INNER EAR DISORDER TREATMENTS

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Medical Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

The section identified as “Description” defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as “Criteria” defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Medical Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Medical Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

Description:

Hearing Loss:
Hearing loss may result from damage to the inner ear or nerve pathways from the inner ear to the brain (sensorineural) or as the result of an autoimmune disease (Cogan Syndrome) or inflammatory inner ear disease.

Meniere’s Disease:
Meniere’s disease is an inner ear disorder of unknown cause characterized by tinnitus, vertigo, hearing loss and increased sensitivity to loud sounds.

Tinnitus:
Tinnitus is the perception of sound in the absence of an external stimulus. It may be subjective or objective. Subjective tinnitus (the most common form) is audible only to the affected individual. It can be caused by disorders of the auditory system or may be a symptom or side effect of an otological, neurological, psychological or metabolic disease or pharmacological, infectious, neoplastic or autoimmune disorder. Objective tinnitus is audible to the individual and to an examiner with a stethoscope. It can be caused by middle ear and skull base tumors, vascular abnormalities and metabolic derangements.
INNER EAR DISORDER TREATMENTS (cont.)

Description: (cont.)

Treatments for Hearing Loss and Meniere’s Disease:

Intratympanic Pharmacologic Agents:
Pharmacologic agents infused into the middle ear include:

- Intratympanic Dexamethasone (ID), which has been investigated as a treatment for Meniere’s disease, sensorineural hearing loss, autoimmune disease hearing loss and other inflammatory inner ear diseases. Dexamethasone has been used for anti-inflammation and immunosuppression. Injections are made via tympanostomy or myringotomy with or without placement of tubes.
- Intratympanic Latanoprost (IL), a sterile ophthalmic solution used for the treatment of glaucoma, which has been investigated as a treatment for Meniere’s disease.

Transtympanic Micropressure:
Application of low frequency, low-amplitude pressure to the middle ear has been investigated in the symptomatic treatment of Meniere’s disease. The Meniett® device is a hand-held air pressure generator that delivers intermittent low-pressure pulses to the middle ear causing displacement of inner ear fluid and vertigo relief. Following the surgical placement of a ventilation tube, the individual places an ear cuff in the external ear canal and intermittent pressure pulses are applied to the middle ear. Treatments are 3 times daily for 3 minutes each. The treatment is continued for as long as the individual is having vertigo. Treatment is not needed during periods of remission.

Treatments for Tinnitus:

Botulinum Toxin Type A:
Toxin produced by the anaerobic organism Clostridia botulinum. Investigated as a treatment for tinnitus by reducing autonomic nerve pathway response.

Electromagnetic Energy:
Pulsed, high frequency electromagnetic energy is delivered via a Diapulse® device.

Lidocaine Perfusion Therapy:
Using a laser, two small holes are made in the eardrum followed by an injection of 0.5ml hyaluronan and 20mg lidocaine. The individual remains with the operated ear up while receiving 500mg lidocaine intravenously over the next 2 hours. This therapy is repeated the next 2 days.

Tinnitus Maskers:
Maskers resemble hearing aids that produce a low level sound to mask or reduce the tinnitus.
INNER EAR DISORDER TREATMENTS (cont.)

Description: (cont.)

Treatments for Tinnitus: (cont.)

Tinnitus-Retraiming Therapy:
Maskers are set at a level that the tinnitus can still be detected. Counseling is added to focus on changing the perception of the tinnitus to where the individual essentially becomes unaware of it.

Transcranial Magnetic Stimulation (TMS):
Electrical current is delivered through a small coil over the scalp to produce targeted magnetic fields within the auditory cortex of the brain.

Transcutaneous Electrical Stimulation:
Stimulation with a probe to the nerve endings in the external ear.

Transmeatal Laser Irradiation:
Applicator delivers low level laser light to the inner ear from the outer auditory canal and middle ear.

Criteria:

Hearing Loss and Meniere’s Disease Treatments:

➢ Intratympanic dexamethasone for the following indications is considered experimental or investigational based upon:

  1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  2. Insufficient evidence to support improvement of the net health outcome.

These indications include, but are not limited to:

▪ Autoimmune disease-related hearing loss
▪ Inflammatory inner ear disease
▪ Meniere’s disease
▪ Sensorineural hearing loss
INNER EAR DISORDER TREATMENTS (cont.)

Criteria:

Hearing Loss and Meniere’s Disease Treatments: (cont.)

- Intratympanic latanoprost for the treatment of Meniere’s disease is considered *experimental or investigational* based upon:
  1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  2. Insufficient evidence to support improvement of the net health outcome, and
  3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
  4. Insufficient evidence to support improvement outside the investigational setting.

- Transtympanic micropressure applications for the treatment of Meniere’s disease is considered *experimental or investigational* based upon:
  1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  2. Insufficient evidence to support improvement of the net health outcome.

Tinnitus Treatments:

- The following treatments for tinnitus are considered *experimental or investigational* based upon:
  1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  2. Insufficient evidence to support improvement of the net health outcome.

These treatments include, *but are not limited to*:

- Lidocaine perfusion
- Tinnitus maskers
- Tinnitus-retraining therapy
- Transcranial magnetic stimulation
- Transcutaneous electrical stimulation
- Transmeatal laser irradiation
INNER EAR DISORDER TREATMENTS (cont.)

Criteria: (cont.)

Tinnitus Treatments: (cont.)

➢ The following treatments for tinnitus are considered experimental or investigational based upon:

1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
2. Insufficient evidence to support improvement of the net health outcome, and
3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
4. Insufficient evidence to support improvement outside the investigational setting.

These treatments include, but are not limited to:

- Botulinum Toxin Type A
- Electromagnetic energy

Resources:


INNER EAR DISORDER TREATMENTS (cont.)

Resources: (cont.)


INNER EAR DISORDER TREATMENTS (cont.)

Resources: (cont.)


INNER EAR DISORDER TREATMENTS (cont.)

Resources: (cont.)


INNER EAR DISORDER TREATMENTS (cont.)

Resources: (cont.)


42. Shea Ear Clinic. Lidocaine Perfusion of the Inner Ear Plus IV Lidocaine for Intractable Tinnitus.


FDA Summary Statements for Tinnitus Masker. Device names include, but are not limited to:

UltraQuiet™
TST-Suppressor® 1000
HiSonic® TRD

- FDA-approved indication: To suppress the symptoms of tinnitus.

FDA Product Approval Information for Diapulse:

- FDA-approved indication: For adjunctive use in the palliative treatment of postoperative edema and pain in superficial soft tissue.

FDA 510K Summary for Meniett® Device:

- FDA-approved indication: For symptomatic treatment of Meniere’s disease. The therapeutic effect of Meniett 20 is achieved by applying low frequency, low amplitude pressure pulses to the middle ear whereby inner ear endolymphatic fluids are assumed to be evacuated from the cochlea and thus relieve the patient of the symptoms associated with endolymphatic hydrops.