# [DATE]

To Whom It May Concern:

[PATIENT NAME] has been diagnosed as having Ménière's disease, a progressive and debilitating inner ear disorder characterized by recurrent spells of vertigo, tinnitus, and hearing loss. The patient was initially treated with diet, lifestyle, and medical treatment, but the symptoms have worsened to the point where it adversely affects his/her mobility and ability to perform daily routines.

Since this patient has failed medical treatment and a low-sodium diet, other treatment options have been entertained. The surgical options include an endolymphatic mastoid shunt, a selective vestibular nerve section and transtympanic gentamycin injections. All of these options are invasive and carry a significant risk of hearing loss and possibly loss of balance.

A minimally invasive option is available through the use of the Meniett Low-Pressure Pulse Generator (HCPCS code E2120). The Meniett device delivers micropressure pulses into the ear canal, which are subsequently transmitted through a tympanostomy tube into the middle ear space. The pressure is transmitted through the round window into the inner ear where it is believed to displace the excess fluid within the inner ear. In doing so, the vertigo symptoms of Ménière's disease are controlled in the majority of patients in clinical studies both in the US and internationally, see list of Clinical References enclosed.

I believe that this device would potentially control the patient's vertigo spells at a reduced risk as well as at a reduced cost, and would be in the patient's best interests. The patient would like to proceed with obtaining the Meniett device to control his/her vertigo.

Please consider coverage of the Meniett device for [PATIENT NAME] in lieu of the more invasive, costly, and potentially risky surgical options mentioned above. If additional information would prove helpful, please do not hesitate to contact me.

Sincerely,

[PHYSICIAN NAME]

Enclosure: List of Clinical References on Meniett Low-Pressure Therapy

**Clinical References on Meniett Low-Pressure Therapy**

Randomized Controlled Trials

1. Gurkov R, Filipe Mingas LB, Rader T, Louza J, Olzowy B, Krause E. Effect of transtympanic low-pressure therapy in patients with unilateral Meniere's disease unresponsive to betahistine: A randomised, placebo-controlled, double-blinded, clinical trial. J Laryngol Otol 2012;126:356-362.
2. Thomsen J, Sass K, Odkvist L, Arlinger S. Local overpressure treatment reduces vestibular symptoms in patients with Meniere's disease: A clinical, randomized, multicenter, double-blind, placebo-controlled study. Otology and Neurotology 2005;26:68-73
3. Gates GA, Green J, Tucci DL, Telian SA. The effects of transtympanic micropressure treatment in people with unilateral Meniere's disease. Arch Otolaryngol Head Neck Surg 2004;130:718-725
4. Odkvist LM, Arlinger S, Billermark E, Densert B, Lindholm S, Wallqvist J. Effects of middle ear pressure changes on clinical symptoms in patients with Meniere's disease - A clinical multicentre placebo-controlled study. Acta Oto-Laryngol Suppl 2000;99-101
5. Densert B, Densert O, Arlinger S, Sass K, Odkvist L. Immediate effects of middle ear pressure changes on the electrocochleographic recordings in patients with Meniere's disease: A clinical placebo-controlled study. AM J OTOL 1997;18:726- 733.

Other Clinical References

1. Barbara M, Monini S, Chiappini I, Filipo R. Meniett therapy may avoid vestibular neurectomy in disabling Meniere's disease. Acta Oto-Laryngol 2007;127:1136-1141.
2. Barbara M, Lazzarino AI, Biagini M, Costa M, Monini S. Influence of Meniett treatment on hearing. Acta Oto-Laryngol 2010;130:1256-1259
3. Densert B, Sass K. Control of symptoms in patients with Meniere's disease using middle ear pressure applications: Two years follow-up. Acta Oto-Laryngol 2001;121:616-621
4. Dornhoffer JL, King D. The effect of the Meniett device in patients with Meniere's disease: Long-term results. Otology and Neurotology 2008;29:868-874
5. Huang W, Liu F, Gao B, Zhou J. Clinical long-term effects of Meniett pulse generator for Meniere's disease. Acta Oto-Laryngol 2009;129:819-825.
6. Mattox DE, Reichert M. Meniett device for Meniere's disease: Use and compliance at 3 to 5 years. Otology and Neurotology 2008;29:29-32.
7. Rajan GP, Din S, Atlas MD. Long-term effects of the Meniett device in Meniere's disease: The Western Australian experience. J Laryngol Otol 2005;119:391-395.

1. Shojaku H, Watanabe Y, Mineta H et al. Long-term effects of the Meniett device in Japanese patients with Meniere's disease and delayed endolymphatic hydrops reported by the Middle Ear Pressure Treatment Research Group of Japan. Acta Oto- Laryngol 2011;131:277-283.
2. Gates GA, Verrall A, Green J, Tucci DL, Telian SA. Meniett clinical trial: Long-term follow-up. Arch Otolaryngol Head Neck Surg 2006;132:1311-1316