The following Protocol contains medical necessity criteria that apply for this service. It is applicable to Medicare Advantage products unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Preauthorization is not required but is recommended if, despite this Protocol position, you feel this service is medically necessary. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.

Description

Chronic cerebrospinal venous insufficiency (CCSVI) may be associated with multiple sclerosis (MS), although this is controversial and an active area of research. Correction of CCSVI has been attempted via percutaneous venoplasty. The intent of this procedure is to relieve MS symptoms by improving venous drainage of the central nervous system. Correction of CCSVI by this method may be referred to as the “Liberation Procedure.”

Background

Multiple sclerosis (MS) is generally considered a chronic inflammatory demyelinating disease of the central nervous system (brain, spinal cord, optic nerve) felt to be triggered by an autoimmune response to myelin. However, in part due to the periventricular predilection of the lesions of multiple sclerosis, vascular etiologies (chronic cerebrospinal venous insufficiency [CCSVI]) have also been considered. An animal model for MS was developed by injecting obstructing agents into the venous sinuses. This etiology and treatment approach for MS had not been actively pursued for many years; recent reports by a European researcher have renewed interest in this topic.

The core foundation of this vascular theory is that there is abnormal venous drainage from the brain due to outflow obstruction in the draining jugular vein and/or azygos veins. This abnormal venous drainage, which is characterized by special ultrasound criteria, is said to cause intracerebral flow disturbance or outflow problems that lead to periventricular deposits. In the CCSVI theory, these deposits have a similarity to the iron deposits seen around the veins in the legs of patients with chronic deep vein thrombosis. Those studying this theory have promoted balloon dilatation, with or without stenting, to treat the outflow problems, thereby curing CCSVI and by the same token alleviating MS complaints.

The following five criteria were defined by Zamboni et al as features of CCSVI. In order to make the diagnosis of CCSVI, at least two of the five criteria need to be present:

1. Reflux constantly present (for a duration > 0.8 s) in the supine and upright positions at the level of an internal jugular or vertebral vein. This parameter was evaluated during a short breath-hold following normal breathing and not under Valsalva maneuver.
2. Reflux at the level of veins of the deep cerebral system (for a duration > 0.5 s). This was evaluated with the patient in the sitting and supine positions, and venous flow was enhanced by inviting the patient to breath in.
3. Stenosis (< 0.3 cm), valve abnormalities and septa on B-mode imaging.
4. Absence of flow at the level of the internal jugular or vertebral vein despite numerous deep inspirations.
5. No increase in the diameter of the internal jugular vein when changing from an upright to a supine position (lack of ∆-).

**Policy (Formerly Corporate Medical Guideline)**

The identification and subsequent treatment of chronic cerebrospinal venous insufficiency (CCSVI) in patients with multiple sclerosis is considered **investigational**.

Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this Protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

**References**

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.


