Anthem

Medical Policy

Subject: Spectral Analysis of Prostate Tissue by Fluorescence Spectroscopy
Document #: SURG.00148
Status: Reviewed
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Description/Scope

This document addresses the use of spectral analysis of prostate tissue by fluorescence spectroscopy, which involves using fiber optics to differentiate between normal prostate tissue and suspicious prostate tissue.

Note: Please see the following related documents for additional information:

- CG-MED-45 Transrectal Ultrasonography
- CG-SURG-98 Prostate Biopsy using MRI Fusion Techniques
- SURG.00107 Prostate Saturation Biopsy

Position Statement

Investigational and Not Medically Necessary:

Spectral analysis of prostate tissue by fluorescence spectroscopy is considered**investigational and not medically necessary** for all indications.

Rationale

For those who have been diagnosed with prostate cancer one treatment is radical prostatectomy. This procedure includes removing the prostate gland and some of the tissue around it to biopsy and remove potential prostate cancer. This removed tissue is then sent out to labs for pathology. A new system is in development which has been reported to improve how biopsies are taken from the prostate by using light sensors (fiber optics) that can see changes in the tissue. The new method is intended to tell the difference between normal and suspicious tissue to help guide the physician during a biopsy procedure. The intention is to use spectral analysis and a highly predictive algorithm to rapidly distinguish normal versus suspicious tissue. The light that is reflected back from the optical fiber is sent to a console, where software will be used to perform spectral analysis to distinguish normal versus suspicious tissue in real time.

A 2015 feasibility study was reported by Werahera and colleagues. In this study, 13 participants with prostate cancer who were scheduled to undergo radical prostatectomy also consented to have analysis of prostate tissue by fluorescence spectroscopy during the prostatectomy. The primary objective was to evaluate the safety and effectiveness of the optical biopsy needle to acquire spectral data and correlative tissue biopsy cores for real-time diagnosis of prostate cancer in clinical settings. The in vivo optical biopsies were performed during the radical prostatectomy and multiple biopsy core samples and correlative spectral data were obtained from each participant within a 10-minute time period. Following radical prostatectomy, ex vivo biopsy core samples and spectral data were also obtained from each surgically excised prostate within a 90-minute time period. The spectral data and corresponding tissue biopsy cores were obtained from different locations within each prostate specimen. The biopsy cores were classified as either benign or malignant and then correlated with the corresponding spectral data. In the in vivo samples, histopathological analysis found cancer in 29/208 viable biopsy cores and in the ex vivo samples, cancer was reported in 51/224 viable biopsy cores. For the in vivo samples there was 72% sensitivity, 66% specificity, and 93% negative predictive value. For the ex vivo samples there was 75% sensitivity, 80% specificity, and 93% negative predictive value in malignant versus benign prostatic tissue classification. The study shows a potential clinical application of spectral analysis of prostate tissue by fluorescence spectroscopy, however additional studies are necessary to assess improved net health outcomes.

Clinical trials are in progress to collect information on prostate biopsy tissue using fluorescence spectroscopy during radical prostatectomy surgery. At this time, the device does not have United States Food and Drug Administration approval.

Background/Overview

Prostate cancer is the most commonly diagnosed cancer, other than skin cancers, in North American men. According to the American Cancer Society (ACS), in 2023 there were an estimated 288,300 new cases of prostate cancer and 34,700 deaths. Prostate cancer is the second leading cause of cancer death in American men, exceeded only by lung cancer. Men in the United States have about 1 chance in 8 of eventually being diagnosed with this malignancy and about 1 man in 41 will eventually die of the disease (ACS, 2023).

The ClariCore™ Biopsy System (Precision Biopsy™, Aurora, CO) is the device for collecting prostate biopsy tissue using fluorescence spectroscopy. According to the manufacturer's website, the ClariCore system has been licensed by another manufacturer (PreView Medical, Inc., Longmont, CO).

Definitions

Biopsy: The removal of a sample of tissue for examination under a microscope for diagnostic purposes.

Prostate: A walnut-shaped gland in men that extends around the urethra at the neck of the urinary bladder and supplies fluid that goes into semen.

Radical prostatectomy: Surgical procedure for the removal of the prostate.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider

reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services are Investigational and Not Medically Necessary:
For the following procedure code or when the code describes a procedure indicated in the Position Statement section as investigational and not medically necessary.

CPT	
0443T	Real-time spectral analysis of prostate tissue by fluorescence spectroscopy, including imaging guidance [add-on code]
ICD-10 Diagnosis	
	All diagnoses

References

Peer Reviewed Publications:

1. Werahera PN, Jasion EA, Crawford ED, et al. Systematic diagnosis of prostate cancer using an optical biopsy needle adjunct with fluorescence spectroscopy. Conf Proc IEEE Eng Med Biol Soc. 2014; 2014:2165-2168.
2. Werahera PN, Jasion EA, Liu Y, et al. Human feasibility study of fluorescence spectroscopy guided optical biopsy needle for prostate cancer diagnosis. Conf Proc IEEE Eng Med Biol Soc. 2015; 2015:7358-7361.

Government Agency, Medical Society, and Other Authoritative Publications:

1. Precision Biopsy, Inc. ClariCore Biopsy System in patients undergoing radical retropubic prostatectomy. NLM Identifier: NCT02773940. Last updated on February 15, 2019. Available at: https://www.clinicaltrials.gov/ct2/show/NCT02773940?term=claricore&rank=1. Accessed on December 14, 2023.
2. Precision Biopsy, Inc. ClariCore Optical Biopsy System used in TRUS (trans-rectal ultrasound)-guided prostrate biopsy. NLM Identifier: NCT02928640. Last updated on February 15, 2019. Available at: https://www.clinicaltrials.gov/ct2/show/NCT02928640?term=claricore&rank=2. Accessed on December 14, 2023.

Websites for Additional Information

1. American Cancer Society (ACS). Prostate cancer. Available at:https://www.cancer.org/cancer/prostate-cancer.html. Accessed on December 14, 2023.
2. National Cancer Institute (NCI). A to Z List of Cancers. Available at:http://www.cancer.gov/cancertopics/types/alphalist. Accessed on December 14, 2023.

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ClariCore Biopsy System
Prostate cancer
Prostatectomy

The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

Document History

Status	Date	Action
Reviewed	02/15/2024	Medical Policy & Technology Assessment Committee (MPTAC) review. Revised Background/Overview, References and Websites for Additional Information sections.
Reviewed	02/16/2023	MPTAC review. Updated Background/Overview, References and Websites for Additional Information sections.
Reviewed	02/17/2022	MPTAC review. Updated Rationale, Background/Overview and References sections.
Reviewed	02/11/2021	MPTAC review. Updated Description/Scope, Rationale, Background/Overview, References, and Websites for Additional Information sections.
Reviewed	02/20/2020	MPTAC review. Updated References section.
Reviewed	03/21/2019	MPTAC review.
Reviewed	03/20/2019	Hematology/Oncology Subcommittee review. Updated Background/Overview and References sections.
Reviewed	05/03/2018	MPTAC review.
Reviewed	05/02/2018	Hematology/Oncology Subcommittee review. The document header wording updated from “Current Effective Date” to “Publish Date.” Updated Background/Overview and References sections.
New	05/04/2017	MPTAC review.
New	05/03/2017	Hematology/Oncology Subcommittee review. Initial document development.

Applicable to Commercial HMO members in California: When a medical policy states a procedure or treatment is investigational, PMGs should not approve or deny the request. Instead, please fax the request to Anthem Blue Cross Grievance and Appeals at fax # 818-234-2767 or 818-234-3824. For questions, call G&A at 1-800-365-0609 and ask to speak with the Investigational Review Nurse.

Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage. The member’s contract benefits in effect on the date that services are rendered must be used. Medical Policy, which addresses medical efficacy, should be considered before utilizing medical opinion in adjudication. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.