Medica Coverage Policy

Policy Name: Genetic Testing for Inherited Susceptibility to Melanoma
Effective Date: 8/19/2019

Important Information – Please Read Before Using This Policy

These services may or may not be covered by all Medica plans. Please refer to the member’s plan document for specific coverage information. If there is a difference between this general information and the member’s plan document, the member’s plan document will be used to determine coverage. With respect to Medicare and Minnesota Health Care Programs, this policy will apply unless those programs require different coverage. Members may contact Medica Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions about this Medica coverage policy may call the Medica Provider Service Center toll-free at 1-800-458-5512.

Medica coverage policies are not medical advice. Members should consult with appropriate health care providers to obtain needed medical advice, care and treatment.

Coverage Policy
Genetic testing for inherited susceptibility to melanoma is investigative and unproven, and therefore NOT COVERED. There is insufficient reliable evidence in the form of high quality peer-reviewed medical literature to establish the effects on health care outcomes.

Note: This Position Statement does not apply to pharmacogenetic testing when testing for a specific gene biomarker is required by the FDA prior to initiating drug therapy or testing for molecular and genomic pathology testing of solid tumors. See related Medica coverage policy, Genetic Testing and Pharmacogenetic Testing.

Description
Melanoma is a malignancy of pigment-producing cells (melanocytes) located predominantly in the skin (cutaneous malignant melanoma or CMM), and may occur in other sites including the eyes (uveal melanoma), and rarely, in mucosal tissue. Cutaneous malignant melanoma (CMM) is the most common type of melanoma and occurs in all parts of the skin, including soles of the feet, palms of the hand and under finger/toe nails. Risk of melanoma is higher if one or more first-degree relatives has had melanoma, but most will never develop the disease. Approximately 8% of all individuals with melanoma have a first-degree relative with melanoma and 1% to 2% have two or more close relatives with melanoma. The majority (90%) of melanomas are thought to be caused by exposure to UV light and sunlight.

Cyclin-dependent kinase inhibitor 2A (CDKN2A) is the most common gene mutation in familial melanoma. Other melanoma susceptibility genes are, but not limited to, CDK4, MC1R, TERT, MITF, BAP1, and POT1.

Genetic testing for inherited susceptibility of melanoma is considered germline testing. Germline mutations are a genetic change in all of the cells in the body, usually happen before conception and are generally passed down from a parent. Germline testing is done on cells that do not have cancer and is done to determine if an individual has a gene mutation that is known to increase the risk of developing cancer.
**FDA Approval**
Genetic tests are regulated under the Clinical Laboratory Improvement Amendments (CLIA) of 1988. Premarket approval from the FDA is not required as long as the assay is performed in a laboratory facility that observes CLIA regulations.

**Prior Authorization**
Prior authorization is not applicable. Claims for this service are subject to retrospective review and denial of coverage, as investigative services are not eligible for reimbursement.

**Coding Considerations**
Use the current applicable CPT/HCPCS code(s). The following codes are included below for informational purposes only, and are subject to change without notice. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement.

**CPT Codes:**
- 81404 - Molecular pathology procedure, Level 5 (eg, analysis of 2-5 exons by DNA sequence analysis, mutation scanning or duplication/deletion variants of 6-10 exons, or characterization of a dynamic mutation disorder/triplet repeat by Southern blot analysis)
- 81479 – Unlisted molecular pathology procedure
- 81345 – TERT (telomerase reverse transcriptase) (eg, thyroid carcinoma, glioblastoma multiforme) gene analysis, targeted sequence analysis (eg, promoter region)

Original Effective Date: 8/1/2010

Re-Review Date(s):
- 4/23/2013
- 12/1/2015 – administrative update; Coverage Policy section
- 9/1/2016
- 6/26/2019
- 2/10/2020 – administrative update; format