BlueCross BlueShield Federal Employee Program.

FEP 1.01.23 Transtympanic Micropressure Applications as a Treatment of Meniere Disease

Effective Date: July 15, 2018

Related Policies: None

Transtympanic Micropressure Applications as a Treatment of Meniere Disease

Description

Meniere disease is an idiopathic disorder of the inner ear characterized by episodes of vertigo, fluctuating hearing loss, tinnitus, and ear pressure. Conservative therapy includes a low sodium diet and diuretics to reduce fluid accumulation (ie, hydrops) and pharmacologic therapy to reduce vestibular symptoms. Transtympanic pressure treatment has been proposed as an alternative treatment for Meniere disease. This treatment involves use of a handheld device (eg, Meniett) that delivers air pressure pulses to the ear.

FDA REGULATORY STATUS

In 1999, the Meniett® device (Medtronic Xomed, Jacksonville, FL) was cleared for marketing by the U.S. Food and Drug Administration through the 510(k) process specifically as a symptomatic treatment of Meniere disease.

POLICY STATEMENT

Transtympanic micropressure applications as a treatment of Meniere disease are considered **not medically necessary**.

POLICY GUIDELINES

Use of the Meniett device requires a prior tympanostomy procedure, a novel indication for this common procedure. Plans with specific medical necessity criteria for tympanostomy may thus be able to prospectively identify claims for the Meniett device.

BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

RATIONALE

Summary of Evidence

For individuals who have Meniere disease who receive transtympanic micropressure therapy (Meniett), the evidence includes RCTs and systematic reviews. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Six RCTs of positive pressure therapy have

been reported, with five specifically investigating the Meniett device. Systematic reviews of these 5 trials found that micropressure therapy does not result in a greater reduction in vertigo than placebo. The sixth trial also found no significant benefit of the transtympanic micropressure therapy for Meniere disease. The evidence is sufficient to determine that the technology is unlikely to improve the net health outcome.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

American Academy of Otolaryngology – Head and Neck Surgery

In 2016, the American Academy of Otolaryngology – Head and Neck Surgery updated its position statement on the use of transtympanic micropressure: "We find that there is some medical evidence to support the use of micropressure therapy (such as the Meniett device) in certain cases of Meniere disease. Micropressure therapy is best used as a second level therapy when medical treatment has failed. The device represents a largely non-surgical therapy that should be available as one of the many treatments for Meniere's disease."[16] No supporting evidence was provided.

National Institute for Health and Care Excellence

In 2012, guidance from the U.K.'s National Institute for Health and Care Excellence concluded that "[c]urrent evidence on the safety of micropressure therapy for refractory Ménière's disease is inadequate in quantity. There is some evidence of efficacy, but it is based on limited numbers of patients. Therefore this procedure should only be used with special arrangements…."[17]

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

There is no national coverage determination (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

REFERENCES

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POLICY HISTORY

Date	Action	Description
September 2012	New Policy	
December 2013	Update Policy	Policy updated with literature review, policy statement unchanged. Several references added.
December 2014	Update Policy	Policy updated with literature review, policy statement unchanged.
March 2017	Update Policy	Policy updated with literature review, policy statement unchanged.
June 2018	Update Policy	Policy updated with literature review through December 11, 2017; no references added. Policy statement unchanged.