

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.

About you	
1. Your name	
2. Name of organisation	MS Society
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>We're the MS Society. Our community is here for people with MS through the highs, lows and everything in between. We understand what life's like with MS. Together, we are strong enough to stop MS.</p> <p>We have over 32,000 members and the vast majority of our income comes from voluntary donations and legacies.</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>While we have engaged with people with MS in the past on this procedure, due to the lack of evidence to support its use we have not sought to engage with people for this interventional procedure update.</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?

MS is one of the most common disabling neurological conditions affecting young adults. Around 100,000 people in the UK have MS, 93,000 of whom live in England and Wales, and 5000 people are newly diagnosed each year.¹ MS attacks at random with many of the symptoms invisible to others. It affects almost three times as many women as men with people usually experiencing their first symptoms in their 20s or 30s. Although much progress has been made in developing disease modifying treatments (DMTs), these are not curative and even the most effective carry significant risks for people with MS.

Living with a chronic, disabling and degenerative condition such as MS is hard. It is also expensive. There are often substantial extra costs, such as accessible transport, specialist equipment, medication and help with household activities – a neurological condition like MS can cost, on average, an additional £200 a week².

Around 85% of people with MS are first diagnosed with relapsing MS. A relapse is defined as an episode of neurological symptoms, which lasts for at least 24 hours and occurs at least 30 days after the onset of any previous episode. In relapses, symptoms usually come on over a short period of time but often remain for a number of weeks – usually three to four – and can sometimes last for months.

Our understanding of how MS attacks the body is changing. MS specialists used to think that once a relapse was over, the damage to the brain and spinal cord stops and no new damage was happening. However we now understand that even when people with MS are not having relapses, their MS can still cause damage and neurodegeneration.³ This damage can be happening from onset and even if there are no clinical signs of MS, such as a relapse. As a result early treatment with a DMT is now considered to be the best method of slowing the disability progression by preventing unnecessary neurodegeneration.

People with MS can experience a wide range of distressing and debilitating symptoms from fatigue to visual impairment, mobility problems to cognitive problems. Relapses can vary from mild to severe, with 95% of people with MS feeling relapses left them unable to do the things they wanted to do.⁴ At their worst, acute relapses may need hospital treatment, but many relapses are managed at home, with the support of a GP, MS specialist nurse and other healthcare professionals. Around half of all relapses can leave a range of residual problems. New evidence has highlighted that disability also progresses regardless of whether a person experiences relapses regularly.⁵ These are further important reasons to reduce the frequency and severity of relapses through ensuring that those who are eligible find the best treatment for them as soon as possible.

Due to the varied and unpredictable nature of MS, determining an 'average' relapse rate is not straight forward. Relapses can have a resonating emotional impact on a person. The loss of independence that can often come with a relapse mean that people can often feel a burden on their family (93%). Relapses are often unpredictable and distressing, leaving most people feeling frustrated (80%) and anxious (67%) and causing a disruption to everyday life.⁶

The majority of people with MS experience a progression of disability over the course of the condition. It is estimated that approximately 65% of people with relapsing MS will eventually go on to develop secondary progressive MS 15 years after being diagnosed and 10-15% are affected by primary progressive MS. Progressive forms of MS are characterised by a sustained accumulation of disability independent of relapses. This progression occurs at varying rates and can lead to a worsening of symptoms resulting in a permanent loss of mobility and the need to use a wheelchair, cognitive damage and permanent sight loss. There is also a real risk of accumulating disability for those with relapsing MS who are refractory to first line treatment.

Tackling disability progression is a major issue for people with MS and there are currently insufficient treatment options for slowing progression. Our Research Strategy (2013-17) highlights research into progression as a major priority for the MS Society going forward. The strategy was formed in consultation with people affected by MS and the MS research community. It was approved by our Board of Trustees - the majority of whom are people affected by MS. Proving DMTs slow disability progression is notoriously difficult; but without at all minimising the difficulty of living with relapses, a product that has shown significant benefit over existing treatments (where benefit is less certain) here would be greatly valued by people affected by MS. The potential to maintain function and have a greater quality of life is of critical importance, especially for a chronic, long-term and potentially debilitating condition such as MS that so often evolves from relapsing remitting MS to the secondary progressive phase.

People with MS live with great uncertainty, not knowing from one day to the next whether they will be able to move, to see or to live even a remotely normal life. As each person's response to DMTs is different the more effective

¹ MS Society estimate based on 2010 incidence and prevalence rates (Mackenzie et al. 2013) adjusted for accuracy based on the assumption that 82% of cases from this study can be validated (estimate based on Alonso et al. 2007). These adjusted rates have been applied to 2014 population estimates (Office of National Statistics)

²Extra Costs Commission, Driving down the costs disabled people face : Final report, June 2015, pp. 13

³ [Giovanni et al, 'Brain health: Time Matters in Multiple Sclerosis', 2015](#)

⁴ MS Society's 'Perspectives of people with MS on relapses and disease modifying drugs', 2010.

⁵ [Giovanni et al, 'Brain health: Time Matters in Multiple Sclerosis', 2015](#)

⁶ MS Society's 'Perspectives of people with MS on relapses and disease modifying drugs', 2010.

options available on the NHS will result in more people finding a treatment which best suits them.

Impact on Carers

The progressive, fluctuating nature of MS presents particular challenges to families and carers. It can make balancing work, education and taking care of one's own health and wellbeing difficult.

15% of people with MS consider a family member or carer their main contact for health care support⁷. Our research also shows that 85% of people with MS who need care and support receive unpaid care, support or assistance from a friend or family member. This has increased from 71% in 2013, suggesting carers are taking on more of a role supporting people with MS relative to the state or paid support. In addition, 36% of people who need support told us they rely solely on unpaid care (2016). Based on the latest prevalence data and our research, there could be more than 54,000 people with MS in England who need care and support, indicating there are tens of thousands of carers supporting them.

Carers support people with MS with a wide variety of essential activities. Our research found 63% of people with MS who need support require help carrying out essential activities of daily living such as getting up in the morning, washing and eating. We found that severity of needs increase with age, as the disease progresses. Treatment's that slow the progression of disability therefore not only benefit the person with MS, but impact on their carer too.

But too many carers tell us they don't get the support they need to continue caring, from respite care to social care for the person they care for, financial support and emotion support.

Carers also often act as care coordinators for the person they support, overseeing complex treatment regimens and navigating disjointed health, care and welfare systems. In our survey of over 11,000 people with MS last year, 15% of respondents said a carer or member of their family was their key contact for health care and support. One carer described just how complex this support network can be: "*Between the nurse, the speech and language therapist, the neurologist and various other specialists, there is roughly a team of twenty involved in my wife's care. She relies on me as a part of this team and to co-ordinate them. It's becomes a big 'project' to manage*".

⁷ Redfern-Tofts, D., Wallace, L. and McDougal, A. (2016) My MS, My Needs 2: technical report

Advantages of the procedure or operation

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

A link between CCSVI and MS was first suggested in 2009, but this has since been challenged. Trials of treatments for CCSVI found that it did not reduce MS symptoms or damage on MRI but might worsen relapses and activity on MRI scans.

Since 2009 a number of large studies have investigated the link between CCSVI and MS. This includes seven projects funded by the National Society in the US and the MS Society of Canada, and a large Italian study. No evidence of a link between CCSVI and MS has been established within these studies, nor that procedures proposed to treat CCSVI have had any beneficial effects.

All of these studies involved large numbers of people with and without MS, and used many different techniques to look for CCSVI.

None of these large studies have found a link between CCSVI and MS.

Disadvantages of the procedure or operation

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

- Developing clots in the vein
- Arrhythmias (disruptions to the heart beat and rhythm)
- Vein dissection (separation of the vein)
- In-stent thrombosis (bleeding at the site of the stent placement)
- Vein rupture
- Groin hematoma (collection of blood outside the blood vessel).

In May 2012 the US Food and Drug Administration (FDA) issued a safety warning for liberation therapy.

Patient population
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.
Equality
10. Are there any potential equality issues that should be taken into account when considering this topic?
Other issues
11. Are there any other issues that you would like the Committee to consider?
Key messages
12. In no more than 5 bullet points, please summarise the key messages of your submission. <ol style="list-style-type: none">1. Percutaneous venoplasty for chronic cerebrospinal venous insufficiency in MS is an unproven treatment2. This procedure carries a number of potential side effects3.4.5.

Thank you for your time.

Please return your completed submission to ip@nice.org.uk