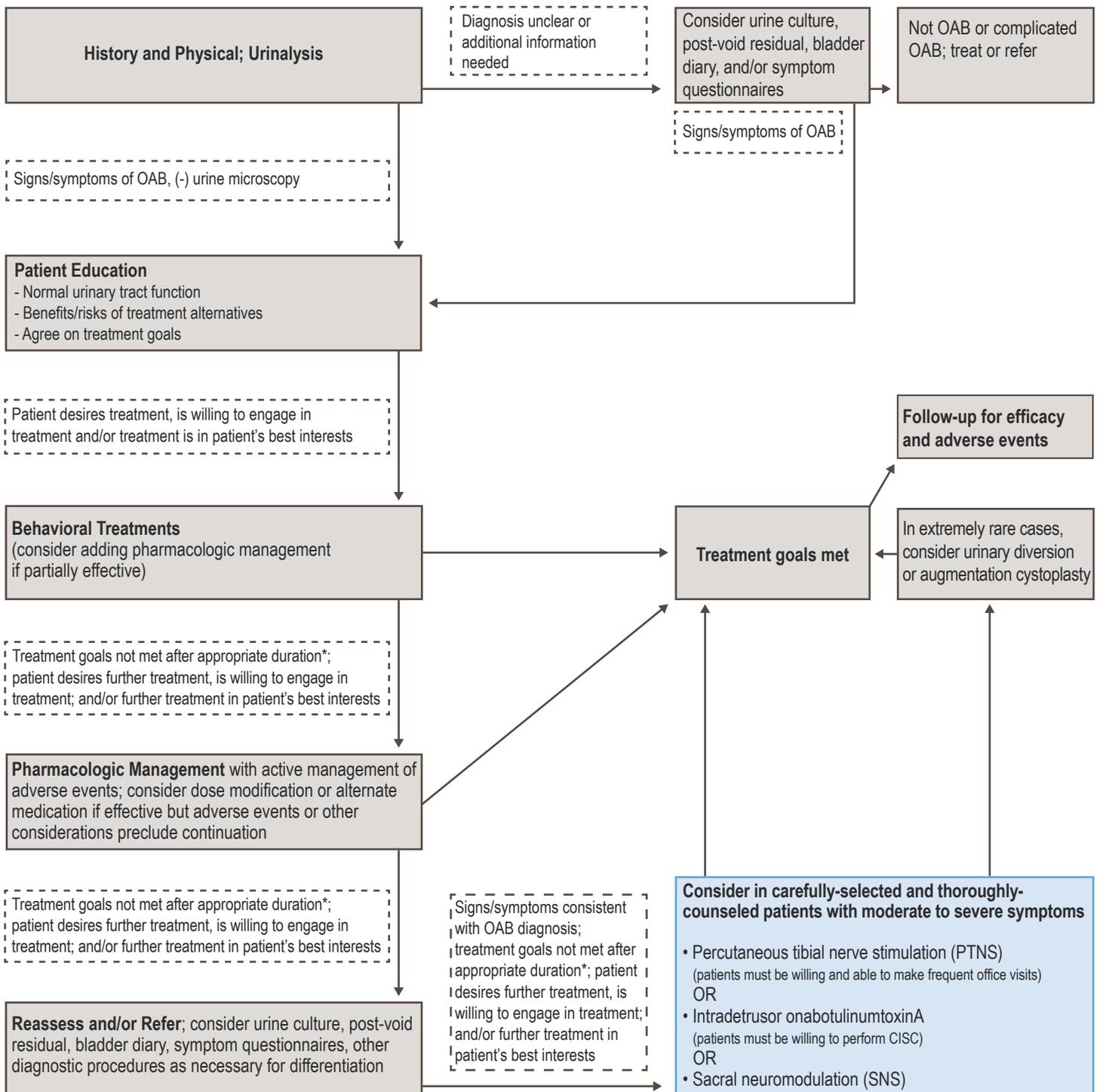


Overactive Bladder

Diagnosis and Treatment

Non-Neurogenic OAB Treatment in Adults Based on AUA/SUFU Guideline Algorithm¹



¹Appropriate duration is 8 – 12 weeks for behavioral therapies; 4 – 8 weeks for pharmacologic therapies

Treating the Refractory OAB Patient

Summarized from the AUA/SUFU Guideline for the Diagnosis and Treatment of Overactive Bladder²

The refractory patient

- » Failed a 8 – 12 week trial of symptom appropriate behavioral therapy
- » Failed a 4 – 8 week trial of at least one pharmacologic therapy
- » Failure is based on efficacy and/or inability to tolerate adverse effects

Treating the refractory patient

- » Some patients and clinicians may choose to try additional combinations of drugs and behavioral therapies before considering third-line therapies
- » Third-line treatments done at the specialist level
- » Clinicians may offer the third-line treatments in any order
- » Combination therapeutic approaches should be assembled methodically with the addition of new therapies occurring only when the relative efficacy of the preceding therapy is known
- » Therapies that do not demonstrate efficacy after adequate trial should be ceased
- » No literature addresses using third-line treatments in combination

Percutaneous Tibial Nerve Stimulation Urgent® PC Neuromodulation System

Guideline Statement 18:

“Clinicians may offer [percutaneous] tibial nerve stimulation (PTNS) as third-line treatment in a carefully selected patient population.”

Patients undergoing PTNS should:

- » Have moderately severe baseline incontinence and frequency
- » Be willing to comply with the PTNS protocol
- » Have the resources to make frequent office visits, during initial treatment phase and to obtain maintenance treatments

Intradetrusor OnabotulinumtoxinA BOTOX®

Guideline Statement 17:

“Clinicians may offer intradetrusor onabotulinumtoxinA (100U) as third-line treatment in the carefully-selected and thoroughly-counseled patient who has been refractory to first- and second-line OAB treatments. The patient must be able and willing to return for frequent post-void residual evaluation and able and willing to perform self-catheterization if necessary.”

Patient undergoing intradetrusor onabotulinumtoxinA should:

- » Accept the possibility of performing self-catheterization for long periods (or to have a caregiver perform catheterization)
- » Have access to a clinician who can measure PVR on a periodic basis if necessary
- » Accept that repeat injections are likely to be necessary to maintain symptom reduction

Sacral Nerve Stimulation InterStim®

Guideline Statement 19:

“Clinicians may offer sacral neuromodulation (SNS) as third-line treatment in a carefully selected patient population characterized by severe refractory OAB symptoms or patients who are not candidates for second-line therapy and are willing to undergo a surgical procedure.”

Patients undergoing SNS should:

- » Understand that SNS can have durable effects but in the context of frequent and moderately severe adverse events, including the need for additional surgeries
- » Accept that SNS requires periodic device replacement in planned surgical procedures, frequency on which is based on device settings
- » Be willing to comply with SNS protocol
- » Have the cognitive capacity to use the remote control to optimize device function
- » Accept that use of diagnostic MRIs is contraindicated

Clinical Review of 3rd Line OAB Treatments

Summarized from the AUA/SUFU Guideline for the Diagnosis and Treatment of Overactive Bladder²

Therapy	Percutaneous Tibial Nerve Stimulation	Intradetrusor onabotulinumtoxinA (100U)	Sacral Nerve Stimulation
Brand Name	Urgent® PC	BOTOX®	InterStim®
Patient Group	» Refractory OAB symptoms with moderately severe baseline levels of incontinence and frequency	» Refractory OAB symptoms; varying baseline	» Extremely severe baseline incontinence and frequency; more than 4 pads used per day
Clinical Results	<ul style="list-style-type: none"> » Most studies show improvements in all measured symptoms including incontinence, frequency, nocturia and QoL » PTNS effects are similar in magnitude to anti-muscarinics » PTNS superior to Sham treatment 	» Most trials reported statistically significant improvement in measured voiding outcomes and in QoL outcomes compared to placebo groups.	<ul style="list-style-type: none"> » Most studies show improvements in all measured parameters including QoL and subjective improvement » Improvement dissipates if treatment ceases » Favorable results compared to antimuscarinics
Durability	» Durable results shown through 36 months with an average of 1 treatment per month after the initial treatment phase.	» Improvements deteriorate in majority of patients after 6 – 9 months	» Improvements sustained for 5 years in 56 – 68% of implanted patients
Adverse Events	“Reported adverse events were minor; the most frequently reported events were painful sensation during stimulation that did not interfere with treatment and minor bleeding at the insertion site.”	<p>“... outcomes occurred ... in the context of high adverse events in the active treatment groups in some studies.”</p> <ul style="list-style-type: none"> » Rates of UTIs ranged from 3.6 – 54.5%; 4 RCTs reported rates of >40% » Urinary retention reported in 10 studies and ranged from 0 – 43% (rates of 43% and 30% in one RCT) » PVR increase reported in 14 studies. Range of 0 – 75% with half reporting rates of 43% or higher » Self-catheterization rates (0 – 43%) reported in 20 studies; 6 studies with rates >20% » Increased PVRs and need for self-catheterization persist for 6 – 9 months in some patients » In one assessment, 54% of patients reported 1+ side-effect including dry mouth (19.6%), gross hematuria (17.9%), urinary retention (8.9%), eyelid weakness (8.9%), arm weakness (8.9%), UTI (7.1%), leg weakness (7.1%), dysphagia (5.4%), torso weakness (5.4%), impaired vision (5.4%). Urinary retention and UTI required further treatment 	<p>“In contrast to PTNS studies ... SNS studies reported frequent adverse events ...”</p> <ul style="list-style-type: none"> » Pain at the stimulator site (3.3 – 19.8%) » Pain at the lead site (4.5 – 19.1%) » Lead migration (2.2 – 8.6%) » Infection/irritation (2.2 – 14.3% of patients) » Electric shock (5.5 – 10.2%) » Need for surgical revision (6.25 – 39.5%). In most studies it was >30% of patients » One study indicated that while 90% of patients reported satisfaction with SNS, 56% reported adverse events
Quality of Evidence	<ul style="list-style-type: none"> » ~20 studies » Predominantly observational designs » Varying patient inclusion criteria » Small sample sizes » Short follow-up durations for most studies 	<ul style="list-style-type: none"> » ~40 studies » Durations were short in the best-designed studies (ranging from 4 – 12 weeks for the RCTs) » Varying doses and injection sites » Varying adverse event reporting 	<ul style="list-style-type: none"> » ~30 studies » Predominantly observational designs » Small sample sizes » Limited number of unique patient groups (multiple reports on the same patient groups) » Limited information regarding the protocols used by patients to maintain symptom control

Urgent[®] PC

NEUROMODULATION SYSTEM

· 10 YEARS ·

The Proven
PTNS Device

· 50 STUDIES ·

Remarkable Results. Reduced Risk.

- » Urgent PC is FDA-cleared to provide percutaneous tibial nerve stimulation (PTNS)
- » PTNS data cited in the AUA/SUFU OAB Guideline is predominantly from clinical studies performed with Urgent PC and its predicate device
- » Up to 80% of patients respond; consistent results in 50 clinical studies³⁻⁵
- » Significant improvements in urgency, incontinence episodes, frequency, nighttime voids and QoL^{4,5}
- » Office treatment with no recovery time and virtually no lingering side-effects
- » 12 weekly, 30-minute sessions to gain maximum results; improvements sustained with a treatment about once a month^{4,5}



1. American Urological Association. (2014). Diagnosis and treatment of overactive bladder (non-neurogenic) in adults: AUA/SUFU Guideline Algorithm [chart]. Retrieved May 19, 2014 from the American Urological Association website: http://www.auanet.org/content/media/OAB_algorithm.pdf
 2. American Urological Association. (2014). Diagnosis and treatment of overactive bladder (non-neurogenic) in adults: AUA/SUFU Guideline. Retrieved May 19, 2014 from the American Urological Association website: http://www.auanet.org/content/media/OAB_guideline.pdf
 3. Visit www.cogentixmedical.com to view clinical abstracts
 4. MacDiarmid, S.A., Peters, K.M., Shobeiri, S.A., Wooldridge, L.S., Rovner, E.S., Leong, F.C., et al. (2010). Long-term durability of percutaneous tibial nerve stimulation for the treatment of overactive bladder. *J Urol*, 183(1), 234-40.
 5. Peters, K., Carrico, D., Wooldridge, L., Miller, C., & MacDiarmid, S. (2013). Percutaneous tibial nerve stimulation for the long-term treatment of overactive bladder: 3-year results of the STEP Study. *J Urol*, 189(6), 2194-2201.
- Urgent PC is indicated for the treatment of Overactive Bladder and associated symptoms of urinary urgency, urinary frequency and urge incontinence. CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician. Most patients do not experience side-effects. If side-effects occur, they are typically temporary and include mild pain and skin inflammation at or near the stimulation site. For complete instructions for use, storage, warnings, indications, contraindications, precautions, adverse reactions and disclaimer of warranties, please refer to the insert accompanying each Urgent PC product or online at www.cogentixmedical.com. Urgent is a registered trademark. InterStim is a registered trademark of Medtronic, Inc. BOTOX is a registered trademark of Allergan, Inc. Urgent PC is manufactured by Uroplasty LLC. ©2015 Cogentix Medical. All rights reserved. 20251K 05/17

Connect with Cogentix Medical



Cogentix
Medical

cogentixmedical.com

Cogentix Medical
5420 Feltt Road
Minnetonka, MN 55343

TEL 866.258.2182
FAX 866.255.4522