OVERVIEW
This policy documents coverage guidelines for posterior tibial nerve stimulation (PTNS) affecting nerves and sensation as a treatment for urinary dysfunction

PRIOR AUTHORIZATION
BlueCHiP for Medicare: Required
Commercial products: Not applicable.

POLICY STATEMENT
BlueCHiP for Medicare:
PTNS for voiding dysfunctions, including but not limited to urinary frequency, urgency, incontinence and non-obstructive retention is covered when the criteria is met. The standard treatment regimen for PTNS is 30-minute weekly sessions for 12 weeks once per lifetime.

Note: Medicare policy is developed separately from BCBSRI policy. Medicare policy incorporates consideration of governmental regulations from CMS (Centers for Medicare and Medicaid Services), such as national coverage determinations or local coverage determinations. In addition to benefit differences, CMS may reach different conclusions regarding the scientific evidence than does BCBSRI. Medicare and BCBSRI policies may differ. However, BlueCHiP for Medicare members must be offered, at least, the same services as Medicare offers.

Commercial Products:
PTNS for voiding dysfunctions, including but not limited to urinary frequency, urgency, incontinence and non-obstructive retention **is not medically necessary** as there is insufficient, long-term, peer reviewed scientific literature, including randomized controlled clinical trials to demonstrate its efficacy and to support its use.

MEDICAL CRITERIA

BlueCHiP for Medicare
PTNS will be covered for overactive bladder (OAB) symptoms for patients who are:
- Either, resistance or intolerant to standard anticholinergic/antispasmodics drug therapy (i.e., failed treatment with two anticholinergic drugs, each taken for at least 4 weeks duration, prior to the PTNS therapy initiation).

Contraindications to PTNS include any of the following:
- A cardiac pacemaker,
- An implantable defibrillator,
- Whether the patient is prone to excessive bleeding, if the patient has nerve damage that could impact either percutaneous tibial nerve or pelvic floor function or whether the
patient is pregnant or planning to become pregnant during the duration of PTNS treatment.

BACKGROUND

Posterior tibial nerve stimulation (PTNS) is a technique of electrical neuromodulation (affecting nerves and sensation) for the treatment of voiding dysfunction in patients who have failed behavioral and/or pharmacologic therapies. Voiding dysfunction includes urinary frequency, urgency, incontinence, and non-obstructive retention. Common causes of these conditions are pelvic floor dysfunction, inflammation, medications like diuretics and anticholinergics, obesity, psychologically based disorders, and diseases (for example, Multiple Sclerosis (MS), spinal cord injury, diabetes with peripheral nerve involvement, detrusor hyperreflexia). Altering the function of the posterior tibial nerve with PTNS is believed to improve voiding function and control. While the posterior tibial nerve is located near the ankle, it originates from the lumbar-sacral nerves (L4-S3), which control the bladder detrusor and perineal floor.

The procedure for PTNS includes the insertion of a needle above the medial malleolus into the posterior tibial nerve followed by the use of low voltage electrical stimulation that produces sensory and motor responses. Noninvasive PTNS has also been delivered with surface electrodes. PTNS is typically 30-minute sessions given weekly for 10–12 weeks. Consideration has been given to increasing the number of treatments to 3 times per week to speed up the success of the desired outcome. However, an optimal treatment approach has not been identified in the literature, and long-range use and efficacy of PTNS is uncertain.

A number of multicenter, randomized, controlled studies have been published comparing PTNS to both pharmacologic treatment (1-2), and sham treatment (3-4). In the former, PTNS appeared to be safe with statistically significant improvements in patient assessment of overactive bladder symptoms and with objective effectiveness comparable to that of pharmacotherapy. However, the double-blinded sham studies were particularly important in order to control for placebo effect. These studies showed statistically significant improvements in patient assessment of overactive bladder (OAB) symptoms (frequency, nocturia, urgency and urge incontinence) with PTNS compared to sham (54.5-71% vs. 0-20.9%). Medicare covers PTNS according to the medical criteria below.

For BCBSRI commercial members, the evidence is insufficient to permit conclusions concerning the effect of this technology on health outcomes. Randomized trials with appropriate control groups are needed to determine the durability and short- and long-term effects of PTNS on voiding dysfunction. In addition, further randomized trials are needed to determine appropriate maintenance therapy.

COVERAGE

Benefits may vary between groups/contracts. Please refer to the appropriate Evidence of Coverage, Subscriber Agreement for applicable Services Not Medically Necessary coverage.

CODING

The following CPT code is covered with prior authorization for BlueCHiP for Medicare and not medically necessary for Commercial products:

64566
RELATED POLICIES
None

PUBLISHED
- Provider Update  Nov 2013
- Provider Update  Jul 2012
- Provider Update  Jan 2012
- Provider Update  Oct 2010
- Provider Update  Sep 2009
- Provider Update  Jun 2008
- Policy Update    Aug 2007

REFERENCES

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