Laser applications for treatment of the genitourinary tract, including the genitalia, urinary tract, bladder, prostate, kidneys, and related structures

Background

Laser surgery is used to treat issues such as kidney damage, bladder damage that results in incontinence or urinary retention, bladder stones, kidney stones, and prostate issues that restrict the flow of urine, according to the American Urological Association (AUA).

Non–laser treatment options for these conditions include transurethral needle ablation, transurethral microwave therapy, transurethral incision of the prostate, transurethral resection of the prostate, and open prostate surgery (open prostatectomy). However, laser surgery offers a much less invasive alternative along with some distinct advantages, including a lower risk of bleeding, a short hospital stay, quick recovery, less need for catheters, and more immediate results. Although there are some small short-term side effects, long-term complications are much less likely to occur with laser surgery.

Laser treatments are commonly used to treat prostate health issues, which can restrict the flow of urine. During the procedure, a narrow fiber-optic viewing scope is inserted through the urethra. There are three primary types of lasers used to treat enlarged prostate and other genitourinary tract complications:

➤ Holmium laser enucleation of the prostate: A laser is used to cut the prostate into small fragments, ultimately removing the prostate completely, with fewer risks and the same desired results as prostate removal surgeries.

➤ Photosensitive vaporization of the prostate: Also known as green light laser therapy, this procedure uses a potassium titanyl phosphate laser or a lithium triborate to melt away an enlarged prostate.

➤ Holmium laser ablation of the prostate: This method uses a laser energy source that is absorbed by water for better precision, which stops it from penetrating deep tissues. This kind of laser treatment is also used to treat bladder or kidney tumors, urinary tract blockage, and kidney or urethral stones.

Generally, these laser treatments take 30 minutes to an hour to complete. Laser treatments have several advantages over open prostatectomies and other more invasive surgeries; for one, they often culminate in a shorter hospital stay (one night) or no hospital stay at all, since most laser treatments are conducted in an outpatient setting.
Furthermore, patients experience a quicker recovery and can be back to doing normal activities in a much shorter time frame compared to more invasive surgeries.

**Involved specialties**

Urologists

**Positions of specialty boards**

**ABU**

The American Board of Urology (ABU) does not publish certification guidelines specifically for genitourinary treatment using lasers. However, the ABU does have a certification program for urologic physicians who meet specific core competencies in all areas of urology.

Physicians must complete five clinical years of postgraduate training in urology. Four of those years (48 months) must be spent in an Accreditation Council for Graduate Medical Education (ACGME)–approved urology program. Training must include:

- Three months in general surgery
- Three months of core surgical training
- Six months of other rotations, which must be approved by the program director

Candidates who complete the prescribed residency requirements will be eligible for board certification, which assures the public that the physician has received appropriate training and has a level of urologic knowledge to practice safely and effectively.

Candidates must first complete a qualifying examination, which is a computer-based test that determines a minimum level of knowledge in urology. The candidate must then meet criteria set forth by the board, including unrestricted medical licensure, assessment of clinical practice through practice logs, peer review, and a 16-month practice requirement in a single community. Finally, the candidate must pass an oral certifying exam to become certified. The ABU also includes requirements for maintenance of certification over a 10-year period, including practice assessment protocols, documented CME credits, peer review, practice log reviews, and a computer-based examination.

**AOBS**

The American Osteopathic Association (AOA) offers specialty certification in urological surgery through the American Osteopathic Board of Surgery (AOBS), although a specific subspecialty in laser treatments of the genitourinary tract is not available.
In addition to having graduated from an AOA-accredited college of osteopathic medicine, obtaining a state license to practice, the candidate must have completed all of the prescribed years of an AOA-approved residency training program. For urological surgery, this includes one of the following:

- Two years of training in general surgery, followed by three years of training in urological surgery
- One year of training in general surgery, followed by four years of training in urological surgery
- Five years of training in urological surgery

Qualifying candidates are also required to pass a written, oral, and clinical exam in general surgery to become certified. The clinical examination for general surgery will be waived for those already certified in the three-part examination in urological surgery, as long as the candidate has AOA-verified documentation on file showing completion of a general surgery residency, and as long as he or she has successfully completed the general surgery written and oral exams.

**Positions of societies, academies, colleges, and associations**

**AUA**

The AUA does not have a specific position regarding the competency required to perform laser treatments. However, the AUA does have a policy statement regarding general privileging of urologists, which requires successful completion of the ABU examination within four years of completing residency training, and maintenance of ABU certification through periodic examination.

The AUA has officially advised the American Hospital Association and The Joint Commission that ABU certification should be made a prerequisite for receiving specialty privileges.

**ASLMS**

The American Society for Laser Medicine and Surgery (ASLMS) has published *Standards of Training for Physicians for the Use of Lasers in Medicine and Surgery*. The position paper states that hospitals are responsible for establishing privileging requirements regarding the use of lasers. However, ASLMS recommends that all physicians requesting privileges for the use of lasers must first meet initial hospital standards, such as board certification, board eligibility, specialty training, ethical character, and good standing. Furthermore, physicians “should have interventional privileges in the specialty before requesting laser privileges,” according to ASLMS.

ASLMS also recommends that the physician be familiar with recent literature and complete a training program “devoted to the principles of lasers, their instrumentation and physiological effects and safety requirements.”
This program should include a minimum of 8–10 hours of hands-on sessions with lasers. An additional 40% of the program should focus on practical sessions, with additional time built in if needed to complete basic course requirements. Physicians may need additional training on different wavelengths or applications, in which case 50% of the time should be devoted to hands-on training.

Instead of a training program, physicians may also obtain privileges after completing a residency program that includes significant training and practice with multiple wavelengths. ASLMS urges residents to obtain this training during residency, particularly if they anticipate applying for laser privileges.

ASLMS also recommends that physicians spend time in a clinical setting with a preceptor or a clinical expert. In terms of the number of cases that should be observed, ASLMS recommends “several brief visits or a more prolonged period suffices provided that a variety of cases is observed.”

In another position paper, *Procedural Skills for Using Lasers in General Surgery*, ASLMS outlines credentialing and privileging criteria for physicians who are doing procedures involving lasers. ALSMS recommends the following guidelines for credentialing physicians:

➤ Physicians should be reviewed annually for safe and effective use of lasers
➤ Newly credentialed physicians must be observed in the operating room using the laser
➤ At each biannual renewal period, the physician should have done at least five procedures to be re-credentialed
➤ Those who have not completed five procedures may reapply after providing documentation of laser usage from another institution or attend a specialty-specific hands-on laser training program

Those who are applying for laser privileges need to meet the following requirements:

➤ Be certified by a specialty board such as surgery, plastic surgery, orthopedics, otolaryngology, ophthalmology, urology, dermatology, plastic surgery, cardiovascular surgery, or neurosurgery
➤ Be trained to use lasers in a recognized residency program or CME course
➤ Those applying for privileges for lasers with an operating microscope must also be proficient in the use of optical equipment
➤ Know the safety hazards associated with laser use
➤ Initial use will be provisional until a qualified member of the medical staff grants approval

Residents using lasers may not perform procedures until they have received in-depth training and been supervised by an attending physician.
ACGME

The ACGME outlines specific educational requirements for urology residencies. Within those guidelines, ACGME requires that clinical residency programs must “ensure the availability of adequate resources for resident education.” ACGME goes on to list state-of-the-art equipment that should be made available for diagnostic and therapeutic procedures, including laser therapy.

Positions of subject matter experts

Demetrius Bagley, MD
Philadelphia

Demetrius Bagley, MD, is a professor of urology at Jefferson Medical College in Philadelphia. Because there are no cut-and-dry privileging guidelines on the use of laser treatment of the genitourinary tract, most credentialing departments are forced to create their own requirements. This is usually decided based on the volume of patients coming through that facility, as well as the specific procedure for which privileges are being requested.

The number of required hands-on and proctored cases will depend on the procedure. Using lasers for bladder tumors and urethral stones is fairly straightforward and may only need a few live cases and some hands-on experience in the lab, Bagley says.

“For instance, the ureteroscopic lasers are just breaking stones, which is really pretty simple,” he says. “You just need to know the use of the holmium laser, the parameters to use, breaking up the fiber, and getting the pieces out.”

At the bare minimum, physicians applying for laser treatment privileges mid-career should be certified by the manufacturer that they have been instructed on the use of that specific laser and completed a laser safety course. Typically physicians who get this training during their residency will have adequate hands-on, proctored experience along with the basic educational requirements.

Carson Wong, MD, FRCSC, FACS
Cleveland

It’s important to separate privileging criteria according to both the procedure and the laser that is being used, says Carson Wong, MD, FRCSC, FACS, medical director of the Center for Minimally Invasive and Robotic Surgery at Parma Community General Hospital, and codirector of Minimally Invasive and Robotic Surgery at SouthWest Urology, Inc., in Cleveland. There should also be some delineation between those who have completed laser training during their residency, and those that have decided to become certified mid-career.
“For example, my residents have done more green light treatments then most physicians have done in their career, so you can’t exactly have uniform credentialing criteria for both those populations,” Wong says. “Plus they are residents, so they have been apprenticed, if you will, using that laser, whereas a guy who is mid-career is going to take a course, get a certificate—usually vendor sponsored—then he ends up coming back, watching a couple cases, getting a proctor, and he’s doing his first case live.”

Privileging criteria must also consider the varying skills of urologists. Medical staff offices should be judicious in requiring a flat number of proctored cases, both because of the cost of proctoring cases and because it may take some physicians fewer cases to gain competence than others. Establishing these standards within the facility can be difficult since it requires a balance between allowing physicians to use the latest technology, while also ensuring they are properly trained and proctored if need be.

“Technical abilities of technicians vary,” Wong says. “Some people may be fine after the first or second case; some people may not be fine after the tenth case.”

In terms of recredentialing, hospitals should look at the volume of patients associated with the type of laser and the procedures. In general, medical staff offices should consider at least one procedure each month to maintain competency. Since the recredentialing cycle is every two years, some facilities may set 24 procedures as their benchmark number, Wong says, so that physicians average one procedure each month. Some procedures, like urethral stones, may have a much higher volume than prostate treatments, so that number may vary. However, just because a physician has low volume doesn’t mean he or she should get a pass.

“Maybe I’ve been blessed with having high volume and been fortunate in that way, and maybe other surgeons aren’t as fortunate, but the reality is maybe you shouldn’t be doing it if your volume is that low,” Wong says.

**Positions of accreditation bodies**

**CMS**

CMS has no formal position concerning the delineation of privileges for laser applications for treatment of the genitourinary tract. However, the CMS *Conditions of Participation (CoP)* define a requirement for a criteria-based privileging process in §482.22(c)(6) stating, “The bylaws must include criteria for determining the privileges to be granted to individual practitioners and a procedure for applying the criteria to individuals requesting privileges.”

§482.12(a)(6) states, “The governing body must assure that the medical staff bylaws describe the privileging process. The process articulated in the bylaws,
rules or regulations must include criteria for determining the privileges that may be granted to individual practitioners and a procedure for applying the criteria to individual practitioners that considers:

➤ Individual character
➤ Individual competence
➤ Individual training
➤ Individual experience
➤ Individual judgment

The governing body must ensure that the hospital’s bylaws governing medical staff membership or the granting of privileges apply equally to all practitioners in each professional category of practitioners.”

Specific privileges must reflect activities that the majority of practitioners in that category can perform competently and that the hospital can support. Privileges are not granted for tasks, procedures, or activities that are not conducted within the hospital, regardless of the practitioner’s ability to perform them.

Each practitioner must be individually evaluated for requested privileges. It cannot be assumed that every practitioner can perform every task, activity, or privilege specific to a specialty, nor can it be assumed that the practitioner should be automatically granted the full range of privileges. The individual practitioner’s ability to perform each task, activity, or privilege must be individually assessed.

CMS also requires that the organization have a process to ensure that practitioners granted privileges are working within the scope of those privileges.

CMS’ CoPs include the need for a periodic appraisal of practitioners appointed to the medical staff/granted medical staff privileges (§482.22[a][1]). In the absence of a state law that establishes a time frame for the periodic appraisal, CMS recommends that an appraisal be conducted at least every 24 months. The purpose of the periodic appraisal is to determine whether clinical privileges or membership should be continued, discontinued, revised, or otherwise changed.

The Joint Commission

The Joint Commission has no formal position concerning the delineation of privileges for laser applications for treatment of the genitourinary tract. However, in its Comprehensive Accreditation Manual for Hospitals, The Joint Commission states, “The hospital collects information regarding each practitioner’s current license status, training, experience, competence, and ability to perform the requested privilege” (MS.06.01.03).
In the introduction for MS.06.01.03, The Joint Commission states that there must be a reliable and consistent system in place to process applications and verify credentials. The organized medical staff must then review and evaluate the data collected. The resultant privilege recommendations to the governing body are based on the assessment of the data.

The Joint Commission introduces MS.06.01.05 by stating, “The organized medical staff is responsible for planning and implementing a privileging process.” It goes on to state that this process typically includes:

➤ Developing and approving a procedures list
➤ Processing the application
➤ Evaluating applicant-specific information
➤ Submitting recommendations to the governing body for applicant-specific delineated privileges
➤ Notifying the applicant, relevant personnel, and, as required by law, external entities of the privileging decision
➤ Monitoring the use of privileges and quality-of-care issues

MS.06.01.05 further states, “The decision to grant or deny a privilege(s) and/or to renew an existing privilege(s) is an objective, evidence-based process.”

The EPs for standard MS.06.01.05 include several requirements as follows:

➤ The need for all licensed independent practitioners who provide care, treatment, and services to have a current license, certification, or registration, as required by law and regulation
➤ Established criteria as recommended by the organized medical staff and approved by the governing body with specific evaluation of current licensure and/or certification, specific relevant training, evidence of physical ability, professional practice review data from the applicant’s current organization, peer and/or faculty recommendation, and a review of the practitioner’s performance within the hospital (for renewal of privileges)
➤ Consistent application of criteria
➤ A clearly defined (documented) procedure for processing clinical privilege requests that is approved by the organized medical staff
➤ Documentation and confirmation of the applicant’s statement that no health problems exist that would affect his or her ability to perform privileges requested
➤ A query of the NPDB for initial privileges, renewal of privileges, and when a new privilege is requested
➤ Written peer recommendations that address the practitioner’s current medical/clinical knowledge, technical and clinical skills, clinical judgment, interpersonal skills, communication skills, and professionalism
➤ A list of specific challenges or concerns that the organized medical staff must evaluate prior to recommending privileges (MS.06.01.05, EP 9)
➤ A process to determine whether there is sufficient clinical performance information to make a decision related to privileges
A decision (action) on the completed application for privileges that occurs within the time period specified in the organization’s medical staff bylaws
- Information regarding any changes to practitioners’ clinical privileges, updated as they occur

The Joint Commission further states, “The organized medical staff reviews and analyzes information regarding each requesting practitioner’s current licensure status, training, experience, current competence, and ability to perform the requested privilege” (MS.06.01.07).

In the EPs for standard MS.06.01.07, The Joint Commission states that the information review and analysis process is clearly defined and that the decision process must be timely. The organization, based on recommendations by the organized medical staff and approval by the governing body, develops criteria that will be considered in the decision to grant, limit, or deny a request for privileges. The criteria must be consistently applied and directly relate to the quality of care, treatment, and services. Ultimately, the governing body or delegated governing body has the final authority for granting, renewing, or denying clinical privileges. Privileges may not be granted for a period beyond two years.

Criteria that determine a practitioner’s ability to provide patient care, treatment, and services within the scope of the privilege(s) requested are consistently evaluated.

The Joint Commission further states, “Ongoing professional practice evaluation information is factored into the decision to maintain existing privilege(s), to revise existing privileges, or to revoke an existing privilege prior to or at the time of renewal” (MS.08.01.03).

In the EPs for MS.08.01.03, The Joint Commission says there is a clearly defined process facilitating the evaluation of each practitioner’s professional practice, in which the type of information collected is determined by individual departments and approved by the organized medical staff. Information resulting from the ongoing professional practice evaluation is used to determine whether to continue, limit, or revoke any existing privilege.

**HFAP**

The Healthcare Facilities Accreditation Program (HFAP) has no formal position concerning the delineation of privileges for laser applications for treatment of the genitourinary tract. The bylaws must include the criteria for determining the privileges to be granted to the individual practitioners and the procedure for applying the criteria to individuals requesting privileges (03.01.09). Privileges are granted based on the medical staff’s review of an individual practitioner’s qualifications and its recommendation regarding that individual practitioner to the governing body.
It is also required that the organization have a process to ensure that practitioners granted privileges are working within the scope of those privileges.

Privileges must be granted within the capabilities of the facility. For example, if an organization is not capable of performing open-heart surgery, no physician should be granted that privilege.

In the explanation for standard 03.01.13 related to membership selection criteria, HFAP states, “Basic criteria listed in the bylaws, or the credentials manual, include the items listed in this standard. (Emphasis is placed on training and competence in the requested privileges.)”

The bylaws also define the mechanisms by which the clinical departments, if applicable, or the medical staff as a whole establish criteria for specific privilege delineation.

Periodic appraisals of the suitability for membership and clinical privileges is required to determine whether the individual practitioner’s clinical privileges should be approved, continued, discontinued, revised, or otherwise changed (03.00.04). The appraisals are to be conducted at least every 24 months.

The medical staff is accountable to the governing body for the quality of medical care provided, and quality assessment and performance improvement (03.02.01) information must be used in the process of evaluating and acting on re-privileging and reappointment requests from members and other credentialed staff.

**DNV**

DNV has no formal position concerning the delineation of privileges for laser applications for treatment of the genitourinary tract. MS.12 Standard Requirement (SR) #1 states, “The medical staff bylaws shall include criteria for determining the privileges to be granted to individual practitioners and a procedure for applying the criteria to those individuals that request privileges.”

The governing body shall ensure that under no circumstances is medical staff membership or professional privileges in the organization dependent solely upon certification, fellowship, or membership in a specialty body or society.

Regarding the Medical Staff Standards related to Clinical Privileges (MS.12), DNV requires specific provisions within the medical staff bylaws for:

➤ The consideration of automatic suspension of clinical privileges in the following circumstances: revocation/restriction of licensure; revocation, suspension, or probation of a DEA license; failure to maintain professional liability insurance as specified; and noncompliance with written medical record delinquency/deficiency requirements.
Immediate and automatic suspension of clinical privileges due to the termination or revocation of the practitioner’s Medicare/Medicaid status

Fair hearing and appeal

The Interpretive Guidelines also state that core privileges for general surgery and surgical subspecialties are acceptable as long as the core is properly defined.

DNV also requires a mechanism (outlined in the bylaws) to ensure that all individuals provide services only within the scope of privileges granted (MS.12, SR.4).

Clinical privileges (and appointments or reappointments) are for a period as defined by state law or, if permitted by state law, not to exceed three years (MS.12, SR.2).

Individual practitioner performance data must be measured, utilized, and evaluated as a part of the decision-making for appointment and reappointment. Although not specifically stated, this would apply to the individual practitioner’s respective delineation of privilege requests.

**CRC draft criteria**

The following draft criteria are intended to serve solely as a starting point for the development of an institution’s policy regarding laser applications for treatment of the genitourinary tract.

*Minimum threshold criteria for requesting privileges in laser applications for treatment of the genitourinary tract*

**Basic education:** MD

**Minimal formal training:** Successful completion of an ACGME- or AOA-accredited urology residency program that included training in laser principles, or completion of an approved 8- to 10-hour CME course that included training in laser principles. In addition, an applicant for privileges should spend time after the basic training course in a clinical setting with an experienced operator who has been granted laser privileges acting as a preceptor. The practitioner agrees to limit practice to only the specific laser types for which he or she has provided documentation of training and experience. The applicant must supply a certificate documenting that he or she attended a wavelength- and specialty-specific laser course and also present documentation as to the content of that course.

**Required current experience:** Demonstrated current competence and evidence of the performance of at least 12 procedures in the past 12 months or completion of training in the past 12 months.
References

If the applicant is recently trained, a letter of reference should come from the director of the applicant’s training program. Alternatively, a letter of reference may come from the applicable department chair and/or clinical service chief at the facility where the applicant most recently practiced.

Reappointment

Reappointment should be based on unbiased, objective results of care according to a hospital’s quality assurance mechanism. The applicant should demonstrate current competence and evidence of the performance of at least 12 procedures in the past 24 months based on results of ongoing professional practice evaluation and outcomes. In addition, continuing education related to laser applications for treatment of the genitourinary tract should be required.

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