Clinical Review Criteria

Urgent PC Neuromodulation System for Overactive Bladder
Percutaneous Tibial Nerve Stimulation (PTNS)

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Criteria
See criteria for treatment of urinary incontinence.

The following information was used in the development of this document and is provided as background only. It is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background
Urinary incontinence (UI) refers to an involuntary leak of urine. There are several types of UI. Stress UI, the most common form, is an involuntary leak on effort or exertion and urge UI is an involuntary leak accompanied or immediately preceded by a sense of urgency. Mixed UI is a combination of stress and urge UI. Another diagnosis is overactive bladder syndrome (OAB), an urge that occurs with or without a leak of urine, and usually occurs with increased urinary frequency and nocturia. The condition is often categorized as either OAB dry (without incontinence) or OAB wet (with incontinence).

The prevalence of urinary incontinence in women is approximately 50% when defined as any urine loss and is 8-36% when limited to bothersome urine loss. About half of all cases are stress incontinence. Urinary incontinence that is severe enough it cannot be easily concealed can have a major impact on quality of life, especially if it includes urinary urgency. Severe urinary incontinence has been found to increase the risk of urinary tract infections in post-menopausal women, and the risk of falls and hip fractures in elderly women (Gray, 2005).

Treatments for urge incontinence include the use of absorbent pads, bladder training/pelvic floor muscle exercises, treatment with medications (anti-cholinergic agents, antispasmodics, tricyclic antidepressants), topical estrogen, pelvic floor electrical stimulation, and surgery.

Percutaneous tibial nerve stimulation (PTNS) is proposed as an alternative treatment for patients with symptoms of urinary urgency, urinary frequency and urge incontinence. PTNS was developed as a less invasive alternative to sacral nerve stimulation (SNS). Unlike sacral nerve stimulation with a bladder pacemaker, the Urgent PC does not involve implantation. Similar to SNS, Urgent PC is not proposed for stress incontinence, the most common form of urinary incontinence.

The Urgent PC Neuromodulation System (Uroplasty Inc, formerly Cystomedix) received pre-market clearance from the FDA in July, 2005. The system includes a battery-operated hand-held electrical generator and lead set (small gauge needle, electrode and lead wire). Another similar device, the Percutaneous Stoller Afferent Nerve Stimulation System (PerQ SANS) by Urosurge, received FDA clearance in 2000. It is not clear whether the PerQ SANS is currently commercially available in the United States. The FDA deemed Urgent PC to be substantially equivalent to the PerQ SANS device.
The PTNS treatment process using Urgent PC is as follows: At the beginning of each treatment session, a needle electrode is inserted into the ankle and the lead wire is connected to the stimulator. A surface electrode is then placed in the medial aspect of the calcaneus on the same leg as the needle electrode. When the electrodes are in place, the stimulator can be turned on. The amplitude is slowly increased until the patient has a response, generally a toe flex or fan, or extension of the entire foot. The stimulator is then set on therapy mode which automatically lasts for 30 minutes. According to a Blue Cross Blue Shield report, the optimal treatment approach with the Urgent PC system has not been determined (BSBC NC report). The manufacturer recommends an initial course of one 30 minute session per week for 12 weeks, followed by a reduced maintenance regimen.

It is challenging to evaluate the efficacy of treatments for urinary incontinence because there is no gold standard for outcome assessment. In addition, there is a high placebo effect in randomized incontinence studies; as many as 30-40% of patients in placebo groups report success. The high placebo effect has been attributed to several factors including the strong subjective component in voiding dysfunction, and potentially therapeutic effects of study design components such as keeping a voiding diary and interacting with study personnel (Dmochowski, 2001). Because of the high placebo effect, in order to show that an intervention is effective, it is necessary to show that the treatment has an impact beyond that of a placebo.

Medical Director Clinical Review and Policy Committee

10/15/07 The committee recommended this device not be covered as there is insufficient evidence in the published literature.

Medical Technology Assessment Committee (MTAC)

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<th>Date</th>
<th>Evidence Conclusion</th>
<th>Outcome</th>
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<td>10/01/07</td>
<td>There is insufficient evidence to determine the safety and efficacy of percutaneous tibial nerve stimulation (PTNS) for treating urinary urgency, urinary frequency and urge incontinence. No published randomized or non-randomized controlled trials were identified. This is particularly problematic because there is known to be a high placebo effect in studies evaluating treatments for urinary incontinence. Only case series were available. A team based in the Netherlands published several case series that used either the Urgent PC Neuromodulation System (Uroplasty) or a precursor of this device. The studies were conducted before FDA approval. Results of the case series on the Urgent PC were similar. Vandoninck et al. (2003), for example, reported a substantial reduction in incontinence episodes and voiding frequency at the end of treatment among patients for whom data were available. Two other case series were evaluated. Both of these utilized the PerQ Sans (UroSurge), a device similar to the Urgent PC. It is not known whether the PerQ Sans is currently commercially available in the U.S. The Ruiz (2004) and Govier (2001) case series found significant improvement in urinary incontinence symptoms. One study was conducted in the United States; two of the five authors in the U.S. study reported financial relationships with the device manufacturer. Other limitations of the case series include missing data and lack of long-term follow-up.</td>
<td>The use of Percutaneous tibial nerve stimulation in the treatment of overactive bladder does not meet the Group Health Medical Technology Assessment Criteria.</td>
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Evidence/ Source Documents

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<tr>
<th>Date of Literature Search</th>
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<td>10/1/2007</td>
<td>The ideal study is a randomized controlled trial comparing PTNS to a placebo and/or</td>
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alternative established intervention. No randomized controlled trials or non-randomized comparison studies were identified. The search yielded only case series. Sample sizes ranged from 11 to 132, most were in the range of 35 to 55 patients.

Seven out of the 10 case series identified were conducted by the same research group in the Netherlands. The articles differed on the indications for treatment (urge incontinence, overactive bladder syndrome, etc.) and the outcomes reported. The largest case series from the Netherlands team, and two other case series (one conducted in Spain, the other in the U.S.) were critically appraised. The remaining case series was excluded because they did not report clinical outcomes.

A news release from Uroplasty in July, 2006 stated that the company is initiating a randomized controlled trial comparing Urgent PC to anticholinergic medication for patients with symptoms of urge incontinence and urgency and frequency. The announcement did not report the expected date of study completion.

_The studies critically appraised in evidence tables are:_

