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Posterior tibial neurostimulation treatment

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Policy contains: Acupuncture, percutaneous tibial neurostimulation, posterior tibial nerve stimulation, overactive bladder stimulation

This policy is a Sandhills Center Clinical Coverage Policy adopted from AmeriHealth Caritas of North Carolina. These clinical policies are used to assist with making coverage determinations. Sandhills Center's clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of "medically necessary," and the specific facts of the particular situation are considered by Sandhills Center when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. Sandhills Center clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. Sandhills Center's clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Sandhills Center will update its clinical policies as necessary. Sandhills Center clinical policies are not guarantees of payment.

Coverage policy

Posterior tibial neurostimulation treatment is clinically proven and, therefore, medically necessary for overactive bladder, when all of the following criteria are met:

- Overactive bladder symptoms have existed for at least 12 months.
- After behavioral therapy (first-line therapy) has been tried and failed, or when members are unwilling or unable to comply with behavioral therapy regimens and instructions.
- Failure or experience of adverse events with one medication have been followed by an attempt with at least one other medication (which also failed or adverse effects were experienced) (Centers for Medicare & Medicaid Services, 2019a, 2019b; Gormley, 2019).

A total of 12 weekly treatments are considered necessary for initial treatment. If successful, continued monthly treatments can also be considered necessary (Gormley, 2019), at a frequency of every one to two months for the remainder of a year, up to three years or 45 lifetime treatments (Centers for Medicare & Medicaid Services, 2019a, 2019b).

Limitations

If the member fails to respond after the initial six treatments, continued treatment is considered investigational/not clinically proven and, therefore, not medically necessary (Centers for Medicare & Medicaid Services, Local Coverage Determination, 2019a).

All other uses of posterior tibial neurostimulation for overactive bladder syndrome are investigational/not clinically proven and, therefore, not medically necessary.

Alternative covered services

Behavioral and pharmaceutical therapy (as first- and second-line therapies), and sacral neuromodulation or onabotulinumtoxinA (as other third-line therapies).

Background

Overactive bladder syndrome, defined as urgency to void, usually with accompanying frequency and nocturia, with or without urge urinary incontinence, in the absence of urinary tract infection or other obvious pathology, is a common condition in adults and children. Causes are multiple, although there is some evidence that genetic predisposition may be one factor (de Wall, 2017). Behavioral therapy and drug therapy are first- and second-line treatments (Centers for Medicare & Medicaid Services, 2019).

Several types of neuromodulation, including sacral nerve stimulation and posterior tibial neurostimulation, are used as (non-first-line) treatments for overactive bladder syndrome. Neuromodulation is defined as the effect of cross-signaling between sympathetic and parasympathetic postganglionic nerve terminals and synapses, altering nerve signals involved in the voiding reflex (De Groat, 2015).

Peripheral neurostimulation, including posterior tibial neurostimulation, is derived from traditional Chinese medicine, or acupuncture. A commonly used acupuncture point is San-Yin-Jiao, or Spleen 6 (SP-6), on the medial side of the lower leg. The location of the SP-6 point and the organs affected by its stimulation make posterior tibial neurostimulation treatment for overactive bladder syndrome possible (de Wall, 2017).

The technique uses a 34 gauge needle electrode inserted 4 cm – 5 cm cephalad to the medial malleolus to stimulate the nerve. After current is applied, the flexion of the big toe or the movement of the other toes confirms the correct positioning of the needle electrode. The electric current is a continuous, square wave form with a duration of 200 μ s and a frequency of 20 Hz. The intensity is determined by the highest level tolerated by the patient (Gaziev, 2013).

The first mention in the literature of using posterior tibial neurostimulation for overactive bladder syndrome discovered that 87% of 22 patients with the syndrome experienced partial or total improvement (McGuire, 1983). The commonly used time interval of 12 weeks to determine efficacy and safety was a result of clinical trials (Peters, 2010).

In October 2010, the Food and Drug Administration approved the Urgent® PC Neuromodulation System (Uroplasty, Inc., Minnetonka Minnesota) for overactive bladder syndrome (Food and Drug Administration, 2010). In November 2013, the Administration approved the NURO™ Neuromodulation System (Advanced Uro-Solutions, Suwanee Georgia) for overactive bladder syndrome, but not other disorders (Food and Drug Administration, 2013).

Data from the International Continence Society showed a sharp increase in the number of third-line procedures for overactive bladder syndrome from 2010 to 2013 ($n = 1,822$ to $6,143$), before leveling off in the succeeding two years at $5,340$ and $5,946$ (Drangsholt, 2018).

Findings

The 2019 updated guideline of the American Urological Association/Society of Urodynamics and Female Urology on overactive bladder considers behavioral therapies as first-line treatment because they can resolve some cases while presenting essentially no risks to the patient. The guideline recommended pharmacology therapies as second-line treatment for patients unwilling or unable to comply with behavioral therapy regimens and instructions. Third-line therapies, including posterior tibial neurostimulation treatment, can be considered after failure or an adverse event for at least two medications (Gormley, 2019).

The 2019 guideline follows a 2013 guideline by the American Urological Association that mentions peripheral tibial nerve stimulation can be offered “in select patients,” as a third-line treatment (Armstrong, 2013). The National Institute for Health and Care Excellence recommended the treatment for overactive bladder syndrome, based on evidence of effectiveness and safety (National Institutes for Health and Care Excellence, 2010).

A guideline from the European Menopause and Andropause Society states that third-line therapies including peripheral tibial nerve stimulation can be a useful third-line treatment in managing refractory urge incontinence commonly seen in post-menopausal women (Russo, 2021).

The Centers for Medicare & Medicaid Services have produced a Local Coverage Determination on posterior tibial neurostimulation treatment, last updated January 8, 2019. The covered indications, along with limitations, are the basis for the coverage section of this policy (Centers for Medicare & Medicaid Services, 2019a). Another Local Coverage Determination states that if 12 weekly treatments show improvement, additional treatments every 1 – 2 months are appropriate, to a maximum of three years and 45 treatments lifetime (Centers for Medicare & Medicaid Services, 2019b).

Systematic reviews have been published in the professional literature, with the following findings:

- In a review of 28 studies ($n = 2,461$), percutaneous tibial nerve stimulation reduced voiding frequency per day ($P < .001$), nocturia frequency per day ($P < .001$), urgency episodes per day ($P = .006$), incontinence episodes per day ($P < .001$), maximum cystometric capacity ($P < .001$) and compliance ($P = .033$) (Wang, 2020).
- In nine randomized controlled trials of adults with overactive bladder syndrome, effectiveness of improving daily urine frequency and urinary incontinence episodes was compared for three third-line therapies recommended in the American Urological Association guideline. Improvements were ranked (most effective first) as sacral neuromodulation, onabotulinumtoxinA, peripheral tibial nerve stimulation, and placebo (Lo, 2020).
- In 32 studies of overactive bladder syndrome, combinations of medications and behavioral therapy were judged to be effective. However, few combination therapies of only third-line treatments only were included (Kasman, 2019).

- In seven studies, posterior tibial neurostimulation treatment improved symptoms (subjectively) in about 60% of the patients (and 47% to 56% in the long run, much greater than the estimated placebo effect of 21% The treatment was not considered costly, but was considered time-consuming (de Wall, 2017).
- Twenty-one reports compared sacral neuromodulation with percutaneous tibial nerve stimulation for patients with lower urinary tract dysfunction. Per-study ranges of improvement >50% were observed in the sacral group (29% to 76%) and the percutaneous group (54% to 59%), with percutaneous patients showing fewer side effects. Authors conclude percutaneous tibial nerve stimulation is a less invasive technique that is effective and safe, but has not been tested in the long term (Tutolo, 2018).
- Sixteen trials, 11 randomized, of adults with overactive bladder syndrome included a meta-analysis of four studies of percutaneous tibial nerve stimulation versus sham procedures. Compared to sham, the percutaneous group had an overall risk ratio of 7.32, borderline significant at $P = .09$ (Wibisono, 2015).
- Of 16 studies (n = 469) of patients with neurogenic lower urinary tract dysfunction, only four were randomized and controlled. In both acute and chronic tibial nerve stimulation, increases were observed for maximum cystometric capacity, and bladder volume at first detrusor over-activity. Decreases were observed in maximum detrusor pressure during the storage phase, number of voids per 24 hours, and number of leakages per 24 hours, along with increases for post-void residual (Schneider, 2015).
- Of 32 studies (n = 1,087), 16 addressed overactive bladder syndrome (640 treated, 189 controls). A total of 59% of patients treated with percutaneous tibial nerve stimulation responded positively, leading authors to conclude the therapy is effective and safe for overactive bladder syndrome (Gaziev, 2013).
- Ten studies, four of which were randomized, included adults with overactive bladder syndrome. Strong evidence showed percutaneous tibial nerve stimulation to be more effective than sham treatment, while limited evidence showed it to be as effective as tolterodine (extended-release) (Moosdorff-Steinhauser, 2013).
- Ten studies evaluating treatment of overactive bladder syndrome with percutaneous tibial nerve stimulation revealed success rates from 37% to 82% (total 61.4%). Four randomized trials showed the treatment was significantly more effective than sham, while two others showed no difference in outcomes with anti-muscarinic medication. Authors recommend more long-term studies (Burton, 2012).
- A review of 73 studies of lower urinary tract dysfunction compared implanted sacral nerve stimulation, percutaneous posterior tibial nerve stimulation, and transcutaneous electrical stimulation therapy modalities. Reductions in incontinence for the sacral nerve and percutaneous tibial nerve approaches were similar, but more long-term follow-up studies for the latter are needed (Monga, 2012).
- A review of posterior tibial nerve stimulation for overactive bladder syndrome in women identified 17 articles, only four of which used high-quality data. A range of 54% to 93% success in reducing symptoms were reported for all studies (Levin, 2012).

Tibial nerve stimulation can also be used transcutaneously for overactive bladder syndrome, in addition to percutaneously. A systematic review of 13 studies (n = 629), 10 of them randomized, showed transcutaneous nerve stimulation to be significantly more effective than sham, and similar to anti-muscarinic treatment, in

reducing overactive bladder symptoms, without adverse events. Authors recommend that this limited evidence be expanded (Booth, 2018).

References

On April 28, 2020, we searched PubMed and the databases of the Cochrane Library, the U.K. National Health Services Centre for Reviews and Dissemination, the Agency for Healthcare Research and Quality, and the Centers for Medicare & Medicaid Services. Search terms were “percutaneous,” “posterior,” “tibial nerve stimulation,” and “transcutaneous.” We included the best available evidence according to established evidence hierarchies (typically systematic reviews, meta-analyses, and full economic analyses, where available) and professional guidelines based on such evidence and clinical expertise.

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Policy updates

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