National Institute for Health and Care Excellence

IP891/2 Percutaneous venoplasty for chronic cerebrospinal venous insufficiency in Multiple Sclerosis

IPAC date: 8 November 2018

Com. no.	Consultee name and organisation	Sec. no.	Comments	Response Please respond to all comments
1	Consultee 1 Patient organisation	**General**	Thank you for the information. The only comment I can make is that I regret that NICE is not willing to investigate further the possibility that treating CCSVI with Percutaneous Venoplasty which is a fairly innocuous treatment and has been shown to help about 30% of people who have payed to have the treatment done. Your sincerely, [redacted]	Thank you for your comment. In their deliberations, the Interventional Procedures Advisory Committee considered data from peer-reviewed published sources that reported safety and efficacy outcomes for patients who had percutaneous venoplasty for chronic cerebrospinal venous insufficiency in multiple sclerosis. The committee concluded that this evidence showed there are serious complications and that the procedure provides no benefit.
2	Consultee 2 MS Society	**1**	The MS Society agree with the provisional recommendations that this procedure should not be used to treat MS.	Thank you for your comments. The consultee agrees with the main recommendation.

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3	Consultee 3 Patient	**General**	While a specific cause for MS is not known there is an ever widening body of evidence regarding factors contributing to its prevalence and progression. A common denominator relates to their collective influence on endothelial (vascular) health. Such factors (individually or in collaboration) include Sunshine, Distance from Equator, Ultra Violet (UV) exposure, Nitric oxide, Vitamin D, Nutrition, Exercise and other Blood Flow/blood vessel related irregularities/inflammation (genetic or acquired). Also referenced is the latest news from the Australian CCSVI Reference Group that evidences the role of disturbed blood flow in the development of many MS disabilities. Highlighted are serious concerns regarding barriers contributing to the ability of vulnerable consumers to readily access independent and unbiased medical guidance and information on this topic.	Thank you for your comment.

4	Consultee 4 Patient	**General**	[redacted] Interventional Procedures Programme Centre for Health Technology Evaluation National Institute for Health and Care Excellence 10 Spring Gardens, London, SW1A 2BU Dear Sirs/Madams 16 October 2018 **[IP891/2] Percutaneous venoplasty for chronic cerebrospinal venous insufficiency in Multiple Sclerosis - NICE Consultation** Regarding the above consultation, I have an MS diagnosis and I would like you to take account of the following matters in your review. See imaging of my vascular conditions including spinal venous aneurysms and a DAVF. (Appendix A) **MS has an underlying venous pathology.** Please read and share the following with particular regard to the work of **Dr Franz Schelling**. Intracranial MS lesions erupt from the lateral ventricles of the brain. **We need neurosurgeons with neuroendovascular experience to work alongside Interventional Radiologists.** https://www.dropbox.com/s/m0yvgmufgfcys1v/MRI%20IN%20MS%20-%20VASCULAR%20PATHOLOGY%20.pdf?dl=0 **Neurology is 'captured' by the pharmaceutical industry.** Please read **Professor George Ebers' whistleblowing letter to the European Medicines Agency (EMA)** regarding corruption in clinical MS drug trials by 'opinion leader' neurologists whose professorships and academic advancement rely on pliability rather than intellect. ***'The key dealbreaker for industry ie being willing to speak up for the truth - is selected against.'*** https://www.dropbox.com/s/xpe57yvz1zdgcga/Ebers%20submission%20to%20EMA%20FINAL%2009%2009%202013.pdf?dl=0 Professor Ebers' presentation to the EMA and 'disturbing' scene from Matt Embry's film 'Living Proof': https://www.youtube.com/watch?v=OqY-_K1fYJY https://www.youtube.com/watch?v=i0m_isndqc0&app=desktop	Thank you for your comment. In their deliberations, the Interventional Procedures Advisory Committee considered data from peer-reviewed published sources that reported safety and efficacy outcomes for patients who had percutaneous venoplasty for chronic cerebrospinal venous insufficiency in multiple sclerosis. This included a recent randomised controlled trial from Zamboni et al. (study 1 in table 2 of the overview). NICE staff, contractors and committee members declare any potential interests, and do not take part in discussions in which they have a conflict of interests (for example, because they are doing consultancy work for another organisation). Declarations of interest by Specialist Advisers advising the NICE Interventional Procedures Advisory Committee are included in the specialist advice questionnaires, which are available on the NICE website.

			Page "1 of "9 **The Association of British Neurologists does nothing to hide its valued MS 'industry partners'** for whom the vascular pathology of MS must be suppressed and all discussion of CCSVI denied. (Appendix B, E) **So called MS 'charities' act as a marketing and PR arm of the MS drugs industry.** At a consultation meeting for IPG 420 did [redacted] disclose his MS drug conflicts of interest whilst denying the specific vascular anatomy of MS? His department has also received a $6 million 'gift' from Genzyme (Alemtuzumab, Lemtrada). (Appendix C, F). See Credit Suisse note on how Novartis should leverage its sales force to **recruit and exploit neurologists** for its Gilenya launch. (Appendix C) **https://www.dropbox.com/s/jwghwzecgufecic/Drugs%20Exploitation%20in** %20Multiple%20Sclerosis%2C%20Open%20Letter%20to%20MS %20Society.pdf?dl=0 The **MS Society** proclaimed Aubagio, (Teriflunomide), as 'good' for us despite a pitiful 19% of data having been published. See Table 1. (Appendix D) Ethical? **https://bmjopen.bmj.com/content/5/11/e009758.full** At ECTRIMS 2014 **Credit Suisse prepared 'Key Session' Notes for** **investment fund managers** who were meeting there**.** Such is the value of the MS patient population, currently around $22 billion a year, **investors** were given lists of neurologists 'to follow'. **Note the UK neurologists Coles and Giovannoni at AAN 2014.** (Appendix D) Giovannoni's blog about CCSVI at ECTRIMS 2014 made no mention of Dr Paulo Zamboni's work with NASA or 7 Tesla MRI evidence of the venous pathology of MS. (Appendix E). Credit Suisse weren't interested either, presumably they'd rather shift 'product' - Lemtrada (Alemtuzumab) and relaunch Cladribine? If I was investing I'd like to know that (non MS) nurses are noticing the numbers of MS patients experiencing total health collapses following MS drug 'infusions'.	

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			Maybe they'll learn to use the Yellow Card Scheme and be brave enough to report the abuse heaped on us. As Professor Ebers writes about medical journals reporting MS drug trials - ***'What has happened has been very much like taking your favourite pet to the veterinarian and discovering he (the vet) moonlights as a taxidermist.'*** Sounds exactly like a hospital appointment with an MS industry neurologist. In reviewing IP891/2 ***PLEASE*** understand the venous anatomy of MS, the total lack of medical ethics in current MS standards of care, be aware of neurologists' Page "2 of "9 industry conflicts and as **vascular doctors *PLEASE keep fighting for us***. Thank you.	

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5	Consultee 5 Specialist Society Association of British Neurologists	**1.1**	Percutaneous venoplasty for chronic cerebrospinal venous insufficiency is an ineffective procedure for the treatment of multiple sclerosis. The Association of British Neurologists recommends that it is not approved for use by NICE. Since this procedure was first proposed by Zamboni et al. (J Vasc Surg 2009;50:1348-58), there have been no studies which have proven its efficacy. A Cochrane review in 2012 found no studies of sufficient methodological quality. Zamboni et al. (JAMA Neurology 2018;75:35-43) have recently published results of a randomised controlled trial which showed the procedure to be ineffective, and concluded that the treatment cannot be recommended in patients with multiple sclerosis. The Pan-Canadian Interventional Clinical Trial for CCSVI in Multiple Sclerosis has also preliminarily reported results of a randomised controlled trial which showed the procedure to be ineffective. It has an associated morbidity with complications reported in up to 17.3% of cases (Sadovnick et al. Can J Neurol Sci 2017;44:246-54). Its use in the treatment of multiple sclerosis should not be recommended.	Thank you for your comment. The consultee agrees with the main recommendation. The studies by Zamboni et al. (2018) and Sadovnick et al. (2017) are included in table 2 of the overview.

6	Consultee 6 Patient	**General**	Dear NICE, In my head I had down the final date was the end of the month – my mistake. I’ve missed the correct comment date but I hope this letter could be added. I’d like to have my comments considered before final decisions are made on the upcoming percutaneous venoplasty by NICE/NHS. NICE came into existence in the mid/late 1990s to help make the prescribing of MS drugs more fair and be less of a ‘postcode lottery’. These same drugs have no effect on the length of time of progression to 2ary progressive MS. Science and medicine need to be open to new information, I believe. I went in 2012 to the US to explore whether the effects of ccsvi were an issue for me. I’d been scanned in Scotland the year before but the result was inconclusive. It seemed there may not have been enough experience in the operator to say whether CCSVI was or wasn’t an issue in my case. I choose to believe the procedure has had a beneficial effect and contributed to my body working better in the heat which has resulted in fewer brain blanks. My brain overheating and shutting down like a computer doeswhen the fan gets blocked every now and then is unsettling for me but I don’t handle machinery or drive for a living so no one is going to die if something doesn’t happen to stop my brain overheating more often. I hope effects like this will be taken into account and there won’t just be a reliance on immediately measureable effects. A handful of centres globally are also looking into how else MS patients can be better served by their healthcare systems. I believe people with MS have been poorly served so far especially when the men who gave the condition a name noticed in post mortem brain matter there was a vein running through all evidence of scarring. With our stupendous advances in brain imaging technology since the 1850s I was really hoping to see this technology being used to good effect on ms patients.	Thank you for your comment. The Committee welcomes hearing from patients who have undergone this procedure and considered your experience and views in their deliberations.

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			I hope that your investigation into venoplasty is a happy move onwards from the original research in the 1850s. Thank you very much for looking into this issue as there really does seem to have been an effect (5 years on I'd like the various veins leaving my brain to be looked at again but can't afford to go overseas for further investigation. Thanks again for your time Best wishes [redacted]	

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