



Clinical Review Criteria Related to Afirma Thyroid FNA Analysis Testing

I. Criteria for Approval

- A. The use of the Gene Expression Classifier (GEC) test Afirma is considered to be medically necessary when findings from the fine needle aspiration (FNA) biopsy of the thyroid nodules are indeterminate.
 - 1. Patient is ≥ 21 years of age.
 - 2. Nodule is at least ≥ 1 centimeter (cm) in size.

- B. Fine needle aspirate samples from thyroid nodules that have indeterminate cytology as indicated by one or more of the following conditions:
 - 1. Diagnosis of atypia of undetermined significance (AUS)
 - 2. Follicular lesion of undetermined significance (FLUS)
 - 3. Follicular neoplasm or suspicious for follicular neoplasm on fine needle aspiration (FNA)

- C. The use of a thyroid nodule gene expression classifier is considered **NOT MEDICALLY NECESSARY** if above criteria are not met.

II. Required Documentation

- A. Clinical notes from the Provider who requested the biopsy, indicating how the results of the diagnostic test will be used to change management of the patient

III. What is Not Covered

- A. The use of the Afirma test to identify primary tumors or guide treatment decisions in cancers of unknown origin

- B. Mutation analysis (i.e., MiRinformo, ThyGenX) in fine needle aspirates of the thyroid is considered **INVESTIGATIONAL**.

CPT Code

81545 Oncology (thyroid) gene expression analysis of 142 genes, utilizing fine needle aspirate; algorithm reported as a categorical result (e.g., benign or suspicious).

References:

NCQA Standard, UM 2, Clinical Criteria for Utilization Management Decisions, Element A

Alexander EK, Schorr M, Klopper J, et al. Multicenter Clinical Experience With the Afirma Gene Expression Classifier. *Journal of Clinical Endocrinology Metabolism* 2014 Jan;99(1):119-25
<http://press.endocrine.org/doi/full/10.1210/jc.2013-2482>

Alexander EK, Kennedy GC, Baloch ZW, et al. Preoperative Diagnosis of Benign Thyroid Nodules With Indeterminate Cytology. *N Engl J Med.* 2012;367(8):705-715
<http://www.nejm.org/doi/full/10.1056/nejmoa1203208>

Syed Z Ali MD, Stephanie A Fish. MD, Richard Lanman MD, Gregory W. Randolph MD, Julie Ann Sosa MD. Use of Afirma Gene Expression Classifier for Preoperative Identification of Benign Thyroid Nodules with Indeterminate Fine needle Aspiration Cytopathology. *PLoS Current Version* 1,2013 Feb 11;(5): Published on line 2013 February 11
<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3574863>

Afirma Thyroid FNA Analysis (Veracyte. Inc.) <https://www.hayesinc.com/subscribers/displaySubscriberArticle>

NCCN guidelines Version 1.2016 Thyroid Carcinoma - Follicular Carcinoma https://www.nccn.org/professionals/physician_gls/pdf/thyroid.pdf

Medicare Local Coverage Article: MoIDX: Afirma Assay by Veracyte Update (A55139) LCD L36807
<https://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleId>

Summary of Changes:

02/09/2017

- **Under I., Criteria for Approval, removed:** 3-Family history of thyroid cancer; 4-Hoarseness, difficulty swallowing or breathing; 5- History of exposure to ionizing radiation; 6- Presence of cervical adenopathy