KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Bone Anchored Hearing System (BAHA)

- BONEBRIDGE Bone Conduction Implant
- Osia®
- Vibrant Soundbridge
- Softband
- Adhear

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	Chapter 16, section 100 – "Hearing Aids and Auditory Implants" and section 180 – "Services Related to and Required as a Result of Services Which Are Not Covered Under Medicare." 42 CFR § 411.15(d)(2) – Medicare covers devices that replace the function of the middle ear, cochlea, or auditory nerve
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	None

For Non-Medicare Members

Service	Criteria Used
Bone Anchored and Bone Conduction Hearing System	**Effective September 1st, 2025** Kaiser Permanente has elected to use the Bone Anchored Hearing System (BAHS) (KP-0564 09012023) MCG* for medical necessity determinations. For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access. **Effective until September 1st, 2025** Kaiser Permanente has elected to use the Hearing Aids, Bone Anchored and Bone Conduction (KP-0564 09.01.2025) MCG* for medical necessity determinations. For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access.
Vibrant Soundbridge	There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

Back to Top

If requesting these services, please send the following documentation to support medical necessity:

- Most recent audiogram/hearing test
- Most recent clinical notes from requesting provider &/or specialist (otolaryngology, ENT)

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Vibrant Soundbridge System

The Vibrant Soundbridge System is an implantable alternative to standard hearing aids. It is intended for use in adults with moderate to severe sensorineural hearing loss, who desire an alternative to an acoustic hearing aid. Common limitations of conventional hearing aids are acoustic feedback, sound and voice distortion, and need for frequent servicing and maintenance (FDA documents, Sterkers et al., 2003; Luetje, 2002).

The Soundbridge system consists of a middle-ear implant known as the Vibrating Ossicular Prosthesis (VORP) and an external portion, the amplification system called the Audio Processor. The Audio Processor is about 1.2 inches in diameter and designed to be worn behind or above the ear. It contains a microphone that converts environmental sound to electrical signals. These signals are delivered to the VORP, causing the Floating Mass Transducer (FMT), one of its components, to vibrate. The vibration manually stimulates the auditory ossicles and is perceived by the patient as sound (manufacturer's documents).

Potential adverse effects of the Vibrant Soundbridge include the usual risks of major ear surgery and a possible decrease in residual hearing (FDA documents).

The Vibrant Soundbridge has been available commercially since February 1998 in Europe and received FDA approval in the US in August 2000. The FDA recommends that patients have experience with appropriately fitting conventional hearing aids before using the Vibrant Soundbridge.

Bone Anchored Hearing Aid (BAHA) (Entific Medical Systems)

The BAHA is an alternative device for hearing-impaired patients who are unable to wear traditional hearing aids. According to the manufacturer, the BAHA can be beneficial to individuals with chronic inflammation or infection of the ear canal, an incomplete ear canal e.g. congenital ear malformation and single-sided hearing loss. The BAHA is based on bone conduction technology, sound transmission without involvement of the skin and soft tissue and thus can be used by individuals with an impaired or diseased external or middle ear (Tjellstrom & Hakansson, 1995).

The BAHA device consists of an implant and an external sound processor attached to a subcutaneous abutment. The implant, a titanium fixture, is implanted behind the ear where it "osseointegrates" or bonds with the living bone. After healing from surgery, a percutaneous abutment is attached to the fixture. The sound processor "snaps" into the abutment. The sound processor, which transmits sound directly via the bone to the inner ear can be connected and disconnected at will (FDA and manufacturer's documents)

The BAHA was developed in Sweden in the 1980s. It was approved by the FDA in August 1996 and was introduced in the US market in January 1997. There are several different models, all of which were considered by the FDA to be Class II devices, substantially equivalent to air conduction hearing aids with digital sound processing.

Medical Technology Assessment Committee (MTAC)

Vibrant Soundbridge

06/06/2005: MTAC REVIEW

Back to Top

Evidence Conclusion: There are studies with pre- and post-implantation data, but no controlled studies on the efficacy of either the Vibrant Soundbridge or the BAHA. Data from case series suggest that patients who meet eligibility requirements may experience improvement and hearing from the Vibrant Soundbridge and BAHA. Lack of blinding and lack of a control group limit the validity of case series. The publications are further limited by small sample sizes and/or missing data.

Articles: *Vibrant Soundbridge*: Only case series were identified. Most were conducted in Europe where there is longer experience with the device compared to the U.S. Two studies were selected for review: The largest case series, a French study (n=125), and the strongest US study (n=54). The US study was the one used by the FDA to grant approval. *BAHA*: Only case series were identified, all with sample sizes <100. The two best-case series were reviewed. They were selected based on sample size and length of follow-up. There were two publications on one of the studies, so a total of three articles were reviewed. *The studies that were critically appraised are*: Sterkers O, Boucarra D, Labassi S. A middle ear implant, the Symphonix Vibrant Soundbridge: Retrospective study of the first 125 patients implanted in France. *Otol Neurotol* 2003; 24: 427-436. See Evidence Table Luetje CM, Brackman D, Balkany TJ et al. Phase III clinical trial results with the Vibrant Soundbridge implantable middle ear hearing device: A prospective controlled multicenter study. See Evidence Table Mylanus EA, van der Pouw KC, Snik AFM et al. Intraindividual comparison of the bone-anchored hearing aid and air-conduction hearing aids. *Arch Otolaryngol Head Neck Surg* 1998; 124: 271-276. See Evidence Table Hol MKS, Snik AFM, Mylanus EAM et al. Long-term results of bone-anchored hearing aid recipients who had previously used air-conduction hearing aids. *Arch Otolaryngol Head Neck Surg* 2005; 131: 321-325. See Evidence Table Lustig LR, Arts A. Brackmann DE. Hearing rehabilitation using the BAHA bone-anchored hearing aid: Results in 40 patients. *Otol Neurotol* 2001; 22: 328-334. See Evidence Table

The use of Vibrant Soundbridge or the BAHA in the treatment of hearing loss does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Bone anchored or transcutaneous bone-conduction hearing systems

Medicare –

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® Codes	Description
69711	Removal or repair of electromagnetic bone conduction hearing device in temporal bone
69714	Implantation, osseointegrated implant, temporal bone, with percutaneous attachment to external speech processor/cochlear stimulator; without mastoidectomy
69715	Implantation, osseointegrated implant, temporal bone, with percutaneous attachment to external speech processor/cochlear stimulator; with mastoidectomy
69717	Replacement (including removal of existing device), osseointegrated implant, temporal bone, with percutaneous attachment to external speech processor/cochlear stimulator; without mastoidectomy
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
69718	Replacement (including removal of existing device), osseointegrated implant, temporal bone, with percutaneous attachment to external speech processor/cochlear stimulator; with mastoidectomy
69719	Revision or replacement (including removal of existing device), osseointegrated implant, skull; with magnetic transcutaneous attachment to external speech processor
69726	Removal, osseointegrated implant, skull; with percutaneous attachment to external speech processor
69727	Removal, osseointegrated implant, skull; with magnetic transcutaneous attachment to external speech processor
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 of the mastoid and resulting in removal of greater than or equal to 100

Back to Top

	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
HCPC Codes	**Description**
L8690	Auditory osseointegrated device, includes all internal and external components
L8691	Auditory osseointegrated device, external sound processor, excludes transducer/actuator, replacement only, each
L8692	Auditory osseointegrated device, external sound processor, used without osseointegration, body worn, includes headband or other means of external attachment
L8693	Auditory osseointegrated device abutment, any length, replacement only

Considered Not Medically Necessary:

CPT® Codes	Description
69710	Implantation or replacement of electromagnetic bone conduction hearing device in temporal bone

Non-Medicare - Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® Codes	Description
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, temporal bone, with percutaneous attachment to external speech processor/cochlear stimulator; without mastoidectomy
69715	Implantation, osseointegrated implant, temporal bone, with percutaneous attachment to external speech processor/cochlear stimulator; with mastoidectomy
69716	Implantation, osseointegrated implant, skull; with magnetic transcutaneous attachment to external speech processor
69717	Replacement (including removal of existing device), osseointegrated implant, skull; with percutaneous attachment to external speech processor
69718	Replacement (including removal of existing device), osseointegrated implant, temporal bone, with percutaneous attachment to external speech processor/cochlear stimulator; with mastoidectomy
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 of 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
HCPC Codes	**Description**
L8690	Auditory osseointegrated device, includes all internal and external components

Back to Top

L8691	Auditory osseointegrated device, external sound processor, excludes transducer/actuator, replacement only, each
L8692	Auditory osseointegrated device, external sound processor, used without osseointegration, body worn, includes headband or other means of external attachment
L8693	Auditory osseointegrated device abutment, any length, replacement only

Vibrant Soundbridge - Considered Not Medically Necessary:

HCPC Codes	Description
S2230	Implantation of magnetic component of semi-implantable hearing device on ossicles in middle ear
V5095	Semi-implantable middle ear hearing prosthesis

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

Date Created	Review Dates	Date Last Revised
06/06/2005	09/07/2010[MDCRPC], 07/05/2011[MDCRPC], 05/01/2012[MDCRPC], 10/02/2012[MDCRPC], 08/06/2013[MPC],10/01/2013[MPC], 06/03/2014[MPC], 04/07/2015[MPC], 02/02/2016[MPC], 12/06/2016[MPC], 10/03/2017[MPC], 08/07/2018[MPC], 08/06/2019[MPC], 08/04/2020[MPC], 08/03/2021[MPC], 08/02/2022[MPC], 08/01/2023[MPC], 07/02/2024[MPC], 07/07/2025[MPC]	04/01/2025

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description
10/9/2018	Added Adhear to non-coverage statement
04/21/2020	Added applicable CPT codes: 69714, 69715, 69717, 69718
08/04/2020	MPC approved to adopt updates for Non-Medicare, adding clinical indications for BONEBRIDGE (MCG* KP-0564-see KP-0564 v2 eff 01.01.2021). Requires 60-day notice, effective date 01/01/2021.
12/08/2022	Added New CPT Codes applicable for MA and Non-MA.
04/04/2023	MPC approved modification to criteria to include OSIA and clarification to hearing thresholds.
07/02/2024	MPC approved BAHA for the Care Delivery Medical Necessity Review program
04/01/2025	MPC approved the recommended changes for Bone Anchored Hearing System hybrid criteria. 60-day notice required, effective 09/01/2025.

Back to Top