Medical Policy

Blue Cross Blue Shield Blue Care Network of Michigan

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***Current Policy Effective Date: 1/1/23**
(See policy history boxes for previous effective dates)

Title: Spectral Analysis of Prostate Tissue

Description/Background

Prostate cancer is the most commonly diagnosed cancer, other than skin cancers, in North American men. According to the American Cancer Society (ACS), in 2020 there will be an estimated 191,930 new cases of prostate cancer and 31,620 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 9 of eventually being diagnosed with this malignancy and about 1 man in 41 will eventually die of the disease.[7]

Regulatory Status

On September 12, 2016, Precision Biopsy received investigational device exemption (IDE) from the US Food and Drug Administration (FDA) to expand the clinical trial of its ClariCore Biopsy System for prostate Cancer. At this time, the device does not have full FDA approval.

Medical Policy Statement

Spectral analysis of prostate tissue by fluorescence spectroscopy is experimental/investigational. It has not been scientifically demonstrated to improve patient clinical outcomes.

Inclusionary and Exclusionary Guidelines (Clinically based guidelines that may support individual consideration and pre-authorization decisions)

N/A

CPT/HCPCS Level II Codes *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure.)*

Established codes:

N/A

Other codes (investigational, not medically necessary, etc.):

0443T

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.

Werahera et al (2014) investigated the ability to target prostate cancer lesions while reducing the sampling of benign tissue.[1] The concentrations of natural fluorophores in prostate tissue fluctuate with disease states. Therefore, fluorescence spectroscopy could be used to quantify these fluctuations to identify prostate cancer. An optical biopsy needle with a light sensitive optical probe at the tip of the inner needle was developed to take prostate biopsies after measuring tissue fluorescence with a laboratory fluorometer. The optical probe consists of eight 100 µm fibers for tissue excitation and a single 200 µm fiber to capture fluorescence spectra. Random biopsy cores were taken from 20 surgically excised prostates after measuring fluorescence spectra of tissue between 295-550nm for several excitations between 280-350nm. Each biopsy core was histopathologically classified and correlated with corresponding spectra. Prostate biopsies were grouped into benign or malignant based on the histological findings. Out of 187 biopsy cores, 109 were benign and 78 were malignant. Partial least square analysis of tissue spectra was performed to identify diagnostically significant principal components as potential classifiers. A linear support vector machine and leave-one-out cross validation method was employed for tissue classification. Study results show 86% sensitivity, 87% specificity, 90% negative predictive value, and 83% positive predictive value

for benign versus malignant prostate tissue classification. This study demonstrates potential clinical applications of fluorescence spectroscopy guided optical biopsy needle for prostate cancer diagnosis with the consequent improvement of patient care.

A 2015 feasibility study was reported by Werahera and colleagues.[2] 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.

SUMMARY OF EVIDENCE

Although initial studies show a potential clinical application of spectral analysis of prostate tissue by fluorescence spectroscopy, larger participant groups are necessary to study safety and effectiveness. Clinical trials are in progress to collect information on prostate biopsy tissue collected with the ClariCore™ Biopsy System (Precision Biopsy™, Aurora, CO) during radical prostatectomy surgery.

Ongoing and Unpublished Clinical Trials

No clinical trials are currently in progress that might influence this policy, see Table 1.

Table 1. Summary of Key Clinical Trials

NCT No.	Trial Name	Enrolled Participants	Completion Date
Unpublished			
NCT02928640*	ClariCore optical biopsy system used in TRUS (trans-rectal ultrasound) guided prostate biopsy	200	Dec 2020 (unknown)
NCT02773940*	ClariCore biopsy system in patients undergoing radical retropublic prostatectomy	100	June 2020 (unknown)
NCT03504761	ClariCore system used in transrectal ultrasound guided prostate biopsy for real-time tissue evaluation (SCORE)	325	Dec 2020 (unknown)

NCT: national clinical trial
*Trial sponsored by the device manufacturer

SUPPLEMENTAL INFORMATION

PRACTICE GUIDELINES AND POSITION STATEMENTS

National Institute of Health and Care Excellence (NICE)[3]
NICE does not address spectral analysis by fluorescence spectroscopy for prostate tissue in their 2014 Prostate Cancer: Diagnosis and Management guidelines (last updated December 2021).

National Comprehensive Cancer Network (NCCN)[4]
NCCN does not address spectral analysis by fluorescence spectroscopy for prostate tissue in their 2021 (v 4.2022) practice guidelines on prostate cancer.

Government Regulations

National:
There is no national coverage determination (NCD) for cryoablation of peripheral nerves.

Local:
There is no local coverage determination (LCD) for spectral analysis of prostate tissue. However, there is an LCD (L35490), Category III Codes effective for services on or after 06/12/2022 that address coverage of certain codes. Code 0443T is not on this list of covered codes.

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

- Saturation Biopsy for the Diagnosis and Staging of Prostate Cancer

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References

1. Werahera P, Jasion E, Crawford D, et al. Systematic diagnosis of prostate cancer using an optical biopsy needle adjunct with fluorescence spectroscopy. Conf Proc IEEE Eng Med Biol Soc. 2014;2165-2168
2. Werahera P, Jasion E, Liu Y, et al. Human feasibility study of fluorescence guided optical biopsy needle for prostate cancer diagnosis. Conf Proc IEEE Eng Med Biol Soc. 2015;4358-7361.
3. National Institute for Health and Care Excellence. Prostate cancer: diagnosis and management. https://www.nice.org.uk/. Accessed September 2022.
4. National Comprehensive Cancer Network. Prostate Cancer. Clinical Practice Guidelines. V4.2022. Published June 2018. https://www.nccn.org/. Accessed September 2022.

5. Centers for Medicare and Medicaid. Local Coverage Determination (L35490) Category III Codes. https://www.cms.gov/medicare-coverage-database/. Accessed September 2022.
6. Michigan Department of Health and Human Services. 2017 Fee Schedule. http://www.michigan.gov/mdhhs/0,5885,7-339-71551_2945_42542_42543_42546_42551-151022--,00.html. Accessed September 2020.
7. American Cancer Society (ACS). Prostate cancer. Last Revised: January 4, 2018. Available at: https://www.cancer.org/cancer/prostate-cancer.html. Accessed September 2020.

The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through September 2022 the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
01/01/18	10/19/17	10/19/17	Joint policy established
01/01/19	10/16/18	10/16/18	Routine policy maintenance, no change in policy status.
01/01/20	10/15/19		Routine policy maintenance, no change in policy status.
01/01/21	10/20/20		Routine policy maintenance. No change in policy status.
01/01/22	10/19/21		Routine policy maintenance. No change in policy status.
01/01/23	10/18/22		Routine policy maintenance, no new supporting literature available. Policy to be retired.

Next Review Date: Spectral analysis of prostate tissue has been determined to be obsolete and is no longer subject to routine review.

Pre-Consolidation Medical Policy History

Original Policy Date	Comments
BCN:	Revised:
BCBSM:	Revised:

BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: SPECTRAL ANALYSIS OF PROSTATE TISSUE

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Not covered
BCNA (Medicare Advantage)	See government section.
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.

II. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- Coverage is based on each member's certificate and is not guaranteed. Please consult the individual member's certificate for details. Additional information regarding coverage or benefits may also be obtained through customer or provider inquiry services at BCN.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.