Hearing aid, analog, monaural, cic (completely in the ear canal)
V5243	Hearing aid, analog, monaural, itc(in the canal)
V5244	Hearing aid, digitally programmable analog, monaural, CIC
V5245	Hearing aid, digitally programmable, analog, monaural, ITC
V5246	Hearing aid, prog, monaural, ITE (In the Ear)
V5247	Hearing aid, prog, 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, prog, binaural, ITE

V5253	Hearing aid, prog, binaural, BTE
V5254	Hearing aid, digital, monaural, CIC (Completely in Canal)
V5255	Hearing aid, digital, monaural, ITC (In the Canal)
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
V5264	Ear mold/insert, not disposable, any type
V5265	Ear mold/insert, disposable, any type
V5266	Battery for use in hearing device
V5267	Hearing aid supplies / accessories
V5268	Assistive listening device, telephone amplifier, any type
V5269	Assistive listening device, alerting, any type
V5270	Assistive listening device, television amplifier, any type
V5271	Assistive listening device, television caption decoder
V5272	Assistive listening device, TDD
V5273	Assistive listening device, for use with cochlear implant
V5274	Assistive listening device, not otherwise specified
V5275	Ear impression, each
V5298	Hearing aid, not otherwise classified

REVISION HISTORY EXPLANATION: ORIGINAL EFFECTIVE DATE: 10/01/2007

Date	Explanation & Changes
04/01/09	<ul style="list-style-type: none"> Updated verbiage
02/01/10	<ul style="list-style-type: none"> Updated verbiage
09/01/11	<ul style="list-style-type: none"> No changes
11/12/13	<ul style="list-style-type: none"> Added codes S2230 & V5095 Combined medical policies PG-0190 Hearing Aid Dispensing Fees and PG-0191 Hearing Aid Repairs with this policy Deleted ICD-9 Codes Policy reviewed and updated to reflect most current clinical evidence Approved by Medical Policy Steering Committee as revised
05/10/16	<ul style="list-style-type: none"> Added verbiage, "A single hearing aid for an Advantage member does not require prior authorization when meets Medicaid criteria" per change in coverage determination. Policy reviewed and updated to reflect most current clinical evidence per Medical Policy Steering Committee
10/09/18	<ul style="list-style-type: none"> Effective 01/01/19 two TruHearing-branded hearing aids (one per ear) are covered per year for Elite Removed code V5273 refer to PG0281 Cochlear and Auditory Brainstem Implants Policy reviewed and updated to reflect most current clinical evidence per Medical Policy Steering Committee
12/15/2020	<ul style="list-style-type: none"> Medical policy placed on the new Paramount Medical Policy Format
12/01/2021	<ul style="list-style-type: none"> Removed deleted codes V5170, V5180, V5210, V5220 Added codes V5011, V5171, V5172, V5181, V5211, V5212, V5213, V5214, V5215, V5221 Elite/ProMedica Medicare Plan hearing aid coverage documented as indicated in the CY 2022 Hearing Benefits as described in the EOC

	<ul style="list-style-type: none"> • Advantage hearing aid coverage documented as per ODM coverage Ohio Laws & Administrative Rules Rule 5160-10-11 DMEPOS: hearing aids
02/09/2023	<ul style="list-style-type: none"> • Medical Policy updated to reflect Medicaid coverage to Anthem as of 02/01/2023
3/30/2023	<ul style="list-style-type: none"> • Medical Policy updated to reflect DME limits calculated by CMS criteria/guidelines.
02/21/2024	<ul style="list-style-type: none"> • Medical Policy placed on the new Paramount Medical Policy format
09/01/2024	<ul style="list-style-type: none"> • Medical Policy reviewed, no changes

Paramount reserves the right to review and revise our policies periodically when necessary. When there is an update, we will publish the most current policy to

<https://www.paramounthealthcare.com/providers/medical-policies/policy-library>

REFERENCES/RESOURCES

Centers for Medicare and Medicaid Services, CMS Manual System and other CMS publications and services <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals> <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs>

American Medical Association, *Current Procedural Terminology (CPT®)* and associated publications and services <https://www.ama-assn.org/amaone/cpt-current-procedural-terminology>

Centers for Medicare and Medicaid Services, Healthcare Common Procedure Coding System, HCPCS Release and Code Sets <https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/HCPCS-Quarterly-Update>

U.S. Preventive Services Task Force, <https://www.uspreventiveservicestaskforce.org/uspstf/>
Industry Standard Review

Hayes, Inc., <https://www.hayesinc.com/>

Industry Standard Review

Medical Policy History – Prior to 02/21/2024

Paramount Commercial Insurance Plans, Medicare Advantage Plans, and Paramount Advantage Medicaid

Paramount Commercial Insurance Plans and Medicare Advantage Plans

- Covered hearing aids do not require prior authorization.
- See terms of Benefit coverage/non-coverage for hearing aids below.

Paramount Advantage Medicaid

- Covered binaural hearing aids & related supplies require prior authorization for Advantage, V5130, V5140, V5150, V5160, V5211, V5212, V5213, V5214, V5215, V5221, V5230, V5240, V5252, V5253, V5260, V5261, V5298.
- A single hearing aid for an Advantage member does not require prior authorization.
- See terms of Benefit coverage/non-coverage for hearing aids below.

Paramount Commercial Insurance Plans, Medicare Advantage Plans, and Paramount Advantage Medicaid

Refer to these medical policies for coverage determinations:

- PG0218 Bone-Anchored Hearing Aids (BAHAs)
- PG0281 Cochlear Implants

Non-participating providers are required to obtain prior authorization BEFORE any services are rendered.

Paramount Advantage Medicaid

Ohio Laws & Administrative Rules Rule 5160-10-11 DMEPOS: hearing aids

Hearing aids and related supplies are covered for Advantage members providing the medical necessity of the requested hearing aid be established. Requests for two hearing aids on the same date of service will be reimbursed using binaural (for two ears) reimbursement codes only.

One conventional hearing aid every four years; one digital or programmable hearing aid every five years. Two hearing aids may be considered in special circumstances.

(A) Definition. "Basic hearing test" is an evaluation of an individual's ability to hear that includes the following components:

- (1) Testing of air-conducted stimuli at thresholds of five hundred hertz (Hz), one thousand Hz, two thousand Hz, and four thousand Hz;
- (2) Assessment of air-conducted speech awareness or speech reception threshold;
- (3) Establishment of most comfortable and most uncomfortable listening levels;
- (4) Pure-tone bone conduction audiometry (unless the individual's age or capability precludes such testing); and
- (5) For an individual younger than twenty-one years of age, the following components:
 - (a) Tympanometry;
 - (b) Acoustic reflex battery; and
 - (c) Otoacoustic emissions testing.

(B) Coverage.

- (1) The default certificate of medical necessity (CMN) form is the ODM 01915, "Certificate of Medical Necessity: Hearing Aids" (rev. 7/2018).
- (2) A completed CMN, signed and dated not more than ninety days before the requested dispensing date, must be accompanied by a hearing evaluation report, compiled not more than six months before the requested dispensing date, made up of the following components:
 - (a) A detailed description of the hearing test, signed by the physician specializing in otology or otolaryngology, audiologist, or licensed hearing aid fitter who administered it;
 - (b) A copy of the hearing test results; and
 - (c) A written summation of the hearing test results, prepared, and signed by a physician specializing in otology or otolaryngology or by an audiologist.
- (3) Separate payment may be made for the hearing test itself. All hearing tests must be administered by authorized individuals working within their scope of practice and must be conducted in an appropriate sound environment in accordance with nationally accepted standards. Hearing tests should be performed on both ears; a detailed explanation must be included in a PA request if bilateral testing cannot be done.

(4) The need for a hearing aid is demonstrated when the results of a basic hearing test performed on one ear indicate the following minimum best pure-tone average hearing loss:

(a) Thirty-one decibels (dB); or

(b) In an individual younger than twenty-one years of age, twenty-six dB.

(5) To assess the performance and acceptability of the hearing aid, the provider must attempt to schedule a follow-up visit with the individual within thirty days after delivery. No claim for payment should be submitted during this period. The provider must keep on file, for at least four years, either a confirmation of the follow-up visit signed by the individual or an explanation of why the visit was not conducted. If as a result of the follow-up visit the hearing aid is deemed unacceptable by either the provider or the individual, then payment is limited to the cost of the earmold insert and batteries. In such an instance, if payment has already been made for the hearing aid, then the provider must arrange for adjustment of the claim.

(6) The following warranty periods apply:

(a) For a covered hearing aid, it is the greater of the manufacturer's warranty period or one year from the date of delivery; and

(b) For an earmold insert, it is ninety days.

(7) A warranty comprehensively covers the following services:

(a) Repair, including labor and parts (except earmold inserts and batteries);

(b) Replacement necessitated by damage or loss; and

(c) Two adjustments per year for changes in hearing sensitivity or growth of the ear canal (after which additional adjustments made during the year will be treated as repairs).

(8) A programmable hearing aid, such as a hearing aid employing contralateral routing of signal (CROS) or binaural contralateral routing of signal (BiCROS), may be indicated if an individual has a documented need for such technology in noisy or otherwise adverse hearing environments.

(9) Separate payment may be made for the taking of an impression for an earmold insert (other than an insert dispensed with a hearing aid). Such payment is limited neither by the place of service nor by the individual's living arrangement.

(10) Regardless of how a hearing aid was purchased, payment may be made for necessary repair only if the following conditions are satisfied:

(a) The medical necessity of the hearing aid has been established;

(b) The repair is not covered by warranty or insurance; and

(c) The repair is not associated with routine maintenance or cleaning of the hearing aid.

(C) Requirements, constraints, and limitations.

(1) The provider must keep on file a copy of the manufacturer's original cost estimate, a copy of the manufacturer's final invoice detailing discounts and shipping costs, and (if applicable) an explanation of any differences between the figures.

(2) No payment will be made for the following hearing aids:

- (a) A hearing aid designed to be worn inside the ear canal;
- (b) A disposable hearing aid; and
- (c) A hearing aid that has been previously used by another individual.

(3) No payment (including payment of a deductible amount) will be made for replacement if either of the following conditions is satisfied:

- (a) The hearing aid is covered by warranty or insurance; or
- (b) Repair or reconditioning would be more cost-effective.

(4) Concurrent requests or claims for two separate hearing aids will be treated as a single request or claim for a binaural hearing aid.

(5) Payment for a hearing aid includes the following items:

- (a) A cleaning kit;
- (b) An initial ear mold insert (applicable to behind-the-ear hearing aids); and
- (c) One month's supply of batteries. 48 batteries per year per hearing aid.

(6) Payment for hearing aid dispensing includes the following services:

- (a) The taking of initial earmold impressions;
- (b) Assistance with selection of the hearing aid;
- (c) Up to three hours of counseling;
- (d) All visits (including travel) necessary for the dispensing and fitting of the hearing aid (regardless of place of service); and
- (e) All service calls and follow-up visits during the warranty period.

NOT Covered: S2230, V5090, V5095, V5100, V5110, V5120, V5170, V5242-V5245, V5248-V5251, V5254, V5255, V5258, V5259, V5262, V5263, V5265, V5268-V5275 and V5298, per Durable medical equipment, prostheses, orthoses, and supplies (DMEPOS), Appendix to OAC rule 5160-10-01, Payment schedule effective 07/01/2021.

Auditory evaluations are considered medical and do not fall under the hearing benefit.

Paramount Commercial Insurance Plans, Medicare Advantage Plans, and Paramount Advantage Medicaid

The following types of hearing aids are not covered:

- All types of "in the canal" and "completely in the canal" hearing aids
- All types of disposable hearing aids
- Used or reconditioned hearing aids, which are defined as hearing aids that have been previously utilized by another individual

Limitations, not all-inclusive:

- Malformations of the external or middle ear (e.g., microtic ears, congenital atresia, small ear canals, tumor)
- Conditions involving chronic middle ear drainage (e.g., dermatitis, severe chronic otitis media)
- Documentation of chronic ear infection/inflammation
- Digital, computerized, programmable, or other non-conventional hearing aids, as well as added features for cosmetic purposes are not a covered benefit.
- Replacement or repair from misuse or abuse.
- Replacement for a lost hearing aid, unless 48 months have passed since receipt of the device
- Hearing aid spectacles
- Assistive listening devices
- Laser or light-based Hearing Aids, unproven and not medically necessary for treating hearing loss due to insufficient evidence of efficacy

Any hearing aid that is not FDA approved