

# Local Coverage Determination (LCD) for Genetic Testing (L24308)

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## Contractor Information

**Contractor Name**

Noridian Administrative Services, LLC

[Back to Top](#)**Contractor Number**

03402

**Contractor Type**

MAC - Part B

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## LCD Information

### Document Information

**LCD ID Number**

L24308

**Primary Geographic Jurisdiction**

South Dakota

**LCD Title**

Genetic Testing

**Oversight Region**

Region X

**Contractor's Determination Number**

J3 CB2006.31 R11

**Original Determination Effective Date**

For services performed on or after 12/01/2006

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**Original Determination Ending Date****Revision Effective Date**

For services performed on or after 09/15/2011

**Revision Ending Date**

### 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.*

*"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."*

### **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 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. Similarly, Medicare may not reimburse the costs of tests/examinations that assess the risk for and/or of a condition unless the risk assessment clearly and directly effects the management of the patient. 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://www.cms.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.

### **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**

Lynch Syndrome (previously denoted in this policy as Hereditary Non-Polyposis Colorectal Cancer (HNPCC) 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, hMSH6, PMS2 and EPCAM. Colorectal cancers associated with Lynch 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 Lynch syndrome-associated cancers include endometrial, ovarian, gastric, pancreas, ureter and renal pelvis, biliary tract, brain (usually glioblastoma), and small intestine cancers, as well as sebaceous gland adenomas/carcinomas and keratoacanthomas (AKs). Female carriers of a specific Lynch gene mutation have up to a 71% risk of endometrial cancer and 12% risk of ovarian cancer, in addition to the other Lynch syndrome cancer risks. Furthermore, gynecologic cancers may precede colorectal cancer in as many as 50% of female gene mutation carriers.

Inherited mutations in MLH1 and MSH2 account for the majority (~70%) of mutations detected with MSH6 and PMS2 found in the remainder of mutation positive cases. MSH6 mutations are responsible for approximately 15% of Lynch syndrome cases. Recent reports confirm that PMS2 mutations are a significant contributor to Lynch syndrome. Estimates of the proportion of Lynch syndrome cases due to PMS2 vary and are as high as 15%.

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.

**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).

## 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  $\leq 45$  y, with or without family history
- Diagnosed age  $\leq 50$  y or two breast primaries, with  $\geq 1$  close blood relative(s) with breast cancer  $\leq 50$  y and/or  $\geq 1$  close blood relative(s) with epithelial ovarian/fallopian tube/primary peritoneal cancer
- Two breast primaries when first breast cancer diagnosis occurred prior to age 50
- Diagnosed at any age, with  $\geq 2$  close blood relatives with breast and/or epithelial ovarian/fallopian tube/primary peritoneal cancer, at any age
- Close male blood relative with breast cancer
- Personal history of epithelial ovarian/fallopian tube/primary peritoneal cancer
- If of certain ethnicity associated with higher mutation frequency, (eg, founder populations of Ashkenazi Jewish, Icelandic, Swedish, Hungarian or other) no additional family history required
- a close relative with a known BRCA1 or BRCA2 gene mutation

### 2. Personal history of epithelial ovarian/fallopian tube/primary peritoneal cancer.

### 3. Personal history of male breast cancer.

## Hereditary Colorectal Cancer Syndromes

**hMLH1, hMSH2, hMSH6 and PMS2 gene tests** are covered to diagnose Lynch syndrome. hMLH1, hMSH2 and hMSH6 gene testing must be negative before a test for the less common PMS2 gene mutations 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 Lynch syndrome genetic testing

At least two close relatives of the affected beneficiary must have or have had a cancer associated with Lynch syndrome; and all of the following criteria must 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. Revised Bethesda guidelines

- Colorectal cancer diagnosed in a beneficiary at less than 50 years of age
- Presence of synchronous or metachronous Lynch syndrome-associated cancers\*, regardless of age
- Colorectal cancer with the MSI-H histology diagnosed in a beneficiary who is less than 60 years of age
- Colorectal cancer with one or more first-degree relatives with a Lynch syndrome-associated cancer\*, with one of the cancers being diagnosed under age 50 years

- Colorectal cancer with two or more first- or second-degree relatives with Lynch syndrome-associated cancers\*, regardless of age

\* Lynch syndrome-associated cancers include endometrial, ovarian, gastric, pancreas, ureter and renal pelvis, biliary tract, brain (usually glioblastoma), and small intestine cancers, as well as sebaceous gland adenomas/carcinomas and keratoacanthomas.

3. Has a blood relative with a known Lynch syndrome related gene mutation

4. Endometrial cancer diagnosed in a beneficiary at less than 50 years of age

5. If any of the Bethesda guidelines are met, microsatellite instability (MSI) and/or immunohistochemistry (IHC) testing on the colon cancer tissue may be clinically appropriate. 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. Further unnecessary testing can often be avoided by performance of IHC prior to any MSI testing. NAS leaves to the provider's judgment and the individual clinical situation in determining the order of performance of any of these two test protocols. 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  $\geq 20$  cumulative colorectal adenomas over a lifetime.
- Testing for APC gene mutations should precede testing for the less common MYH mutation.

### **HLA-B\*5701 Testing**

The Department of Health and Human Services (DHHS) Panel on Antiretroviral Guidelines for Adults and Adolescents (the Panel) is a working group of the Office of AIDS Research Advisory Council (OARAC).

The Panel recommends HLA-B\*5701 testing prior to initiating abacavir therapy to reduce the risk of hypersensitivity reaction. HLA-B\*5701-positive patients should not be prescribed abacavir, and the positive status should be recorded as an abacavir allergy in the patient's medical record (All). Based on this recommendation, NAS has added this testing to the list of covered Genetic Tests under this LCD.

### **Therapy-Directing testing**

**NAS has determined that sufficient literature support now exists to allow coverage for KRAS testing. Its coverage is limited to use in patients with metastatic colorectal cancer for whom either cetuximab (Erbix) or panitumumab (Vectibix) therapy is contemplated as being appropriate. Although there remain some unanswered questions concerning the role of "personalized medicine," it appears that there is sufficient sensitivity and specificity in the K-RAS testing to allow the decision to be made that use of either of the two drugs noted above would be inappropriate if the KRAS mutation is identified. For further billing information, see Coding Guidelines via the link noted below.**

**In addition, NAS has determined that JAK2 testing is appropriate in patients with signs or symptoms suggesting an underlying chronic myeloproliferative disorder, including increased red-cell mass, increased platelets, unexplained persistent peripheral cytopenia to cytosis, unexplained peripheral or hepatic vein thrombosis (Budd-Chiari Syndrome) or bone marrow examination showing features of a chronic myeloproliferative disorder. Documentation must also indicate that the provider anticipates that the test result is likely to be of use in management of the condition.**

The **BCR/ABL fusion** gene is the classic mutation seen in Chronic Myelogenous Leukemia (CML) and is also seen in Acute Lymphocytic Leukemia (ALL) and certain other hematologic diseases. Major factors influencing providers' consideration of testing for this gene include some that are too non-specific to support coverage under this LCD. NAS does, however, consider some to support the BCR/ABL fusion gene testing and those are listed in the payable ICD-9 code section below.

Noridian is aware that there remain numerous potentially medically reasonable and necessary “therapy-directing” genetic tests, either currently available or in the development “pipeline” for emerging use in coming months and years. Many questions remain, among them the lack of – and difficulty in establishing – good literature support of medical necessity; lack of standardized testing protocols; lack of good data for establishing patient-selection criteria; absence of test-specific CPT coding, which we believe to be essential for future development of this potentially monumental enhancement to patient care.

Noridian has decided that no additional “personalized medicine” or “therapy-directing” testing will be included under the coverage purview of this LCD. Instead, providers are reminded that Noridian will allow payment for such tests, either those currently available or those to be brought into use in the future, based on applicable FDA approval and labeling (if such exists) and appropriate standards of medical reasonableness and necessity. Thus, the medical record must contain documentation that the testing is expected to influence treatment of the condition toward which the testing is directed. Providers are also reminded that all such claims will be subject to post pay review. It is our hope that subsequent developments in this field will lead to Contractors’ ability to monitor development and ascertain coverage and payment criteria to the extent that LCD coverage can be appropriately and timely extended. The rapidity and non-standardized development of the current reality in this field mitigates against being able to do so at the present time.

**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.

[Back to Top](#)

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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.

### 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
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### CPT/HCPCS Codes

#### GroupName

83890	MOLECULAR DIAGNOSTICS; MOLECULAR ISOLATION OR EXTRACTION, EACH NUCLEIC ACID TYPE (IE, DNA OR RNA)
83891	MOLECULAR DIAGNOSTICS; ISOLATION OR EXTRACTION OF HIGHLY PURIFIED NUCLEIC ACID, EACH NUCLEIC ACID TYPE (IE, DNA OR RNA)
83892	MOLECULAR DIAGNOSTICS; ENZYMATIC DIGESTION, EACH ENZYME TREATMENT
83893	MOLECULAR DIAGNOSTICS; DOT/SLOT BLOT PRODUCTION, EACH NUCLEIC ACID PREPARATION
83894	MOLECULAR DIAGNOSTICS; SEPARATION BY GEL ELECTROPHORESIS (EG, AGAROSE, POLYACRYLAMIDE), EACH NUCLEIC ACID PREPARATION
83896	MOLECULAR DIAGNOSTICS; NUCLEIC ACID PROBE, EACH
83898	MOLECULAR DIAGNOSTICS; AMPLIFICATION, TARGET, EACH NUCLEIC ACID SEQUENCE

83900	MOLECULAR DIAGNOSTICS; AMPLIFICATION, TARGET, MULTIPLEX, FIRST 2 NUCLEIC ACID SEQUENCES
83904	MOLECULAR DIAGNOSTICS; MUTATION IDENTIFICATION BY SEQUENCING, SINGLE SEGMENT, EACH SEGMENT
83909	MOLECULAR DIAGNOSTICS; SEPARATION AND IDENTIFICATION BY HIGH RESOLUTION TECHNIQUE (EG, CAPILLARY ELECTROPHORESIS), EACH NUCLEIC ACID PREPARATION
83912	MOLECULAR DIAGNOSTICS; INTERPRETATION AND REPORT
88363	EXAMINATION AND SELECTION OF RETRIEVED ARCHIVAL (IE, PREVIOUSLY DIAGNOSED) TISSUE(S) FOR MOLECULAR ANALYSIS (EG, KRAS MUTATIONAL ANALYSIS)

### ICD-9 Codes that Support Medical Necessity

**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:

158.0	MALIGNANT NEOPLASM OF RETROPERITONEUM
158.8	MALIGNANT NEOPLASM OF SPECIFIED PARTS OF PERITONEUM
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
183.2	MALIGNANT NEOPLASM OF FALLOPIAN TUBE
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, as well as for KRAS testing, within the limitations noted above:

153.0	MALIGNANT NEOPLASM OF HEPATIC FLEXURE
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
171.9	MALIGNANT NEOPLASM OF CONNECTIVE AND OTHER SOFT TISSUE SITE UNSPECIFIED
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 MENTION OF HAVING ACHIEVED REMISSION
203.01	MULTIPLE MYELOMA IN REMISSION
203.02	MULTIPLE MYELOMA, IN RELAPSE
204.00	ACUTE LYMPHOID LEUKEMIA, WITHOUT MENTION OF HAVING ACHIEVED REMISSION
204.10	CHRONIC LYMPHOID LEUKEMIA, WITHOUT MENTION OF HAVING ACHIEVED REMISSION
205.00	ACUTE MYELOID LEUKEMIA, WITHOUT MENTION OF HAVING ACHIEVED REMISSION
205.10	CHRONIC MYELOID LEUKEMIA, WITHOUT MENTION OF HAVING ACHIEVED REMISSION
238.4	POLYCYTHEMIA VERA
238.71	ESSENTIAL THROMBOCYTHEMIA
238.75	MYELODYSPLASTIC SYNDROME, UNSPECIFIED
238.76	MYELOFIBROSIS WITH MYELOID METAPLASIA
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
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
V42.82	PERIPHERAL STEM CELLS REPLACED BY TRANSPLANT

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

**The following diagnosis codes meet coverage criteria for JAK2 testing:**

204.00	ACUTE LYMPHOID LEUKEMIA, WITHOUT MENTION OF HAVING ACHIEVED REMISSION
204.10	CHRONIC LYMPHOID LEUKEMIA, WITHOUT MENTION OF HAVING ACHIEVED REMISSION
204.11	LYMPHOID LEUKEMIA CHRONIC IN REMISSION
204.12	CHRONIC LYMPHOID LEUKEMIA, IN RELAPSE
205.00	ACUTE MYELOID LEUKEMIA, WITHOUT MENTION OF HAVING ACHIEVED REMISSION
205.10	CHRONIC MYELOID LEUKEMIA, WITHOUT MENTION OF HAVING ACHIEVED REMISSION
238.4	POLYCYTHEMIA VERA
238.71	ESSENTIAL THROMBOCYTHEMIA
238.75	MYELODYSPLASTIC SYNDROME, UNSPECIFIED
238.76	MYELOFIBROSIS WITH MYELOID METAPLASIA
238.79	OTHER LYMPHATIC AND HEMATOPOIETIC TISSUES
287.5	THROMBOCYTOPENIA UNSPECIFIED

288.50	LEUKOCYTOPENIA, UNSPECIFIED
288.51	LYMPHOCYTOPENIA
288.59	OTHER DECREASED WHITE BLOOD CELL COUNT
288.61	LYMPHOCYTOSIS (SYMPTOMATIC)
288.69	OTHER ELEVATED WHITE BLOOD CELL COUNT
288.8	OTHER SPECIFIED DISEASE OF WHITE BLOOD CELLS
453.0	BUDD-CHIARI SYNDROME
789.2	SPLENOMEGALY

The following diagnosis codes meet coverage criteria as indications for molecular testing of lymphoma, so long as documentation of medical necessity for the specific test in question is present in the medical record, as noted elsewhere in this LCD:

200.40	MANTLE CELL LYMPHOMA, UNSPECIFIED SITE, EXTRANODAL AND SOLID ORGAN SITES
200.41	MANTLE CELL LYMPHOMA, LYMPH NODES OF HEAD, FACE, AND NECK
200.42	MANTLE CELL LYMPHOMA, INTRATHORACIC LYMPH NODES
200.43	MANTLE CELL LYMPHOMA, INTRA-ABDOMINAL LYMPH NODES
200.44	MANTLE CELL LYMPHOMA, LYMPH NODES OF AXILLA AND UPPER LIMB
200.45	MANTLE CELL LYMPHOMA, LYMPH NODES OF INGUINAL REGION AND LOWER LIMB
200.46	MANTLE CELL LYMPHOMA, INTRAPELVIC LYMPH NODES
200.47	MANTLE CELL LYMPHOMA, SPLEEN
200.48	MANTLE CELL LYMPHOMA, LYMPH NODES OF MULTIPLE SITES
200.70	LARGE CELL LYMPHOMA, UNSPECIFIED SITE, EXTRANODAL AND SOLID ORGAN SITES
200.71	LARGE CELL LYMPHOMA, LYMPH NODES OF HEAD, FACE, AND NECK
200.72	LARGE CELL LYMPHOMA, INTRATHORACIC LYMPH NODES
200.73	LARGE CELL LYMPHOMA, INTRA-ABDOMINAL LYMPH NODES
200.74	LARGE CELL LYMPHOMA, LYMPH NODES OF AXILLA AND UPPER LIMB
200.75	LARGE CELL LYMPHOMA, LYMPH NODES OF INGUINAL REGION AND LOWER LIMB
200.76	LARGE CELL LYMPHOMA, INTRAPELVIC LYMPH NODES
200.77	LARGE CELL LYMPHOMA, SPLEEN
200.78	LARGE CELL LYMPHOMA, LYMPH NODES OF MULTIPLE SITES
202.00	NODULAR LYMPHOMA UNSPECIFIED SITE
202.01	NODULAR LYMPHOMA INVOLVING LYMPH NODES OF HEAD FACE AND NECK
202.02	NODULAR LYMPHOMA INVOLVING INTRATHORACIC LYMPH NODES
202.03	NODULAR LYMPHOMA INVOLVING INTRA-ABDOMINAL LYMPH NODES
202.04	NODULAR LYMPHOMA INVOLVING LYMPH NODES OF AXILLA AND UPPER LIMB
202.05	NODULAR LYMPHOMA INVOLVING LYMPH NODES OF INGUINAL REGION AND LOWER LIMB
202.06	NODULAR LYMPHOMA INVOLVING INTRAPELVIC LYMPH NODES
202.07	NODULAR LYMPHOMA INVOLVING SPLEEN
202.08	NODULAR LYMPHOMA INVOLVING LYMPH NODES OF MULTIPLE SITES

The following diagnosis codes meet coverage criteria as indications for testing for BCR/ABL fusion gene so long as documentation of medical necessity for the specific test in question is present in the medical record, as noted elsewhere in this LCD:

288.61	LYMPHOCYTOSIS (SYMPTOMATIC)
288.69	OTHER ELEVATED WHITE BLOOD CELL COUNT
288.8	OTHER SPECIFIED DISEASE OF WHITE BLOOD CELLS
789.2	SPLENOMEGALY

The following diagnosis codes meet coverage criteria as indications for HLA-B\*5701 testing prior to initiating abacavir therapy in patients with either Human Immunodeficiency Virus (HIV) disease or Asymptomatic Human Immunodeficiency virus (HIV) infection.

042	HUMAN IMMUNODEFICIENCY VIRUS (HIV) DISEASE
V08	ASYMPTOMATIC HUMAN IMMUNODEFICIENCY VIRUS (HIV) INFECTION STATUS

### **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.

[Back to Top](#)

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## **General Information**

### **Documentations 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)
- 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.

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

## 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 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.

### 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, 2010.
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
9. NCCN Guidelines™ , Colon Cancer Screening v2.2011, available at [www.nccn.org](http://www.nccn.org)

**Advisory Committee Meeting Notes** 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.

**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  
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.**

8. NAS received a number of thoughtful and largely correct recommendations concerning coverage criteria related to the "Amsterdam II" criteria, coverage of MSI/IHC testing and NAS' previous requirement for MLH1 and MSH2 testing to precede MSH6 testing in order for there to be coverage for the MSH6 testing. NAS agrees and has accepted these recommendations and has revised this LCD accordingly.

9. We have received requests for coverage of JAK2 testing, along with a growing body of supportive literature.

**NAS has adopted the position that JAK2 will be covered, under the conditions set out in the Indications and Limitations section, as noted above. We continue to review submitted literature on other examples of this emergin genetic testing field and will consider adding coverage of new disease-specific tests if and as literature support warrants.**

10. We received a request to add HLA-B\*5701 testing prior to instituting treatment with Abacavir and abacavir-containing regimens in HIV positive patients.

Based on compelling literature and the recommendation of The Department of Health and Human Services (DHHS) Panel on Antiretroviral Guidelines for Adults and Adolescents (the Panel) is a working group of the Office of AIDS Research Advisory Council (OARAC), NAS agrees and has added this coverage.

**Start Date of Comment Period**

**End Date of Comment Period**

**Start Date of Notice Period**

**Revision History Number R11**

**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

08/10/2008 - This policy was updated by the ICD-9 2008-2009 Annual Update.

**J3 CB2006.31 R2**

2008-2009 ICD-9-CM updates were applied. Diagnosis code 203.02 has been added to Group 2 with an effective date of October 1, 2008.

11/09/2008 - The description for CPT/HCPCS code 83890 was changed in group 1

11/09/2008 - The description for CPT/HCPCS code 83891 was changed in group 1

11/09/2008 - The description for CPT/HCPCS code 83892 was changed in group 1

11/09/2008 - The description for CPT/HCPCS code 83893 was changed in group 1

11/09/2008 - The description for CPT/HCPCS code 83894 was changed in group 1

**J3 CB2006.31 R3**

CPT code 83909 was added to the LCD effective 06/01/2009. Coverage of KRAS testing is added effective 06/01/2009. Amsterdam II criteria was expanded.

**J3 CB2006.31 R4**

Revisions made to "Hereditary Colorectal Cancer Syndromes" in section "Indications and Limitations of Coverage and/or Medical Necessity".

Changed "three" to "two" in third paragraph under "Hereditary Colorectal Cancer Syndromes".

Paragraph three in section "Utilization Guidelines" is revised. The revision is listed below.

"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 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."

**J3 CB2006.31 R5**

The following ICD-9-CM 171.9, 204.00, 204.10, 205.00, 205.10, 238.4, 238.71, 238.75, 238.76, V42.82 meet criteria coverage to the hereditary colorectal cancer (HNPCC) and Familial Adenomatous Polyposis (FAP) testing including APC, MYH, and HNPCC syndromes, including endometrial cancer, as well as KRAS testing and were added to the LCD with an effective of 10/15/2009.

ICD-9-CM 238.79 and 453.0 meet coverage criteria for JAK2 testing and were added with an effective of 10/15/2009.

Revisions were also made to the following sections of the LCD: "Indications and Limitations of Coverage and/or Medical Necessity" under "Hereditary Breast and Ovarian Cancer Syndromes", and under "Therapy -Directing testing" and to the "Advisory Committee Meeting Notes" with an effective date of 10/15/2009.

**J3 CB2006.31 R6**

The following revisions were made to:

"1. Personal history of breast cancer+ one or more of the following" in the "Indications and Limitations of Coverage and/or Medical Necessity".

Expanded ICD9-CM diagnosis codes 204.00, 204.10, 205.00, 205.10, 238.4, 238.71, 238.75, 238.76 from HNPCC, FAP and KRAS coverage section to also apply to JAK2 Testing.

Additional information added to paragraph 3 in "Utilization and Guidelines".

**J3 CB2006.31 R7**

Added ICD-9-CM 158.0 and 158.8 to the BRCA1 and BRCA2 gene mutation testing with an effective date 1/1/2010.

Revised "Hereditary Breast and Ovarian Cancer Syndromes" numbers 2 and 3 under the section "Indications and Limitations of Coverage and/or Medical Necessity".

**J3 CB2006.31 R8**

ICD-9-CM codes 204.11 and 204.12 were added as payable for JAK2 testing effective for dates of service on or after April 1, 2010.

Group 4 for molecular testing of lymphoma was added with the following ICD-9-CM codes effective for dates of service on or after April 1, 2010:  
200.40-200.48, 200.70-200.78, 202.00-202.08.

05/17/2010 - the following link in the Indications and Limitations of Coverage section was updated to:  
<http://new.cms.gov/PrevntionGenInfo/>

11/21/2010 - For the following CPT/HCPCS codes either the short description and/or the long description was changed. Depending on which description is used in this LCD, there may not be any change in how the code displays in the document:  
83898 descriptor was changed in Group 1  
83909 descriptor was changed in Group 1

### **J3 CB2006.31 R9**

This LCD was updated with CPT/HCPCS 2011 changes. Effective for dates of service on/after 01/01/2011: CPT code 88363 was added.

Indications and Limitations of Coverage and/or Medical Necessity was updated adding a section for BCR/ABL fusion gene.

The following ICD-9-CM codes were added for JAK2 testing: 287.5, 288.50, 288.51, 288.59, 288.61, 288.69, 288.8, 789.2

The following ICD-9-CM codes were added for testing for BCR/ABL fusion gene: 288.61, 288.69, 288.8, 789.2.

**Effective 06/15/2011**, the following language was added to the Documentation Requirements section of the LCD: When requesting an individual consideration through the written redetermination (formerly appeal) process, providers must include all relevant medical records and literature that supports the request. At a minimum two (2) Phase II studies (human feasibility studies suggesting efficacy, pilots) or one (1) Phase III study (primary evidence of safety and efficacy, pivotal) must be submitted for the Medical Director's review.

### **J3 CB2006.31 R10**

Effective 6/15/2011, the LCD is revised consistent with recent updates to the NCCN Guidelines and the Bethesda and Amsterdam genetic testing criteria. "Hereditary Non-Polyposis Colorectal Cancer (HNPCC) syndrome" was replaced with the more currently acceptable description "Lynch Syndrome" wherever appropriate in the LCD. ICD-9-CM code 183.2 is added as payable to Group 1 diagnosis codes.

### **J3 CB2006.31 R11**

Effective 09/15/2011, the following diagnosis codes 042,V08 and CPT codes 83896, and 83900 were added to the LCD. HLA-B\*5701 Testing for coverage is added to the "Indications and Limitations of Coverage and/or Medical Necessity". In addition, in the "Advisory Committee Meeting Notes" section of the LCD, #10 was added to the NAS Response to Provider Recommendations.

## **Reason for Change**

### **Related Documents**

This LCD has no Related Documents.

### **LCD Attachments**

There are no attachments for this LCD.

[Back to Top](#)

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## **All Versions**

Updated on 08/11/2011 with effective dates 09/15/2011 - N/A

Printed on 10/28/2011. Page 15 of 16

Updated on 05/09/2011 with effective dates 06/15/2011 - 09/14/2011  
Updated on 04/19/2011 with effective dates 06/15/2011 - N/A  
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Updated on 11/04/2009 with effective dates 10/15/2009 - 12/31/2009  
Updated on 09/23/2009 with effective dates 10/15/2009 - N/A

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[Back to Top](#)