MENIETT LOW PRESSURE PULSE GENERATOR FOR MENIERE’S DISEASE
DME101.043
POSTED DATE: 8/22/2003
EFFECTIVE DATE: 12/1/2003

COVERAGE:

Meniett Low Pressure Generator is considered medically necessary for patients with Meniere’s disease who are experiencing intractable vertigo (vertigo resistant to relief or control) with or without nausea and/or vomiting, hearing loss, tinnitus or a feeling of fullness in the ear and for whom other conservative medical therapy has failed to control symptoms.

Other conservative medical therapies may include symptomatic treatments such as:

- dietary changes such as restriction of salt,
- lifestyle changes such as the elimination of smoking and caffeine, and an increase in exercise, and
- medications such as diuretics, Valium (Diazepam) and Benzodiazepines.

There should be a six-week trial period before final purchase of the Meniett pulse generator to determine if it is effective for the individual patient. There should be a decrease in the subjective symptoms, which may be evaluated using patient diaries or visual analog scales. Return to work or return to activities of daily living are also signs that the Low Pulse Generator is helping to control the symptoms.

DESCRIPTION:

Meniere’s disease is a complex progressive disorder of the inner ear characterized by dizziness or a “spinning” sensation (rotary vertigo), hearing loss, fullness or pressure in the ear, and roaring or ringing (tinnitus) in the ear. Nausea or vomiting frequently accompanies severe attacks of vertigo. Some patients also experience headaches as part of their symptoms. Attacks can last from 20 minutes to a day or more with a recovery period often lasting from one to three days. The effect of these symptoms can be debilitating. About 80% of patients with Meniere’s disease experience the problem in one ear (unilateral), while 20% of patients have the disease in both ears.

Research has shown that by applying pressure to the inner ear the excess endolymph fluid can be reduced and thus relieve the symptoms. It is believed that the mechanism of the reduction is a combination of mechanical and chemical processes.

A system called the Meniett Low Pressure Pulse Generator delivers a complex algorithm of low-pressure pulses (a maximum of 35 cm of H2O) that are transmitted to the middle ear space and act on the round
window membrane. It is believed that the energy of the pressure pulses causes a displacement of the perilymphatic fluid which stimulates endolymphatic fluid flow resulting in a reduction of endolymphatic fluid.

This treatment requires the prior placement of a tympanostomy tube to the affected ear. This is necessary in order to transmit the pressure pulses into the middle ear where they have a positive effect. The eardrum will block the pulses from reaching through if a tube is not inserted.

The patient receives in-office training with the device. The stimulator is used to administer treatment three times a day (5 minutes each time). The treatments continue until remission. Thereafter, treatment depends on the duration and severity of symptoms.

NOTE: If conservative treatment is not effective, surgeries and other procedures are sometimes performed. A list of procedures that have been performed for Meniere’s disease include:

- ENDOLYMPHATIC SAC DECOMPRESSION,
- LABYRINTHECTOMY,
- VESTIBULAR NEURECTOMY,
- CHEMICAL LABYRINTHECTOMY (using Gentamycin or Streptomycin).

There is no cure for Meniere’s disease.

FDA APPROVAL

The Meniett 20 has received FDA approval Dec. 28, 1999 to be marketed in the U.S. as it was determined that “the device is substantially equivalent to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug and Cosmetic Act.” The predicate devices mentioned are the Tympanometer and Hyper/Hypo baric Chambers.

RATIONALE:

When conservative treatment has been tried and has failed, a patient with Meniere’s disease has few other non-surgical options. Even though the Meniett Low Pressure Pulse Generator requires an office based tympanostomy tube placement, it is less invasive than other surgical alternatives. There were no adverse effects noted in the studies reviewed. In the studies, no patient became worse while using...
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It. There were relapses if treatment was not continued and symptoms were relieved when treatment was resumed.

PRICING:

The appropriate modifiers should be used to signify whether the generator is being rented (RR) or purchased (NU).

REFERENCES:


DISCLAIMER:

State and federal law, as well as contract language, including definitions and specific inclusions/exclusions, takes precedence over Medical Policy and must be considered first in determining coverage. The member’s contract benefits in effect on the date that services are rendered must be used. Any benefits are subject to the payment of premiums for the date on which services are rendered. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically. HMO Blue Texas physicians who are contracted/affiliated with a capitated IPA/medical group must contact the IPA/medical group for information regarding HMO claims/reimbursement information and other general polices and procedures.