I. Policy: Osseointegrated Hearing Device (eg. Bone Anchored hearing Aid (BAHA) Hearing Device)

II. Purpose/Objective:
To provide a policy of coverage regarding Osseointegrated Hearing Device (eg. Bone Anchored hearing Aid (BAHA) Hearing Device)

III. Responsibility:
A. Medical Directors
B. Medical Management

IV. Required Definitions
1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions
Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
b. provided for the diagnosis, and the direct care and treatment of the Member's condition, illness disease or injury;
c. in accordance with current standards of good medical treatment practiced by the general medical community.
d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

Medicaid Business Segment
Medical Necessity shall mean a service or benefit that is compensable under the Medical Assistance Program and if it meets any one of the following standards:

(i) The service or benefit will, or is reasonably expected to, prevent the onset of an illness, condition or disability.
(ii) The service or benefit will, or is reasonably expected to, reduce or ameliorate the physical, mental or development effects of an illness, condition, injury or disability.
(iii) The service or benefit will assist the Member to achieve or maintain maximum functional
capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for members of the same age.

DESCRIPTION:
Osseointegrated hearing devices [eg, BAHA (bone-anchored hearing aid)] are devices which are partially or totally implanted in the skull to replace the function of the middle ear by applying mechanical energy to the cochlea via a mechanical transducer. Geisinger Health Plan follows the Centers for Medicare and Medicaid Services (CMS) rules in considering osseointegrated implants as prosthetics:
- “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.”

INDICATIONS:
An osseointegrated hearing device is considered to be medically necessary for members who are 5 years of age or older with documented moderately severe to severe unilateral or bilateral conductive or mixed conductive and sensorineural hearing loss* for whom conventional air conduction hearing aids are medically inappropriate or cannot be utilized, and any of the following conditions are met:
- documentation of chronic ear infection/inflammation, refractory to maximized treatment, that would preclude the use of air-conduction hearing aids
- malformations of the external or middle ear canal (either congenital or surgically induced) that would preclude the use of air-conduction hearing aids
- tumors of the external canal and/or tympanic cavity
- moderately severe to severe conductive hearing loss as a result of otosclerosis and for which stapedectomy is contraindicated.

*Severity of hearing loss is defined as follows:
- **Mild** 26–40 dBHL
- **Moderate** 41–55dBHL
- **Moderately severe** 56–70 dBHL
- **Severe** 71–90 dBHL
- **Profound** ≥ 91 dBHL


Soft-Band
Children under the age of five may wear a transcutaneous, non-surgical application of the BAHA device on a headband. The BAHA can be fitted onto a soft band as soon as the hearing loss has been diagnosed, thus reducing the effects of hearing deprivation. The soft band, used with the headband, work like the conventional bone conductor. A BAHA is worn on a soft band until the child is over the age of five as FDA approved and the implant surgery is scheduled.

REPLACEMENT OF COMPONENTS
Replacement of components or upgrades to existing osseointegrated hearing devices are covered when all of the following criteria are met:
- The current component or processor was being used daily until the malfunction occurred; and
- The current component or processor is no longer functional and cannot be repaired; and
- There is no evidence to suggest that the device has been lost, abused or neglected; and
- The replacement is not being requested solely for better technology or improved aesthetics

*NOTE: PA Medical Assistance will cover technology replacement in scenarios of equipment loss, abuse or neglect, if otherwise medically necessary.

EXCLUSIONS:
Osseointegrated hearing devices are excluded from coverage when qualifying criteria are not met.

The Plan does **NOT** provide coverage for the use of Intra-oral bone conduction hearing aids (e.g., the SoundBite hearing system) for the treatment of hearing loss because it is considered **experimental, investigational or unproven**. There is insufficient evidence in the peer-reviewed published medical literature to establish the effectiveness of this treatment on health outcomes when compared to established treatments or technologies.
The Plan does NOT provide coverage for replacement of a functional osseointegrated hearing device based on age of the device or current state of technology. The processor must be non-functional. Age of the device alone does not meet medical necessity for replacement of the processor or components.

**Medicaid Business Segment:**
Any requests for services, that do not meet criteria set in the PARP, will be evaluated on a case by case basis.

**Note:** A complete description of the process by which a given technology or service is evaluated and determined to be experimental, investigational or unproven is outlined in MP 15 - Experimental Investigational or Unproven Services or Treatment.

**CODING ASSOCIATED WITH:** Osseointegrated Hearing Device (eg. Bone Anchored hearing Aid (BAHA) Hearing Device)

*The following codes are included below for informational purposes and may not be all inclusive. Inclusion of a procedure or device code(s) does not constitute or imply coverage nor does it imply or guarantee provider reimbursement. Coverage is determined by the member specific benefit plan document and any applicable laws regarding coverage of specific services. Please note that per Medicare coverage rules, only specific CPT/HCPCS Codes may be covered for the Medicare Business Segment. Please consult the CMS website at [www.cms.gov](http://www.cms.gov) or the local Medicare Administrative Carrier (MAC) for more information on Medicare coverage and coding requirements.*

69710 Implantation or replacement of electromagnetic bone conduction hearing device in temporal bone
69711 removal or repair of electromagnetic bone-conduction hearing device in temporal bone
69714 Implantation, osseointegrated implant, skull, with percutaneous attachment to external speech processor
69716 Implantation, osseointegrated implant, skull; with magnetic transcutaneous attachment to external speech processor, within the mastoid and/or resulting in removal of less than 100 sq mm surface area of bone deep to the outer cranial cortex
69717 Replacement (including removal of existing device), osseointegrated implant, skull, with percutaneous attachment to external speech processor
69719 Replacement (including removal of existing device), osseointegrated implant, skull; with magnetic transcutaneous attachment to external speech processor, within the mastoid and/or involving a bony defect less than 100 sq mm surface area of bone deep to the outer cranial cortex
69726 Removal, entire osseointegrated implant, skull; with percutaneous attachment to external speech processor
69727 Removal, entire osseointegrated implant, skull; with magnetic transcutaneous attachment to external speech processor, within the mastoid and/or involving a bony defect less than 100 sq mm surface area of bone deep to the outer cranial cortex
69728 Removal, entire osseointegrated implant, skull; with magnetic transcutaneous attachment to external speech processor, outside the mastoid and involving a bony defect greater than or equal to 100 sq mm surface area of bone deep to the outer cranial cortex
69729 Implantation, osseointegrated implant, skull; with magnetic transcutaneous attachment to external speech processor, outside the mastoid and resulting in removal of greater than or equal to 100 sq mm surface area of bone deep to the outer cranial cortex
69730 Replacement (including removal of existing device), osseointegrated implant, skull; with magnetic transcutaneous attachment to external speech processor, outside the mastoid and involving a bony defect greater than or equal to 100 sq mm surface area of bone deep to the outer cranial cortex
S2230 Implantation of magnetic component of semi-implantable hearing device on ossicles in middle ear
L8690 Auditory osseointegrated device, includes all internal and external components
L8691 Auditory osseointegrated device, external sound processor, replacement
L8692 Auditory osseointegrated device, external sound processor, used without osseointegration, body worn, includes headband or other means of external attachment
L8693 AUDITORY OSSEOEINTEGRATED DEVICE ABUTMENT, ANY LENGTH, REPLACEMENT ONLY
L8694 Auditory osseointegrated device, transducer/actuator, replacement only, each
V5095 semi-implantable middle ear hearing prosthesis

*Current Procedural Terminology (CPT®) © American Medical Association: Chicago, IL*
LINE OF BUSINESS:
Eligibility and contract specific benefits, limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy. For Medicare, applicable LCD's and NCD's will supersede this policy. For PA Medicaid Business segment, this policy applies as written.

REFERENCES:

CMS 42 CFR 411.15  http://www.asha.org/about/publications/leader-online/b-line/b1030624.htm


This policy will be revised as necessary and reviewed no less than annually.

Devised: 6/04

Revised: 12/05, 12/06, 06/09 (updated criteria per CMS Mandate); 5/10 (updated criteria), 7/15 (added soft band coverage); 5/16 (Removed PA); 4/17 (added intra-oral aid exclusion); 4/18 (clarified Transcutaneous aid); 4/20 (added replacement criteria)

Reviewed: 6/05; 12/07, 05/09, 5/11, 5/12, 5/13, 5/14, 4/19, 4/21, 4/22, 4/23

Geisinger Health Plan may refer collectively to health care coverage sponsors Geisinger Health Plan, Geisinger Quality Options, Inc., and Geisinger Indemnity Insurance Company, unless otherwise noted. Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

Coverage for experimental or investigational treatments, services and procedures is specifically excluded under the member's certificate with Geisinger Health Plan. Unproven services outside of an approved clinical trial are also specifically excluded under the member's certificate with Geisinger Health Plan. This policy does not expand coverage to services or items specifically excluded from coverage in the member's certificate with Geisinger Health Plan. Additional information can be found in MP015 Experimental, Investigational or Unproven Services.

Prior authorization and/or pre-certification requirements for services or items may apply. Pre-certification lists may be found in the member's contract specific benefit document. Prior authorization requirements can be found at https://www.geisinger.org/health-plan/providers/ghp-clinical-policies

Please be advised that the use of the logos, service marks or names of Geisinger Health Plan, Geisinger Quality Options, Inc. and Geisinger Indemnity Insurance Company on a marketing, press releases or any communication piece regarding the contents of this medical policy is strictly prohibited without the prior written consent of Geisinger Health Plan. Additionally, the above medical policy does not confer any endorsement by Geisinger Health Plan, Geisinger Quality Options, Inc. and Geisinger Indemnity Insurance Company regarding the medical service, medical device or medical lab test described under this medical policy.