I. Policy: Oncotype Dx - Multi-gene Expression Assay for Predicting Recurrence in Colon Cancer

II. Purpose/Objective:
To provide a policy of coverage regarding Oncotype Dx - Multi-gene Expression Assay for Predicting Recurrence in Colon Cancer

III. Responsibility:
A. Medical Directors
B. Medical Management Department

IV. Required Definitions
1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions
Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
b. provided for the diagnosis, and the direct care and treatment of the Member's condition, illness disease or injury;
c. in accordance with current standards of good medical treatment practiced by the general medical community;
d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

Medicaid Business Segment
Medical Necessity shall mean a service or benefit that is compensable under the Medical Assistance Program and if it meets any one of the following standards:
(i) the service or benefit will, or is reasonably expected to, prevent the onset of an illness, condition or disability.
(ii) the service or benefit will, or is reasonably expected to, reduce or ameliorate the physical, mental or development effects of an illness, condition, injury or disability.
(iii) the service or benefit will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for members of the same age.

DESCRIPTION:
Oncotype DX® Colon Cancer Test is a 12-gene expression test designed to predict the likelihood of disease recurrence for stage II colon cancer patients following surgery. Gene expression is quantified from microdissected fixed paraffin-embedded primary colon cancer tissue. The level of expression of the prognosis and predictive signature are then reported as a recurrence score.

INDICATIONS: Requires Prior Medical Director or designee Authorization
The Plan considers Oncotype DX™ colon assay as medically necessary to assess the need for adjuvant chemotherapy in newly diagnosed colon cancer when all of the following are met:

- Diagnosis of Stage II colon cancer is made; and
- Member has undergone initial surgical resection; and
- Provider and member are committed to utilize the recurrence risk score to guide the treatment plan

For the Medicare and Medicaid Business Segments – Although there is no National Coverage Determination issued for this service, CMS directives may allow this testing to be considered for coverage when used to predict risk of recurrence risk in patients with stage II colon cancer. Effective Sept 18, 2011, Palmetto GBA established a formal coverage policy for all Medicare patients. This local carrier determination is applicable nationally. Please refer to policy number A51725 on Centers for Medicare & Medicaid Services website.

CODING ASSOCIATED WITH: Oncotype Dx - Multi-gene Expression Assay for Predicting Recurrence in Colon Cancer The following codes are included below for informational purposes and may not be all inclusive. Inclusion of a procedure or device code(s) does not constitute or imply coverage nor does it imply or guarantee provider reimbursement. Coverage is determined by the member specific benefit plan document and any applicable laws regarding coverage of specific services. Please note that per Medicare coverage rules, only specific CPT/HCPCS Codes may be covered for the Medicare Business Segment. Please consult the CMS website at www.cms.gov or the local Medicare Administrative Carrier (MAC) for more information on Medicare coverage and coding requirements

81525 Oncology (colon), MRNA, gene expression profiling by real-time R-PCR of 12 genes (7 context and 5 housekeeping), utilizing formalin-fixed paraffin embedded tissue, algorithm reported as a recurrence score


LINE OF BUSINESS:
Eligibility and contract specific benefits, limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy. For Medicare, applicable LCD’s and NCD’s will supersede this policy. For PA Medicaid Business segment, this policy applies as written.

REFERENCES:


Colon Cancer: Third Successful Prospectively Designed Study of Oncotype DX Colon Cancer Test In Patients with Stage II Disease, First Validation Study in Patients with Stage III Disease (Abstract #3512); Separate Study Demonstrates 29 percent Change in Treatment Recommendations in Stage II Colon Cancer Patients (Abstract #3626)


Schwartzberg L, Babkowski R. Oncotype DX assay for predicting recurrence of stage II colon cancer Community Oncology 2010;7:198-201


UpToDate. Pathology and Prognostic Determinants of Colorectal Cancer. Carolyn C. Compton M.D., PhD. Topic last updated April 8, 2016


This policy will be revised as necessary and reviewed no less than annually.

Devised: 11/2010

Revised: 2/12 (CMS mandate), 7/12 (criteria), 8/12 (exclusions removed and Medicare info added)

Reviewed: 11/11, 8/13, 8/14; 8/15, 7/16, 7/17, 6/18, 7/19