

LCD for Genetic Testing (L24308)

Contractor Information

Contractor Name

Noridian Administrative Services

Contractor Number

03102

Contractor Type

MAC - Part B

LCD Information

LCD ID Number

L24308

LCD Title

Genetic Testing

Contractor's Determination Number

J3 CB2006.31 R1

AMA CPT / ADA CDT Copyright Statement

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CMS National Coverage Policy

Social Security Act:

Title XVIII of the Social Security Act, section 1862 (a) (1) (A). this section allows coverage and payment for only those services that are considered to be medically reasonable and necessary.

Medicare Program Integrity Manual, Chapter 3, Section 3.4.1.2.B governs development of lab claims for additional documentation.

Medicare Claims Processing Manual, Chapter 16, Section 40.7 governs the right of the beneficiary to require a lab to file a claim for a lab test that the lab believes Medicare will not cover.

Medicare Claims Processing Manual, Chapter 16, Section 120.1 governs diagnosis information submitted by the ordering physician to the performing laboratory. The instruction states: *Tests that are performed in the absence of signs, symptoms, complaints, personal history of disease, or injury are not covered except when there is a statutory provision that explicitly covers tests for screening as described.*

LCD Information

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"The final rule clarifies that effective February 21, 2002, the use of the term "screening" or "screen" in CPT code descriptor does not necessarily describe a test performed in the absence of signs and symptoms of illness, disease or condition. Contractors do not deny a service based solely on the presence of the term "screening" or "screen" in the descriptor.

If a person is tested to rule out or to confirm a suspected diagnosis because the patient has a sign and/or symptoms, this is considered a diagnostic test, not a screening test. Contractors have discretionary authority to make reasonable and necessary scope of benefit determinations."

Primary Geographic Jurisdiction

Arizona

Oversight Region

Region VIII

Original Determination Effective Date

For services performed on or after 12/01/2006

Original Determination Ending Date

Revision Effective Date

For services performed on or after 11/01/2007

Revision Ending Date

Indications and Limitations of Coverage and/or Medical Necessity

Title XVIII of the Social Security Act, Section 1862(a)(1)(A) states " ...no Medicare payment shall be made for items or services which are not reasonable and necessary for the diagnosis and treatment of illness or injury...". Furthermore, it has been longstanding CMS policy that "tests that are performed in the absence of signs, symptoms, complaints, or personal history of disease or injury are not covered unless explicitly authorized by statute". **Screening services**, such as predictive and pre-symptomatic genetic tests and services, are those used to detect an undiagnosed disease or disease predisposition, and as such are not a Medicare benefit and not covered by Medicare. However, Medicare does cover a broad range of legislatively mandated **preventive services** to prevent disease, detect disease early when it is most treatable and curable, and manage disease so that complications can be avoided. These services can be found on the CMS website at <http://new.cms.hhs.gov/PrevntionGenInfo/>. Any preventive services and tests not listed on the CMS Preventive Services webpage are considered non-covered screening (preventive) tests or services which are not a benefit of the Medicare program.

LCD Information

LCD ID Number

Hereditary Breast and Ovarian Cancer

Families can be suspected of having hereditary breast or ovarian cancer based on occurrence at an early age, in multiple generations, often bilaterally, and in a pattern suggesting an autosomal dominant pattern of inheritance. The susceptibility may be transmitted through the maternal or paternal side of the family.

Germ-line alterations in two genes, BRCA1 and BRCA2, are associated with an increased risk of breast and ovarian cancer. Alterations in BRCA1 and BRCA2 explain many, but not all, of inherited forms of breast and ovarian cancer. With the identification of BRCA1 and BRCA2, it is now possible to test for abnormalities in the genes to provide information on the future risk of cancer and to make important treatment decisions in affected individuals. Approximately five- to ten-percent of all breast cancers, and a similarly small percentage of ovarian cancers, are attributed to dominantly inherited susceptibility.

Families at high risk of harboring a BRCA1 or BRCA2 mutation are those in which the incidence of breast or ovarian cancer suggests an autosomal dominant inheritance (i.e., about half the family members are affected). Men rarely develop breast cancer and, thus, there may not be an affected first-degree relative, and the size of the family may not permit analysis of possible autosomal dominant inheritance.

In patients with breast or ovarian cancer who are from high-risk families without a known BRCA1 or BRCA2 gene, the entire gene must be sequenced to identify possible mutations. In those families with a known BRCA1 or BRCA2 gene mutation, only a single mutation site sequence is required. In the case of individuals with Ashkenazi Jewish ancestry, testing for 3 mutations common in this population may be warranted even after a single mutation has been identified in their family member.

The clinical information preceding this statement notwithstanding, testing of unaffected family members or other individuals is considered by Medicare to be screening and is not payable under the Medicare program.

Hereditary Colorectal and Endometrial Cancer Syndromes

Hereditary Non-Polyposis Colorectal Cancer (HNPCC) syndrome (also known as Lynch Syndrome), is an autosomal dominant syndrome that accounts for about 3-5% of colorectal cancer cases. HNPCC syndrome mutations occur in the following genes: hMLH1, hMSH2, and hMSH6. Colorectal cancers associated with HNPCC syndrome occur at a younger age (average age of onset between 44-61 years of age) compared with the more common colorectal cancers typically found during the seventh decade of life. Other HNPCC syndrome-associated cancers include endometrial, ovarian, stomach, small bowel, urinary tract, biliary tract and glioblastoma. Female carriers of a specific HNPCC gene mutation have up to a 71% risk of endometrial cancer and 12% risk of ovarian cancer, in addition to the other HNPCC cancer risks. Furthermore, gynecologic cancers may precede colorectal cancer in as many as 50% of female HNPCC gene mutation carriers.

Familial Adenomatous Polyposis (FAP) is an autosomal dominant syndrome caused by a germ-line mutation of the APC gene. Characteristically, affected patients develop multiple adenomas diffusely throughout the colon beginning in their teens. Colorectal cancer is inevitable in patients with FAP if colectomy is not performed. The average age at symptomatic diagnosis ranges from 34 to 45 years of age. However, the average age of colonic adenoma appearance is 16 years and of cancer diagnosis is 39 years. The FAP gene mutation occurs in approximately 1/10,000 - 1/30,000 live births in the United States, affects both sexes equally, and accounts for up to 1% of colorectal cancers.

MYH-associated polyposis (MAP) is an autosomal recessive syndrome linked to germ-line mutations of the MYH gene. The full clinical picture of MYH-associated polyposis (MAP) is incompletely understood at this time. Current evidence suggests it is associated with about 0.4-1.0% of colorectal cancers.

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The clinical information preceding this statement notwithstanding, testing of unaffected family members or other individuals is considered by Medicare to be screening and is not payable under the Medicare program.

General Coverage Rules

Although there are still many unanswered questions regarding optimal clinical management of patients with inherited cancer-predisposing gene mutations, there is increasing data documenting benefits from increased surveillance, prophylactic surgery, hormonal manipulation, and changes in chemotherapy. Individuals who are carriers of a mutation, even if they have already been diagnosed and treated for a primary cancer, can be provided with additional information regarding their risk for further disease development and possible treatment and surveillance options.

For the above syndromes, those individuals who are determined not to be carriers may be prevented from undergoing unnecessary prophylactic surgery such as total versus partial colectomy, mastectomy, hysterectomy, and oophorectomy. Frequency of surveillance procedures (mammography, colonoscopy, etc.) may be affected depending on the presence or absence of a mutation.

1. Genetic tests for cancer are only a covered benefit for a **beneficiary with a personal history** of an illness, injury, or signs/symptoms thereof (i.e. clinically affected). A person with a personal history of a relevant cancer is a clinically affected person, even if the cancer is considered cured. Genetic testing is considered a non-covered screening test for patients unaffected by a relevant illness, injury, or signs/symptoms thereof.

2. Predictive or pre-symptomatic genetic tests and services, in the absence of past or present illness in the beneficiary, are not covered under national Medicare rules. For example, Medicare does not cover genetic tests based on family history alone.

3. A covered genetic test must be used to manage a patient. Medicare does not cover a genetic test for a clinically affected individual for purposes of family planning, disease risk assessment of other family members, when the treatment and surveillance of the beneficiary will not be affected, or in any other circumstance that does not directly affect the diagnosis or treatment of the beneficiary.

4. The results of the genetic test must potentially affect at least one of the management options considered by the referring physician in accordance with accepted standards of medical care (e.g. surgery, the extent of surgery, a change in surveillance, hormonal manipulation, or a change from standard therapeutic or adjuvant chemotherapy).

5. Pre-test genetic counseling must be provided by a qualified and appropriately trained practitioner.

6. An informed consent form signed by the patient prior to testing which includes a statement that he/she agree to post-test counseling is required. This consent form must be available on request by Medicare.

7. Genetic analysis must be provided through a laboratory which meets the American Society of Clinical Oncology (ASCO) recommended requirements:

- The lab must meet appropriate Clinical Laboratory Improvement Amendment (CLIA) 1988 regulations;
- Successful participation in the American College of Medical Genetics (ACMG)/College of American Pathologists (CAP) inspection and survey program;
- appropriate state licensing; and
- credentialing of laboratory directors and staff by the American Board of Medical Genetics (ABMG).

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Hereditary Breast and Ovarian Cancer Syndromes

BRCA1 and BRCA2 genetic testing is covered only for the following individuals: For the purpose of this policy, only genetic relations are relevant (i.e. "blood relatives"). Non-genetic relations, such as through marriage or adoption are not relevant to coverage. A close relative means a first degree (parents, full siblings, offspring), second degree (grandparents, grandchildren, aunts, uncles, nephews, nieces, half-siblings), or third degree (great-grandparents, great-aunts, great-uncles, first cousins) relatives.) Also, for this policy, invasive and ductal carcinoma in situ (DCIS) breast cancers should be included. If the individual is of Ashkenazi Jewish descent, test the three common mutations first. Then if negative, consider full sequence ("Reflex") testing based on assessment of individual and family history as if the individual is of non-Ashkenazi Jewish descent.

1. Personal history of breast cancer + one or more of the following:

- Diagnosed age 40 y, with or without family history
- Diagnosed age 50 y or two breast primaries, with 1 close blood relative(s) with breast cancer 50 y or 1 close blood relative(s) with ovarian cancer
- Diagnosed at any age, with 2 close blood relatives with ovarian cancer at any age
- Diagnosed at any age, with 2 close blood relatives with breast cancer, especially if 1 woman is diagnosed before age 50 y or has two breast primaries (see NCCN Guidelines, ref. 9 below)
- Close male blood relative with breast cancer
- Personal history of ovarian cancer
- If of certain ethnic descent associated with deleterious mutations (eg, founder populations of Ashkenazi Jewish) no additional family history required
- a first or second-degree relative with a known BRCA1 or BRCA2 gene mutation

2. Personal history of ovarian cancer + one or more of the following:

- 1 close blood relative(s) with ovarian cancer
- 1 close female blood relative(s) with breast cancer at age 50 y or two breast primary cancers
- 2 close blood relatives with breast cancer
- 1 close male blood relative(s) with breast cancer
- If of Ashkenazi Jewish descent, no additional family history is required
- a first or second-degree relative with a known BRCA1 or BRCA2 gene mutation

3. Personal history of male breast cancer if one or more of the following is present:

- 1 close male blood relative(s) with breast cancer
- 1 close female blood relative(s) with breast or ovarian cancer
- If of certain ethnic descent associated with deleterious mutations (eg, founder populations of Ashkenazi Jewish), no additional family history is required
- a first or second-degree relative with a known BRCA1 or BRCA2 gene mutation

Hereditary Colorectal Cancer Syndromes

hMLH1, hMSH2, and hMSH6 gene tests are covered to diagnose Hereditary non-Polyposis Colorectal Cancer (HNPCC) syndrome. hMLH1 and hMSH2 gene testing must be negative before a test for the less common hMSH6 gene mutation is considered reasonable and necessary. The tests are covered for a **beneficiary who has or has had colorectal or endometrial cancer and meets one of the following criteria:**

1. Amsterdam II Criteria for HNPCC genetic testing

LCD Information

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At least two close relatives of the affected beneficiary must have or have had a cancer associated with hereditary nonpolyposis colorectal cancer (colorectal, cancer of endometrium, ovarian, stomach, small bowel, biliary tract, ureter or renal-pelvis, or glioblastoma); and all of the following criteria should be present:

- One must be a first-degree relative of the other two;
- At least two successive generations must be affected;
- At least one of the relatives or the beneficiary with cancer associated with hereditary non-polyposis colorectal cancer should be diagnosed before the age 50 years;
- Familial adenomatous polyposis (FAP) should be excluded in the colorectal cancer case(s) (if any);
- Histologic diagnosis of tumors should be verified whenever possible.

2. Has or has had a second HNPCC-associated malignancy

3. Has a blood relative with a known HNPCC related gene mutation

4. If there is family history of colon cancer, but Amsterdam criteria are not met, then Revised Bethesda Guidelines are evaluated. If any of the Bethesda guidelines are met, microsatellite instability (MSI) and/or immunohistochemistry (IHC) testing is done on the colon cancer tissue. If the tumor is MSI positive or mutation of one of the mismatch repair genes is indicated by failure of IHC staining, then genetic testing should be undertaken. This does not apply to MSI or IHC testing of non-GI primary tumors since the sensitivity and specificity of MSI/IHC testing in these tumors is poorly documented at this time.

APC and MYH gene testing for Familial Adenomatous Polyposis (FAP), Attenuated FAP (AFAP), or MYH-associated polyposis (MAP) is covered for the following individuals;

- A beneficiary with 20 cumulative colorectal adenomas over a lifetime.
- Testing for APC gene mutations should precede testing for the less common MYH mutation.

As noted in each major section above providers are once again reminded: The clinical information preceding this statement notwithstanding, testing of unaffected family members or other individuals is considered by Medicare to be screening and is not payable under the Medicare program.

Compliance with the provisions in this policy is subject to monitoring by post payment data analysis and subsequent medical review.

Coverage Topic

Outpatient Hospital Services

Coding Information

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.

999x Not Applicable

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.

99999 Not Applicable

CPT/HCPCS Codes

83890	MOLECULAR DIAGNOSTICS; MOLECULAR ISOLATION OR EXTRACTION
83891	MOLECULAR DIAGNOSTICS; ISOLATION OR EXTRACTION OF HIGHLY PURIFIED NUCLEIC ACID
83892	MOLECULAR DIAGNOSTICS; ENZYMATIC DIGESTION
83893	MOLECULAR DIAGNOSTICS; DOT/SLOT BLOT PRODUCTION
83894	MOLECULAR DIAGNOSTICS; SEPARATION BY GEL ELECTROPHORESIS (EG, AGAROSE, POLYACRYLAMIDE)
83898	MOLECULAR DIAGNOSTICS; AMPLIFICATION, TARGET, EACH NUCLEIC ACID SEQUENCE
83904	MOLECULAR DIAGNOSTICS; MUTATION IDENTIFICATION BY SEQUENCING, SINGLE SEGMENT, EACH SEGMENT
83912	MOLECULAR DIAGNOSTICS; INTERPRETATION AND REPORT

ICD-9 Codes that Support Medical Necessity

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.

Note: Diagnosis codes are based on the current ICD-9-CM codes that are effective at the time of LCD publication. Any updates to ICD-9-CM codes will be reviewed by NAS, and coverage should not be presumed until the results of such review have been published/posted.

These are the **only** covered ICD-9-CM codes that support medical necessity:

The following Diagnosis codes meet criteria for BRCA1 and BRCA2 gene mutation testing:

174.0	MALIGNANT NEOPLASM OF NIPPLE AND AREOLA OF FEMALE BREAST
174.1	MALIGNANT NEOPLASM OF CENTRAL PORTION OF FEMALE BREAST
174.2	MALIGNANT NEOPLASM OF UPPER-INNER QUADRANT OF FEMALE BREAST
174.3	MALIGNANT NEOPLASM OF LOWER-INNER QUADRANT OF FEMALE BREAST
174.4	MALIGNANT NEOPLASM OF UPPER-OUTER QUADRANT OF FEMALE BREAST
174.5	MALIGNANT NEOPLASM OF LOWER-OUTER QUADRANT OF FEMALE BREAST
174.6	MALIGNANT NEOPLASM OF AXILLARY TAIL OF FEMALE BREAST
174.8	MALIGNANT NEOPLASM OF OTHER SPECIFIED SITES OF FEMALE BREAST
174.9	MALIGNANT NEOPLASM OF BREAST (FEMALE) UNSPECIFIED SITE
175.0	MALIGNANT NEOPLASM OF NIPPLE AND AREOLA OF MALE BREAST
175.9	MALIGNANT NEOPLASM OF OTHER AND UNSPECIFIED SITES OF MALE BREAST
183.0	MALIGNANT NEOPLASM OF OVARY
233.0	CARCINOMA IN SITU OF BREAST
V10.3	PERSONAL HISTORY OF MALIGNANT NEOPLASM OF BREAST
V10.43	PERSONAL HISTORY OF MALIGNANT NEOPLASM OF OVARY

The following diagnosis codes meet criteria for hereditary colorectal cancer (HNPCC) and Familial Adenomatous Polyposis (FAP) testing including APC, MYH, and HNPCC syndromes, including endometrial cancer:

153.0	MALIGNANT NEOPLASM OF HEPATIC FLEXURE
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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.

153.1	MALIGNANT NEOPLASM OF TRANSVERSE COLON
153.2	MALIGNANT NEOPLASM OF DESCENDING COLON
153.3	MALIGNANT NEOPLASM OF SIGMOID COLON
153.4	MALIGNANT NEOPLASM OF CECUM
153.5	MALIGNANT NEOPLASM OF APPENDIX VERMIFORMIS
153.6	MALIGNANT NEOPLASM OF ASCENDING COLON
153.7	MALIGNANT NEOPLASM OF SPLENIC FLEXURE
153.8	MALIGNANT NEOPLASM OF OTHER SPECIFIED SITES OF LARGE INTESTINE
153.9	MALIGNANT NEOPLASM OF COLON UNSPECIFIED SITE
154.0	MALIGNANT NEOPLASM OF RECTOSIGMOID JUNCTION
154.1	MALIGNANT NEOPLASM OF RECTUM
154.8	MALIGNANT NEOPLASM OF OTHER SITES OF RECTUM RECTOSIGMOID JUNCTION AND ANUS
179	MALIGNANT NEOPLASM OF UTERUS-PART UNS
182.8	MALIGNANT NEOPLASM OF OTHER SPECIFIED SITES OF BODY OF UTERUS
183.2	MALIGNANT NEOPLASM OF FALLOPIAN TUBE
203.00	MULTIPLE MYELOMA WITHOUT REMISSION
203.01	MULTIPLE MYELOMA IN REMISSION
286.3	CONGENITAL DEFICIENCY OF OTHER CLOTTING FACTORS
289.81	PRIMARY HYPERCOAGULABLE STATE
753.13	POLYCYSTIC KIDNEY AUTOSOMAL DOMINANT
753.14	POLYCYSTIC KIDNEY AUTOSOMAL RECESSIVE
756.51	OSTEOGENESIS IMPERFECTA
756.83	EHLERS-DANLOS SYNDROME
757.1	ICHTHYOSIS CONGENITA
759.83	FRAGILE X SYNDROME

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.

V10.05	PERSONAL HISTORY OF MALIGNANT NEOPLASM OF LARGE INTESTINE
V10.06	PERSONAL HISTORY OF MALIGNANT NEOPLASM OF RECTUM RECTOSIGMOID JUNCTION AND ANUS
V10.42	PERSONAL HISTORY OF MALIGNANT NEOPLASM OF OTHER PARTS OF UTERUS
V12.72*	PERSONAL HISTORY OF COLONIC POLYPS

*V12.72 should be used to denote any of the polyposis conditions as described under Indications and Limitations above.

Diagnoses that Support Medical Necessity

All ICD-9-CM codes listed above under ICD-9-CM Codes that Support Medical Necessity above.

ICD-9 Codes that DO NOT Support Medical Necessity

All ICD-9-CM codes not listed above under ICD-9-CM Codes that Support Medical Necessity above.

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

Diagnoses that DO NOT Support Medical Necessity

All ICD-9-CM codes not listed above under ICD-9-CM Codes that Support Medical Necessity above.

General Information

Documentation Requirements

The documentation is not required at the time of the initial claim, but may be requested for post-payment review. Documentation must be adequate to verify that coverage guidelines listed above have been met.

The documentation, which must be made available upon request from the laboratory or billing provider, must include personal and family history information consistent with this policy, and a signed informed consent indicating that the patient was informed of the following issues and information:

- cancer risks associated with each possible test result
- likelihood of carrying a gene mutation given the patient's personal and family history (e.g. pedigree analysis)

General Information

Documentation Requirements

- implication for family members
- potential adverse effects, benefits, and limitations of testing
- relevant management options such as surveillance, prophylactic surgery, and medical preventive or therapeutic measures if available and risks associated with them.

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

The laboratory or billing provider must have on file the physician requisition which sets forth the diagnosis or condition (ICD-9-CM code) that warrants the test.

The documentation must be made available from the billing provider (i.e. the laboratory) upon request by the contractor.

Before furnishing a beneficiary a test which the physician or laboratory believes is excluded from coverage as not reasonable and necessary (rather than excluded from coverage as part of a routine test), the physician or laboratory must obtain a signed Advanced Beneficiary Notice (ABN) from the beneficiary (or representative) that the physician or laboratory has informed him/her of the non-coverage of the test and that there will be a charge for the test. (Medicare Claims Processing Manual, Chapter 16, Section 40.7 - Billing for Noncovered Clinical Laboratory Tests)

The HCPCS/CPT code(s) may be subject to Correct Coding Initiative (CCI) edits. This policy does not take precedence over CCI edits. Please refer to the CCI for correct coding guidelines and specific applicable code combinations prior to billing Medicare.

When the documentation does not meet the criteria for the service rendered or the documentation does not establish the medical necessity for the services, such services will be denied as not reasonable and necessary under Section 1862(a)(1) of the Social Security Act.

If you disagree with some aspect of a final LCD, you have the option of submitting a formal reconsideration to NAS Medicare Part B . See www.noridianmedicare.com for the reconsideration process. This reconsideration must be accompanied by complete copies of relevant peer-reviewed literature that support the recommendation. Abstracts are not sufficient for this purpose. Keep in mind that no change will be made that will put the LCD in conflict with CMS regulations.

When requesting a written redetermination (formerly appeal), providers must include all relevant documentation with the request.

Appendices

Utilization Guidelines

Genetic testing is considered a screening test for unaffected patients. **Medicare does not cover screening tests.** Predictive and pre-symptomatic genetic tests and services are not covered under this policy.

Statute does not permit genetic counselors to directly bill Medicare.

A specific genetic test may only be performed once in a lifetime per beneficiary.

General Information

Documentation Requirements

Sources of Information and Basis for Decision

1. Screening for the Lynch Syndrome (HNPCC), The New England Journal of Medicine, Vol. 352, No. 18, May 5, 2005.
2. Prophylactic Surgery to Reduce the Risk of Gynecologic Cancers in the Lynch Syndrome, The New England Journal of Medicine, Vol. 354, No. 3, January 19, 2006.
3. Genetic Risk Assessment and BRCA Mutation Testing for Breast and Ovarian Cancer Susceptibility. U.S. Preventive Services Task Force, Sept. 2005.
4. Technology Assessment, Genetic Tests for Cancer; Agency for Healthcare Research and Quality (AHRQ), January 9, 2006.
5. National Comprehensive Cancer Network (NCCN), "Genetic/Familial High-Risk Assessment: Breast and Ovarian", Clinical Practice Guidelines in Oncology, Vol. 1, 2006.
6. Screening Services Reminder; Noridian Medicare B News, Issue 218, March 3, 2005.
7. Prophylactic Oophorectomy in Carriers of BRCA1 or BRCA2 Mutations; The New England Journal of Medicine, Vol. 346, No. 21, May 23, 2002.
8. NAS Carrier Advisory Committee Members

Advisory Committee Meeting Notes

Notice of this DRAFT medical policy was made available to providers and the public in the following states:

Arizona, Montana, North Dakota, South Dakota, Utah and Wyoming.

This policy does not reflect the sole opinion of the contractor or the 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 of various medical specialty societies.

The Section titled "Does the 'CPT 30% Rule' apply?" needs clarification. This rule comes from the AMA (American Medical Association), the organization that holds the copyrights for all CPT codes. The rule states that if, in a given section (e.g., **surgery**) or subsection (e.g., surgery, **integumentary**) of the CPT Manual, more than 30% of the codes are listed in the LCD, then the short descriptors must be used rather than the long descriptors found in the CPT Manual.

This policy is subject to the reasonable and necessary guidelines and the limitation of liability provision.

This medical policy consolidates and replaces all previous policies and publications on this subject by NAS and its predecessors for Medicare Part B.

NAS' Response to Provider Recommendations:

1. Several requests were received for the addition of diagnoses for which we received no literature suggesting that therapy would be affected by Genetic Testing results.

General Information

Documentation Requirements

NAS has declined to add these conditions where there is no evidence that results of testing will affect therapy.

2. NAS received comments that Part A and Part B do not have identical LCDs on this subject.

NAS strives to have consistent Part A and B policies to the extent possible, given that there are systemic differences between Parts A&B.

3. One commenter noted that the CPT codes used for molecular testing are also used for infectious disease molecular testing, remarking that steps that are in common to both genetic and infectious disease testing must be adequately dealt with

NAS has taken those concerns into account and believes that edits put in place to adjudicate these claims will not cause inappropriate denials.

4. Numerous requests were made for payment for testing that appears to be screening, by definition, including a request for "...coverage to include any gene with cancer predisposition." One request was also made to include "...among qualifying diagnoses having a family member with a positive gene test of non-cancer related diagnoses directly caused by the gene change (such as macrocephaly for PTEN or CHRPE for FAP, etc.)"

NAS reminds the provider community that screening test, other than those expressly provided for by Congressional action, are not payable by Medicare.

Also, it is always a good idea to not use abbreviations or acronyms without defining them.

5. One request was received requesting that we "...consider sebaceous neoplasm as an HNPCC-associated cancer because we have patients with Muir-Torre syndrome who are not able to get the appropriate genetic testing because of Medicare's (sic) exclusion of sebaceous neoplasms.

NAS must remind all providers requesting new coverage that you must include relevant literature supporting your request. None was received concerning this provider request, so we have no rationale for adding it.

6. One request was received (which contained numerous supportive articles) requesting that NAS add multiple myeloma to the list of covered conditions for genetic testing.

**NAS has added the appropriate diagnosis codes:
203.00 Multiple myeloma without mention of remission
203.01 Multiple myeloma in remission**

7. NAS received several requests for the coverage of several conditions, on the assumption that the testing would be for diagnostic and therapeutic purposes, not screening.

286.3 Congenital deficiency of other clotting factors

289.81 Primary hypercoagulable state

753.13 Polycystic kidney, autosomal dominant

753.14 Polycystic kidney, autosomal recessive

756.51 Osteogenesis imperfecta

756.83 Ehlers-Danlos syndrome

757.1 Ichthyosis congenita

General Information

Documentation Requirements

759.83 Fragile X syndrome

NAS has reviewed these conditions and has decided to add coverage for the above conditions so long as they are used for diagnostic and therapeutic purposes, not screening.

Start Date of Comment Period

09/15/2006

End Date of Comment Period

10/31/2006

Start Date of Notice Period

09/12/2007

Revision History Number

R1

Revision History Explanation

J3 CB2006.31

The LCD for Genetic Testing was in Utah only. However, the original Utah policy included some codes as payable, which on closer consideration represented screening tests. These screening tests have been removed. The policy was reviewed in it other aspects and updated.

J3 CB2006.31 R1

This is the first revision to this LCD. It has been brought to NAS' attention that due to a clerical error, an early draft version of this LCD was inadvertently posted as final. This revision corrects that error and brings the LCD into compliance with National CMS coverage. It also incorporates provider comments received and NAS' responses to those comments.

11/10/2007 - The description for CPT/HCPCS code 83898 was changed in group 1

Reason for Change

Last Reviewed On Date

09/06/2007

Related Documents

This LCD has no Related Documents.

General Information

Documentation Requirements

LCD Attachments

There are no attachments for this LCD.

Other Versions

Updated on 09/06/2007 with effective dates 11/01/2007 - N/A

Updated on 11/20/2006 with effective dates 12/01/2006 - N/A