TITLE: PERCUTANEOUS TIBIAL NERVE STIMULATION

EFFECTIVE DATE: March 1, 2017

This policy was developed with input from specialists in urology and endorsed by the Medical Policy Committee.

IMPORTANT INFORMATION – PLEASE READ BEFORE USING THIS POLICY

These services may or may not be covered by all Medica plans. Please refer to the member’s plan document for specific coverage information. If there is a difference between this general information and the member’s plan document, the member’s plan document will be used to determine coverage. With respect to Medicare and Minnesota Health Care Programs, this policy will apply unless those programs require different coverage. Members may contact Medica Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions about this Medica utilization management policy may call the Medica Provider Service Center toll-free at 1-800-458-5512.

Medica utilization management policies are not medical advice. Members should consult with appropriate health care providers to obtain needed medical advice, care and treatment.

PURPOSE

To promote consistency between reviewers in utilization management decision-making by providing the criteria that generally determine the medical necessity of posterior tibial nerve stimulation for overactive bladder. The Coverage Issues box below outlines the process for addressing the needs of individuals who do not meet these criteria.

BACKGROUND

I. Definitions

A. Behavioral therapies are designated as first-line treatments because they are as effective in reducing symptom levels as are anti-muscarinic medications and they consist of many components that can be tailored to address the individual patient’s needs and capacities. In addition, they are relatively non-invasive and, in contrast to medications, are associated with virtually no adverse events. Components of conservative behavioral therapies may include the following modalities:
   1. Pelvic floor muscle therapy, including kegel exercises with biofeedback and vaginal weight training
   2. Bladder training programs, such as challenged voiding, timed/promoted interval voiding, and urge suppression techniques
   3. Fluid and dietary modification, such as scheduled fluid intake, eliminating or limiting caffeine and alcohol intake, no use of smoking or tobacco products and increasing high fiber foods.

B. Overactive bladder (OAB) is the presence of urinary urgency, usually accompanied by frequency and nocturia, with or without urinary urge incontinence, in the absence of UTI or other obvious pathology.
   1. Nocturia is the complaint of interruption of sleep one or more times because of the need to void.
   2. Urinary frequency is the need to urinate eight or more times in a 24 hour period. Urinary frequency can be reliably measured with a voiding diary. Traditionally, up to seven voiding episodes during waking hours has been considered normal, but this number is highly variable based upon hours of sleep, fluid intake, comorbid medical conditions and other factors.
   3. Urinary urgency is the complaint of a sudden, compelling desire to pass urine that is difficult to defer. Urgency is considered the hallmark symptom of OAB, but it has proven difficult to precisely define or to characterize for research or clinical purposes.
   4. Urinary urge incontinence is the involuntary leakage of urine, associated with a sudden compelling desire to void. Incontinence episodes can be measured reliably with a diary, and the quantity of urine leakage can be measured with pad tests.

C. Percutaneous tibial nerve stimulation (PTNS), also referred to as posterior tibial neuromodulation, is a minimally invasive, office-based treatment for urinary voiding dysfunction in patients who have failed behavioral and/or pharmacologic therapies. PTNS consists of a battery powered, external pulse generator.
that delivers a low voltage electrical impulse using a needle electrode placed near the ankle as an entry point. The stimulator’s impulses travel along the tibial nerve to the nerves in the spine that control pelvic floor function.

II. Comments
A. OAB prevalence rates range from 7% to 27% in men and 9% to 43% in women. OAB symptom prevalence and severity tend to increase with age. The majority of patients experience symptoms for years, which negatively impacts psychosocial functioning and quality of life. Activities of daily living and social and occupational activities may be profoundly affected by OAB. Urinary incontinence, in particular, may result in activity restrictions and unwillingness to be exposed to environments where access to a bathroom may be difficult.
B. OAB is not a disease. It is a symptom complex that may compromise quality of life but generally does not affect survival. Given this context, in pursuing a treatment plan, the clinician should carefully weigh the potential benefit to the patient of a particular treatment against that treatment's risk for adverse events, the severity of adverse events and the reversibility of adverse events. After assessment has been performed to exclude conditions requiring treatment and counseling, no treatment is an acceptable choice made by some patients and caregivers.
C. Members must have the resources to make frequent office visits in order to obtain PTNS because treatment effects dissipate once treatment ceases. Initial treatment regimens vary but typically consist of 30 minute sessions given weekly in the physicians’ office for 10 to 12 weeks. Patients treated with PTNS may begin to see changes in their voiding patterns after four to six treatments, with nocturia and urge incontinence decreases usually reported first. Patients who respond to the treatment require maintenance therapy at individually defined treatment intervals for sustained relief of symptoms. Maintenance therapy generally consists of 30 minute sessions every two to three weeks for up to two years in patients who demonstrate significant improvement in OAB symptoms at the end of the standard 12-week course of therapy. Documentation must support the initial improvement and the need for the additional treatments.

MEDICAL NECESSITY CRITERIA
I. Indications for PTNS
PTNS is medically necessary when documentation in the medical record indicates that all of the following criteria are met:
A. The member is 18 years of age or older.
B. The member has experienced OAB with one of the following symptoms for at least six months:
   1. Urinary urgency
   2. Urinary frequency
   3. Urinary urge incontinence.
C. The member has tried and failed conservative behavioral therapies for at least six months.
D. The member meets one of the following:
   1. The member has failed trials of at least two standard anticholinergic medications and/or smooth muscle relaxants for a total of at least three months despite best attempts at management of the most common side effects of such therapy, such as dry mouth and constipation.
   2. The member has a contraindication to drug therapy.
E. Medical records document symptoms that have resulted in significant disability (e.g., the frequency and/or severity of leakages are limiting the patient’s ability to work or participate in activities outside the home).
F. Absence of underlying neurologic condition that could impact either tibial nerve or pelvic floor function
G. Absence of bladder outlet obstruction.

COVERAGE ISSUES
1. Prior authorization is required for PTNS.
2. Coverage may vary according to the terms of the member’s plan document.
3. Percutaneous tibial nerve stimulation is investigational and therefore not covered for all indications not specifically mentioned in the Medical Necessity Criteria section, including but not limited to, neurogenic bladder, fecal incontinence, constipation, chronic pelvic pain, and use in individuals less than 18 years of age.
4. For Medicare members, refer to the following, as applicable.
References

**Pre-08/2015 Medical Technology Assessment Committee (MTAC) and Medical Policy Committee (MPC):**


11/2015 MPC:

11/2016 MPC: