

THYROID-RELATED PROCEDURES

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Status: New

This medical policy addresses the following thyroid-related procedures:

- Screening for thyroid cancer
- Thyroid ultrasound (US)
- Thyroid fine needle aspiration (FNA) with associated cytopathology
- Thyroid molecular diagnostic tests
- Thyroidectomy (partial lobectomy, total lobectomy, subtotal, or complete)

I. POLICY/CRITERIA

- A. **Screening for thyroid cancer.** The United States Preventive Service Task Force (USPSTF) recommends against screening for thyroid cancer in asymptomatic adults. Therefore, screening for thyroid cancer in asymptomatic adults is NOT a covered benefit.
- B. **Thyroid ultrasound (US).** A thyroid **ultrasound (US)** is a covered benefit only when one or more of the following criteria are met:
1. A patient exhibits one or more clinical risk factors for thyroid cancer. Examples include:
 - history of exposure to ionizing radiation, such as a history of radiation therapy administered for benign conditions of the head and neck
 - family history of thyroid disease or multiple endocrine neoplasia (MEN) syndrome,
 - RET gene mutation,
 - history of goiter;
 2. A thyroid nodule is known or is suspected on exam;
 3. For an **incidental thyroid nodule (ITN)** – a thyroid nodule identified by an imaging study that was not previously detected or suspected clinically — a thyroid ultrasound (US) is a covered benefit only when the criteria from the **American College of Radiology (ACR)** are met [Reference 6].
- C. **Thyroid fine needle aspirate (FNA).** A thyroid FNA (with associated cytopathology) is performed when certain sonographic features, typically in combination, are revealed by a thyroid ultrasound. Sonographic features of thyroid nodules that are evaluated in consideration of a thyroid FNA include, but are not limited to, the following:

- Size
- Shape
- Composition (e.g., spongiform, mixed cystic and solid)
- Echogenicity (e.g., anechoic, hyperechoic, isoechoic, hypoechoic)
- Echogenicity of foci (e.g., large comet-tail artifacts, macrocalcifications, peripheral, punctate echogenic foci)
- Margin (e.g., lobulated, irregular, extrathyroidal extension)

Thyroid FNA with associated cytopathology is a covered benefit only when a thyroid ultrasound meets the criteria from at least one of the following three guidelines:

1. The American College of Radiology (ACR) Thyroid Imaging, Reporting and Data System (TI-RADS) [Reference 15]
2. National Comprehensive Cancer Network® (NCCN) Clinical Practice Guidelines in Oncology (NCCN Guidelines®): Thyroid Carcinoma [Reference 10]
3. American Thyroid Association (ATA) Management Guidelines for Adult Patients with Thyroid Nodules and Differentiated Thyroid Cancer [Reference 4]

D. **Thyroidectomy (partial lobectomy, total lobectomy, subtotal, or complete)**. Qualifying criteria must be met in order for a thyroidectomy to be a covered benefit for the following diagnoses:

1. Thyroid nodule
2. Thyroid neoplasm
3. Thyroid goiter that is NOT obstructive or substernal

Qualifying criteria are based on the categorization of thyroid **fine needle aspirate (FNA)** cytopathology according to the Bethesda System for Reporting Thyroid Cytopathology (Categories I through VI; see Table 1, following page) [Reference 2]:

Table 1. 2017 Bethesda System for Reporting Thyroid Cytopathology

Bethesda Category	Description	Examples (not all-inclusive)	Thyroidectomy a Covered Benefit?
I	Non-diagnostic or Unsatisfactory	<ul style="list-style-type: none"> • Cyst fluid only • Virtually acellular specimen • Obscuring blood • Clotting artifact 	No
II	Benign	<ul style="list-style-type: none"> • Consistent with a benign follicular nodule • Consistent with lymphocytic (Hashimoto) thyroiditis in the proper clinical context • Consistent with granulomatous (subacute) thyroiditis 	No
III	Atypia of Undetermined Significance (AUS), or, Follicular Lesion of Undetermined Significance (FLUS)		Possibly <i>(see “Thyroid molecular diagnostic tests” below)</i>
IV	Follicular Neoplasm (FN), or, Suspicious for a Follicular Neoplasm (SFN)		Possibly <i>(see “Thyroid molecular diagnostic tests” below)</i>
V	Suspicious for malignancy	<ul style="list-style-type: none"> • Suspicious for papillary carcinoma • Suspicious for medullary carcinoma • Suspicious for metastatic carcinoma • Suspicious for lymphoma 	Yes
VI	Malignant	<ul style="list-style-type: none"> • Papillary thyroid carcinoma • Poorly differentiated carcinoma • Medullary thyroid carcinoma • Undifferentiated (anaplastic) carcinoma • Squamous-cell carcinoma • Carcinoma with mixed features • Metastatic carcinoma • Non-Hodgkin lymphoma 	Yes

- **Thyroid molecular diagnostic tests.** For thyroid FNA cytopathology characterized as Bethesda Category III or IV, a Priority Health-contracted thyroid molecular diagnostic test must be conducted to further characterize the thyroid fine needle aspirate*:
 - If the result of the thyroid molecular diagnostic test indicates malignant, positive for malignancy, suspicious for malignancy, or similar, a thyroidectomy will be covered.
 - If the result of the thyroid molecular diagnostic test is non-diagnostic or unsatisfactory; or benign or similar, then a thyroidectomy will NOT be covered without detailed justification as to the rationale for thyroidectomy when not indicated by the thyroid molecular diagnostic test.

*Note: Medicaid members do NOT require a thyroid molecular diagnostic test.

II. MEDICAL NECESSITY REVIEW

- Required for thyroidectomy, partial or total
 Not Required
 Not Applicable

III. APPLICATION TO PRODUCTS

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

- ❖ **HMO/EPO:** *This policy applies to insured HMO/EPO plans.*
- ❖ **POS:** *This policy applies to insured POS plans.*
- ❖ **PPO:** *This policy applies to insured PPO plans. Consult individual plan documents as state mandated benefits may apply. If there is a conflict between this policy and a plan document, the provisions of the plan document will govern.*
- ❖ **ASO:** *For self-funded plans, consult individual plan documents. If there is a conflict between this policy and a self-funded plan document, the provisions of the plan document will govern.*
- ❖ **INDIVIDUAL:** *For individual policies, consult the individual insurance policy. If there is a conflict between this medical policy and the individual insurance policy document, the provisions of the individual insurance policy will govern.*
- ❖ **MEDICARE:** *Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, this policy applies.*
- ❖ **MEDICAID/HEALTHY MICHIGAN PLAN:** *For Medicaid/Healthy Michigan Plan members, this policy will apply. Coverage is based on medical necessity criteria being met and the appropriate code(s) from the coding section of this policy being included on the Michigan Medicaid Fee Schedule located at: http://www.michigan.gov/mdch/0,1607,7-132-2945_42542_42543_42546_42551-159815--,00.html. If there is a discrepancy between this policy and the Michigan Medicaid Provider Manual located at: http://www.michigan.gov/mdch/0,1607,7-132-2945_5100-87572--,00.html, the Michigan Medicaid Provider Manual will govern. If there is a discrepancy or lack of guidance in the Michigan Medicaid Provider Manual, the Priority Health contract with Michigan Medicaid will govern. For Medical Supplies/DME/Prosthetics and Orthotics, please refer to the Michigan Medicaid Fee Schedule to verify coverage.*

IV. BACKGROUND

Incidental thyroid nodules (ITNs): Many thyroid nodules not previously detected or suspected clinically are discovered incidentally by an imaging study. ITNs are seen in:

- 20%-67% of ultrasound studies
- Up to 25% of contrast-enhanced chest CT scans
- 16%-18% of CT and MR scans of the neck
- 1%-2% of 18FDG-PET scans

The American College of Radiology (ACR) has specific criteria for dedicated thyroid ultrasound for ITNs found by each modality.

Fine needle aspirates (FNAs): Evidence shows overuse of fine needle aspirates (FNAs) for analysis of thyroid nodules. The ACR, the NCCN, and the ATA all have evidence-based guidelines for which thyroid nodules should be aspirated. The incidence of detected thyroid cancer cases has been rising in the United States for both men and women, from 4.9 cases per 100,000 persons in 1975 to 14.3 cases per 100,000 persons in 2014. However, mortality rates have remained stable at about 0.5 per 100,000 persons per year. Differentiated thyroid cancer generally has a very good prognosis and accounts for about 90% of all cases of thyroid cancer. These findings support the overuse of FNA.

Thyroidectomy: There is also evidence of the overuse of thyroidectomy, particularly as a diagnostic procedure following indeterminate FNA cytopathology. FNA cytopathology yields a final diagnosis in 70–80% of cases, and the remaining 20–30% of samples are characterized as indeterminate for malignancy. Thyroid nodules with indeterminate features on FNA cause a significant problem for the clinician and the patient, and until the advent of molecular diagnostic tests, surgical excision with histopathological analysis was an acceptable clinical approach. A high volume of diagnostic surgeries is performed every year in the USA and potentially results in morbidity and higher healthcare costs.

Molecular diagnostic tests: Several companies have developed and marketed molecular diagnostic tests that differentiate between benign and malignant pathology in patients with indeterminate thyroid nodule FNAs. Such tests include the Afirma® Gene Expression Classifier and Genomic Sequencing Classifier (Veracyte, Inc.), the ThyroSeq® Thyroid Genomic Classifier (Sonic Healthcare), and the ThyGenX® Thyroid Oncogene Panel; ThyraMIR™ Thyroid miRNA Classifier (Interpace® Diagnostics). These tests have demonstrated utility in reducing the number of diagnostic thyroidectomies.

V. CODING INFORMATION

ICD-10 Codes that *may* apply:

C73	Malignant neoplasm of thyroid gland
D09.3	Carcinoma in situ of thyroid and other endocrine glands
D34	Benign neoplasm of thyroid gland
D44.0	Neoplasm of uncertain behavior of thyroid gland
E03.4	Atrophy of thyroid (acquired)
E07.89	Other specified disorders of thyroid
R94.6	Abnormal results of thyroid function studies

- Z15.09 Genetic susceptibility to other malignant neoplasm
- Z40.09 Encounter for prophylactic removal of other organ
- Z40.8 Encounter for other prophylactic surgery
- Z41.8 Encounter for other procedures for purposes other than remedying health state
- Z41.9 Encounter for procedure for purposes other than remedying health state, unspecified
- Z80.8 Family history of malignant neoplasm of other organs or systems
- Z80.9 Family history of malignant neoplasm, unspecified
- Z85.850 Personal history of malignant neoplasm of thyroid

CPT/HCPCS Codes:**No prior authorization required**

- 10021 Fine needle aspiration; without imaging guidance
- 10022 Fine needle aspiration; with imaging guidance
- 60100 Biopsy thyroid, percutaneous core needle

- 76536 Ultrasound, soft tissues of head and neck (eg, thyroid, parathyroid, parotid), real time with image documentation

- 78013 Thyroid imaging (including vascular flow, when performed);
- 78018 Thyroid carcinoma metastases imaging; whole body
- 78020 Thyroid carcinoma metastases uptake (List separately in addition to code for primary procedure)
- 78015 Thyroid carcinoma metastases imaging; limited area (eg, neck and chest only)
- 78016 Thyroid carcinoma metastases imaging; with additional studies (eg, urinary recovery)

Prior Authorization Required

- 60210 Partial thyroid lobectomy, unilateral; with or without isthmusectomy
- 60212 Partial thyroid lobectomy, unilateral; with contralateral subtotal lobectomy, including isthmusectomy
- 60220 Total thyroid lobectomy, unilateral; with or without isthmusectomy
- 60225 Total thyroid lobectomy, unilateral; with contralateral subtotal lobectomy, including isthmusectomy
- 60240 Thyroidectomy, total or complete
- 60252 Thyroidectomy, total or subtotal for malignancy; with limited neck dissection
- 60254 Thyroidectomy, total or subtotal for malignancy; with radical neck dissection
- 60260 Thyroidectomy, removal of all remaining thyroid tissue following previous removal of a portion of thyroid
- 60270 Thyroidectomy, including substernal thyroid; sternal split or transthoracic approach
- 60271 Thyroidectomy, including substernal thyroid; cervical approach

No Prior Authorization Required as of October 1, 2018

- 0026U Oncology (thyroid), DNA and mRNA of 112 genes, next-generation sequencing, fine needle aspirate of thyroid nodule, algorithmic analysis reported as a categorical result ("Positive, high probability of malignancy" or "Negative, low probability of malignancy") (*Not covered for Medicaid*)

81545 Oncology (thyroid), gene expression analysis of 142 genes, utilizing fine needle aspirate, algorithm reported as a categorical result (eg, benign or suspicious) **Afirma®** (Not covered for Medicaid)

Not Covered

81479 Unlisted molecular pathology procedure (*explanatory notes must accompany claims*) (When billed for **ThyGenX®**)

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 **ThyraMIR®**

VI. REFERENCES

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