Medica Coverage Policy

Policy Name: Genetic Testing for Thyroid Cancer
Effective Date: 3/16/2016

Product Application 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
Afirma® Thyroid FNA Analysis is COVERED when fine needle aspirate is inconclusive.

All other genetic testing for thyroid cancer, including but not limited to, ThyroSeq Next Generation sequencing panel, ThyGenX oncogene panel, ThyraMIR miRNA gene expression classifier, and BRAF p.Val600Glu testing, is investigative and therefore NOT COVERED.

Description
Thyroid nodules are a common clinical finding. Epidemiological studies show prevalence of palpable thyroid nodules of about 5% in the United States population for ages 50 and older. Thyroid nodules are approximately 4 times more common in women than in men. Thyroid cancer, however, is uncommon, with a risk of less than 1% in the U.S.

Fine needle aspiration (FNA) biopsy (or FNAB) is the gold standard for preoperative differential diagnosis of thyroid nodules. However, in 20% - 25% of cases, nodules are indeterminate, usually due to overlapping cytologic features between benign and malignant nodules. Follow-up of patients with indeterminate results on FNA often includes surgical resection of the nodule or entire thyroid gland. Recent studies have sought to identify genetic or genomic markers that may differentiate between benign and malignant thyroid tumors. Currently, there are two methods of analysis of FNA aspirates available: identification of molecular markers of malignancy, such as BRAF and RAS mutational status as well as panels that include multiple genes and the use of a gene expression classifier, such as the Afirma® Thyroid FNA Analysis.

Afirma® (Veracyte) is an example of a gene expression test that uses a proprietary classifier to categorize nodules as either “benign” or “suspicious.” According to Veracyte, the goal of the assay is to identify patients who likely have benign thyroid masses in order to avoid unnecessary thyroid surgery. ThyGenX (formerly mirInform) is a panel of eight analytically validated molecular markers (KRAS, BRAF, HRAS, NRAS, PIK3CA, RET/PTC 1, RET/PTC3 and PAX8/PPARγ) associated with papillary carcinoma and follicular carcinoma. ThyGenX is offered in conjunction with ThyraMIR, a miRNA gene expression classifier.

BRAF mutations are found in 40-50% of papillary thyroid carcinoma (PTC). BRAF p.Val600Glu testing is available.
from multiple commercial laboratories in the United States and may be used for individuals with indeterminate thyroid nodules and for the evaluation of patient prognosis in patients diagnosed with PTC.

ThyroSeq® v.2 (CBLPath) is an example of next generation sequencing panel and does simultaneous sequencing of 400 mutations and/or fusions and expression in more than 60 genes. miRNA. This next generation testing purportedly enhances accuracy of cancer detection by testing for a significantly larger group of mutational markers.

FDA Approval
Genetic tests are regulated under the Clinical Laboratory Improvement Amendments (CLIA) Act 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 and does not market the test for distribution.

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:
- 0018U - Oncology (thyroid), microRNA profiling by RT-PCR of 10 microRNA sequences, utilizing fine needle aspirate, algorithm reported as a positive or negative result for moderate to high risk of malignancy
- 81545 - Oncology (thyroid), gene expression analysis of 142 genes, utilizing fine needle aspirate, algorithm reported as a categorical result (eg, benign or suspicious)

Original Effective Date: 5/1/2014

Re-Review Date(s): 1/4/2016 – Administrative update – code added
3/16/2016
10/1/2017 – Administrative update – code added