Medical Coverage Policy

Transtymppanic Micropressure Applications as a Treatment of Meniere's Disease

- Device/Equipment   - Drug   - Medical   - Surgery   - Test   - Other

| Effective Date: | 2/16/2010 | Policy Last Updated: | 3/5/2013 |

☐ Prospective review is recommended/required. Please check the member agreement for preauthorization guidelines.

☒ Prospective review is not required.

Description:

Transtymppanic micropressure treatment for Meniere’s disease involves use of a hand-held air pressure generator that delivers intermittent complex pressure pulses. For this device to be used, a conventional ventilation tube is surgically placed in the eardrum. Patients then place an ear-cuff in the external ear canal and treat themselves for 3 minutes, 3 times daily. Treatment is continued for as long as patients find themselves in a period of attacks of vertigo.

Meniere’s disease is an idiopathic disorder of the inner ear characterized by episodes of vertigo, fluctuating hearing loss, tinnitus, and ear pressure. The vertigo attacks are often unpredictable and incapacitating, and may prevent activities of daily living. Therapy is symptomatic in nature and does not address the underlying pathophysiology. Although the pathophysiology of Meniere’s disease is not precisely known, it is thought to be related to a disturbance in the pressure/volume relationship of the endolymph within the inner ear. Conservative therapy includes a low sodium diet and diuretics to reduce fluid accumulation (i.e., hydrops) and pharmacologic therapy to reduce vestibular symptoms. Persons who do not respond to these conservative measures may receive gentamicin drops in the ear, as a technique of chemical labyrinthectomy to ablate vestibular function on the affected side. No therapy is available to restore hearing loss.

There has been interest in developing a more physiologic approach to treatment by applying local pressure treatment to restore the underlying fluid homeostasis. Researchers have noted that symptoms of Meniere’s disease improve with fluctuations in ambient pressure, and patients with acute vertigo have been successfully treated in hypobaric chambers. It is hypothesized that the application of low-frequency, low-amplitude pressure pulse to the middle ear functions to evacuate endolymphatic fluids from the inner ear, thus relieving vertigo. In 1999, the Meniett device (Medtronic) received clearance to market through a U.S. Food and Drug Administration (FDA) 510(k) process specifically as a symptomatic treatment of Meniere's disease.

Data submitted to the U.S. Food and Drug Administration (FDA) as part of the FDA-approval process consisted of a case series of 20 patients. Other case series have also been published in the peer-reviewed literature, some reporting 2- to 4-year outcomes in patients who had failed medical therapy. (1-8) These case series are inadequate to form conclusions due to the lack of a control group.

Currently 3 randomized controlled trials of the Meniett device have been published. Results of the 2 most recent trials show a marginal improvement at short-term follow-up in some subjective outcome measures when compared with insertion of ventilation tubes and use of a sham device. Other primary and secondary outcome measures, including objective measures, were not improved. Analysis of these data...
on a per-patient level, i.e., by reporting the percent of responders who achieve a minimal clinically important difference on each outcome measure, would allow greater certainty on whether improvements with this device are clinically significant. At this time, the scientific evidence does not permit conclusions concerning the effect of this technology on health outcomes. Therefore, it is considered not medically necessary.

Medical Criteria:

Not applicable.

Policy:

Transtypmanic micropressure applications as a treatment for Meniere’s disease is considered not medically necessary due to the lack of peer-review medical literature indicating that it is effective.

Coverage:

Benefits may vary between groups/contracts. Please refer to the appropriate Evidence of Coverage, Subscriber Agreement, Benefit Booklet for applicable not medically necessary benefits/coverage.

Coding:

E2120, pulse generator system for tympanic treatment of inner ear endolymphatic fluid

Published:

Provider Update, May 2013
Provider Update, Apr 2012
Provider Update, Jun 2011
Provider Update, Apr 2010

References:


History:

January 2013 - annual review

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