Protocol

Saturation Biopsy for Diagnosis and Staging of Prostate Cancer

(701121)

Medical Benefit		**Effective Date**: 04/01/12	**Next Review Date**: 01/15
Preauthorization	No	**Review Dates**: 09/09, 03/10, 01/11, 01/12, 01/13, 01/14	

The following Protocol contains medical necessity criteria that apply for this service. It is applicable to Medicare Advantage products unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. ***Preauthorization is not required but is recommended if, despite this Protocol position, you feel this service is medically necessary; supporting documentation must be submitted to Utilization Management.*** *Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.*

Description

Saturation biopsy, generally considered obtaining more than 20 biopsy tissue cores from the prostate in a systematic manner has been proposed in the diagnosis (for initial or repeat biopsy), staging, and management of patients with prostate cancer.

Prostate cancer is a common cancer and is the second leading cause of cancer-related deaths in men in the U.S. 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, since repeat biopsy specimens may be positive for cancer in a substantial percentage of patients.

In the early 1990s, use of sextant biopsies involving six 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 10–14 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%. (1)

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 under-sampled in standard peripheral zone biopsy strategies and may lead to 17% of cancers being missed, according to one study. (2) 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.

Related Protocol

Cryoablation of Prostate Cancer

Policy (Formerly Corporate Medical Guideline)

Saturation biopsy, taking more than 20 core tissue samples at one time, is considered **investigational** in the diagnosis, staging, and management of prostate cancer.

Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this Protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

References

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

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