

Corporate Medical Policy

Multigene Expression Assay for Predicting Recurrence in Colon Cancer

File Name:	multigene_expression_assay_for_predicting_recurrence_in_colon_cancer
Origination:	4/2011
Last CAP Review:	4/2012
Next CAP Review:	4/2013
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Description of Procedure or Service

A 12-gene expression test (Oncotype DX® colon cancer test; Genomic Health, Inc., Redwood City, CA) has been developed to predict the likelihood of disease recurrence for patients with stage II colon cancer following surgery.

Background

Of patients with stage II colon cancer, 75–80% are cured by surgery alone, and the absolute benefit of chemotherapy for the patient population is small. Those patients who are most likely to benefit from chemotherapy are difficult to identify by standard clinical and pathological risk factors. The 12-gene expression test is intended to be used as an aid in identifying those stage II patients most likely to experience recurrence after surgery and therefore those most likely to benefit from additional treatment.

Colorectal cancer is classified stage II when it has spread outside the colon and/or rectum to nearby tissue, but is not detectable in the lymph nodes and has not metastasized to distant sites (also called Dukes B). The primary treatment is surgical resection of the primary cancer and colonic anastomosis. After surgery the prognosis is very good, with survival rates of 75% to 80% at 5 years. Meta-analysis of several trials of adjuvant therapy vs. surgery alone in all stage II patients found statistically significant, although small, absolute benefit of chemotherapy for disease-free survival but not for overall survival. Therefore, adjuvant chemotherapy with 5-fluorouracil (5-FU) or capecitabine is recommended only as an option for resected patients with high-risk stage II disease (i.e. those with poor prognostic features). However, the clinical and pathological features used to identify high-risk disease are not well-established and the patients for whom the benefits of adjuvant chemotherapy would most likely outweigh the harms cannot be identified with certainty.

Regulatory Status

The 12-gene expression test was launched by Genomic Health as the Oncotype DX® colon cancer test in January 2010. The test has not been submitted to or cleared for marketing by the U.S. Food and Drug Administration (FDA). The test is offered as a laboratory-developed assay service conducted in the CLIA-licensed Genomic Health clinical laboratory.

******Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.***

Policy

The multigene expression assay is considered investigational for predicting recurrence in colon cancer. BCBSNC does not provide coverage for investigational services or procedures.

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Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

When multigene expression assay for predicting recurrence in colon cancer is covered

Not applicable

When multigene expression assay for predicting recurrence in colon cancer is not covered

The 12-gene expression test (Oncotype DX® colon cancer test) is considered **investigational**, including use for predicting the likelihood of disease recurrence for patients with stage II colon cancer following surgery.

Policy Guidelines

While there is a report clearly detailing the methodology used for developing the algorithms for this test, the only fully published evidence suggesting the recurrence score (RS) is prognostically sound is based on bootstrapping methodologies. Preliminary promising reports on the validation of this tool as a prognostic indicator of stage II tumor recurrence have appeared in abstract form and been briefly described in a review article. However, an assessment of both clinical validity and clinical utility of testing awaits publication of more detailed results.

The evidence to date is insufficient to permit conclusions concerning the effect of the 12-gene expression test (Oncotype DX® colon cancer test) on health outcomes.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable service codes: There is no specific code for this laboratory test. It will likely be coded using an unlisted code such as 84999 or 88299.

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.04.61, 3/11/2010

Specialty Matched Consultant Advisory Panel review – 4/2011

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BCBSA Medical Policy Reference Manual [Electronic Version]. 2.04.61, 8/11/2011

Medical Director – 9/2011

Specialty Matched Consultant Advisory Panel – 4/2012

Policy Implementation/Update Information

- 5/10/11 New policy developed. The multigene expression assay is considered investigational for predicting recurrence in colon cancer. Specialty Matched Consultant Advisory Panel review 4/27/11. (adn)
- 10/11/11 “Policy Guidelines” updated. Reviewed by Senior Medical Director. Reference added. (btw)
- 5/15/12 Specialty Matched Consultant Advisory Panel review 4/18/2012. No change to policy intent. (btw)

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.