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MEDICAL POLICY – 8.01.61

Focal Treatments for Prostate Cancer

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POLICY CRITERIA | CODING | RELATED INFORMATION
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Introduction

There are several ways to treat prostate cancer, depending on how large the cancer is and whether it has spread. Some treatment choices are surgery, several different types of radiation, or watchful waiting. A new type of treatment has been proposed. This treatment, known as focal therapy, aims at destroying specific areas of cancer without taking out the prostate gland. There are different ways of trying to treat the tumor while it's still inside the gland. These are laser, ultrasound, extreme cold, radiofrequency, and cell-killing drugs that are activated by a special type of light. All forms of focal therapy for prostate cancer are unproven (investigational). Larger and longer studies are needed to see if focal treatments are as good as or better than proven methods of treating prostate cancer.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Policy Coverage Criteria

Service	Investigational
Focal treatments for prostate cancer	**Use of any focal therapy modality to treat individuals with localized prostate cancer is investigational, including, but not limited to, any of the following treatments:** • Focal laser ablation • High-intensity focused ultrasound • Cryoablation • Radiofrequency ablation • Photodynamic therapy • Irreversible electroporation (i.e. NanoKnife)

Coding

Code	Description
CPT	
0582T	Transurethral ablation of malignant prostate tissue by high-energy water vapor thermotherapy, including intraoperative imaging and needle guidance
0600T	Ablation, irreversible electroporation; 1 or more tumors per organ, including imaging guidance, when performed, percutaneous
0601T	Ablation, irreversible electroporation; 1 or more tumors, including fluoroscopic and ultrasound guidance, when performed, open
0655T	Transperineal focal laser ablation of malignant prostate tissue, including transrectal imaging guidance with MR-fused images or other enhanced ultrasound imaging
0738T	Treatment planning for magnetic field induction ablation of malignant prostate tissue, using data from previously performed magnetic resonance imaging (MRI) examination
0739T	Ablation of malignant prostate tissue by magnetic field induction, including all intraprocedural, transperineal needle/catheter placement for nanoparticle installation and intraprocedural temperature monitoring, thermal dosimetry, bladder irrigation, and magnetic field nanoparticle activation
0950T	Ablation of benign prostate tissue, transrectal, with high intensity-focused ultrasound (HIFU), including ultrasound guidance (new code effective 07/01/25)
55880	Ablation of malignant prostate tissue, transrectal, with high intensity-focused ultrasound (HIFU), including ultrasound guidance
55899	Unlisted procedure, male genital system

Related Information

N/A

Evidence Review

Description

Prostate cancer is the second most common cancer diagnosis men receive in the United States (US), and the behavior of localized prostate cancer can prove difficult to predict on a case-by-case basis. Most men with prostate cancer undergo whole-gland treatments, which can often lead to substantial adverse events. To reduce tumor burden and minimize morbidity associated with radical treatments, investigators have developed a therapy known as focal treatment. Focal treatment seeks to ablate either an "index" lesion (defined as the largest cancerous lesion with the highest-grade tumor), or alternatively, to ablate nonindex lesions and other areas where cancer has been known to occur. This policy addresses several ablative methods used to remove cancerous lesions in localized prostate cancer (e.g., focal laser ablation, high-intensity focused ultrasound (HIFU), cryoablation, radiofrequency ablation (RFA), photodynamic therapy, irreversible electroporation).

Background

Prostate Cancer

Prostate cancer is the second most common cancer diagnosed among men in the US. According to the National Cancer Institute, nearly 268,490 new cases are estimated to be diagnosed in the US in 2022 and associated with around 34,500 deaths.[1] Prostate cancer is more likely to develop in older men and in non-Hispanic Black men. About 6 in 10 cases are diagnosed in men who are ≥65 years of age, and it is rare in men <40 years of age. Autopsy studies in the pre-prostate-specific antigen (PSA) screening era identified incidental cancerous foci in 30% of men 50 years of age, with incidence reaching 75% at age 80 years.[2] However, the National Cancer Institute

Surveillance Epidemiology and End Results Program data have shown age-adjusted cancer-specific mortality rates for men with prostate cancer declined from 40 per 100,000 in 1992 to 19 per 100,000 in 2018. This decline has been attributed to a combination of earlier detection via PSA screening and improved therapies.

Diagnosis

From a clinical standpoint, different types of localized prostate cancers may appear similar during initial diagnosis.[15] However, prostate cancer often exhibits varying degrees of risk of progression that may not be captured by accepted clinical risk categories (e.g., D'Amico criteria) or prognostic tools based on clinical findings (e.g., PSA titers, Gleason grade, or tumor stage).[4-8] In studies of conservative management, the risk of localized disease progression based on prostate cancer–specific survival rates at 10 years may range from 15%[21,22] to 20%[23] to perhaps 27% at 20-year follow-up.[24] Among elderly men (≥ 70 years) with this type of low-risk disease, comorbidities typically supervene as a cause of death; these men will die from the comorbidities of prostate cancer present rather than from the cancer itself. Other very similar-appearing low-risk tumors may progress unexpectedly and rapidly, quickly disseminating and becoming incurable.

Treatments

The divergent behavior of localized prostate cancers creates uncertainty whether to treat immediately.[43,44] An individual may choose definitive treatment upfront.[45] Surgery (radical prostatectomy) or external beam radiotherapy are frequently used to treat individuals with localized prostate cancer.[44,46] Complications most commonly reported with radical prostatectomy or external-beam radiotherapy and with the greatest variability are incontinence (0% to 73%) and other genitourinary toxicities (irritative and obstructive symptoms); hematuria (typically ≤5%); gastrointestinal and bowel toxicity, including nausea and loose stools (25%-50%); proctopathy, including rectal pain and bleeding (10% to 39%); and erectile dysfunction, including impotence (50% to 90%).[46]

American Urological Association guidelines state that for individuals with low-risk prostate cancer, clinicians should recommend active surveillance.[47] With this approach, individuals forego immediate therapy but continue regular monitoring until signs or symptoms of disease progression are evident — at which point curative treatment is instituted.[48,49]

Focal Treatments of Localized Prostate Cancer

Given significant uncertainty in predicting the behavior of individual localized prostate cancers, and the substantial adverse effects associated with definitive treatments, investigators have sought a therapeutic middle ground. The latter seeks to minimize the morbidity associated with radical treatment in those who may not actually require surgery while reducing tumor burden to an extent that reduces the chances for rapid progression to incurability. This approach is termed focal treatment, in that it seeks to remove — using any of several ablative methods described next — cancerous lesions at high risk of progression, leaving behind uninvolved glandular parenchyma. The overall goal of any focal treatment is to minimize the risk of early tumor progression and preserve erectile, urinary and rectal functions by reducing damage to the neurovascular bundles, external sphincter, bladder neck, and rectum.[3-7]

Patient Selection

A proportion of men with localized prostate cancer have been reported to have (or develop) serious misgivings and psychosocial problems in accepting active surveillance, sometimes leading to inappropriately discontinuing it.[25] Thus, the appropriate patient selection is imperative for physicians who must decide whether to recommend active surveillance or focal treatment for individuals who refuse radical therapy or for whom it is not recommended due to the risk/benefit balance.[26]

Lesion Selection

Proper lesion selection is a second key consideration in choosing a focal treatment for localized prostate cancer. Although prostate cancer is a multifocal disease, clinical evidence has shown that between 10% and 40% of men who undergo radical prostatectomy for presumed multifocal disease actually have a unilaterally confined discrete lesion, which, when removed, would "cure" the individual.[27,28,29] This view presumably has driven the use of regionally targeted focal treatment variants, such as hemiablation of half the gland containing the tumor, or subtotal prostate ablation via the "hockey stick" method.[8] While these approaches can be curative, the more extensive the treatment, the more likely the functional adverse outcomes would approach those of radical treatments.

The concept that clinically indolent lesions comprise most of the tumor burden in organ-confined prostate cancer led to the development of a lesion-targeted strategy, which is referred to as "focal therapy" in this policy.[9] This involves treating only the largest and highest grade

cancerous focus (referred to as the "index lesion"), which has been shown in pathologic studies to determine the clinical progression of disease.[30,31] This concept is supported by molecular genetics evidence that suggests that a single index tumor focus is usually responsible for disease progression and metastasis.[10,32] The index lesion approach leaves in place small foci less than 0.5 centimeter^3 (cm) in volume, with a Gleason score less than 7, that are considered unlikely to progress over a 10- to 20-year period.[11,33,34] This also leaves available subsequent definitive therapies as needed should disease progress.

Identification of prostate cancer lesions (disease localization) particularly the index lesion, is critical to the oncologic success of focal therapy; equally important to success is the ability to guide focal ablation energy to the tumor and assess treatment effectiveness. At present, no single modality reliably meets the requirements for all three activities (disease localization, focal ablation energy to the tumor, assessment of treatment effectiveness).[9,26] Systematic transrectal ultrasound–guided biopsy alone has been investigated; however, it has been considered insufficient for patient selection or disease localization for focal therapy.[12,35-38]

Multiparametric magnetic resonance imaging (mpMRI), typically including T1-, T2-, diffusion-weighted imaging, and dynamic contrast-enhanced imaging, has been recognized as a promising modality to risk-stratify prostate cancer and select individuals and lesions for focal therapy.[9,12,25] Evidence has shown mpMRI can detect high-grade, large prostate cancer foci with performance similar to transperineal prostate mapping using a brachytherapy template.[39] For example, for the primary end point definition (lesion, ≥4 millimeter [mm]; Gleason score, ≥3+4), with transperineal prostate mapping as the reference standard, sensitivity, negative predictive value, and negative likelihood ratios with mpMRI were 58% to 73%, 84% to 89%, and 0.3 to 0.5, respectively. Specificity, positive predictive value, and positive likelihood ratios were 71% to 84%, 49% to 63%, and 2.0 to 3.44, respectively. The negative predictive value of mpMRI appears sufficient to rule out clinically significant prostate cancer and may have clinical use in this setting. However, although mpMRI technology has the capability to detect and risk-stratify prostate cancer, several issues constrain its widespread use for these purposes (e.g., mpMRI requires highly specialized MRI-compatible equipment, biopsy within the MRI scanner is challenging, interpretation of prostate MRI images requires experienced uroradiologists), and it is still necessary to histologically confirm suspicious lesions using transperineal prostate mapping.[40]

Modalities Used to Ablate Lesions

The following ablative methods for which clinical evidence is available are considered herein: focal laser ablation; high-intensity focused ultrasound (HIFU); cryoablation; radiofrequency ablation (RFA); photodynamic therapy and irreversible electroporation.[3,4,6,7,8,9,10,11,12,13,14] Each method requires placement of a needle probe into a tumor volume followed by delivery of some type of energy that destroys the tissue in a controlled manner. All methods except focal laser ablation currently rely on ultrasound guidance to the tumor focus of interest; focal laser ablation uses MRI to guide the probe

Focal Laser Ablation

Focal laser ablation refers to the destruction of tissue using a focused beam of electromagnetic radiation emitted from a laser fiber introduced transperineally or transrectally into the cancer focus. The tissue is destroyed through the thermal conversion of the focused electromagnetic energy into heat, causing coagulative necrosis. Other terms for focal laser ablation include photothermal therapy, laser interstitial therapy, and laser interstitial photocoagulation.[41]

High-Intensity Focused Ultrasound

HIFU focuse high-energy ultrasound waves on a single location, which increases the local tissue temperature to over 80°C. This causes a discrete locus of coagulative necrosis of approximately 3x3x10 mm. The surgeon uses a transrectal probe to plan, perform, and monitor treatment in a real-time sequence to ablate the entire gland or small discrete lesions.

Cryoablation

Cryoablation induces cell death through direct cellular toxicity from disruption of the cell membrane caused by ice-ball crystals and vascular compromise from thrombosis and ischemia secondary to freezing below -30°C. Using a transperineal prostate mapping template, cryoablation is performed by transperineal insertion under transrectal ultrasound guidance of a varying number of cryoprobe needles into the tumor.

Radiofrequency Ablation

RFA uses energy produced by a 50-watt generator at a frequency of 460 kHz. Energy is transmitted to the tumor focus through 15 needle electrodes inserted transperineally under

ultrasound guidance. RFA produces an increase in tissue temperature causing coagulative necrosis.

Photodynamic Therapy

Photodynamic therapy uses an intravenous photosensitizing agent, which distributes through prostate tissue, followed by light delivered transperineally by inserted needles. The light induces a photochemical reaction that produces reactive oxygen species that are highly toxic and causes functional and structural tissue damage (i.e., cell death). A major concern with photodynamic therapy is that real-time monitoring of tissue effects is not possible, and the variable optical properties of prostate tissue complicate the assessment of necrosis and treatment progress.

Irreversible electroporation

Electroporation generates high-frequent electric pulses between two or more electrodes which produces an electric current that damages the cell membrane and allows molecules to pass into the cell passively. Electroporation can be temporary (reversible electroporation) or permanent (irreversible electroporation or IRE). In IRE the cell membrane is permanently damaged causing cell death due to the inability to maintain homeostasis. IRE achieves its action with no thermal effect. IRE appears to preserve vessels, nerves and the extracellular matrix.[42,]

Summary of Evidence

For individuals who have primary localized prostate cancer who receive focal therapy using laser ablation, HIFU, cryoablation, RFA, photodynamic therapy, or irreversible electroporation, the evidence includes systematic reviews, studies from a registry cohort, and numerous observational studies. The relevant outcomes are overall survival (OS), disease-specific survival, symptoms, change in disease status, functional outcomes, quality of life, and treatment-related morbidity. The evidence is highly heterogeneous and inconsistently reports clinical outcomes. No prospective, comparative evidence was found for the majority of focal ablation techniques versus current standard treatment of localized prostate cancer, including radical prostatectomy, external-beam radiotherapy, or active surveillance. Methods have not been standardized to determine which and how many identified cancerous lesions should be treated for best outcomes. No evidence supports which, if any, of the focal techniques leads to better functional outcomes. Although high disease-specific survival rates have been reported, the short follow-up

periods and small sample sizes preclude conclusions on the effect of any of these techniques on OS rates. The adverse event rates associated with focal therapies appear to be superior to those associated with radical treatments (e.g., radical prostatectomy, external-beam radiotherapy); however, the evidence is limited in its quality, reporting, and scope. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this policy are listed in **Table 1**.

Table 1. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT04049747	Imperial Prostate 4: Comparative Health Research Outcomes of NOvel Surgery in Prostate Cancer	2450	May 2027
NCT04972097	Pivotal Study of the NanoKnife System for the Ablation of Prostate Tissue (PRESERVE)	121	Jul 2024
NCT03531099	Phase 3, Multicenter, Randomized Study, Evaluating the Efficacy and Tolerability of Focused HIFU Therapy Compared to Active Surveillance in Patients With Significant Low Risk Prostate Cancer	108	Oct 2026
NCT04045756	Short-term Efficacy of Transperineal Laser Ablation (TPLA) with Image Fusion and Multi-parametric (mpMRI) Follow-up in Focal Low-intermediate Risk Prostate Cancer: Interventional Pilot Study	50	Aug 2024
NCT01835977	Multi-Center Randomized Clinical Trial Irreversible Electroporation for the Ablation of Localized Prostate Cancer	106	Jan 2025
NCT04549688	Active Surveillance Plus (AS+): Local Tumor Control with High-intensity Focused Ultrasound (HIFU) in Patients with Localized Prostate Cancer	250	Sep 2030

NCT No.	Trial Name	Planned Enrollment	Completion Date
NCT03568188	Phase 2, Multicenter, Prospective Cohort Study, Estimating the Efficacy of Focused HIFU Therapy in Patients with Localized Intermediate Risk Prostate Cancer	170	Sep 2025
NCT05454488	An Evidence-Based Focal Cryotherapy Protocol for Focal Ablation of Intermediate Risk Prostate Cancer	30	Jan 2024
NCT03668652	A Randomized Control Trial of Focal Prostate Ablation Versus Radical Prostatectomy	200	Sep 2024
NCT05610852	Prospective Single-Center Randomized Study Of Single-Port Transvesical Partial Prostatectomy Versus High Intensity Focused Ultrasound (HIFU)	276	Jul 2028
NCT05027477	Customized Ablation of the Prostate With the TULSA Procedure Against Radical Prostatectomy Treatment: a Randomized Controlled Trial for Localized Prostate Cancer (CAPTAIN)	201	Dec 2032
NCT06223295	Effectiveness of Focal Therapy in Men With Prostate Cancer (ENFORCE)	356	Feb 2031
NCT06451445	A Pan-Canadian, Investigator Initiated Clinical Trial With Focal IRE Directed to Intermediate-Risk Prostate Cancer (WIRED)	100	May 2032
Unpublished			
NCT04307056	Evaluation of high intensity focused ultrasound (hifu) in curative treatment of localized prostate cancer at low or intermediate risk and in treatment of recurrence after radiotherapy	3862	Aug 2022 (completed)

NCT: national clinical trial

[a]Denotes industry-sponsored or cosponsored trial

Practice Guidelines and Position Statements

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the policy conclusions.

Guidelines or position statements will be considered for inclusion if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are

informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American Urological Association et al

The American Urological Association, in collaboration with the American Society for Radiation Oncology (ASTRO) with additional representation from the American Society of Clinical Oncology (ASCO), and Society of Urologic Oncology (SUO) published updated guidelines on the management of clinically localized prostate cancer in 2022.[47] The guidelines included the following recommendation on focal treatments:

- "Clinicians should inform patients with intermediate-risk prostate cancer considering whole gland or focal ablation that there are a lack of high-quality data comparing ablation outcomes to radiation therapy, surgery, and active surveillance. (Expert Opinion)"
- "Clinicians should not recommend whole gland or focal ablation for patients with high-risk prostate cancer outside of a clinical trial. (Expert Opinion)"

National Comprehensive Cancer Network

The National Comprehensive Cancer Network (NCCN) guidelines for prostate cancer (v.4.2024) recommend only cryosurgery or HIFU as local therapy options for radiotherapy recurrence in the absence of metastatic disease (category 2B). Cryotherapy or other local therapies are not recommended as routine primary therapy for localized prostate cancer due to lack of long-term data comparing these treatments to radiation or radical prostatectomy.[55]

National Cancer Institute

The National Cancer Institute (NCI; 2023) updated its information on prostate cancer treatments.[56] The NCI indicated that cryoablation, photodynamic therapy, and HIFU were new treatment options currently being studied in national trials. The NCI offered no recommendation for or against these treatments.

National Institute for Health and Care Excellence

The NICE (2019; updated in 2021) issued guidance on management for for localized prostate cancer.[13] Cryoablation and high-intensity ultrasound are not recommended for the treatment of localized prostate cancer because there was a lack of evidence on quality-of-life benefits and long-term survival.

US Preventive Services Task Force Recommendations

The US Preventive Services Task Force published recommendations for prostate cancer screening.[57] However, there are no recommendations for focal treatment of prostate cancer.

Medicare National Coverage

There is no national coverage determination.

Regulatory Status

Focal Laser Ablation

In 2010, the Visualase Thermal Therapy System (Medtronic) and, in 2015, the TRANBERG CLS|Laser fiber (Clinical Laserthermia Systems) were cleared for marketing by the US Food and Drug Administration (FDA) through the 510(k) process to necrotize or coagulate soft tissue through interstitial irradiation or thermal therapy under MRI guidance for multiple indications including urology, at wavelengths from 800 to 1064 nm. In 2020, the FDA cleared the Avenda Health focal laser ablation system and in 2021, the FDA granted a breakthrough device designation to a novel artificial intelligence (AI)-enabled focal therapy system for the treatment of localized prostate cancer. In 2023, FDA cleared the Elesta Laser Thermal Therapy Kit to direct laser energy to soft tissue, to necrotize or coagulate soft tissue through interstitial irradiation in medicine and surgery including urology, at a wavelength of 1064nm.FDA product code: LLZ, GEX, FRN.

High-Intensity Focused Ultrasound

In October 2015, the Sonablate 450 (SonaCare Medical) was cleared for marketing through the 510(k) process after approval of a de novo request and classification as class II under the generic name "high intensity ultrasound system for prostate tissue ablation". This device was the first of its kind to be approved in the US. In November 2015, Ablatherm-HIFU (EDAP TMS) was cleared for marketing by the FDA through the 510(k) process. In June 2018, EDAP received 510(k) clearance for its Focal-One HIFU device designed for prostate tissue ablation procedures. This device fuses magnetic resonance and 3D biopsy data with real-time ultrasound imaging, allowing urologists to view detailed images of the prostate on a large monitor and direct high-intensity ultrasound waves to ablate the targeted area.

Cryoablation

Some cryoablation devices cleared for marketing by the FDA through the 510(k) process for cryoablation of the prostate include: Visual-ICE (Galil Medical), Ice Rod CX, CryoCare (Galil Medical), IceSphere (Galil Medical), and Cryocare Systems (Endocare; HealthTronics). FDA product code: GEH.

Radiofrequency Ablation

RFA devices have been cleared for marketing by the FDA through the 510(k) process for general use for soft tissue cutting, coagulation, and ablation by thermal coagulation. Under this general indication, RFA may be used to ablate tumors. FDA product code: GEI.

Photodynamic Therapy

The FDA has granted approval to several photosensitizing drugs and light applicators. Porfimer sodium (Photofrin; Axcan Pharma) and psoralen are photosensitizer ultraviolet lamps used to treat cancer; they were cleared for marketing by the FDA through the 510(k) process. FDA product code: FTC.

In 2020, an FDA advisory committee voted against recommending approval of padeliporfin di-potassium (Tookad; Steba Biotech), a minimally invasive photodynamic therapy for localized prostate cancer, citing concerns that men with very low-risk disease would potentially choose

this therapy instead of active surveillance, despite the unproven long-term benefits and harms of treatment.

Magnetic Nanoparticles

MagForce USA, Inc. is conducting a clinical study evaluating NanoTherm under an FDA Investigational Device Exemption (IDE) (NCT05010759). NanoTherm uses magnetic nanoparticles and an alternating magnetic field to create heat and local ablation in the ablation of prostate cancer.

Irreversible electroporation

The NanoKnife System was cleared through the 510(k) process (K102329) in 2011 for the surgical ablation of soft tissue. NanoKnife has not received clearance for the treatment of any specific disease.

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History

Date	Comments
07/14/15	New Policy. Policy created with literature review through March 3, 2015. Use of any focal therapy modality is considered investigational for treatment of localized prostate cancer.
11/10/15	Annual Review. Policy updated with literature review through July 28, 2015; reference 55 added. Policy statement unchanged.
11/01/16	Annual Review, approved October 11, 2016. Policy updated with literature review through July 26, 2016; references 55-57 and 59-63 were added. Policy statement unchanged.
08/01/17	Interim review, approved July 11, 2017. Policy moved into new format. No changes to policy statement.

Date	Comments
11/01/17	Annual Review, approved October 19, 2017. Policy updated with literature review through July 20, 2017; reference 16 added. Policy statement unchanged.
12/01/18	Annual Review, approved November 6, 2018. Policy updated with literature review through July 2018; reference 57 added; reference 61 updated; several references removed. Policy statement unchanged. Removed CPT code 53899, added CPT code 53854 (new code effective 1/1/19).
05/10/19	Minor edit, added note to clarify that this policy does not address Rezum System for Benign Prostatic Hyperplasia (BPH).
09/01/19	Minor edit, added 2.01.49 to Related Policies.
12/01/19	Annual Review, approved November 6, 2019. Policy updated with literature review through July 2019; reference on NCCN updated. Policy statement unchanged.
01/01/20	Coding update, added CPT code 0582T (new code effective 1/1/20).
08/01/20	Coding update. Removed CPT code 0582T.
12/01/20	Annual Review, approved November 3, 2020. Policy updated with literature review through August 2020; no references added. Policy statement unchanged. Removed CPT code 53854 and added CPT code 0582T. Added new CPT code 55880 effective 1/1/2021.
07/01/21	Coding update, Added CPT code 0655T.
12/01/21	Annual Review, approved November 2, 2021. Policy updated with literature review through July 28, 2021; references added. Policy statement unchanged.
12/01/22	Annual Review, approved November 7, 2022. Policy updated with literature review through August 2, 2022; references added. Minor editorial refinements to policy statements; intent unchanged. Changed the wording from "patient" to "individual" throughout the policy for standardization.
01/01/23	Coding update. Added new CPT codes 0738T and 0739T.
12/01/23	Annual Review, approved November 6, 2023. Policy updated with literature review through July 11, 2023; references added. Policy statement unchanged.
12/01/24	Annual Review, approved November 11, 2024. Policy updated with literature review through July 18, 2024; references added. Policy statement reformatted; however, policy intent unchanged. Added CPT codes 0600T and 0601T to match content update.
07/01/25	Coding update. Added new CPT code 0950T due to Q3 code updates.

Scope: Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.