Medical Coverage Policy | Saturation Biopsy for Diagnosis, Staging and Management of Prostate Cancer

EFFECTIVE DATE: 10|01|2015
POLICY LAST UPDATED: 11|05|2019

OVERVIEW
Saturation biopsy of the prostate, in which more cores are obtained than by standard biopsy protocol, has been proposed in the diagnosis (for initial or repeat biopsy), staging, and management of patients with prostate cancer.

MEDICAL CRITERIA
Not applicable

PRIOR AUTHORIZATION
Not applicable

POLICY STATEMENT
BlueCHiP for Medicare
Saturation biopsy is not covered in the diagnosis, staging, and management of prostate cancer as the evidence is insufficient to determine the effects of the technology on health outcomes.

Commercial Products
Saturation biopsy is considered not medically necessary in the diagnosis, staging, and management of prostate cancer as the evidence is insufficient to determine the effects of the technology on health outcomes.

COVERAGE
Benefits may vary between groups and contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage or Subscriber Agreement for applicable not medically necessary/not covered benefits/coverage.

BACKGROUND
Prostate cancer is a common cancer and is the second leading cause of cancer-related deaths in men in the United States.

Diagnosis
The diagnosis of prostate cancer is made by biopsy of the prostate gland. The approach to biopsy has changed over time, especially with the advent of prostate-specific antigen (PSA) screening programs that identify cancer in prostates that are normal to palpation and to transrectal ultrasound. For patients with an elevated PSA level but with a normal biopsy, questions exist about subsequent evaluation, because repeat biopsy specimens may be positive for cancer in a substantial percentage of patients.

In the early 1990s, use of sextant biopsies involving 6 random, evenly distributed biopsies became the standard approach to the diagnosis of prostate cancer. In the late 1990s, as studies showed high false negative rates for this strategy (missed cancers), approaches were developed to increase the total number of biopsies and to change the location of the biopsies. While there is disagreement about the optimal strategy, most would agree that initial prostate biopsy strategies should include at least 10 to 14 cores. Additional concerns have been raised about drawing conclusions about the stage (grade) of prostate cancer based on limited biopsy specimens. Use of multiple biopsies has also been discussed as an approach to identify tumors that may be eligible for subtotal cryoablation therapy.

At present, many practitioners use a 12 to 14 core "extended" biopsy strategy for patients undergoing initial biopsy. This extended biopsy is done in an office setting and allows for more extensive sampling of the lateral peripheral zone; a sampling of the lateral horn may increase the cancer detection rate by approximately 25%.

Another approach to increasing the number of biopsy tissue cores is "saturation" biopsy. In general, saturation biopsy is considered as more than 20 cores taken from the prostate, with an improved sampling of the anterior zones of the gland, which may be undersampled in standard peripheral zone biopsy strategies and may lead to missed cancers. Saturation biopsy may be performed transrectally or with a transperineally; the transperineal approach is generally performed as a stereotactic template-guided procedure with general anesthesia.

Surveillance
In addition to diagnosis of prostate cancer, some have suggested that saturation biopsy could be a part of active surveillance (a treatment approach that involves surveillance with PSA, digital rectal exam, and routine prostate biopsies in men whose cancers are small and expected to behave indolently). Saturation biopsy has the potential to identify tumor grade more accurately than standard biopsy.

For individuals who have suspected prostate cancer who receive repeat saturation biopsy, the evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have prostate cancer and are candidates for active surveillance who receive saturation biopsy, the evidence is insufficient to determine the effects of the technology on health outcomes.

CODING
The following CPT code is not covered for BlueCHiP for Medicare and not medically necessary for Commercial Products:
55706 Biopsies, prostate, needle, transperineal, stereotactic template guided saturation sampling, including imaging guidance

When performing saturation biopsy, claims should not be filed with codes 55700 or G0416, as these are not specific to saturation sampling.

RELATED POLICIES
Not applicable

PUBLISHED
Provider Update, January 2020
Provider Update, January 2019
Provider Update, February 2018
Provider Update, January 2017
Provider Update, August 2015

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