

## **NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE**

### **Interventional procedures**

#### **Patient Organisation Submission**

##### **Percutaneous venoplasty for chronic cerebrospinal venous insufficiency for multiple sclerosis IP891/2**

Thank you for agreeing to give us your views on this procedure or operation and how it could be used in the NHS.

When we are developing interventional procedures guidance we are looking at how well a procedure or operation works and how safe it is for patients to have.

Patient and carer organisations can provide a unique perspective on conditions and their treatment that is not typically available from other sources. We are interested in hearing about:

- the experience of having the condition or caring for someone with the condition
- the experience of having the procedure or operation
- the outcomes of the procedure or operation that are important to patients or carers (which might differ from those measured in clinical studies, and including health-related quality of life)
- the impact of the procedure or operation on patients and carers. (What are the benefits to patients and their families, how does it affect quality of life, and what are the side effects after the procedure or operation.)
- the expectations about the risks and benefits of the procedure or operation.

To help you give your views, we have provided this template. You do not have to answer every question — they are there as prompts. The text boxes will expand as you type, the length of your response should not normally exceed 10 pages.

**Please note, all submissions will be published on the NICE website alongside all evidence the committee reviewed. Identifiable information will be redacted.**

<b>About you</b>	
1. Your name	
2. Name of organisation	Multiple Sclerosis Trust
3. Job title or position	
4. Brief description of the organisation (e.g. who funds the organisation? How many members does the organisation have?)	<p>The MS Trust is a UK-based charity which works with and for over 40,000 people affected by MS; that's people with MS, their families, friends and the health care professionals who help manage MS. We provide trusted information to help people with MS live the best life possible; train and educate MS health professionals to offer the best care and fund MS nurses in the areas of greatest need.</p> <p>Our information is free so we rely on donations, fundraising and gifts in wills to fund our services.</p>
<p>5. How did you gather the information about the experiences of patients and carers to help your submission?</p> <p>(For example, information may have been gathered from one to one discussions with colleagues, patients or carers, telephone helplines, focus groups, online forums, published or unpublished research or user-perspective literature.)</p> <p>Information provided in this submission is based on knowledge gained from published research and discussions with colleagues and clinicians.</p>	

**Living with the condition**

6. What is it like to live with the condition or what do carers experience when caring for someone with the condition?

Not completed for this response – the description of MS in the current version of IPG420 is sufficient.

**Advantages of the procedure or operation**

7. What do patients (or carers) think the advantages of the procedure or operation are?

Since the initial NICE guidance was published in 2012, there has been further research into the occurrence of vein abnormalities and two double-blind clinical trials of venous angioplasty for CCSVI.

While there remains a small number of people with MS who continue to defend the treatment, the vast majority have accepted that the underlying theory and treatment for CCSVI have been disproved by well-conducted, independent clinical research.

Some researchers have shown an association between vein abnormalities and MS, while others have not. Overall, research suggests there is no association between CCSVI and MS. Discrepancies in results may be attributed to inconsistencies in imaging techniques, training of personnel, the interpretation of results, and even on the hydration status of people undergoing testing.

The proposed treatment for CCSVI, sometimes referred to as “liberation therapy” involves opening blocked or narrowed veins by inflating a small balloon or inserting a stent to allow for better blood flow and improve drainage of blood from the brain.

A double-blind, sham-controlled Italian study lead by Dr Zamboni (the original proponent of this theory) found that venous angioplasty was safe but largely ineffective; the technique was not recommended in people with MS<sup>1</sup>.

A second clinical trial has been completed, but the detailed results have not yet been published in a peer-reviewed medical journal. On March 8 2017, preliminary results were presented at the Society for Interventional Radiology meeting in Washington, DC. Participants were randomly allocated to receive either venoplasty (49 people) or a sham operation (55 people) and were monitored for 48 weeks. Participants were then "crossed-over" to receive the opposite treatment and followed for a further 48 weeks. At 48 weeks there were no statistical differences between the two groups in terms of MRI measures, neurologist assessment of MS symptoms or participant self-assessments. The researchers concluded that venoplasty is ineffective as a treatment for MS<sup>2</sup>.

A follow-up of people who had been treated with venous angioplasty found that initial perceptions of the positive impact of surgery on the health condition of people with MS was not sustained over time. In addition, venoplasty was not without associated morbidity<sup>3</sup>.

**Disadvantages of the procedure or operation**

8. What do patients (or carers) think the disadvantages of the procedure or operation are?

<b>Patient population</b>
9. Are there any groups of patients who might benefit either more or less from the procedure or operation than others? If so, please describe them and explain why.  None, to the best of our knowledge.
<b>Equality</b>
10. Are there any potential <a href="#">equality issues</a> that should be taken into account when considering this topic?  None
<b>Other issues</b>
11. Are there any other issues that you would like the Committee to consider?  None
<b>Key messages</b>
12. In no more than 5 bullet points, please summarise the key messages of your submission.  1. Studies have failed to show a consistent or higher incidence of venous abnormalities with multiple sclerosis 2. Two clinical trials to treat venous abnormalities have not shown improvements in MS 3. Follow-up of people who had received this intervention found that initial perceptions of improved health were not sustained over time. 4.

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<sup>1</sup> Zamboni P, et al. Efficacy and safety of extracranial vein angioplasty in multiple sclerosis: a randomized clinical trial. JAMA Neurol. 2018 Jan 1;75(1):35-43.  
<https://www.ncbi.nlm.nih.gov/pubmed/29150995>

<sup>2</sup> University of British Columbia press release. Controversial treatment for MS found to be ineffective.  
<http://www.med.ubc.ca/controversial-liberation-therapy-fails-to-treat-multiple-sclerosis-ubc-researchers-find/>

<sup>3</sup> Sadvnick AD, et al. Patient-reported benefits of extracranial venous therapy: British Columbia CCSVI registry. Can J Neurol Sci. 2017 May;44(3):246-254.  
<https://www.ncbi.nlm.nih.gov/pubmed/28270250>

Thank you for your time.

Please return your completed submission to [ip@nice.org.uk](mailto:ip@nice.org.uk)