

Medical Coverage Policy | Molecular Markers in Fine Needle Aspiration of the Thyroid



EFFECTIVE DATE: 02/01/2026

POLICY LAST REVIEWED: 10/01/2025

OVERVIEW

To determine which patients need thyroid resection, many physicians will perform a cytologic examination of fine needle aspirate (FNA) samples from a thyroid lesion; however, this method has diagnostic limitations. As a result, assays using molecular markers have been developed to improve the accuracy of thyroid FNA biopsies.

The following tests are addressed in this policy:

- Afirma GSC (Genomic Sequencing Classifier) (Veracyte) (CPT Code 81546)
- Afirma BRAF (proto-oncogene B-Raf and v-Raf murine sarcoma viral oncogene homolog B) (Veracyte) (CPT Code 81479)
- Afirma MTC (Medullary Thyroid Carcinoma) (Veracyte) (CPT Code 81479)
- RosettaGX Reveal (Rosetta Genomics) (CPT Code 81479)
- ThyGeNEXT (Interpace Diagnostics) (CPT Code 0245U)
- ThyraMIR (Interpace Diagnostics) (CPT Code 0018U)
- ThyroSeq (CBLPath, Inc, University of Pittsburgh Medical Center) (CPT Code 0026U)

MEDICAL CRITERIA

Medicare Advantage Plans and Commercial Products

Effective 2/1/2026, the following test(s) are considered medically necessary when the medical criteria in the online authorization tool for participating providers is met:

- ThyroSeq Cancer Risk Classifier (CRC) (CBLPath, Inc, University of Pittsburgh Medical Center), CPT Code 0287U

PRIOR AUTHORIZATION

Medicare Advantage Plans and Commercial Products

Effective 2/1/2026, prior authorization is required for Medicare Advantage Plans and recommended for Commercial Products via the online tool for participating providers for the following test(s):

- ThyroSeq CRC, CPT Code 0287U

There is no specific CPT coding for some of the services referenced in this policy. Therefore, an Unlisted CPT code should be used (see Coding Section for details). All Unlisted genetic testing CPT codes require prior authorization to determine what service is being rendered and if the service is covered or not medically necessary. See the Related Policies section.

Note: Laboratories are not allowed to obtain clinical authorization or participate in the authorization process on behalf of the ordering physician. Only the ordering physician shall be involved in the authorization, appeal or other administrative processes related to prior authorization/medical necessity.

In no circumstance shall a laboratory or a physician/provider use a representative of a laboratory or anyone with a relationship to a laboratory and/or a third party to obtain authorization on behalf of the ordering physician, to facilitate any portion of the authorization process or any subsequent appeal of a claim where the authorization process was not followed and/or a denial for clinical appropriateness was issued, including any element of the preparation of necessary documentation of clinical appropriateness. If a laboratory or a third party is found to be supporting any portion of the authorization process, BCBSRI will deem the action a

violation of this policy and severe action will be taken up to and including termination from the BCBSRI provider network. If a laboratory provides a laboratory service that has not been authorized, the service will be denied as the financial liability of the participating laboratory and may not be billed to the member.

POLICY STATEMENT

Medicare Advantage Plans and Commercial Products

Effective 2/1/2026, the following test(s) are covered:

- Afirma GSC, CPT Code 81546
- Afirma BRAF, CPT Code 81479
- Afirma MTC, CPT Code 81479
- RosettaGX Reveal, CPT Code 81479
- ThyGeNEXT, CPT Code 0245U
- ThyraMIR, CPT Code 0018U
- ThyroSeq, CPT Code 0026U

Effective 2/1/2026, the following test(s) may be considered medically necessary when the medical criteria in the online authorization tool for participating providers is met:

- ThyroSeq CRC, CPT Code 0287U

Commercial Products

Some genetic testing services are not covered and a contract exclusion for any self-funded group that has excluded the expanded coverage of biomarker testing related to the state mandate, R.I.G.L. §27-19-81 described in the Biomarker Testing Mandate policy. For these groups, a list of which genetic testing services are covered with prior authorization, are not medically necessary or are not covered because they are a contract exclusion can be found in the Coding section of the Genetic Testing Services or Proprietary Laboratory Analyses policies. Please refer to the appropriate Benefit Booklet to determine whether the member's plan has customized benefit coverage. Please refer to the list of Related Policies for more information.

COVERAGE

Benefits may vary between groups/contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage, or Subscriber Agreement for limitations of benefits/coverage for laboratory tests or when services are not medically necessary.

BACKGROUND

Thyroid nodules are common, present in 5% to 7% of the U.S. adult population. Most are benign, and most cases of thyroid cancer are curable by surgery when detected early.

Diagnosis

Sampling thyroid cells by fine needle aspirate (FNA) is currently the most accurate procedure to distinguish benign thyroid lesions and malignant ones, reducing the rate of unnecessary thyroid surgery for patients with benign nodules and triaging patients with thyroid cancer to appropriate surgery.

About 60% to 70% of thyroid nodules are classified cytologically as benign, and 4% to 10% of nodules are cytologically deemed malignant. However, the remaining 20% to 30% have equivocal findings usually due to overlapping cytologic features between benign and malignant nodules; these nodules usually require surgery for a final diagnosis. Thyroid FNA cytology is classified by Bethesda System criteria into the following groups: nondiagnostic; benign; follicular lesion of undetermined significance (FLUS) or atypia of undetermined significance (AUS); follicular neoplasm (or suspicious for follicular neoplasm); suspicious for malignancy; and malignant. Lesions with FNA cytology in the AUS or FLUS or follicular neoplasm categories are often considered indeterminate.

Management

There is some individualization of management for patients with FNA-indeterminate nodules, but many patients will require a surgical biopsy, typically thyroid lobectomy, with intraoperative pathology. Consultation would typically be the next step in diagnosis. Approximately 80% of patients with indeterminate cytology undergo surgical resection; postoperative evaluation has revealed a malignancy rate ranging from 6% to 30%, making this a clinical process with very low specificity. Thus, if analysis of FNA samples could reliably identify the risk of malignancy as low, there is potential for patients to avoid surgical biopsy.

Preoperative planning of optimal surgical management in patients with equivocal cytologic results is challenging, because different thyroid malignancies require different surgical procedures (eg, unilateral lobectomy vs total or subtotal thyroidectomy with or without lymph node dissection) depending on several factors, including histologic subtype and risk-stratification strategies (tumor size, patient age). If a diagnosis cannot be made intraoperatively, a lobectomy is typically performed, and, if on postoperative histology the lesion is malignant, a second surgical intervention may be necessary for completion thyroidectomy.

Thyroid Cancer

Most thyroid cancers originate from thyroid follicular cells and include well-differentiated papillary thyroid carcinoma (PTC; 80% of all thyroid cancers) and follicular carcinoma (15%). Poorly differentiated and anaplastic thyroid carcinomas are uncommon and can arise de novo or from preexisting well differentiated papillary or follicular carcinomas. Medullary thyroid carcinoma originates from parafollicular or C cells and accounts for about 3% of all thyroid cancers.

The diagnosis of malignancy in the case of PTC is primarily based on cytologic features. If FNA in a case of PTC is indeterminate, surgical biopsy with intraoperative pathology consultation is most often diagnostic, although its efficacy and therefore its use will vary across institutions, surgeons, and pathologists. In 2016, reclassification of encapsulated follicular-variant PTC as a noninvasive follicular tumor with papillary-like nuclei was proposed and largely adopted; this classification removes the word carcinoma from the diagnosis to acknowledge the indolent behavior of these tumors.

For follicular carcinoma, the presence of invasion of the tumor capsule or of blood vessels is diagnostic and cannot be determined by cytology, because tissue sampling is necessary to observe these histologic characteristics. Intraoperative diagnosis of follicular carcinoma is challenging and often not feasible because extensive sampling of the tumor and capsule is usually necessary and performed on postoperative permanent sections.

New approaches for improving the diagnostic accuracy of thyroid FNA include variant analysis for somatic genetic alterations, to more accurately classify which patients need to proceed to surgery (and may include the extent of surgery necessary), and a gene expression classifier to identify patients who do not need surgery and can be safely followed.

CODING

Medicare Advantage Plans and Commercial Products

Effective 2/1/2026, the following CPT code(s) are covered:

- Afirma GSC, CPT Code 81546
- Afirma BRAF (CPT Code 81479)
- Afirma MTC (CPT Code 81479)
- RosettaGX Reveal, CPT Code 81479
- ThyGeNEXT, CPT Code 0245U
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- ThyroSeq CRC, CPT Code 0287U

RELATED POLICIES

Biomarker Testing Mandate
Genetic Testing Services
Proprietary Laboratory Analyses (PLA)
Unlisted Procedures

PUBLISHED

Provider Update, January/December 2025
Provider Update, November 2023
Provider Update, December 2022
Provider Update, June 2021
Provider Update, December 2020

REFERENCES

1. Centers for Medicare and Medicaid Services (CMS). Local Coverage Determination (LCD): MolDX: Molecular Testing for Risk Stratification of Thyroid Nodules (L39682)
2. Centers for Medicare and Medicaid Services (CMS). Local Coverage Article: Billing and Coding: MolDX: Molecular Diagnostic Tests (MDT) (A59509)
3. Centers for Medicare and Medicaid Services (CMS). Local Coverage Determination (LCD): Biomarkers for Oncology (L35396)
4. Centers for Medicare and Medicaid Services (CMS). Local Coverage Article: Billing and Coding: Biomarkers for Oncology (A52986)
5. Centers for Medicare and Medicaid Services (CMS). Local Coverage Determination (LCD): Thyroid Nodule Molecular Testing (L38968)
6. Centers for Medicare and Medicaid Services (CMS). Local Coverage Article: Billing and Coding: Thyroid Nodule Molecular Testing (A58656)

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