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Australian Chapter of the
International League Against Epilepsy

October 5th, 2008

Mr Phil Dunkley
Senior Project Manager
MSAC Projects, Health Technology & Medical Services Group
Medical Benefits Division
Federal Department of Health and Ageing
GPO Box 9848
CANBERRA ACT 2601

Dear Mr Dunkley,

RE: MSAC Application 1118 - Vagus Nerve Stimulation (VNS Therapy)
Application for CMBS procedural item numbers for VNS-related procedures by the Epilepsy Society of Australia

I write in reply to your letter of September 17th in which you referred to the ESA's MSAC application as being for "public funding for VNS therapy" and stated "there is insufficient evidence of effectiveness and net benefit of VNS therapy for patients with medically refractory epilepsy… MSAC recommending that public funding arrangements for VNS for epilepsy remain unchanged".

I find this a very disappointing response to a very long and detailed application and review process in which very clear evidence for efficacy, safety and cost-effectiveness was provided. Furthermore, our application was for **procedural item numbers for VNS insertion/changing/removal**, to be used for private inpatients during VNS surgery, and not for public funding of VNS therapy as a whole. This was clearly stated in the application and referred to in the various stages of review and response process that followed. In the April 2008 report, your office calculated a total annual cost of $422,000 based on 30 patients annually, with the bulk of this cost being for the device, the VNS device not being the subject of the application and it already being rebated by private health insurers. Your estimates of the neurological and neurosurgical procedural costs (table 51 in the April 2008 report) were negligible, less than $1,500 for procedures performed in only a small number of patients each year.

VNS therapy is approved in Australia and private health insurers currently rebate the VNS device. This application for procedural item numbers, to be used for private inpatients having VNS devices implanted or changed, was prepared and submitted on the advice of your Department following a directive in January 2005 to cease using procedural item numbers meant for other neuro-stimulating devices. The discussions and correspondence with your office were positive throughout this process and gave the impression that procedural item numbers would be forthcoming, given that their main purpose was to accurately account for VNS therapy separate to other neurostimulator procedures and the costs to the Federal Government would be negligible.

At no time was the ESA or our colleagues under the impression that the Federal Department of Health and Aging would provide funding for VNS devices and procedures for public patients, that being an issue for practitioners to take up with their individual public

hospitals and their state health funding authorities. Arrangements for public funding are in place in many Australian centres and it was hoped that MSAC provision of procedural item numbers for VNS, along with current TGA approval of VNS therapy, the private health insurance coverage for VNS, and the abundant medical literature on VNS, would strengthen the applications for more public funding as needed.

I hope this application was not incorrectly represented to the Minister in the last phase as a plea for public funding when the sole intention was to allow patients with private health insurance to have VNS therapy, the health insurer picking up the considerable cost of the device and most of the associated procedural and hospital costs.

The ESA is extremely disappointed that this process which we were instructed to undertake, done without industry and AMA lobbying as it seemed to simply be a formality, has not led to the expected outcome, particularly given the formidable evidence supporting VNS and the negligible financial impact of the treatment. This outcome will mean that some health insurers will no longer cover the procedure and device for private patients (resulting in a $20-30,000 charge to their patients), that some surgeons will go back to using inappropriate CMBS item numbers to perform VNS procedures in private patients, that some private patients will now join the queue for limited publicly-funded VNS, and most unfortunately, that some people with severe uncontrolled epilepsy will be denied a proven and effective treatment.

I would very much appreciate the opportunity to speak with you and seek clarification of this decision which, to my reading, misrepresents the application in terms of the available evidence and the intended purpose.

Yours Sincerely

Dr Simon Harvey
President
Epilepsy Society of Australia

cc:
ESA Committee
Professor Stephen Davis, President, Australian & New Zealand Association of Neurologists
Mr Eric Guazzo, President, Neurosurgical Society of Australasia
Mr Glen Moore, Managing Director, Aurora Bioscience, PO Box 946, Baulkham Hills NSW 2153
Ms Jacinta Cummins, Convener, Parliamentary Friends of Epilepsy, Joint Epilepsy Council of Australia
Ms Carol Ireland, CEO, Epilepsy Action