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

EFFECTIVE DATE: 10|01|2015
POLICY LAST UPDATED: 07|07|2015

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 and Commercial Products
Saturation biopsy is considered not medically necessary in the diagnosis, staging, and management of prostate cancer.

COVERAGE
Benefits may vary between groups/contracts. Please refer to the appropriate Evidence of Coverage or Subscriber Agreement for limitations of benefits/coverage when services are not medically necessary.

BACKGROUND
Prostate cancer is a common cancer and is the second leading cause of cancer-related deaths in men in the United States. 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 material. 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; sampling of the lateral horn may increase the cancer detection rate by approximately 25%.

Another approach to increase the number of biopsy tissue cores is use of the "saturation" biopsy. In general, saturation biopsy is considered as more than 20 cores taken from the prostate, with improved sampling of the

anterior zones of the gland, which may be undersampled in standard peripheral zone biopsy strategies and may lead to 17% of cancers being missed, according to 1 study. Saturation biopsy may be performed transrectally or with a transperineal approach; the transperineal approach is generally performed as a stereotactic template-guided procedure with general anesthesia.

Studies showing improved initial detection of prostate cancer using saturation biopsy compared with the use of extended biopsies are inconclusive. Evidence is lacking as to whether saturation biopsy leads to improved health outcomes, including the possibility of detecting clinically insignificant cancers, which could lead to unnecessary treatment. Few studies show improvement in clinical outcomes with the use of saturation biopsy as part of active surveillance. Thus, the technique of saturation biopsy is considered not medically necessary.

CODING

BlueCHiP for Medicare and Commercial Products

The following code is not medically necessary:
55706

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

RELATED POLICIES

Cryoablation of Prostate Cancer

PUBLISHED

Provider Update, August 2015

REFERENCES

1. Zaytoun OM, Jones JS. Prostate cancer detection after a negative prostate biopsy: lessons learnt in the Cleveland Clinic experience. Int J Urol. Aug 2011;18(8):557-568. PMID 21692866
2. Wright JL, Ellis WJ. Improved prostate cancer detection with anterior apical prostate biopsies. Urol Oncol. Nov-Dec 2006;24(6):492-495. PMID 17138129
3. Jiang X, Zhu S, Feng G, et al. Is an initial saturation prostate biopsy scheme better than an extended scheme for detection of prostate cancer? A systematic review and meta-analysis. Eur Urol. Jun 2013;63(6):1031-1039. PMID 23414775
4. Li YH, Elshafei A, Li J, et al. Transrectal saturation technique may improve cancer detection as an initial prostate biopsy strategy in men with prostate-specific antigen <10 ng/ml. Eur Urol. Jun 2014;65(6):1178-1183. PMID 23768632
5. Li YH, Elshafei A, Li J, et al. Potential benefit of transrectal saturation prostate biopsy as an initial biopsy strategy: decreased likelihood of finding significant cancer on future biopsy. Urology. Apr 2014;83(4):714-718. PMID 24680442
6. Eichler K, Hempel S, Wilby J, et al. Diagnostic value of systematic biopsy methods in the investigation of prostate cancer: a systematic review. J Urol. 2006;175(5):1605-1612.
7. Mabjeesh NJ, Lidawi G, Chen J, et al. High detection rate of significant prostate tumours in anterior zones using transperineal ultrasound-guided template saturation biopsy. BJU Int. Oct 2012;110(7):993-997. PMID 22394668
8. Lee MC, Moussa AS, Zaytoun O, et al. Using a saturation biopsy scheme increases cancer detection during repeat biopsy in men with high-grade prostatic intra-epithelial neoplasia. Urology. Nov 2011;78(5):1115-1119. PMID 22054382
9. Zaytoun OM, Moussa AS, Gao T, et al. Office based transrectal saturation biopsy improves prostate cancer detection compared to extended biopsy in the repeat biopsy population. J Urol. 2011;186(3):850-854.
10. Linder BJ, Frank I, Umbreit EC, et al. Standard and saturation transrectal prostate biopsy techniques are equally accurate among prostate cancer active surveillance candidates. Int J Urol. Sep 2013;20(9):860-864. PMID 23278942

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