

Cystoscopy

ACG: A-0153 (AC)

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MCG Health
Ambulatory Care
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Clinical Indications

- Cystoscopy may be indicated for **1 or more** of the following:
 - Abnormal urine cytology(2)(3)(4)(5)[N](#)
 - ☐ Bladder cancer, known or suspected, and **1 or more** of the following(6)(7)(8)(9)(10)(11)(12):[N](#)
 - Initial evaluation or staging(15)(16)
 - Following completion of intravesical immunotherapy with Bacillus Calmette-Guerin
 - Recurrent or persistent disease, known or suspected
 - Restaging after initial treatment
 - Surveillance of patient following bladder preservation surgery for muscle-invasive disease(16)
 - Surveillance of patient with history of non-muscle-invasive (Ta, T1, Tis) transitional bladder cancer(17)
 - Hematospermia, persistent, in patient age 40 years or older[N](#)
 - ☐ Hematuria, as indicated by **1 or more** of the following(9)(19)(20):[N](#)
 - Gross hematuria (macroscopic) in absence of urinary tract infection(5)(21)(25)

- Hematuria (microscopic) and high or intermediate risk of urothelial cancer, as indicated by **ALL** of the following(20)(21)(23)(26)(27):
 - Urothelial cancer risk factor, as indicated by **1 or more** of the following(9)(28):
 - Analgesic abuse (eg, phenacetin)
 - Chronic indwelling foreign body in urinary tract
 - Chronic inflammation of urinary tract
 - Current cigarette smoker or positive smoking history[A]
 - Exposure to chemical carcinogens (eg, aromatic amines)
 - Family history of Lynch syndrome or urothelial cancer
 - History of gross hematuria
 - Irritative voiding symptoms
 - Male age 40 years or older or female age 50 years or older
 - Occupational carcinogens (eg, metal workers, painters, rubber manufacturers)
 - Pelvic irradiation
 - Prior treatment with cyclophosphamide or other alkylating agent
 - Prior urine microscopy with 3 or more red blood cells per high-power field and urologic evaluation (eg, cystoscopy and/or renal imaging) not performed
 - Urine microscopy with 11 or more red blood cells per high-power field
 - Urine microscopy with 3 or more red blood cells per high-power field in absence of current menstruation or urinary tract infection or recent urologic procedure, vigorous exercise, or viral infection
 - Hematuria re-evaluation needed, as indicated by **ALL** of the following(21):
 - Adult patient
 - Previous evaluation of hematuria yielded no diagnosis.
- ☐ Interstitial cystitis (ie, bladder pain syndrome), known or suspected, and **1 or more** of the following(29)(30)(31):[N](#)
- Instillation of intravesical medication needed for treatment
 - Need for diagnosis, as indicated by **ALL** of the following:
 - Symptoms consistent with interstitial cystitis (eg, chronic pelvic pain or pressure, dysuria, nocturia, urinary frequency or urgency, discomfort with bladder filling, decreased discomfort with urination)(34)
 - Urine culture negative for urinary tract infection
 - Intraoperatively, after laparoscopic hysterectomy, pelvic organ prolapse repair, or incontinence surgery, or when urinary tract injury suspected(35)(36)(37)(38)(39)(40)[N](#)
 - Prostate cancer, urothelial, known or suspected(12)[N](#)
- ☐ Upper genitourinary tract tumor (eg, renal pelvis, urothelial carcinoma of ureter), known or suspected, and **1 or more** of the following(12)(42):[N](#)
- Initial evaluation or staging
 - Post-treatment surveillance
 - Urethral carcinoma, suspected(44)[N](#)
- ☐ Urinary incontinence and **1 or more** of the following(45):[N](#)
- Acute-onset or refractory urgency incontinence(40)
 - Bladder pain
 - Child with suspected urinary tract anomaly
 - Failure to respond to conservative therapy
 - Foreign body, suspected
 - History of pelvic or prostate irradiation

- History of previous anti-incontinence, gynecologic, or radical pelvic surgery(40)
- Lack of correlation between symptoms and clinical findings
- Persistent symptoms of difficult bladder emptying
- Postvoid residual urine volume greater than 200 mL
- Surgical intervention evaluation needed (eg, sling procedure)
- Symptomatic pelvic organ prolapse
- Urogenital fistula, known or suspected
- Urinary tract infection (recurrent or persistent)(46)[N](#)
- ☐ Urinary tract obstruction (lower) and **ALL** of the following(47)(51)(52)(53):[N](#)
 - Findings of other testing nondiagnostic (eg, bladder ultrasound, voiding cystourethrography, urinalysis)
 - Obstructive lower urinary tract symptoms, including **1 or more** of the following:
 - Abdominal straining
 - Decreased force of urinary stream
 - Hesitancy (ie, difficulty starting urinary stream)
 - Incomplete emptying
 - Intermittency (ie, stopping and starting urinary stream)
 - Terminal dribbling
 - Urinary urgency, daytime urinary frequency
 - Urinary tract abnormalities, as indicated by **1 or more** of the following:
 - Hematuria
 - History of lower urinary tract surgery (eg, transurethral resection of prostate)
 - Postvoid residual urine volume greater than 200 mL
 - Recurrent or persistent urinary tract infection(48)
 - Sterile pyuria
 - Urethral stricture, known or suspected(59)(60)(61)
 - Urethral valves, known or suspected(54)(55)(56)(57)
- ☐ Vesicoureteral reflux and **1 or more** of the following(62):[N](#)
 - Grade III, IV, or V reflux demonstrated on voiding cystourethrography
 - Nonadherence to prophylactic antibiotics
 - Renal scarring seen on imaging (eg, ultrasound or scintigraphy)
 - Urinary tract infection despite continuous antibiotic prophylaxis(66)

Alternatives

- Alternatives include(8)(21)(26):
 - CT urography. See Urography, CT (CT IVP) [AC](#) for further information.
 - Intravenous pyelogram. See Intravenous Pyelogram (Excretory Urography, IVP) [AC](#) for further information.
 - Magnetic resonance urography
 - Medical therapy(32)(45)(47)(66)
 - Renal and bladder ultrasound. See Renal Ultrasound [AC](#) for further information.
 - Transrectal ultrasound. See Transrectal Ultrasound [AC](#) for further information.

- o Voiding cystourethrography. See Voiding Cystourethrography (VCUG) [AC](#) for further information.

Evidence Summary

Background

Cystoscopy is the direct visualization and detailed inspection of the bladder wall using an endoscope inserted through the urethra. The procedure is performed for both diagnostic and therapeutic indications.(1) **(EG 2)**

Criteria

The evidence for the clinical indications found in this guideline includes 48 published peer reviewed articles, 11 specialty society or other evidence-based guidelines, and 1 Cochrane systematic review.

For abnormal urine cytology, evidence demonstrates at least moderate certainty of at least moderate net benefit. **(RG A1)** An international consensus guideline states that urine cytology and cystoscopy are superior to cystoscopy alone for detection of high-grade urothelial bladder cancers and upper urinary tract tumors.(5) **(EG 2)** An observational study of 503 patients with biopsy-proven bladder cancer found that the overall sensitivity of urine cytology for the detection of bladder cancer was 47%. Increased sensitivity was associated with bladder washings (as compared with voided urine), increased cancer stage, and increased tumor grade.(2) **(EG 2)** An observational study of 200 patients with asymptomatic microscopic hematuria reported that no patients had positive cytology, 23 patients had atypical urine cytology, and 177 patients had negative cytology. However, cystoscopic examination identified 8 patients with bladder tumors, 4 of whom had atypical cytology and 4 of whom had negative cytology. The sensitivity and specificity of voided urine cytology for detecting bladder cancer in patients with asymptomatic microscopic hematuria were 50% and 90%, respectively.(4) **(EG 2)** A prospective randomized clinical trial of 448 patients with non-muscle-invasive urothelial carcinoma showed that knowledge of a positive urine test significantly improves the detection rate of urothelial carcinoma using cystoscopy.(3) **(EG 1)**

For bladder cancer, evidence demonstrates at least moderate certainty of at least moderate net benefit. **(RG A1)** Specialty society guidelines support the use of transurethral resection of bladder tumors for initial management of non-muscle-invasive lesions.(7)(8) **(EG 2)** A systematic review and meta-analysis of 12 randomized controlled trials (with a total of 2258 patients) comparing the outcomes of fluorescence cystoscopy-guided and white light cystoscopy-guided transurethral resection of non-muscle-invasive bladder cancer found that fluorescence cystoscopy was associated with a lower recurrence rate and increased 2-year recurrence-free survival. However, there was no significant difference between the technologies with regard to reducing the rate of progression to muscle-invasive bladder cancer.(13) **(EG 1)** A multicenter randomized phase III trial of 516 patients comparing the efficacy of fluorescence cystoscopy and white light cystoscopy on long-term recurrence rates for non-muscle-invasive bladder cancer found that fluorescence cystoscopy was associated with increased recurrence-free survival.(14) **(EG 2)**

For hematospermia, evidence demonstrates a net benefit, but of less than moderate certainty, and may consist of a consensus opinion of experts, case studies, and common standard care. **(RG A2)** Cystoscopy should be reserved for older individuals with macroscopic blood in the semen for whom no etiology is established after performance of history, physical examination, and routine diagnostic testing (eg, urinalysis, complete blood count, sexually transmitted disease screening).(18) **(EG 2)**

For hematuria, evidence demonstrates at least moderate certainty of at least moderate net benefit. **(RG A1)** Acute diagnostic cystoscopy may be indicated for evaluation of gross macroscopic hematuria.(21)(22) **(EG 2)** An international consensus guideline states that cystoscopy is the cornerstone of investigation for patients with suspected bladder cancer, such as those with microscopic hematuria who have risk factors for urothelial carcinoma.(5) **(EG 2)** A systematic review-based specialty society guideline recommends cystoscopy for patients with microscopic hematuria who have risk factors for urothelial cancer in the absence of a nonmalignant or gynecologic source. In addition, the guideline recommends consideration of repeat evaluation, including cystoscopy, based on shared decision making for persistent or recurrent microscopic hematuria when the initial workup is negative.(21) **(EG 1)** A specialty society guideline recommends cystoscopy for

adults when microscopically confirmed hematuria is identified in the absence of a benign etiology.(23) **(EG 2)** Database analysis of 2118 patients who underwent cystoscopy for asymptomatic microscopic hematuria observed bladder cancer in 1% of patients. The authors noted that noncancer etiologies may also be detected by cystoscopy (eg, bladder stones, urethral stricture).(24) **(EG 2)**

For interstitial cystitis, evidence demonstrates a net benefit, but of less than moderate certainty, and may consist of a consensus opinion of experts, case studies, and common standard care. **(RG A2)** Cystoscopy under general anesthesia may be performed for diagnosis or treatment. Symptoms include chronic pelvic pain and dysuria, urinary frequency, and urgency. Therapy includes bladder distention, bladder instillation, and oral medication.(29)(32)(33) **(EG 2)**

For cystoscopy intraoperatively, after laparoscopic hysterectomy, pelvic organ prolapse repair, or incontinence surgery, or when urinary tract injury is suspected, evidence demonstrates at least moderate certainty of at least moderate net benefit. **(RG A1)** A practice guideline based on a systematic review recommends intraoperative cystoscopy after laparoscopic hysterectomy, citing a sensitivity of 80% to 90% for diagnosis of ureteral trauma; available data suggest that fewer than 25% of bladder injuries and fewer than 50% of ureteral injuries are detected intraoperatively when cystoscopy is not utilized.(38) **(EG 1)** A randomized single-blind pilot study of 66 patients undergoing laparoscopic hysterectomy suggested that laparoscopic cystoscopy was a cost-efficient and cost-effective alternative to traditional cystoscopy.(41) **(EG 1)** A systematic review and meta-analysis of 79 studies found that routine intraoperative cystoscopy during laparoscopic hysterectomy was associated with increased detection rates of ureteral and bladder injury.(35) **(EG 1)** Specialty society guidelines recommend intraoperative cystoscopy after incontinence surgery and at the time of all pelvic reconstructive surgeries except those performed for isolated posterior compartment defects.(37) (40) **(EG 2)** A prospective observational study including 839 patients undergoing benign hysterectomy with universal cystoscopy found a bladder injury rate of 2.9%, ureteral injury rate of 1.8%, and 3 cases of combined bladder and ureteral injury, resulting in a cumulative lower urinary tract injury rate after benign hysterectomy of 4.3%. The injury detection rate using intraoperative diagnostic cystoscopy was 97%.(36) **(EG 2)**

For urothelial prostate cancer, evidence demonstrates a net benefit, but of less than moderate certainty, and may consist of a consensus opinion of experts, case studies, and common standard care. **(RG A2)** A specialty society guideline recommends cystoscopy with bladder biopsies during the initial evaluation of urothelial prostate cancer.(12) **(EG 2)**

For upper genitourinary tract tumor, evidence demonstrates a net benefit, but of less than moderate certainty, and may consist of a consensus opinion of experts, case studies, and common standard care. **(RG A2)** Specialty society guidelines recommend cystoscopy for initial evaluation and subsequent surveillance of upper tract urothelial carcinoma.(12)(42) **(EG 2)** An observational study of 614 patients who had undergone nephroureterectomy or distal ureterectomy for upper urinary tract tumor found that 31% of patients developed a bladder tumor, with 82% of cases diagnosed within 2 years of the index procedure. The authors recommended that cystoscopy be done at short intervals during the first 2 years after the index procedure; for patients who remained tumor-free during the entire follow-up period, surveillance could be safely terminated at 5 years.(43) **(EG 2)**

For urethral carcinoma, evidence demonstrates at least moderate certainty of at least moderate net benefit. **(RG A1)** Based on a systematic review, a specialty society guideline supports the use of diagnostic cystoscopy to assess the extent, location, and histology of suspected urethral carcinoma.(44) **(EG 1)**

For urinary incontinence, evidence demonstrates at least moderate certainty of at least moderate net benefit. **(RG A1)** An evidence-based guideline recommends cystoscopy for patients with "complicated" urinary incontinence (eg, bladder pain, following radical pelvic surgery or irradiation, poor bladder emptying, pelvic organ prolapse).(45) **(EG 2)**

For urinary tract infection (recurrent or persistent), evidence demonstrates at least moderate certainty of at least moderate net benefit. **(RG A1)** A clinical guideline based on a systematic review recommends cystoscopy for men with lower urinary tract symptoms and recurrent urinary tract infection or sterile pyuria.(47) **(EG 1)** A study of 1809 patients (both male and female) who underwent cystoscopy for profound lower urinary tract symptoms or recurrent urinary tract infection detected relevant pathology (eg, cancer, calculi) in approximately 10% of patients.(48) **(EG 2)** An observational study of 133 women evaluating the diagnostic yield of cystoscopy for recurrent urinary tract infection found that only 5.5% of cases had significant clinical findings and that only 3.8% of cases had significant clinical findings that were uniquely identified on cystoscopy and missed by ultrasound or CT scan. The authors concluded that the diagnostic yield of cystoscopy was low in women with recurrent urinary tract infection and normal imaging.(49) **(EG 2)** A systematic review and meta-analysis of 12 studies evaluated 656 female patients who

underwent cystoscopy for recurrent simple urinary tract infection and found carcinoma in 0.15%, consequential findings (eg, stricture) in 2.7%, and incidental findings (eg, inflammation) in 19%. The authors concluded that the evidence did not support performing routine cystoscopy to evaluate recurrent urinary tract infection.(50) **(EG 1)**

For urinary tract obstruction (lower), evidence demonstrates a net benefit, but of less than moderate certainty, and may consist of a consensus opinion of experts, case studies, and common standard care. **(RG A2)** Videourodynamic testing can accurately diagnose bladder neck obstruction; however, other conditions that cause symptoms of bladder outlet obstruction, such as urethral strictures, posterior urethral valves, inflammatory lesions, or foreign bodies, can be ruled out by cystourethroscopy.(52) **(EG 2)** Cystoscopic ablation is indicated for diagnostic confirmation or ablation of anterior and posterior urethral valves that cause lower urinary tract obstruction.(54)(55)(56)(57)(58) **(EG 2)**

For vesicoureteral reflux, evidence demonstrates a net benefit, but of less than moderate certainty, and may consist of a consensus opinion of experts, case studies, and common standard care. **(RG A2)** A review article reported that endoscopic treatment of vesicoureteral reflux is indicated for patients with reflux grade III through V, for patients who do not consistently adhere to antibiotic therapy or in whom antibiotic prophylaxis is ineffective, and for those with progressive renal scarring.(62) **(EG 2)** Observational studies of pediatric patients with vesicoureteral reflux who underwent endoscopic correction found that reflux was corrected in 87% to 89% of cases after a single injection and in an additional 5% to 11% of cases after a second injection. Indications for the procedure included breakthrough urinary tract infection and high-grade reflux.(63)(64) **(EG 2)** A systematic review and meta-analysis reported that 3 randomized controlled trials (254 children) found that endoscopic ureteral correction by polymer injection produced similar outcomes (ie, febrile urinary tract infection and progressive renal damage) as compared with long-term prophylactic antibiotics.(65) **(EG 1)**

Rationale

Use of this MCG care guideline helps the clinician determine if a particular treatment, medication, or service might be appropriate for a specific patient, taking into account their unique health complexities.

Use of these evidence-based clinical criteria to support decision making benefits the patient by identifying patient-specific complex clinical factors and conditions, promoting personalized treatment. Utilizing evidence-based clinical criteria promotes patient safety by helping ensure that potential patient benefits outweigh the risks. In addition, the use of evidence-based guidelines can increase consistency in treatment thresholds, leading to less variation in care and promoting equitable treatment among patients.

Related CMS Coverage Guidance

This guideline supplements but does not replace, modify, or supersede existing Medicare regulations or applicable National Coverage Determinations (NCDs) or Local Coverage Determinations (LCDs).

Code of Federal Regulations (CFR): 42 CFR 419.22(67); 42 CFR 422.101(68)

Internet-Only Manual (IOM) Citations: CMS IOM Publication 100-02, Medicare Benefit Policy Manual, Chapter 14 - Medical Devices(69); CMS IOM Publication 100-02, Medicare Benefit Policy Manual, Chapter 15 - Covered Medical and Other Health Services(70); CMS IOM Publication 100-02, Medicare Benefit Policy Manual, Chapter 16 - General Exclusions from Coverage(71)

Medicare Coverage Determinations: Medicare Coverage Database(72)

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Footnotes

[A] For the evaluation of urothelial cancer risk, a positive smoking history is considered 10 or more pack-years.(21) [A in Context Link 1]

Codes

CPT®: 52000, 52001, 52005, 52007, 52010, 52204

HCPCS: C1747, C7550, C7554

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