Diagnosis and treatment of overactive bladder (non-neurogenic) in adults: AUA/SUFU guideline.


Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: Gormley EA, Lightner DJ, Burgio KL, Chai TC, Clemens JQ, Culkin DJ, Das AK, Foster HE Jr, Scarpero HM, Tessier CD, Vasavada SP. Diagnosis and treatment of overactive bladder (non-neurogenic) in adults: AUA/SUFU guideline. Linthicum (MD): American Urological Association (AUA); 2012 May. 36 p. [222 references]

Recommendations

Major Recommendations

Definitions for the body of evidence strength (grade A, B, or C), the strength of the recommendations (Standard, Recommendation, Option), and for statements labeled as Clinical Principle and Expert Opinion are provided at the end of the "Major Recommendations" field.

Diagnosis

1. The clinician should engage in a diagnostic process to document symptoms and signs that characterize overactive bladder (OAB) and exclude other disorders that could be the cause of the patient's symptoms; the minimum requirements for this process are a careful history, physical exam, and urinalysis. (Clinical Principle)

2. In some patients, additional procedures and measures may be necessary to validate an OAB diagnosis, exclude other disorders and fully inform the treatment plan. At the clinician's discretion, a urine culture and/or post-void residual assessment may be performed and information from bladder diaries and/or symptom questionnaires may be obtained. (Clinical Principle)

3. Urodynamics, cystoscopy and diagnostic renal and bladder ultrasound should not be used in the initial workup of the uncomplicated patient. (Clinical Principle)

4. OAB is not a disease; it is a symptom complex that generally is not a life threatening condition. After assessment has been performed to exclude conditions requiring treatment and counseling, no treatment is an acceptable choice made by some patients and caregivers. (Expert Opinion)

5. Clinicians should provide education to patients regarding normal lower urinary tract function, what is known about OAB, the benefits vs.
risks/burdens of the available treatment alternatives and the fact that acceptable symptom control may require trials of multiple therapeutic options before it is achieved. (Clinical Principle)

Treatment

First-Line Treatments

6. Clinicians should offer behavioral therapies (e.g., bladder training, bladder control strategies, pelvic floor muscle training, fluid management) as first-line therapy to all patients with OAB. (Standard; Evidence Strength Grade B)

7. Behavioral therapies may be combined with anti-muscarinic therapies. (Recommendation; Evidence Strength Grade C)

Second-Line Treatments

8. Clinicians should offer oral anti-muscarinics or oral β3-adrenoceptor agonists as second-line therapy. (Standard; Evidence Strength Grade B)

9. If an immediate release (IR) and an extended release (ER) formulation are available, then ER formulations should preferentially be prescribed over IR formulations because of lower rates of dry mouth. (Standard; Evidence Strength Grade B)

10. Transdermal (TDS) oxybutynin (patch [now available to women ages 18 years and older without a prescription]* or gel) may be offered. (Recommendation; Evidence Strength Grade C) (*Revised June 11, 2013)

11. If a patient experiences inadequate symptom control and/or unacceptable adverse drug events with one anti-muscarinic medication, then a dose modification or a different anti-muscarinic medication may be tried. (Clinical Principle)

12. Clinicians should not use anti-muscarinics in patients with narrow-angle glaucoma unless approved by the treating ophthalmologist and should use anti-muscarinics with extreme caution in patients with impaired gastric emptying or a history of urinary retention. (Clinical Principle)

13. Clinicians should manage constipation and dry mouth before abandoning effective anti-muscarinic therapy. Management may include bowel management, fluid management, dose modification or alternative anti-muscarinics. (Clinical Principle)

14. Clinicians must use caution in prescribing anti-muscarinics in patients who are using other medications with anticholinergic properties. (Expert Opinion)

15. Clinicians should use caution in prescribing anti-muscarinics or β3-adrenoceptor agonists in the frail OAB patient. (Clinical Principle)

16. Patients who are refractory to behavioral and medical therapy should be evaluated by an appropriate specialist if they desire additional therapy. (Expert Opinion)

Third-Line Treatments

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. (Standard; Evidence Strength Grade B)

18. Clinicians may offer peripheral tibial nerve stimulation (PTNS) as third-line treatment in a carefully selected patient population. (Recommendation; Evidence Strength Grade C)

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. (Recommendation; Evidence Strength Grade C)

20. Practitioners and patients should persist with new treatments for an adequate trial in order to determine whether the therapy is efficacious and tolerable. 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 an adequate trial should be ceased. (Expert Opinion)

Additional Treatments

21. Indwelling catheters (including transurethral, supra pubic, etc.) are not recommended as a management strategy for OAB because of the adverse risk/benefit balance except as a last resort in selected patients. (Expert Opinion)

22. In rare cases, augmentation cystoplasty or urinary diversion for severe, refractory, complicated OAB patients may be considered. (Expert Opinion)

Follow-up

23. The clinician should offer follow up with the patient to assess compliance, efficacy, side effects and possible alternative treatments. (Expert Opinion)
Definitions:

Body of Evidence Strength

Grade A: Well-conducted and highly-generalizable randomized controlled trials (RCTs) or exceptionally strong observational studies with consistent findings

Grade B: RCTs with some weaknesses of procedure or generalizability or generally strong observational studies with consistent findings

Grade C: Observational studies that are inconsistent, have small sample sizes, or have other problems that potentially confound interpretation of data

Note: By definition, Grade A evidence is evidence about which the Panel has a high level of certainty, Grade B evidence is evidence about which the Panel has a moderate level of certainty, and Grade C evidence is evidence about which the Panel has a low level of certainty.

American Urological Association (AUA) Nomenclature Linking Statement Type to Level of Certainty and Evidence Strength

Standard: Directive statement that an action should (benefits outweigh risks/burdens) or should not (risks/burdens outweigh benefits) be undertaken based on Grade A (high quality; high certainty) or B (moderate quality; moderate certainty) evidence

Recommendation: Directive statement that an action should (benefits outweigh risks/burdens) or should not (risks/burdens outweigh benefits) be undertaken based on Grade C (low quality; low certainty) evidence

Option: Non-directive statements that leave the decision to take an action up to the individual clinician and patient because the balance between benefits and risks/burdens appears equal or appears uncertain based on Grade A (high quality; high certainty), B (moderate quality; moderate certainty), or C (low quality; low certainty) evidence

Clinical Principle: A statement about a component of clinical care that is widely agreed upon by urologists or other clinicians for which there may or may not be evidence in the medical literature

Expert Opinion: A statement, achieved by consensus of the Panel, that is based on members’ clinical training, experience, knowledge, and judgment for which there is no evidence

Clinical Algorithm(s)

An algorithm titled “Diagnosis & Treatment Algorithm: AUA/SUFU Guideline on Non-Neurogenic Overactive Bladder in Adults” is available from the American Urological Association, Inc. (AUA) Web site.

Scope

Disease/Condition(s)

Non-neurogenic overactive bladder (OAB)

Guideline Category

Diagnosis

Management

Treatment

Clinical Specialty

Family Practice
Guideline Objective(s)

- To provide a clinical framework for the diagnosis and treatment of non-neurogenic overactive bladder (OAB)
- To provide direction to clinicians and patients regarding how to recognize non-neurogenic OAB, conduct a valid diagnostic process and approach treatment with the goals of maximizing symptom control and patient quality of life while minimizing adverse events and patient burden
- To serve as a guide for all types of providers who evaluate and treat OAB patients, including those in general practice as well as those who specialize in various branches of medicine

Target Population

Adult patients with non-neurogenic overactive bladder (OAB)

Interventions and Practices Considered

Diagnosis

1. Patient history
2. Physical examination
3. Urinalysis
4. Urine culture and/or post-void residual assessment, as indicated
5. Urodynamics, cystoscopy, diagnostic renal and bladder ultrasound (not recommended for the initial workup of the uncomplicated patient)

Management/Treatment

1. Patient education regarding normal lower urinary tract function
2. Discussion of benefits vs. risk/burdens of treatments
3. First-line treatment
   - Behavioral therapies, including bladder training and control strategies, pelvic floor muscle training, and fluid management
   - Combination behavioral and pharmacologic management
4. Second-line treatment
   - Oral anti-muscarinics
   - Oral β3-adrenoceptor agonists
   - Transdermal oxybutynin
   - Dose modification or drug change for inadequate symptom control or unacceptable adverse events
   - Management of side effects (constipation and dry mouth)
   - Considerations in prescribing to frail or elderly patients
5. Third-line treatment in a carefully selected patient population
   - Intradetrusor onabotulinumtoxinA (100U)
   - Sacral neuromodulation (SNS)
   - Peripheral tibial nerve stimulation (PTNS)

6. Additional treatment
   - Indwelling catheters (transurethral, suprapubic) (not recommended)
   - Augmentation cystoplasty or urinary diversion

7. Follow-up

Major Outcomes Considered

- Reductions in frequency, urgency incontinence, incontinence and urgency
- Quality of life
- Degree of bother
- Patient's expectations of treatment
- Patient compliance with therapy
- Rates of adverse events
- Dry mouth/constipation rates

Methodology

Methods Used to Collect/Select the Evidence

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

The primary source of evidence for the first version of this guideline was the systematic review and data extraction conducted as part of the Agency for Healthcare Research and Quality (AHRQ) Evidence Report/Technology Assessment Number 187 titled *Treatment of Overactive Bladder in Women* (2009). That report, prepared by the Vanderbilt University Evidence-based Practice Center (EPC), searched PubMed, MEDLINE, EMBASE and CINAHL for English-language studies published from January 1966 to October 2008 relevant to OAB and excluded non-relevant studies, studies with fewer than 50 participants and studies with fewer than 75% women. The American Urological Association Education and Research, Inc. (AUA) conducted an additional literature search to capture articles published between October 2008 and December 2011. In addition, because the Panel wished to consider data for male as well as female patients, studies excluded by the AHRQ report because there were fewer than 75% women participants were extracted and added to the database. Studies that focused primarily on nocturia were also added to the database. Given that the AHRQ report included limited information regarding use of neuromodulation therapies, including sacral neuromodulation (SNS) and peripheral tibial nerve stimulation (PTNS) (also known as posterior tibial nerve stimulation) and limited information regarding the use of intravesical onabotulinumtoxinA to treat non-neurogenic OAB patients, additional searches were performed to capture this literature and relevant data were added to the database. The AUA update literature review process, in which an additional systematic review is conducted periodically to maintain guideline currency with newly-published relevant literature, was conducted in February 2014. This review identified an additional 72 articles relevant to treatment. These articles were added to the database, and AUA's qualitative and quantitative analyses were updated as appropriate.

Data from studies published after the literature search cut-off will be incorporated into the next version of this guideline. Preclinical studies (e.g., animal models), pediatric studies, commentary and editorials were eliminated. Review article references were checked to ensure inclusion of all possibly relevant studies. Multiple reports on the same patient group were carefully examined to ensure inclusion of only nonredundant information.

Number of Source Documents

With regard to treatment, a total of 151 articles met the inclusion criteria; an additional 72 relevant articles were retrieved as part of the update.
Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Body of Evidence Strength

Grade A: Well-conducted and highly-generalizable randomized controlled trials (RCTs) or exceptionally strong observational studies with consistent findings

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Methods Used to Analyze the Evidence

Meta-Analysis

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

The American Urological Association Education and Research, Inc. (AUA) performed its own qualitative and quantitative analyses of the extracted data, including meta-analyses as appropriate.

Overactive Bladder (OAB) Diagnosis

The review revealed insufficient publications to address OAB diagnosis from an evidence basis.

OAB Treatment

The Panel judged that there was a sufficient evidence base from which to construct the majority of the treatment portion of the algorithm. Data on study type (e.g., randomized controlled trial (RCT), controlled clinical trial, observational study), treatment parameters (e.g., dose, administration protocols, follow-up durations), patient characteristics (i.e., age, presence of specific symptoms such as urgency, urgency incontinence and/or frequency, detrusor overactivity documented by urodynamics), adverse events, and primary outcomes (as defined by study authors) were extracted. The primary outcomes for most studies were reductions in frequency, urgency incontinence, incontinence and urgency.

Quality of Individual Studies and Determination of Evidence Strength

The quality of individual studies was assessed by the Vanderbilt University Evidence-based Practice Center (EPC), using accepted criteria to determine the quality of internal and external validity. The criteria and rating scheme are described in detail in the published report (see the "Availability of Companion Documents" field). The same system was used to assess the quality of additional included studies.

The categorization of evidence strength (ES) is conceptually distinct from the quality of individual studies. Evidence strength refers to the body of evidence available for a particular question and includes consideration of study design, individual study quality, consistency of findings across studies, adequacy of sample sizes and generalizability of samples, settings and treatments for the purposes of the guideline. See the "Rating Scheme for the Strength of the Evidence" field.

Limitations of the Literature

The Panel proceeded with full awareness of the limitations of the OAB literature. For example, despite the relatively large number of RCTs with
placebo control groups and randomized designs with active controls that assessed pharmacologic OAB treatments, the overwhelming majority of trials followed patients for only 12 weeks. Additional limitations included the use of different inclusion criteria across studies assessing the same treatment, poorly defined patient groups or use of patient groups with limited generalizability to the typical clinical setting in which OAB patients are seen, lack of consistency in outcome measures and limited outcome measure and adverse event reporting. With regard to measures, although most studies reported urinary frequency and urinary incontinence, many studies did not report other key measures such as urgency, and only a handful reported nocturia data. With regard to adverse events, most pharmacologic studies reported rates of dry mouth and constipation, but few reported on other clinically relevant issues such as cardiac or cognitive adverse events. The completed evidence report may be requested from AUA.

Methods Used to Formulate the Recommendations

Expert Consensus

Expert Consensus (Delphi)

Description of Methods Used to Formulate the Recommendations

The Overactive Bladder Panel was created in 2009 by the American Urological Association Education and Research, Inc. (AUA). The Practice Guidelines Committee (PGC) of the AUA selected the Panel Chair and Vice Chair who in turn appointed the additional panel members with specific expertise in this area.

The review revealed insufficient publications to address overactive bladder (OAB) diagnosis from an evidence basis; the diagnosis portions of the algorithm (see the "Clinical Algorithm(s)" field), therefore, are provided as Clinical Principles or as Expert Opinion with consensus achieved using a modified Delphi technique if differences of opinion emerged. A Clinical Principle is a statement about a component of clinical care that is widely agreed upon by urologists or other expert clinicians for which there may or may not be evidence in the medical literature. Expert Opinion refers to a statement, achieved by consensus of the Panel, that is based on members' clinical training, experience, knowledge and judgment for which there is no evidence.

Linking Statement Type to Evidence Strength

The AUA nomenclature system explicitly links statement type to body of evidence strength and the Panel's judgment regarding the balance between benefits and risks/burdens.

Rating Scheme for the Strength of the Recommendations

American Urological Association (AUA) Nomenclature Linking Statement Type to Level of Certainty and Evidence Strength

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Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.
Method of Guideline Validation

Peer Review

Description of Method of Guideline Validation

The American Urological Association Education and Research, Inc. (AUA) conducted a thorough peer review process of the original document. The draft guidelines document was distributed to 78 peer reviewers, of whom 31 provided comments. The panel reviewed and discussed all submitted comments and revised the draft as needed. Once finalized, the guideline was submitted for approval to the Practice Guidelines Committee (PGC). Then it was submitted to the AUA Board of Directors for final approval. The Guideline was approved by the AUA Board of Directors in May 2014.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendation" field).

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Appropriate diagnosis and treatment of non-neurogenic overactive bladder (OAB) in adults

Potential Harms

- The choice of oral anti-muscarinics as second-line therapy reflects the fact that these medications reduce symptoms but also can commonly have non-life-threatening side effects such as dry mouth, constipation, dry or itchy eyes, blurred vision, dyspepsia, urinary tract infection (UTI), urinary retention and impaired cognitive function. Rarely, life-threatening side effects such as arrhythmias have been reported.
- In frail patients, defined as patients with mobility deficits (i.e., require support to walk, have slow gait speed, have difficulty rising from sitting to standing without assistance), weight loss and weakness without medical cause and who may have cognitive deficits, the use of overactive bladder (OAB) medications may have a lower therapeutic index and a higher adverse drug event profile. In the Panel's experience, adverse drug events in addition to the typically reported events of dry mouth and constipation may occur, including impaired thermoregulation that can cause dangerous core temperature elevation. Clinicians should begin with the lowest possible dose and increase doses slowly while carefully assessing for the balance between symptom control and adverse events. The use of transdermal anti-muscarinics should be monitored to ensure that the skin where the medication is applied remains intact.
- Cognitive deficits, particularly memory difficulties, have been reported in response to anti-muscarinics, and clinical experience suggests that elderly patients may be particularly prone to these adverse effects. In dementia patients, anti-muscarinics should be used with extreme caution or may be contraindicated entirely depending on the level of cognitive impairment.
- The concurrent use of other medications with anti-cholinergic activity may potentiate the side effects of the anti-muscarinic class of OAB medications. These medications include tricyclic antidepressants, those used in the treatment of Parkinsonism and other extra-pyramidal diseases and of Alzheimer's disease, and include benztrapine, biperiden hydrochloride (HCl), galantamine, rivastigmine and trihexyphenidyl HCl. Certain antinausea medications and those with atropine-like properties, such as trimethaphan, methscopolamine bromide and ipratropium, may also potentiate these side effects. Providers also should exercise caution in patients who are prescribed acetylcholinesterase inhibitors such as donepezil. This list is not intended to be exhaustive; prescribers should be aware of precautions and contraindications for these medications.
- Sacral neuromodulation (SNS) studies reported frequent adverse events, including pain at the stimulator site (3.3% to 19.8% of patients), pain at the lead site (4.5% to 19.1% of patients), lead migration (1.1% to 8.6% of patients), infection/irritation (2.2% to 14.30% of patients), electric shock (5.5% to 10.2% of patients) and need for surgical revision (6.25% to 39.5% of patients). In most studies, the need for surgical revision occurred in greater than 30% of patients.
• Reported adverse events with peripheral tibial nerve stimulation (PTNS) 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.
• Adverse events of neuromodulation such as pain and collateral stimulation should be assessed, and sacral neuromodulation wound complications should be evaluated.
• One study focused broadly on side effects and interviewed patients who had been administered onabotulinumtoxinA (100, 150 or 200 U) or abobotulinumtoxinA (500 U) regarding the occurrence of gross hematuria, dry mouth, dysphagia, speech problems, impaired vision and weakness of the eyelids, arms, legs, torso and/or whole body. Approximately 54% of patients reported at least one side effect, including urinary retention (8.9%), gross hematuria (17.9%), UTI (7.1%), dry mouth (19.6%), dysphagia (5.4%), impaired vision (5.4%), eyelid weakness (8.9%), arm weakness (8.9%), leg weakness (7.1%) and torso weakness (5.4%). The authors note that symptoms other than urinary retention and UTI were transient and resolved without the need for further treatment.
• There are substantial risks to surgical procedures, including the likely need for long-term intermittent self-catheterization and the risk of malignancy.

Contraindications

Contraindications

• Anti-muscarinics are contraindicated in patients using solid oral forms of potassium chloride, as the reduced gastric emptying potentially caused by the anti-muscarinics may increase the potassium absorption of these agents. If these patients can be switched to alternative forms of potassium chloride, then anti-muscarinic therapy may be possible with caution.
• In dementia patients, anti-muscarinics should be used with extreme caution or may be contraindicated entirely depending on the level of cognitive impairment.
• The use of diagnostic magnetic resonance imaging (MRI) is contraindicated in individuals with sacral neuromodulation (SNS) devices implanted.
• Clinicians should not use anti-muscarinics in patients with narrow angle glaucoma unless approved by the treating ophthalmologist and should use anti-muscarinics with extreme caution in patients with impaired gastric emptying or a history of urinary retention.

Qualifying Statements

Qualifying Statements

• There is a continually expanding literature on overactive bladder (OAB); the Panel notes that this document constitutes a clinical strategy and is not intended to be interpreted rigidly. The most effective approach for a particular patient is best determined by the individual clinician and patient. As the science relevant to OAB evolves and improves, the strategies presented here will require amendment to remain consistent with the highest standards of clinical care.
• While these guidelines do not necessarily establish the standard of care, American Urological Association Education and Research, Inc. (AUA) seeks to recommend and to encourage compliance by practitioners with current best practices related to the condition being treated. As medical knowledge expands and technology advances, the guidelines will change. Today, these evidence-based guideline statements represent not absolute mandates but provisional proposals for treatment under the specific conditions described in each document. For all these reasons, the guidelines do not pre-empt physician judgment in individual cases.
• Treating physicians must take into account variations in resources, and patient tolerances, needs, and preferences. Conformance with any clinical guideline does not guarantee a successful outcome. The guideline text may include information or recommendations about certain drug uses ("off label") that are not approved by the U.S. Food and Drug Administration (FDA), or about medications or substances not subject to the FDA approval process. The AUA urges strict compliance with all government regulations and protocols for prescription and use of these substances. The physician is encouraged to carefully follow all available prescribing information about indications, contraindications, precautions and warnings. These guidelines are not intended to provide legal advice about use and misuse of these substances. Although guidelines are intended to encourage best practices and potentially encompass available technologies with sufficient data as of close of the literature review, they are necessarily time-limited. Guidelines cannot include evaluation of all data on emerging technologies or management, including those that are FDA-approved, which may immediately come to represent accepted clinical practices.
• For this reason, the AUA does not regard technologies or management which are too new to be addressed by these guidelines as
necessarily experimental or investigational.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Implementation Tools

Clinical Algorithm

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

Living with Illness

IOM Domain

Effectiveness

Patient-centeredness

Identifying Information and Availability

Bibliographic Source(s)


Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2012 May (revised 2014 May)
Guideline Developer(s)
American Urological Association Education and Research, Inc. - Medical Specialty Society
Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction - Professional Association

Source(s) of Funding
Funding of the committee was provided by the American Urological Association, Inc. (AUA). Committee members received no remuneration for their work.

Guideline Committee
Overactive Bladder Guidelines Panel

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Financial Disclosures/Conflicts of Interest

Conflict of Interest (COI) Disclosures
All panel members completed COI disclosures. Relationships that have expired (more than one year old) since the panel’s initial meeting, are listed. Those marked with (C) indicate that compensation was received; relationships designated by (U) indicate no compensation was received.

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Other: Toby C. Chai, Taris Biomedical (C)

Guideline Status
This is the current release of the guideline.

This guideline updates a previous version: Gormley EA, Lightner DJ, Burgio KL, Chai TC, Clemens JQ, Culkin DJ, Das AK, Foster HE Jr, Scarpero HM, Tessier CD, Vasavada SP. Diagnosis and treatment of overactive bladder (non-neurogenic) in adults: AUA/SUFU guideline. Linthicum (MD): American Urological Association (AUA); 2012 May. 36 p. [222 references]

Guideline Availability


Availability of Companion Documents

The following is available:


Patient Resources

None available

NGC Status

This NGC summary was completed by ECRI Institute on June 4, 2012. The information was verified by the guideline developer on July 23, 2012. This summary was updated by ECRI Institute on September 8, 2014. The updated information was verified by the guideline developer on September 29, 2014.

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