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Original Effective Date: 05/15/10

Reviewed: 10/22/20

Revised: 01/01/21

Subject: Gene Expression Profile Testing and Circulating Tumor DNA Testing for Predicting Recurrence in Colon Cancer

THIS MEDICAL COVERAGE GUIDELINE IS NOT AN AUTHORIZATION, CERTIFICATION, EXPLANATION OF BENEFITS, OR A GUARANTEE OF PAYMENT, NOR DOES IT SUBSTITUTE FOR OR CONSTITUTE MEDICAL ADVICE. ALL MEDICAL DECISIONS ARE SOLELY THE RESPONSIBILITY OF THE PATIENT AND PHYSICIAN. BENEFITS ARE DETERMINED BY THE GROUP CONTRACT, MEMBER BENEFIT BOOKLET, AND/OR INDIVIDUAL SUBSCRIBER CERTIFICATE IN EFFECT AT THE TIME SERVICES WERE RENDERED. THIS MEDICAL COVERAGE GUIDELINE APPLIES TO ALL LINES OF BUSINESS UNLESS OTHERWISE NOTED IN THE PROGRAM EXCEPTIONS SECTION.

Position Statement	Billing/Coding	Reimbursement	Program Exceptions	Definitions	Related Guidelines
Other	References	Update			

DESCRIPTION:

Of patients with stage II colon cancer, 75–80% are cured by surgery alone, and the absolute benefit of chemotherapy for the overall patient population is small. Patients most likely to benefit from chemotherapy are difficult to identify by standard clinical and pathologic risk factors. Gene expression profiling and circulating tumor DNA tests are intended to facilitate identifying stage II patients most likely to experience recurrence after surgery and most likely to benefit from additional treatment.

Gene expression profile (GEP) and circulating tumor DNA (ctDNA) tests have been developed for use as prognostic markers of stage II or III colon cancer to help identify patients who are at high risk for recurrent disease and could be candidates for adjuvant chemotherapy.

POSITION STATEMENT:

Gene expression assays and circulating tumor DNA assays for determining the prognosis of stage II or stage III colon cancer following surgery are considered **experimental or investigational**. The evidence is insufficient to permit conclusions on health outcomes.

BILLING/CODING INFORMATION:

CPT Coding

81525	Oncology (colon), mRNA, gene expression profiling by real-time RT-PCR of 12 genes (7 content and 5 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithm
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	reported as a recurrence score (Investigational) [Oncotype DX Colon Cancer Assay]
0229U	BCAT1 (Branched chain amino acid transaminase 1) or IKZF1 (IKAROS family zinc finger 1) (eg, colorectal cancer) promoter methylation analysis (Investigational)

Unlisted codes 81599, 84999, & 88299 may be used to report other gene expression assays.

REIMBURSEMENT INFORMATION:

Refer to section entitled **POSITION STATEMENT**.

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Advantage products: No National Coverage Determination (NCD) and/or Local Coverage Determination (LCD) was found at the time of the last guideline reviewed date.

DEFINITIONS:

No guideline specific definitions apply.

RELATED GUIDELINES:

None applicable.

OTHER:

Other names used to report gene expression and ctDNA tests:

Note: The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

ColoPrint® 18-Gene Colon Cancer Recurrence Assay
GeneFx™ Colon (also known as CoIDx)
OncoDefender-CRC™
Oncotype DX® Colon Recurrence Score
Signatera ctDNA.

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COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy & Coverage Committee on 10/22/20.

GUIDELINE UPDATE INFORMATION:

05/15/10	New Medical Coverage Guideline.
03/15/11	Annual review; position statement maintained and references updated.
03/15/12	Annual review; position statement maintained, Program Exceptions section and references updated.
03/15/13	Annual review; investigational status maintained, position statement, description section, and references updated.
03/15/14	Annual review; position statement maintained, Medicare program exception and references updated.
05/15/14	Revision; references updated.
06/15/15	Annual review; position statement and references updated.
01/01/16	Annual HCPCS/CPT update; code 81525 added.
10/15/16	Revision; description, position statement, program exception, and references updated.
10/15/17	Review; investigational position maintained, description, program exception, and references updated.
10/15/18	Review; investigational position maintained, description, coding, and references updated.
11/15/19	Review; position statement maintained and references updated.
11/15/20	Review; Position statement, title, description, and references updated.
01/01/21	Annual CPT/HCPCS update. Code 0229U added.