

# Local Coverage Article: Billing and Coding: Genomic Sequence Analysis Panels in the Treatment of Solid Organ Neoplasms (A56867)

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## Contractor Information

CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATE(S)
National Government Services, Inc.	MAC - Part A	06101 - MAC A	J - 06	Illinois
National Government Services, Inc.	MAC - Part B	06102 - MAC B	J - 06	Illinois
National Government Services, Inc.	MAC - Part A	06201 - MAC A	J - 06	Minnesota
National Government Services, Inc.	MAC - Part B	06202 - MAC B	J - 06	Minnesota
National Government Services, Inc.	MAC - Part A	06301 - MAC A	J - 06	Wisconsin
National Government Services, Inc.	MAC - Part B	06302 - MAC B	J - 06	Wisconsin
National Government Services, Inc.	A and B and HHH MAC	13101 - MAC A	J - K	Connecticut
National Government Services, Inc.	A and B and HHH MAC	13102 - MAC B	J - K	Connecticut
National Government Services, Inc.	A and B and HHH MAC	13201 - MAC A	J - K	New York - Entire State
National Government Services, Inc.	A and B and HHH MAC	13202 - MAC B	J - K	New York - Downstate
National Government Services, Inc.	A and B and HHH MAC	13282 - MAC B	J - K	New York - Upstate
National Government Services, Inc.	A and B and HHH MAC	13292 - MAC B	J - K	New York - Queens
National Government Services, Inc.	A and B and HHH MAC	14111 - MAC A	J - K	Maine
National Government Services, Inc.	A and B and HHH MAC	14112 - MAC B	J - K	Maine
National Government Services, Inc.	A and B and HHH MAC	14211 - MAC A	J - K	Massachusetts

CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATE(S)
National Government Services, Inc.	A and B and HHH MAC	14212 - MAC B	J - K	Massachusetts
National Government Services, Inc.	A and B and HHH MAC	14311 - MAC A	J - K	New Hampshire
National Government Services, Inc.	A and B and HHH MAC	14312 - MAC B	J - K	New Hampshire
National Government Services, Inc.	A and B and HHH MAC	14411 - MAC A	J - K	Rhode Island
National Government Services, Inc.	A and B and HHH MAC	14412 - MAC B	J - K	Rhode Island
National Government Services, Inc.	A and B and HHH MAC	14511 - MAC A	J - K	Vermont
National Government Services, Inc.	A and B and HHH MAC	14512 - MAC B	J - K	Vermont

## Article Information

### General Information

**Article ID**

A56867

**Original Effective Date**

08/15/2019

**Article Title**

Billing and Coding: Genomic Sequence Analysis Panels in the Treatment of Solid Organ Neoplasms

**Revision Effective Date**

10/03/2019

**Article Type**

Billing and Coding

**Revision Ending Date**

N/A

**AMA CPT / ADA CDT / AHA NUBC Copyright Statement**

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**Retirement Date**

N/A

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## **CMS National Coverage Policy**

N/A

## **Article Guidance**

### **Article Text:**

This article contains coding and other guidelines that complement the Local Coverage Determination (LCD) for Genomic Sequence Analysis Panels in the Treatment of Solid Organ Neoplasms.

### **Coding Information:**

Procedure codes may be subject to National Correct Coding Initiative (NCCI) edits or OPPS packaging edits. Refer to NCCI and OPPS requirements prior to billing Medicare.

For services requiring a referring/ordering physician, the name and NPI of the referring/ordering physician must be reported on the claim.

A claim submitted without a valid ICD-10-CM diagnosis code will be returned to the provider as an incomplete claim under Section 1833(e) of the Social Security Act.

The diagnosis code(s) must best describe the patient's condition for which the service was performed.

### **Specific Coding Information:**

Regarding Non-Small Cell Lung Cancer (NSCLC) and Metastatic Colorectal Cancer (mCRC), the following guidelines apply:

Targeted genomic sequence analysis panel, solid organ neoplasm, DNA analysis, 5-50 genes (CPT 81445) is a useful representation of the aggregate of these gene tests, and may be used (along with other listed panel codes) as long as the panel contains, at a minimum, 5 or more gene tests for molecular biomarkers determined to meet Medicare coverage criteria as listed above. Evaluation of other genes or genomic sequences not addressed by NCCN or other professional guidelines are not precluded, but their inclusion in panels recognized by this code should not be interpreted as endorsement of such testing by genomic sequencing procedures and laboratories and users of such testing are advised to adhere to traditional regulatory and institutional oversight mechanisms to assure their clinical validity and utility.

### **Documentation Requirements:**

Documentation must be adequate to verify that coverage guidelines listed above have been met. Thus, the medical record must contain documentation that the testing is expected to influence treatment of the condition toward which the testing is directed. The laboratory or billing provider must have on file the physician requisition which sets forth the diagnosis or condition (ICD-10-CM code) that warrants the test(s).

Examples of documentation requirements of the ordering physician/non-physician practitioner (NPP) include, but are not limited to, history and physical or exam findings that support the decision making, problems/diagnoses, relevant data (e.g., lab testing, imaging results).

Documentation requirements of the performing laboratory (when requested) include, but are not limited to, lab accreditation, test requisition, test record/procedures, reports (preliminary and final), and quality control record.

Documentation requirements for LDT(s)/protocols (when requested) include diagnostic test/assay, lab/manufacturer, names of comparable assays/services (if relevant), description of assay, analytical validity evidence, clinical validity evidence, and clinical utility.

Providers are required to code to specificity however, if CPT 81479 (unlisted molecular pathology procedure) is used the documentation must clearly identify the unique molecular pathology procedure performed. When multiple procedure codes are submitted on a claim (unique and/or unlisted) the documentation supporting each code should be easily identifiable. If on review the contractor cannot link a billed code to the documentation, these services will be denied based on Title XVIII of the Social Security Act, §1833(e).

For these tests, the ordering provider must provide to the laboratory copies of the signed informed consent documentation.

### **Utilization Guidelines:**

Screening services such as pre-symptomatic genetic tests and services used to detect an undiagnosed disease or disease predisposition are not a Medicare benefit and are not covered. Similarly, Medicare may not reimburse the costs of tests/examinations that assess the risk of a condition unless the risk assessment clearly and directly affects the management of the patient.

A specific genetic test may only be performed once in a lifetime per beneficiary for inherited conditions; however, when medically reasonable and necessary, genetic testing may be done on acquired conditions such as malignancies (including separate malignancies developing at different times) as they are treated and are being followed, in order to assess response or other relevant clinical criteria. Likewise, there are situations where medical record and literature documentation are able to demonstrate that serial testing can be reasonably predicted to provide additional

clinically useful information. When the record documents that this information, such as confirmed significant response to current therapy, is likely to assist in modifying treatment, serial testing can be considered reasonable and necessary and eligible for coverage.

## Coding Information

### CPT/HCPCS Codes

#### Group 1 Paragraph:

N/A

#### Group 1 Codes:

CODE	DESCRIPTION
81445	TARGETED GENOMIC SEQUENCE ANALYSIS PANEL, SOLID ORGAN NEOPLASM, DNA ANALYSIS, AND RNA ANALYSIS WHEN PERFORMED, 5-50 GENES (EG, ALK, BRAF, CDKN2A, EGFR, ERBB2, KIT, KRAS, NRAS, MET, PDGFRA, PDGFRB, PGR, PIK3CA, PTEN, RET), INTERROGATION FOR SEQUENCE VARIANTS AND COPY NUMBER VARIANTS OR REARRANGEMENTS, IF PERFORMED
0048U	ONCOLOGY (SOLID ORGAN NEOPLASIA), DNA, TARGETED SEQUENCING OF PROTEIN-CODING EXONS OF 468 CANCER-ASSOCIATED GENES, INCLUDING INTERROGATION FOR SOMATIC MUTATIONS AND MICROSATELLITE INSTABILITY, MATCHED WITH NORMAL SPECIMENS, UTILIZING FORMALIN-FIXED PARAFFIN-EMBEDDED TUMOR TISSUE, REPORT OF CLINICALLY SIGNIFICANT MUTATION(S)

### CPT/HCPCS Modifiers

N/A

### ICD-10 Codes that Support Medical Necessity

#### Group 1 Paragraph:

CPT codes 81445 or 0048U may be used with the following ICD-10-CM diagnosis codes which are considered medically necessary in the treatment of Non-Small Cell Lung Cancer (NSCLC):

#### Group 1 Codes:

ICD-10 CODE	DESCRIPTION
C33 - C34.92	Malignant neoplasm of trachea - Malignant neoplasm of unspecified part of left bronchus or lung

ICD-10 CODE	DESCRIPTION
C38.4	Malignant neoplasm of pleura
C45.0	Mesothelioma of pleura

**Group 2 Paragraph:**

CPT codes 81445 or 0048U may be used with the following ICD-10-CM diagnosis codes which are considered medically necessary in the treatment of Metastatic Colorectal Cancer (mCRC):

**Group 2 Codes:**

ICD-10 CODE	DESCRIPTION
C17.0 - C17.9	Malignant neoplasm of duodenum - Malignant neoplasm of small intestine, unspecified
C18.0 - C19	Malignant neoplasm of cecum - Malignant neoplasm of rectosigmoid junction
C20	Malignant neoplasm of rectum
C21.1	Malignant neoplasm of anal canal
C21.2	Malignant neoplasm of cloacogenic zone
C21.8	Malignant neoplasm of overlapping sites of rectum, anus and anal canal
C7A.020 - C7A.026	Malignant carcinoid tumor of the appendix - Malignant carcinoid tumor of the rectum

**ICD-10 Codes that DO NOT Support Medical Necessity**

**Group 1 Paragraph:**

Any diagnosis code not listed above does not support medical necessity

**Group 1 Codes:**

ICD-10 CODE	DESCRIPTION
XX000	Not Applicable

**Additional ICD-10 Information**

N/A

**Bill Type Codes:**

Contractors may specify Bill Types to help providers identify those Bill Types typically used to report this service. Absence of a Bill Type does not guarantee that the policy does not apply to that Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the policy should be assumed to apply equally to all claims.

N/A

**Revenue Codes:**

Contractors may specify Revenue Codes to help providers identify those Revenue Codes typically used to report this service. In most instances Revenue Codes are purely advisory. Unless specified in the policy, services reported under other Revenue Codes are equally subject to this coverage determination. Complete absence of all Revenue Codes indicates that coverage is not influenced by Revenue Code and the policy should be assumed to apply equally to all Revenue Codes.

N/A

**Other Coding Information**

N/A

## Revision History Information

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION
10/03/2019	R1	<p>This article was converted to the new Billing and Coding Article format.</p> <p>Bill types and Revenue codes have been removed from this article. Guidance on these codes is available in the Bill type and Revenue code sections.</p>

## Associated Documents

**Related Local Coverage Document(s)**

LCD(s)

L37810 - Genomic Sequence Analysis Panels in the Treatment of Solid Organ Neoplasms

**Related National Coverage Document(s)**

N/A

**Statutory Requirements URL(s)**

N/A

**Rules and Regulations URL(s)**

N/A

**CMS Manual Explanations URL(s)**

N/A

**Other URL(s)**

N/A

**Public Version(s)**

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## **Keywords**

N/A