**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, Medicaid and MinnesotaCare members, this policy will apply unless these 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 malignant melanoma is investigative and therefore NOT COVERED.

Note: This Position Statement does not apply to genetic testing for BRAFV600E mutation to assess potential response to dabrafenib (Tafinlar), trametinib (Mekinist), or vemurafenib (Zelboraf), or testing for molecular and genomic pathology testing of solid tumors.

See Medica Utilization Management policy, Vemurafenib (Zelboraf) and 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, and rarely, in mucosal tissue. Cutaneous malignant melanoma (CMM) is an aggressive form of skin cancer with increasing incidence in the Western world. In addition to environmental factors, family history is a significant risk factor for CMM, accounting for 8 to 12 percent of all cases. Inherited sequence variants in the cyclin-dependent kinase inhibitor 2A (CDKN2A) gene on chromosome 9 at band p21 account for susceptibility in about 20 to 25 percent of inherited melanoma families. Lifetime incidence risk of melanoma in carriers is high (greater than 67 percent), but penetrance varies dramatically with sun exposure; it is also influenced by interaction with other high and low-penetrance genes. Uveal melanoma (UM) is the most common form of primary eye cancer, with greater prevalence in older individuals. The choroid is the most common site of UM.

Multiple methods of testing for malignant melanoma are offered. Sequence variants found in the first person of a family to be tested are confirmed by repeat analysis using sequencing, restriction fragment analysis, or another appropriate method. The sample obtained from the patient may be a buccal swab or blood sample.
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)

Original Effective Date: 8/1/2010

Re-Review Date(s): 4/23/2013
12/1/2015 – administrative update Coverage Policy section
9/1/2016

© 2010-2016 Medica. Medica® is a registered service mark of Medica Health Plans. "Medica" refers to the family of health plan businesses that includes Medica Health Plans, Medica Health Plans of Wisconsin, Medica Insurance Company, and Medica Self-Insured, and Medica Health Management, LLC.