Policy:
Genetic tests which are done for clinical purposes including the diagnosis of diseases in children and adults, or for the prediction of drug efficacy require prior authorization. Tests which are done for clinical genetic purposes including the diagnosis of genetic disease in children and adults and the prediction of drug and therapy response and responsiveness.

Procedure:
1. No prior authorization or review is required for the following prenatal tests:
   a. Fetal Karyotype via amniocentesis or CVS
   b. Nuchal Translucency
   c. Quad screen test
   d. Sequential screen

Any other prenatal screening tests including cell free DNA testing e.g. Materna T21, Harmony, etc. requires prior authorization.

2. Genetic testing is considered a clinical option for patients when testing will impact the member’s treatment plan and result in a significant clinical difference for the member.

3. Unless pregnancy related (see #1), Genetic Testing must be prior-authorized by Meridian Health Plan and meet all of the following documentation of medical necessity to be considered for approval:
   a. The test results are expected to both impact both the treatment care plan and result in a significant clinical difference for the member, and documentation of the difference is required.
   b. The member displays clinical features, or is at direct risk of inheriting the mutation.
c. History, physical examination, pedigree analysis and completion of conventional diagnostic studies fail to return a definitive diagnosis and a hereditary diagnosis is suspected.
d. The genetic testing must be ordered by a specialist within the scope of their practice or a genetic counselor working under direction of a specialist. Primary Care physicians will not generally meet this test.
e. Testing is accompanied by both pretest counseling and documentation of posttest follow up where the possible risks and benefits of early detection are reviewed and accepted by the member.
f. Evidence that the requested test is considered diagnostic with high sensitivity and specificity
g. Genetic testing for cancer for a beneficiary with a personal history of a relevant cancer.

4. 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-grandchildren, 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 if the individual is of non-Ashkenazi Jewish descent.

Members will be considered for BRCA1 and BRCA2 genetic testing based on 1 or more of the following:

a. Documentation of a positive first degree relative, showing the member is at direct risk. If after genetic counseling the member is considering medical treatment then consideration for testing may be appropriate. Acceptable forms of documentation include:
   1. A letter from a healthcare facility documenting Breast or Ovarian Cancer in a First-degree relative.
   2. A Death Certificate documenting the same, or
   3. A letter from a provider who cared for the First-degree relative, or an office note from a provider who cared for the First-degree relative, documenting Breast or Ovarian Cancer in the relative.

b. Personal history of breast cancer + one or more of the following:
   i. Diagnosed age ≤45 y, with or without family history
   ii. Diagnosed age ≤50 y or two breast primaries, with ≥1 close blood relative(s) with breast cancer ≤50 y and/or ≥1 close blood relative(s) with epithelial ovarian/fallopian tube/primary peritoneal cancer
   iii. Two breast primaries when first breast cancer diagnosis occurred prior to age 50
   iv. Diagnosed at any age, with ≥2 close blood relatives with breast and/or epithelial ovarian/fallopian tube/primary peritoneal cancer, at any age
   v. Close male blood relative with breast cancer
   vi. Personal history of epithelial ovarian/fallopian tube/primary peritoneal cancer
   vii. If of certain ethnicity associated with higher mutation frequency, (e.g., founder populations of Ashkenazi Jewish, Icelandic, Swedish, Hungarian or other) no additional family history required
   viii. A close relative with a known BRCA1 or BRCA2 gene mutation

c. Personal history of epithelial ovarian/fallopian tube/primary peritoneal cancer and/or

d. 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:

Amsterdam II Criteria for Lynch syndrome genetic testing

a. 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:
   i. One must be a first-degree relative of the other two;
   ii. At least two successive generations must be affected;
   iii. 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;
   iv. Familial adenomatous polyposis (FAP) should be excluded in the colorectal cancer case(s) (if any);
   v. Histologic diagnosis of tumors should be verified whenever possible.

b. Revised Bethesda guidelines
   i. Colorectal cancer diagnosed in a beneficiary at less than 50 years of age
   ii. Presence of synchronous or metachronous Lynch syndrome-associated cancers*, regardless of age
   iii. Colorectal cancer with the MSI-H histology diagnosed in a beneficiary who is less than 60 years of age
   iv. 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
   v. 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.

c. Has a blood relative with a known Lynch syndrome related gene mutation
d. Endometrial cancer diagnosed in a beneficiary at less than 50 years of age
e. 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 ≥ 20 cumulative colorectal adenomas over a lifetime.
- Testing for APC gene mutations should precede testing for the less common MYH mutation.

Suspected Genetic Conditions/Diagnostic testing- Pediatrics (18 years old):
Careful consideration must be given to genetic testing and screening of children to ensure that use of this technology promotes the best interest of the child. Identification of the genetic condition must provide a
clear benefit to the child. Tests would be to confirm or rule out suspected genetic conditions in symptomatic individuals in which confirming a diagnosis would alter the medical management for the individual. This includes but is not limited to the following examples:

1. Chromosomal analysis in a newborn with features of Down Syndrome
2. Sickle Cell Disease

MHP will cover chromosomal microarray (CMA) or comparative genomic hybridization (CGH) to confirm suspected genetic conditions only when ordered by a specialist (Family Practice, Internal Medicine, Neurology, Geneticist, Obstetrics/Gynecology, or Pediatric Physicians) within the scope of their practice or a genetic counselor working under direction of a specialist and in the presence of any of the following:

1. Congenital malformation(s)
2. Conditions with a known or suspected genetic etiology.
3. Unexplained global developmental delay

**Non Covered Testing**

1. Predictive or pre-symptomatic genetic tests and services, in the absence of past or present illness in the beneficiary are not covered.
2. Genetic testing for purposes of family planning, disease risk assessment of other family members, when the treatment and surveillance of the beneficiary will not be affected is not covered.

**Special Instructions:** N/A

**CPT/HCPCS Codes:**

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Approved by: ____________________________  Date: 12/19/2014

Reviewed and approved by Corporate Chief Operating Officer: Date: 10/31/2014

Reviewed and approved by Policy and Procedure Committee: Date: 11/07/2014

Reviewed and approved by Medical Policy Operations Committee: Date: 12/19/2014

Reviewed and approved by Physician Advisory Committee: Date: 01/20/2015

References:


8. Marquez Caldoren S, Briones Perez de la Blanca E. Genetic testing assessment Framework in the Andalusian Public Health System-guidelines [summary]. Report 2/2006. Seveille, Spain: Agencia e Evaluación de Tecnologías Sanitarias de Andalucía (AETSA); 2005. Retrieved from: [http://www.crd.york.ac.uk/crdweb/PrintPDF.php?AccessionNumber=32005000434&Copyright=Health+Technology+Assessment+(HTA)+database%3Cbr+%2f%3EcCopyright+%26copy%3B+2013+Andalusian+Agency+for+Health+Technology+Assessment+(AETSA)%0D%0A%3Cbr+%2f%3E](http://www.crd.york.ac.uk/crdweb/PrintPDF.php?AccessionNumber=32005000434&Copyright=Health+Technology+Assessment+(HTA)+database%3Cbr+%2f%3EcCopyright+%26copy%3B+2013+Andalusian+Agency+for+Health+Technology+Assessment+(AETSA)%0D%0A%3Cbr+%2f%3E)


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