Local Coverage Determination (LCD) for Circulating Tumor Cell Marker Assays (L32535)

Contractor Information
Contractor Name
Noridian Administrative Services, LLC
Contractor Number 00320
Contractor Type FI

LCD Information
Document Information
LCD ID Number L32535

LCD Title
Circulating Tumor Cell Marker Assays

Contractor's Determination Number
A2012.01 R1

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Original Determination Effective Date
For services performed on or after 10/08/2012

Original Determination Ending Date

Revision Effective Date
For services performed on or after 01/01/2013

Revision Ending Date

CMS National Coverage Policy
Internet-Only Manual (IOM) Pub. 100-2, Medicare Benefit Policy, Chapter 15, Section 80


Correct Coding Initiative – Medicare Contractor Beneficiary and Provider Communications Manual – Pub. 100-09, Chapter 5.

Social Security Act (Title XVIII) Standard References, Sections:

- 1862(a)(1)(D) Investigational or Experimental.
- 1833(e) Incomplete Claim.
Indications and Limitations of Coverage and/or Medical Necessity
This is a NON-coverage policy for the circulating tumor cell (CTC) assay, including CellSearch (Veridex) and PCR (RTPCR) Assays.

CTCs are found in the serum during the metastatic process of solid tumors when cells from a primary tumor invade, detach, disseminate, colonize and proliferate to a distant site. Detection of elevated CTCs during therapy is a definitive indication of subsequent rapid disease progression and mortality in breast, colorectal and prostate cancer. CTC testing for all malignant diagnoses will be denied as not reasonable and necessary except under individual consideration.

Noridian will consider payment of a denied individual claim if the claim is appealed and supporting literature is submitted which indicates efficacy of the test in the specific individual.

Coding Information

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.

012x Hospital Inpatient (Medicare Part B only)
013x Hospital Outpatient
014x Hospital - Laboratory Services Provided to Non-patients
022x Skilled Nursing - Inpatient (Medicare Part B only)
023x Skilled Nursing - Outpatient
072x Clinic - Hospital Based or Independent Renal Dialysis Center
085x Critical Access Hospital

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.

030x
031x

CPT/HCPCS Codes

86152 CELL ENUMERATION USING IMMUNOLOGIC SELECTION AND IDENTIFICATION IN FLUID SPECIMEN (EG, CIRCULATING TUMOR CELLS IN BLOOD);
86153 CELL ENUMERATION USING IMMUNOLOGIC SELECTION AND IDENTIFICATION IN FLUID SPECIMEN (EG, CIRCULATING TUMOR CELLS IN BLOOD); PHYSICIAN INTERPRETATION AND REPORT, WHEN REQUIRED

ICD-9 Codes that Support Medical Necessity
xx000
xx000 Not Applicable

Diagnoses that Support Medical Necessity

ICD-9 Codes that DO NOT Support Medical Necessity

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ICD-9 Codes that DO NOT Support Medical Necessity Asterisk Explanation

Diagnoses that DO NOT Support Medical Necessity

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General Information

Documentations Requirements
The HCPCS/CPT code(s) may be subject to Correct Coding Initiative (CCI) edits in addition to guidance in this LCD. Please refer to the CCI for correct coding guidelines and specific applicable code combinations prior to billing Medicare. Whichever guidance is more restrictive should be adhered to.

When requesting an *individual consideration* through the written redetermination (formerly appeal) process, providers must include all relevant medical records and any pertinent peer-reviewed literature that supports the request. At a minimum, literature such as two (2) Phase II studies (human studies of efficacy, pivotal) or one (1) Phase III study (evidence of safety and efficacy, pivotal) must be submitted for the Medical Director's review.

Appendices

Utilization Guidelines

Sources of Information and Basis for Decision


Advisory Committee Meeting Notes
This draft LCD was presented at the Part A Open Door Coverage Meeting held on May 2, 2012.

This medical policy was presented at the Medicare Part B Open Public Meeting held on April 10, 2012. It was also discussed at the following Carrier Advisory Committee meetings on the following dates:

- Alaska 05/10/2012
- Arizona 05/01/2012
- Idaho 05/16/2012
- Montana 05/10/2012
- North Dakota 05/29/2012
- Oregon 05/12/2012
- South Dakota 05/30/2012
- Utah 05/03/2012
- Washington 05/08/2012
- Wyoming 05/03/2012

This policy does not reflect the sole opinion of the contractor or Contractor Medical Director(s). Although the final decision rests with the contractor, this policy was developed in cooperation with the Carrier Advisory Committee(s) which include representatives from various interested medical specialty societies, the Part A Oncology workgroup, and with significant input from solicited providers from all of Noridian’s states.

This medical policy consolidates and replaces all previous policies and publications on this subject by Noridian Administrative Services (NAS) and its predecessors for Medicare Part A.

NAS’ Responses to Provider Recommendations:

Comment: One provider supported use of CTC assay for a specific oncological situations. This oncologist also noted the rarity of any of the situations and his use of the assay on only one occasion since its development in a very busy practice. The commenter suggested some process for claim specific determinations be made.

Response: Noridian and CMS recognize that exceptions are always possible and will review claims’ documentation at the redeterminations level (first level of appeals). An independent payment decision will be made at that level.

Comment: Many oncologists and two Oncology Societies recommended against coverage of the CTC assay, indicating its lack of utility.

Response: Noridian agrees with the providers. The literature does not demonstrate necessity of the test. “The CTC Assay produces prognostic information that is not validated as actionable.” - Provider group. Medicare may not reimburse the costs of services which do not or should not alter patient management.

Comment: Commenter noted utility of test for screening and “rule out” purposes.
Response: Medicare is statutorily excluded from reimbursement of screening tests, except as specifically named in the Law. "Ruling out" any condition with any test in the absence of signs or symptoms of a disease is similarly statutorily excluded. Moreover, the test hadn't been shown to be medically reasonable or necessary for this purpose.

Comment: Many Oncologists reported the assay was not sufficiently specific and should not be generally used.

Response: Noridian concurs.

Start Date of Comment Period
End Date of Comment Period
Start Date of Notice Period 08/23/2012

Revision History Number R1

Revision History Explanation This draft LCD is being released to final. The comments, NAS responses and all updates are found on the final LCD version.

11/25/2012 - The following CPT/HCPCS codes were deleted:
0279T was deleted from Group 1
0280T was deleted from Group 1

A2012.01 R1
CPT/HCPCS codes 0279T and 0280T were deleted and replaced with 86152 and 86153 effective 1/1/2013.

Reason for Change HCPCS Addition/Deletion

Related Documents
This LCD has no Related Documents.

LCD Attachments
There are no attachments for this LCD.

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All Versions
Updated on 11/30/2012 with effective dates 01/01/2013 - N/A
Updated on 08/16/2012 with effective dates 10/08/2012 - N/A
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