Medical Coverage Policy

Multi-Gene Expression Assay for Predicting Recurrence in Colon Cancer

☐ Device/Equipment  ☐ Drug  ☐ Medical  ☐ Surgery  ☒ Test  ☐ Other

Effective Date: 04/20/2010  Policy Last Updated: 4/20/2012

☐ Prospective review is recommended/required. Please check the member agreement for preauthorization guidelines.

☒ Prospective review is not required.

Description:
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 stage II colon cancer patients following surgery. The results of the test, based on an analysis of seven different genes found in colon-cancer tumors, yield a score that is intended to determine whether patients are at low, intermediate or high risk of having the disease come back after it is removed through surgery.

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. Therefore, use of this test to predict the likelihood of disease recurrence for stage II colon cancer patients, is considered not medically necessary.

Medical Criteria:
Not applicable

Policy:
The 12-gene expression test (Oncotype DX® colon cancer test) is considered not medically necessary for predicting the likelihood of disease recurrence for stage II colon cancer patients following surgery as there is insufficient evidence to demonstrate its effect on health outcomes.

Note: Genomix contacts the Health Services Management department for preauthorization when a test is requested.

Coverage:
Benefits may vary between groups/contracts. Please refer to the appropriate Evidence of Coverage or Subscriber Agreement, for the applicable “Not Medically Necessary” services.

Coding:
There is no specific code for this laboratory test therefore the following unlisted codes would be used:
84999 Unlisted chemistry procedure
Unlisted cytogenetic study

Related Topics:
Assays of Genetic Expression to Determine Prognosis of Breast Cancer

Also know as:
Oncotype Dx

Publication:
Provider Update, June 2010
Provider Update, June 2011
Provider Update, June 2012

References:

http://www.asco.org/ASCOv2/Meetings/Abstracts?&vmview=abst_detail_view&confID=115&abstractID=88713

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