Protocol

Systems Pathology in Prostate Cancer

(20464)

(Formerly Systems Pathology for Predicting Risk of Recurrence in Prostate Cancer)

Medical Benefit		**Effective Date**: 10/01/14	**Next Review Date**: 07/15
Preauthorization	No	**Review Dates**: 09/10, 07/11, 07/12, 07/13, 07/14	

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.*** *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

Systems pathology, an approach that combines cellular and biological features to standard clinical parameters such as age, clinical or pathologic stage, grade, percent of cancer on biopsy cores, and prostate-specific antigen (PSA) or its derivatives, is proposed as a way to estimate the probability of disease progression, either before or after prostatectomy.

Background

Predicting risk of recurrence in patients undergoing treatment for prostate cancer is difficult, as it is for most malignancies. Over time, risk models for patients with prostate cancer have evolved from early efforts that relied on grade, stage, and PSA levels to complex multivariate models. A publication in 2008 indicates that there are more than 65 published, externally validated prostate cancer nomograms and other tools that use standard clinical parameters such as age, clinical or pathologic stage, grade, percent of cancer on biopsy cores, and PSA or its derivatives to predict various clinical and pathologic outcomes. (1)

Recent studies have begun to examine a different approach by adding both cellular and biologic features to the clinical and pathologic information just noted. This approach has been called "systems pathology."

Aureon Laboratories offered two pathology tests called the Prostate Px+™ test and the Post-Op Px™ test (formerly called Prostate Px). Prostate Px+ was described as useful at diagnosis to patients considering surgery (radical prostatectomy) or other treatment options by providing physicians with objective information regarding the probability of disease progression. Post-Op Px estimated risk of PSA recurrence and disease progression after surgery. In October 2011, the company ceased operations and the tests are no longer offered.

Iris International offers the NADiA® ProsVue™ test, which received U.S. Food and Drug Administration 510(k) clearance in 2011. The NADiA ProsVue test evaluates risk of prostate cancer recurrence after radical prostatectomy when PSA levels are less than 0.1 ng/mL. The NADiA immunoassay, polymerase chain reaction test is used to determine PSA levels on three serum samples taken between six weeks and 20 months after radical prostatectomy. The PSA data are entered into the ProsVue software to ensure appropriate serum sample use and calculation of assay results and to determine the rate of PSA change, the PSA slope.

Related Protocol

Saturation Biopsy for Diagnosis and Staging of Prostate Cancer

Policy (Formerly Corporate Medical Guideline)

Use of tests utilizing systems pathology that include cellular and biologic features of a tumor is considered **investigational**, including use in predicting risk of recurrence in patients with 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.

1. Shariat SF, Karakiewicz PI, Margulis V et al. Inventory of prostate cancer predictive tools. Curr Opin Urol 2008; 18(3):279-96.
2. Donovan MJ, Hamann S, Clayton M et al. Systems pathology approach for the prediction of prostate cancer progression after radical prostatectomy. J Clin Oncol 2008; 26(24):3923-9.
3. Donovan MJ, Khan FM, Fernandez G et al. Personalized prediction of tumor response and cancer progression on prostate needle biopsy. J Urol 2009; 182(1):125-32.
4. Cordon-Cardo C, Kotsianti A, Verbel DA et al. Improved prediction of prostate cancer recurrence through systems pathology. J Clin Invest 2007; 117(7):1876-83.
5. Eggener SE, Vickers AJ, Serio AM et al. Comparison of models to predict clinical failure after radical prostatectomy. Cancer 2009; 115(2):303-10.
6. Veltri RW, Miller MC, Isharwal S et al. Prediction of prostate-specific antigen recurrence in men with long-term follow-up postprostatectomy using quantitative nuclear morphometry. Cancer Epidemiol Biomarkers Prev 2008; 17(1):102-10.
7. Klein EA, Stephenson AJ, Raghavan D et al. Systems pathology and predicting outcome after radical prostatectomy. J Clin Oncol 2008; 26(24):3916-7.
8. Donovan MJ, Osman I, Khan FM et al. Androgen receptor expression is associated with prostate cancer-specific survival in castrate patients with metastatic disease. BJU Int 2010; 105(4):462-7.
9. Donovan MJ, Khan FM, Bayer-Zubek V et al. A systems-based modelling approach using transurethral resection of the prostate (TURP) specimens yielded incremental prognostic significance to Gleason when predicting long-term outcome in men with localized prostate cancer. BJU Int 2012; 109(2):207-13.
10. Donovan MJ, Khan FM, Powell D et al. Postoperative systems models more accurately predict risk of significant disease progression than standard risk groups and a 10-year postoperative nomogram: potential impact on the receipt of adjuvant therapy after surgery. BJU Int 2012; 109(1):40-5.

11. Moul JW, Lilja H, Semmes OJ et al. NADiA ProsVue prostate-specific antigen slope is an independent prognostic marker for identifying men at reduced risk of clinical recurrence of prostate cancer after radical prostatectomy. Urology 2012; 80(6):1319-25.