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Australia and New Zealand Horizon Scanning Network

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National Horizon Scanning Unit
Horizon scanning prioritising summary

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Meniett™: An alternating pressure ear device for the treatment of people with Meniere's disease.

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AHTA

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PRIORITISING SUMMARY

REGISTER ID: **000109**

NAME OF TECHNOLOGY: **MENIETT™**

PURPOSE AND TARGET GROUP: **ALTERNATING PRESSURE EAR DEVICE FOR TREATMENT OF PEOPLE WITH MENIERE'S DISEASE**

STAGE OF DEVELOPMENT (IN AUSTRALIA):

☐	Yet to emerge	☐	Established
☐	Experimental	☐	Established *but* changed indication or modification of technique
☒	Investigational	☐	Should be taken out of use
☐	Nearly established		

AUSTRALIAN THERAPEUTIC GOODS ADMINISTRATION APPROVAL

☒	Yes	ARTG number	99185
☐	No	☐	Not applicable

The Meniett™ device has been available in the Australian private health system for approximately 2.5 years and is listed on the Australian Register of Therapeutic Goods. The Meniett™ received U.S Food and Drug Administration approval in January 2002.

INTERNATIONAL UTILISATION:

COUNTRY	LEVEL OF USE		
	Trials Underway or Completed	Limited Use	Widely Diffused
Australia	✓		
United States	✓		
Sweden	✓		
Italy	✓		

IMPACT SUMMARY:

Medtronic provides the Meniett™ device with the aim of treating patients with Meniere's disease.

BACKGROUND

Meniere's disease is a progressive disorder characterised by vertigo, tinnitus, pressure in the affected ear and hearing loss. The disease is characterised into separate stages that progress from attacks of nausea to vertigo of varying duration and intensity.

The cause of Meniere's disease is unknown and it is not curable. An over-accumulation of endolymph (an inner ear fluid) is associated with Meniere's (Gibson 2004).
The inner ear is comprised of two sections, one involved in balance and the other with hearing. When excessive endolymph is secreted into the inner ear the pressure of the excess fluid may disrupt the functioning of the inner ear, causing the loss of hearing and tinnitus. During the initial stages of Meniere's disease, the excess endolymph is cleared after each

episode of vertigo and the ear returns to its normal state. However, as the disease progresses, the clearance mechanism fails and the inner ear loses the ability to return to normal, causing damage.

The Meniett™ device is a portable, patient administered, low-intensity alternating pressure device for the treatment of Meniere's disease (Figure 1). Prior to use, a tympanostomy tube or grommet is inserted into the ear under local anaesthetic. The device delivers intermittent low-pressure pulses through the grommet to the middle ear space, which act on the round window membrane. As the fluids of the inner ear are not compressible, the energy of the pressure pulses stimulates endolymphatic fluid flow, resulting in a reduction of static endolymphatic fluid. Each treatment sequence lasts approximately 5 minutes and consists of three cycles. A cycle consists of 1 minute of pressure pulses and 40 seconds of pause. The manufacturer recommends that the device should be used 3 times daily until remission, and thereafter depending on the duration and severity of symptoms.

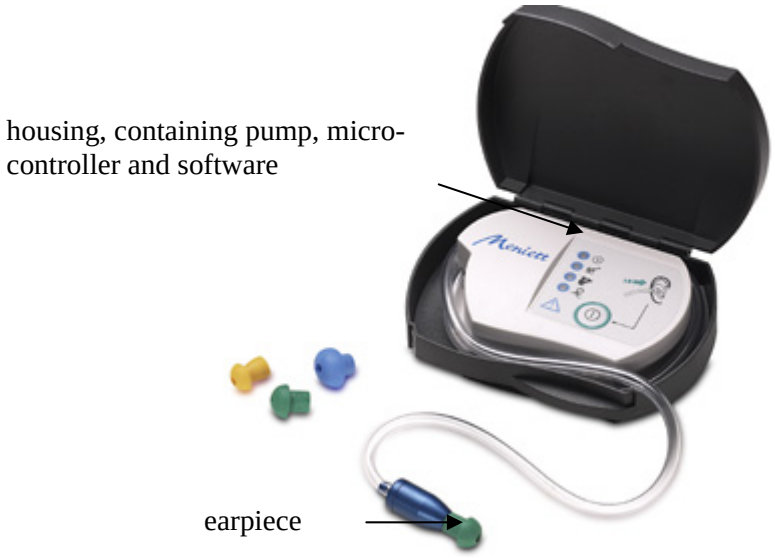

Figure 1 The Meniett™ device (Printed with permission: Medtronic XOMED 2004)

CLINICAL NEED AND BURDEN OF DISEASE

It is estimated that 1 in 1000 Australians are affected by Meniere's disease (Meniere's Resource and Information Centre, 2004). There were 885 hospital separations (code H81.0) for Meniere's disease in 2001-2, (AIHW 2004).

The disease may result in permanent hearing loss and is associated with significant deterioration in quality of life. Vertigo attacks can prevent normal daily activities such as working and driving, and in many cases may lead to chronic disability and anxiety. In approximately 30% of cases, vertigo is unresponsive to conservative medical therapy. In the remaining 70%, symptoms other than hearing loss may improve irrespective of treatment but symptoms usually return intermittently.

DIFFUSION

The Meniett™ device is currently available through private practice and is being trialled in Victoria (personal communication, Medtronic Australia). It was not possible to ascertain the type of trials being conducted with the Meniett™ in Australia. Provided there were studies demonstrating clinical effectiveness, it is believed that the Meniett™ would become widely

diffused (personal communication, Ear, Nose and Throat surgeon, Royal Victoria Eye and Ear Hospital, 2nd August, 2004).

COMPARATORS

Standard treatment options for Meniere's disease include diuretic medications, aimed at decreasing endolymph volume, and lifestyle changes, such as low sodium diet and stress management. Surgical treatment ranges from insertion of ventilation tubes, endolymph sac surgery and Vestibular Nerve Section (VNS). VNS involves cutting the balance nerve to the ear affected by Meniere's disease. This destroys the balance function in the affected ear and requires the other ear to compensate. Balance physiotherapy may be needed to assist the compensation process. VNS has a high success rate in permanently abolishing vertigo attacks in patients who are only affected by Meniere's unilaterally.

EFFECTIVENESS AND SAFETY ISSUES

Two high quality randomised controlled trials (level II evidence) suggest that the short-term use of Meniett™ significantly reduces the frequency and intensity of vertigo attacks, tinnitus and dizziness compared with placebo treatment and significantly improves hearing at frequencies between 500-1000 Hz (Odkvist et al 2000 and Gates et al 2004). Study participants in both studies had a tympanostomy tube (grommet) inserted in the affected ear two weeks prior to any treatment.

One of these studies was a four-month, multicenter trial of 67 people with established, active, unilateral Meniere's disease assigned to either treatment with the Meniett™ (n=34) or a placebo found (n=33) that the Meniett™ treatment group (self-treatment with Meniett™ device administered three times daily) experienced significantly less severe vertigo and fewer sick days from work than did the control group (Gates et al 2004).

Comparison of Proportion of Days with Definitive Vertigo and Sick Days During 4-Month Follow-up Between Groups

Outcome variable	Group	All 4 months	P value
Median proportion of days with definitive vertigo, (25^{th}-75^{th} percentile)	Control (n =32)	0.13 (0.06-0.18)	
	Treatment (n = 30)	0.07 (0.03-0.13)	.048
Median proportion of sick days, (25^{th}-75^{th} percentile)	Control (n = 32)	0.02 (0.00-0.04)	
	Treatment (n =30)	0.00 (0.00-0.01)	.02

Source: Gates et al 2004

In a 2-week prospective, multicentre randomized controlled trial, 56 patients were randomised to receive either active pressure treatment with Meniett™ (n=31) or a placebo device (n=25) (Odkvist et al, 2000). This study reported a statistically significant decrease in the frequency and intensity of vertigo, dizziness, aural pressure, tinnitus and qualitative function in professional and family life in the treatment group. Hearing significantly improved at frequencies of 500 and 1,000 Hz, by 4 dB ($p<.03$) and 5 dB ($p<.01$) respectively, following treatment with Meniett™. Symptoms in the placebo group worsened for some patients, which was not reported in the treatment group.

A two year follow-up study (level IV) of 37 patients found a significant reduction in the frequency of vertigo attacks, improved hearing and functional disability levels (Densert and Sass, 2001). This study included patients in all stages (1–4) of Meniere's disease.

	6 months before Meniett™			24 months after Meniett™		
	Stages 1 and 2 (n=9)	Stages 3 (n=18)	Stage 4 (n=10)	Stages 1and 2 (n=9)	Stages 3 (n=18)	Stages 4 (n=10)
Vertigo	2.3 (2.3) range = 0.5-8	2.6 (2.6) range = 0.3-10	3.9 (3.0) range = 0.3-8	0.3 (0.7) range = 0-2 p=0.012	0.2 (0.4) range = 0-1.7 p<.0005	0.3 (0.3) range = 0-1 p=.008
Functional Disability	5.0 (1.3) range = 3-6	4.8 (0.9) range = 3-6	4.8 (0.8) range = 4-6	2.1 (1.5) range = 1-6 p=.011	1.7 (1.1) range = 1-6 p<.0005	2.3 (1.4) range = 1-6 p=.007
Hearing levels *	26 (8.0) 17-40 dB	52 (7.6) 41-65 dB	74 (4.4) 68-81 dB	21 (11) 8-40 dB NS	46 (11) 25-62 dB p=.002	74 (10) 59-96 dB NS

All results are presented as means with standard deviations in parentheses, followed by the range
*results are presented as means of frequencies 0.5, 1, 2 and 3 kHz
NS = not significant

Studies assessing the effectiveness and safety of the Meniett™ device compared to standard treatments for Meniere's disease (eg. VNS surgery) were not available.

COST IMPACT

The Meniett™ device currently costs approximately $5000 and is currently covered by private medical insurers in Australia (personal communication, Medtronic Australia). If the use of the Meniett™ device were to reduce the number of hospitalisations and costs involved with the current surgical options to treat Meniere's disease it is likely that there would be a significant cost impact. Current fees for endolymphatic sac surgery (MBS item 41590) are $992.40 and for Vestibular Nerve Section are $1,293.55 and $1,445.65 (MBS item numbers 41593 and 41596). The cost of using the Meniett™ would also include the cost of inserting a grommet, which currently costs $198.50 per procedure (MBS item number 41632).

ETHICAL, CULTURAL OR RELIGIOUS CONSIDERATIONS

No issues were identified/raised in the sources examined.

CONCLUSION:

It appears from evidence reported by high quality studies that the Meniett™ provides short term clinical effectiveness for treatment of Meniere's, compared to placebo, suggesting a potential benefit to a large population group. In addition; the device is currently being trialled in Australia.

HEALTHPACT ACTION:

Therefore it is recommended that a Horizon Scanning report be conducted.

SOURCES OF FURTHER INFORMATION:

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Gibson B. *Meniere's Disease* [Internet] Available from: http://www.healthinsite.gov.au/content/internal/page.cfm?ObjID=0009B29B-578E-1F12-B1F083032BFA006D [Accessed 7th July 2004].

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Menieres Resource and Information Centre, 2004 [Internet] Available from: http://www.menieres.org.au/whatis.htm [Accessed 22nd July 2004)

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SEARCH CRITERIA TO BE USED:

Meniere's Disease/ diagnosis/ physiopathology
Middle Ear Ventilation/ instrumentation
Pressure
Vertigo/ etiology/ prevention & control