



PATIENT

DECISION GUIDE

for men with enlarged prostate (BPH)

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Introduction

Learning from your doctor that you have an enlarged prostate gland—or Benign Prostatic Hyperplasia (BPH)—means you are one step closer to treatment and to improving your quality of life.

Your decision about what treatment is best for you will likely involve personal concerns, your spouse or family, and of course, input from your doctor. The purpose of this booklet is to help you understand enlarged prostate and the range of treatments available so that you may make the best decision about treatment. The booklet is divided into the following sections to help you in your decision making:

- What is enlarged prostate?
- What causes enlarged prostate?
- How is enlarged prostate diagnosed?
- Assessing your symptoms
- How is enlarged prostate treated?
- Determining which treatment is right for you
- Questions to ask your doctor
- Commonly used terms

Several sections contain short exercises designed to help you decide what aspects of treatment are most important to you. The “Questions to ask your doctor” section contains note pages so you can write down topics you’d like to talk about with your doctor. Together you can decide what treatment choice is best for you.

What is enlarged prostate?

Benign Prostatic Hyperplasia (BPH) is the medical name for *enlarged prostate*. The prostate is a walnut-sized gland in men. It is located just below the bladder and surrounds the urethra, which carries urine out of the body. While the prostate gland is part of the male reproductive system, it does not affect sexual function. The main function of the prostate is to produce a fluid that is part of semen.

Enlarged prostate is a very common condition in men over 50 years old. While the symptoms of enlarged prostate can be inconvenient, uncomfortable, and embarrassing, the good news is that enlarged prostate is not life threatening. It is not a type of cancer. It's important for you to know that the symptoms of enlarged prostate are not the unavoidable effects of aging. Instead, they can be treated by a variety of methods. According to the American Urological Association (AUA), enlarged prostate occurs in 60% of men over 60 years of age and in up to 80% of men 80 years of age.

SYMPTOMS OF ENLARGED PROSTATE

Symptoms of enlarged prostate can vary. As you age, these problems may become more bothersome.

- Feeling a repeated and instant need to urinate
- Feeling a frequent need to urinate at night, interrupting your sleep
- Having to wait for urine to start flowing
- Having a weak, variable, or dribbling stream of urine
- Feeling pain or burning when urinating
- Feeling that your bladder does not empty

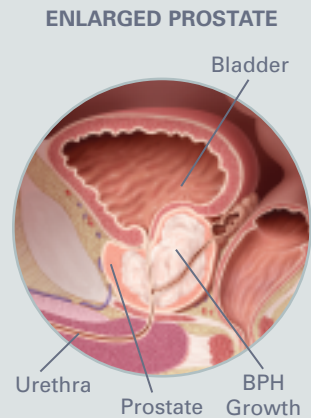


What causes enlarged prostate?

The prostate gland grows quickly in young men during puberty, then maintains its size. Abnormal growth of prostate cells usually takes place after age 40. As the prostate grows around the urethra, it may affect both the urethra and bladder.

In the early stages of enlarged prostate, the bladder muscle can work against the squeezing effect of the prostate and force urine through the urethra. If the prostate continues to grow, it may eventually start to squeeze the urethra, which can cause the bladder to contract, even when it is almost empty. When this happens, you urinate frequently. You may also experience a weak urine flow. Eventually, you may not be able to completely empty your bladder.

If you are experiencing symptoms, it is important for your doctor to determine if they are the result of enlarged prostate or another condition.



How is enlarged prostate diagnosed?

Enlarged Prostate Diagnosis

Doctors diagnose enlarged prostate by understanding your symptoms, evaluating your medical history, determining the size of your prostate, and doing one or more of these common tests:

- *Physical Exam* (including a digital rectal exam to check the size and firmness of the prostate)

- *Urine Analysis and Urine Culture* – checks the urinary tract for infection
- *Uroflowmetry* – measures the rate of urine flow
- *Ultrasound* – creates a visual image of the size and structure of internal organs
- *Cystourethroscopy* – provides a visual image of the inside of the bladder and urethra
- *Prostate-Specific Antigen (PSA)* – a blood test that helps check for prostate cancer, which can cause symptoms similar to those of an enlarged prostate

Your doctor may need to do some additional tests to better understand your specific condition, including any factors that may be caused by, or are related to, your enlarged prostate.

Scoring Symptoms (Mild, Moderate, or Severe)

Your doctor evaluates your symptoms by “scoring” your answers to a standard set of questions, called a Symptom Score Index. Your score will be between 0 and 35 points. Finding out whether your symptoms are mild (0 to 7), moderate (8 to 19), or severe (20 to 35) will help your doctor determine the best treatment for you. See the next section to evaluate your symptoms using the American Urological Association (AUA) Symptom Score Index.

Understanding Your Diagnosis

With the right tests and an in-depth understanding of how badly you are bothered by your symptoms, your doctor should be able to effectively diagnose enlarged prostate. While enlarged prostate is not life threatening, it is important for you to ask questions to fully understand your diagnosis and treatment options (choices).



Assessing your symptoms

You can use the following American Urological Association (AUA) BPH Symptom Score Self-Test to confirm your doctor's evaluation of mild, moderate, or severe enlarged prostate. **Simply check the appropriate box after each question, then add up the numbers you checked in each column.** Then add these six totals to find your score between 0 and 35 points.

	0	1	2	3	4	5
	Not at all	Less than 1 time in 5	Less than half the time	About half the time	More than half the time	Almost always
Over the past month, how often have you had a feeling of not emptying your bladder completely after you finished urinating?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Over the past month, how often have you had to urinate again less than two hours after you finished urinating?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Over the past month, how often have you stopped and started again several times when you urinated?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Over the past month, how often have you found it difficult to postpone urination?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Over the past month, how often have you had a weak urinary stream?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Over the past month, how often have you had to push or strain to begin urination?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

	0	1	2	3	4	5+
		Time	Times	Times	Times	Times
Over the past month, how many times did you usually get up to urinate from the time you went to bed at night until the time you got up in the morning?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

AUA Symptom Score: = + + + + +

(Add up all of your answers to get your score)

What your score means:

- 0-7 Points** Symptoms are considered mild.
- 8-19 Points** Symptoms are considered moderate.
- 20-35 Points** Symptoms are considered severe.

How is enlarged prostate treated?

Your doctor has several ways to treat enlarged prostate. Your decision about which treatment is best for you will depend upon your diagnosis, overall health, your goals for treatment, and the treatment options available. Reviewing the following treatment options may help you determine which features of treatment are most important to you. An exercise in the following section will help you further evaluate the various features of treatment so that you can make an informed decision with your doctor.

Treatments available for enlarged prostate include:

- **Watchful Waiting**—As the name suggests, this involves paying attention to your symptoms and visiting your doctor if they worsen or lead to other urinary tract problems. This is an option if you have mild symptoms or are not bothered by your symptoms.
- **Medications**—Drugs might be an option if you have moderate to severe symptoms, your prostate gland is the right size to respond to this treatment, and you are not already taking other medications that could create a health risk when combined with prostate medications (for example, taking sildenafil for erectile dysfunction). While prostate medications or combinations of drugs usually provide some relief, they may require several weeks to 6 months to take effect. They also may have side effects, and the long-term effectiveness of medications can be limited.
 - *Alpha-blockers* are a class of drugs used to relax the muscles of the prostate.
 - *5 alpha-reductase inhibitors* are a class of drugs used to shrink the prostate.



Office-Based Treatments:

- **The Prolieve Thermodilatation® System**—This less invasive treatment is an option if you have moderate to severe symptoms and your prostate gland is the right size to respond to this treatment. The treatment is performed in your doctor’s office and requires no general anesthesia or incisions. Requiring only a local anesthetic gel, this 45-minute treatment is designed to relieve pressure on the prostatic urethra, resulting in an improvement in urine flow. During the procedure, a balloon attached to a catheter opens up the prostatic urethra while microwave heat reduces the enlarged tissue of your prostate and improves urine flow. The majority of men leave without a catheter and experience few posttreatment complications or sexual side effects.
- **Other Transurethral Office-Based Procedures**—These treatments are generally options for men with moderate to severe symptoms. These treatments provide moderate to large relief, but they may affect sexual function and generally require sedation or general anesthesia for pain management. Your doctor will decide how to best manage the pain associated with treatment. A patient’s ability to tolerate treatment and a doctor’s skill at performing the procedure can also affect the outcome of these procedures. Patients are generally required to wear a catheter for up to several weeks following treatment.
 - *Transurethral Microwave Heat Treatments*—A small catheter is inserted through the urethra to reduce the amount of prostate tissue with microwave energy.
 - *Transurethral Needle Ablation*—A small needle is attached to the end of a rigid catheter. The needle is heated to reduce prostate tissue.
 - *Interstitial Laser Coagulation*—A small laser is attached to the end of a catheter. The laser heats the prostate tissue and reduces it.

Surgical Treatments:

Several surgical options are available if you have moderate to severe enlarged prostate symptoms along with other urinary conditions or when other treatments have not worked well. Generally, these involve removing the inner portion of the prostate gland and usually result in large improvement of symptoms. Ask your doctor about the risks involved with each procedure.

- ***Holmium Laser Therapy***—A surgical alternative to TURP, holmium laser therapy uses laser energy to relieve enlarged prostate symptoms and is designed to reduce traditional complications associated with TURPs. With holmium laser therapy, patients experience minimal pain after the operation and spend less time in the hospital than with TURP. They are also able to resume normal activities within a week. There are few to no sexual side effects with holmium laser therapy, and, unlike TURP, it can be performed on patients taking anticoagulant medications like Coumadin® (warfarin sodium).

Visit www.laserforbph.com for more information.

- ***Transurethral Resection of the Prostate (TURP)***—This is the most common form of surgery. Patients are hospitalized during the procedure and may remain hospitalized for several days. Patients must wear a catheter for up to several weeks following surgery.

Determining which treatment is right for you

There are several questions you should answer when determining which treatment is best for you.



DO I NEED TREATMENT?

If you are truly bothered by your symptoms, or if they prevent you from doing the things you like to do, you are likely a good candidate for treatment. Check the box that answers the question below.

Have your symptoms affected your enjoyment of going out or participating in social events or activities, or they have affected your travel or the quality of your restfulness during the night?

		<input type="checkbox"/> YES
		<input type="checkbox"/> NO

WHAT IS MY SYMPTOM SCORE?

Did your physician identify whether your symptoms are mild, moderate, or severe? Complete the BPH self-test on page 5 to confirm your doctor’s evaluation. Check the box that applies:

- My symptoms are considered mild.
- My symptoms are considered moderate.
- My symptoms are considered severe.

WHAT ARE YOUR GOALS FOR TREATMENT?

Rate the importance of the following treatment goals from 1 (not at all important) to 5 (extremely important). Circle the number that applies.

Sleep without getting up at night to urinate	1	2	3	4	5
Maintain sex life	1	2	3	4	5
Pursue activities without needing to urinate frequently	1	2	3	4	5
Stop spouse/significant other from worrying	1	2	3	4	5
Reduce pain/discomfort	1	2	3	4	5
Minimize long-term financial burden	1	2	3	4	5

WHAT ARE MY TREATMENT OPTIONS?

Check the treatments available to you based on your symptom score. A brief description of treatments is available on pages 6-8. (Your doctor may give you additional information about available treatments.)

- Watchful Waiting (*Mild*)
- Medications (*Moderate*)
- The Prolieve Thermodilatation® System Treatment (*Moderate to severe – nonsurgical*)
- Other Transurethral Office-Based Procedures (*Moderate to severe – nonsurgical*)
- Transurethral Resection of the Prostate (*Severe*)
- Holmium Laser Therapy (*Severe*)

SATISFYING YOUR GOALS FOR TREATMENT OF MODERATE-SEVERE SYMPTOMS

There are several treatments, as described on pages 7-8, that have been shown to provide effective relief of **moderate-severe** symptoms of enlarged prostate. This chart will help you compare those treatments so that you and your doctor can identify the one that is most likely to satisfy your goals. Your doctor can also help you to check the boxes as they apply to each procedure.

	The Prolieve System Treatment	Other Office-Based Procedures	Surgery
Little or no effect on sexual function	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Performed in doctor's office	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
No general anesthesia required	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Majority of men do not require a catheter	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Associated with few posttreatment complications	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Not likely to require follow-up visit	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Covered by medicare	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Commonly used terms *in the treatment of enlarged prostate*

BPH (Benign Prostatic Hyperplasia)	Enlargement of the prostate gland with no cancer
Bladder spasm	Involuntary contraction of muscles affecting the bladder wall
Catheter	A flexible tube for withdrawing fluids from (or introducing fluids into) a cavity of the body, especially one for inserting into the bladder through the urethra to remove urine
Cystourethroscopy	A procedure used to look at the inside of the bladder and urethra, using a flexible tube with a small attached camera to insert through the urethra and into the bladder
Invasive	Involving a puncture or incision of the skin or insertion of an instrument or foreign material into the body
Rectal temperature monitor	A device inserted into the rectum to measure the temperature of the rectal tissue near the prostate gland
Thermodilatation system	A treatment system that combines balloon dilatation with microwave energy
Transurethral	Performed through the urethra
Ultrasound	A technique in which high-frequency sound waves are bounced off internal organs and the echo pattern is converted into a 2-dimensional picture of the structures

Urethra	The tube through which urine is passed from the bladder; the length is about 25 centimeters (or 10 inches) in males
Urinary retention	Inability to empty the bladder
Urinary sphincter	A muscle that is normally tight, and when relaxed allows urine to flow from the bladder
Uroflowmetry	A procedure used to measure the rate of urine flow

INDICATIONS: The Prolieve Thermodilatation® System is a transurethral microwave therapy device for the treatment of symptomatic Benign Prostatic Hyperplasia (BPH) in men with a prostate size of 20 to 80 grams and prostatic urethra length between 1.2 cm and 5.5 cm and in whom drug therapy (finasteride or Proscar®) is typically indicated.

CONTRAINDICATIONS: Patients who have significantly decreased pain responses, severe urethral stricture prohibiting catheterization, current urinary or prostatic infection, penile or urinary sphincter implants, prostate sizes <20 g or >80 g, peripheral arterial disease with intermittent claudication or Leriche's Syndrome, protruding median lobe with obstruction, metallic implants, implanted cardiac pacemakers or defibrillators, previous transurethral prostatectomy, renal impairment, coagulation disorders, neurological disorders that may affect bladder function, bladder stones, evidence of prostate or bladder cancer, or have an interest in the preservation of future fertility.

WARNINGS AND PRECAUTIONS: All components of the Prolieve System must be used in accordance with the User Manual. The emission of microwave energy must be off during placement and removal of the catheter. Patient comments of pain or excess heat should be investigated. Failure to monitor adequately and deliver the procedure per User Manual may lead to decreased patient safety and/or reduced clinical effectiveness. A single high dose of microwave radiation to the testes, or testicular heating for a prolonged period, may result in temporary or permanent sterility. No anesthetic other than aqueous-based topical intraurethral anesthetic used for catheter placement is recommended. The safety and effectiveness of the Prolieve System for men <50 and >80 years old has not been established in clinical studies. If procedure kit seal or internal sterile packaging seals are damaged or broken, the contents may not be sterile and could cause infection.

POTENTIAL ADVERSE EFFECTS: that may occur include but are not limited to bleeding, bowel irritation, urethral injury (irritation), chronic pain at site, bladder spasms, urinary retention (complete or incomplete), urinary incontinence, prostatitis, pressure sensation, urinary urgency, urinary tract infection, urethral tear, anal irritation, urethral stricture, infertility, retrograde ejaculation, and erectile dysfunction.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

Individuals depicted in this brochure are models and included for illustrative purposes only; models depicted are not users and do not endorse the Prolieve Thermodilatation System.

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