



# **The Evaluation of Thyroid Nodules**

## **Physician Performance Measurement Set**

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Endocrine Society  
2055 L Street, NW, Suite 600  
Washington, DC 20036  
(P) 202- 971-3636 (F) 202-736-9706  
[endocrine.org](http://endocrine.org)

## Background

The Endocrine Society (ES) formed a Thyroid Nodules Work Group to identify and define the appropriate evaluation for patients with thyroid nodules. Designed for individual quality improvement efforts, the measures may also be used in data registries, continuing medical education programs, and in board certification programs. The measures include:

**Measure #1:** Documentation of thyroid description

**Measure #2:** TSH measurement

**Measure #3:** Thyroid sonogram

**Measure #4:** Thyroid sonogram characteristics

**Measure #5:** Fine needle aspiration biopsy

**Measure #6:** Additional evaluation for patients with indeterminate fine needle aspiration

The performance measures have been developed with the following clinical guidelines:

- AACE/AME/ETA medical guidelines for clinical practice and management of thyroid nodules. *Endocr Pract* 2010;16(Suppl 1).
- Cooper DS, Doherty GM, Haugen BR, et al The American Thyroid Association Guidelines Task Force. Revised management guidelines for patients with thyroid nodules and differentiated thyroid cancer. *Thyroid* 2009.19:1167-1214.

These measures were determined to be the most clinically relevant based on the medical evidence and they could be used to evaluate care being provided by the individual physician.

This measure set was prepared by a task force of experts in thyroid nodules and performance measures. The measures were provided to the Society's membership for comment, and were reviewed by the Endocrine Society's Performance Measures Subcommittee (PMSC), Clinical Affairs Core Committee (CACC), and ultimately approved by the Society's Council. At each stage of review, the task force received written comments and incorporated needed changes. Task Force members had final responsibility for and control for the development of the measure set.

The Endocrine Society used this measure set to develop *The Evaluation of Thyroid Nodules Practice Improvement Module (PIM)*. *The PIM* is a web based tool that assists participants with the evaluation of their practice standards, to isolate areas of improvement through self-assessment and reduce gaps in the quality of care. This activity is approved by the American Board of Internal Medicine's (ABIM) Approved Quality Improvement (AQI) Pathway for 20 points toward the Self-Evaluation of Practice Performance (Part 4) requirement of Maintenance of Certification (MOC).

## Work Group Members

David Cooper, MD (Chair)  
Erik Alexander, MD  
Howard Baum, MD  
Susan Mandel, MD  
James Rosenzweig, MD  
Janet Schlechte, MD

### Work Group Staff

Rob Bartel, Director of Education (ES)  
Stephanie Kutler, Director of Quality Improvement (ES)  
Rebecca Kresowik, Measure Development Consultant

### Topic Relevance

Thyroid nodular disease is common, yet often asymptomatic. Evaluation of thyroid nodules seeks to detect possible thyroid cancer, which occurs in approximately 10-15% of nodules. At present, the recommended evaluation of thyroid nodules is clear and involved a step-wise approach utilizing clinical examination, ultrasound, and other modalities. However, surveys and assessments suggests that there is high variability in practitioners care of these patients, with some practitioners doing more than is recommended, but others less than recommended. Thyroid nodules are detected in approximately 5-20% of an adult population upon random screening. It is estimated that perhaps 50% of these would be clinically relevant. Nonetheless, this represents approximately 10% of the adult population in the US, and likely a higher prevalence in areas with endemic iodine deficiency. The gap in care involves data confirming increasingly incidental detection of these nodules (such as by cross-sectional imaging performed for another indication) yet the lack of appropriate and complete clinical evaluation thereafter.

Thyroid cancer is a curable illness in most circumstances if detected and effectively managed. Missed (or delayed) diagnosis has been associated with increased mortality. Therefore, these measures will improve patient care by instructing practitioners on the optimal approach to thyroid nodules, and preventing delays in recommended diagnosis and therapy.

The goal of this effort is to improve care nationwide for patients who suffer from this illness, and to increase awareness of practitioners regarding 'best practices'. These performance measures were chosen as they represent key clinical steps in the optimal care and management of patients with thyroid nodular disease. These performance measures are items which practitioners often fail to perform, or appropriate followup is incomplete. By addressing the gap in quality, practitioners will improve their awareness and education of the optimal means of care.

### ES Disclosure Process

The Society's Evaluation of Thyroid Nodules Performance Measures were developed by the Thyroid Nodules Work Group, under guidance of the Society's Performance Measures Sub-Committee (PMSC) and the Clinical Affairs Core Committee (CACC). All persons in control of content, including all members of the various Society committees, subcommittees and faculty workgroups, as well as staff, disclose all relevant financial relationships of the individual or spouse/partner that have occurred within the last 12 months with any commercial interest(s) whose products or services are related to the content. Financial relationships are defined by remuneration in any amount from the commercial interest(s) in the form of grants; research support; consulting fees; salary; ownership interest (e.g., stocks, stock options, or ownership interest excluding diversified mutual funds); honoraria or other payments for participation in speakers' bureaus, advisory boards, or boards of directors; or other financial benefits. Any conflicts of interest are resolved prior to the individual's control of content, using the peer-review process as the primary mechanism to resolve conflicts.

*At the time of Measure Development - the following Thyroid Nodules Measures Task Force members reported no relevant financial relationships:*

**Erik Alexander, MD**

Director, Medical Student Education, Brigham and Women's Hospital

**Howard Baum, MD**

Assistant Professor, Medicine, Vanderbilt University School of Medicine

**David Cooper, MD**

Director, Thyroid Clinic, Professor of Medicine, John Hopkins University School of Medicine

**Susan J. Mandel, M.D., M.P.H.**

Professor of Medicine at the Hospital of the University of Pennsylvania

**James Rosenzweig, MD**

Director of Diabetes Services, Boston Medical Center

**Janet Schlechte, MD**

Professor of Medicine, University of Iowa Hospital & Clinics

Endocrine Society staff associated with the development of content reported no relevant financial relationships.

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## Measure Specifications

### Measure #1: Documentation of Thyroid Description

#### Measure Description

The percentage of patients with thyroid nodule(s) who had a documented physical examination description of the nodule that included all of the following: measurement\* (longest dimension), texture (hard, firm, soft), mobility, location (which lobe and location within lobe) AND presence or absence of palpable cervical lymph node

#### Measure Detail

<b>Numerator Statement</b>	Number of patients with a documented physical examination description of the nodule(s) that included all of the following: measurement* (longest dimension), texture (hard, firm, soft), mobility, location (which lobe and location within lobe) AND presence or absence of palpable cervical lymph nodes
<b>Denominator Statement</b>	All patients with a diagnosis of (palpable) thyroid nodule(s)
<b>Denominator Exceptions</b>	Documentation of medical reason(s) for not describing the nodule (e.g., non-palpable nodule)
<b>Supporting Guideline</b>	AACE/AME/ETA Medical Guidelines for Clinical Practice and Management of Thyroid Nodules. <sup>1</sup>  The American Thyroid Association Guidelines Task Force Revised Management Guidelines for Patients with Thyroid Nodules and Differentiated Thyroid Cancer. <sup>2</sup>

#### Measure Importance

##### Rationale for the Measure:

The physical examination description of a thyroid nodule is important because the physical examination may provide clues about the benign or malignant nature of the nodule. Nodules that on palpation are firm or hard, fixed to underlying structures, or associated with ipsilateral enlarged cervical lymph nodes are more likely to be malignant. Also, documenting the location and size of a thyroid nodule will make it possible to detect changes or stability in the nodule's size on follow-up physical examinations.

##### IOM Domains of Health Care Quality Addressed:

·Safe                      ·Effective                      ·Efficient

<b>Measure Source</b>	Developed from a nationally recognized clinical guideline
<b>Guideline citation</b>	<p><sup>1</sup>AACE/AME/ETA medical guidelines for clinical practice and management of thyroid nodules. Endocr Pract 2010;16(Suppl 1).</p> <p><sup>2</sup>Cooper DS, Doherty GM, Haugen BR, et al The American Thyroid Association Guidelines Task Force. Revised management guidelines for patients with thyroid nodules and differentiated thyroid cancer. Thyroid 2009.19:1167-1214.</p>
<b>Specific guideline recommendation related to the measure</b>	<p>A careful physical examination of the thyroid gland and cervical lymph nodes is mandatory.<sup>1</sup></p> <p>Record location, consistency, and size of the nodule; neck tenderness or pain; cervical adenopathy.<sup>1</sup></p> <p>With the discovery of a thyroid nodule, a complete history and physical examination focusing on the thyroid gland and adjacent cervical lymph nodes should be performed. Pertinent physical findings suggesting possible malignancy include vocal cord paralysis, lateral cervical lymphadenopathy, and fixation of the nodule to surrounding tissues.<sup>2</sup></p>
<b>Grade of level of evidence for this recommendation</b>	<p>Grade A; BEL * 3<sup>1</sup></p> <p>Grade C; BEL * 3<sup>1</sup></p> <p>Not ranked<sup>2</sup></p>
<b>Comments</b>	* The measurement may be completed by using a ruler, tape measure or ultrasound.
<b>Type of Measure</b>	Process Measure

## Measure #2: TSH Measurement

### Measure Description

The percentage of patients with a diagnosis of thyroid nodule(s) who had a TSH measurement performed

### Measure Detail

<b>Numerator Statement</b>	Number of patients who had a TSH measurement performed
<b>Denominator Statement</b>	All patients with a diagnosis of thyroid nodule(s)
<b>Denominator Exceptions</b>	N/A
<b>Supporting Guideline</b>	AACE/AME/ETA Medical Guidelines for Clinical Practice and Management of Thyroid Nodules. <sup>1</sup>  The American Thyroid Association Guidelines Task Force Revised Management Guidelines for Patients with Thyroid Nodules and Differentiated Thyroid Cancer. <sup>2</sup>

### Measure Importance

#### Rationale for the Measure:

The level of serum TSH is the key branch point for decision making in the evaluation of thyroid nodules. If the serum TSH is subnormal or undetectable, this suggests the possibility that the nodule is functioning (an "autonomous" or "hot" nodule). In this case, the next diagnostic step would be the performance of a radionuclide thyroid scan. If the scan shows the nodule to be functioning, then biopsy would be deferred, since functioning nodules are rarely malignant. On the other hand, if the serum TSH is normal or elevated, a radionuclide thyroid scan would not be indicated. Rather, a decision to biopsy the nodule would be made on the basis of other clinical and radiologic studies, including thyroid sonography. Further, an elevated serum TSH suggests the possibility of autoimmune thyroiditis, which itself can be the cause of palpable or sonographic thyroid abnormalities.

#### IOM Domains of Health Care Quality Addressed:

·Safe            ·Effective            ·Efficient

<b>Measure Source</b>	Developed from a nationally recognized clinical guideline
<b>Guideline citation</b>	<sup>1</sup> AACE/AME/ETA medical guidelines for clinical practice and management of thyroid nodules. Endocr Pract 2010;16(Suppl 1).  <sup>2</sup> Cooper DS, Doherty GM, Haugen BR, et al The American Thyroid Association Guidelines Task Force. Revised management guidelines for patients with



	thyroid nodules and differentiated thyroid cancer. Thyroid 2009.19:1167-1214.
<b>Specific guideline recommendation related to the measure</b>	Measure serum TSH in the initial evaluation of a patient with a thyroid nodule. If the serum TSH is subnormal, a radionuclide thyroid scan should be performed using either technetium pertechnetate or radioactive iodine. <sup>2</sup>  Always measure serum TSH. <sup>1</sup>
<b>Grade of level of evidence for this recommendation</b>	Recommendation rating: A <sup>2</sup> Grade B; BEL* <sup>3</sup> <sup>1</sup>
<b>Comments</b>	None
<b>Type of Measure</b>	Process Measure

### Measure #3: Thyroid Sonogram

#### Measure Description

The percentage of patients with a diagnosis of thyroid nodule(s) who had a thyroid sonogram performed

#### Measure Detail

<b>Numerator Statement</b>	Number of patients who had a thyroid sonogram performed
<b>Denominator Statement</b>	All patients with a diagnosis of thyroid nodule(s)
<b>Denominator Exceptions</b>	Documentation of patient reason for not performing a thyroid sonogram (e.g., patient declined)  Documentation of system reason for not performing a thyroid sonogram (e.g., lack of insurance)
<b>Supporting Guideline</b>	AACE/AME/ETA Medical Guidelines for Clinical Practice and Management of Thyroid Nodules. <sup>1</sup>  The American Thyroid Association Guidelines Task Force Revised Management Guidelines for Patients with Thyroid Nodules and Differentiated Thyroid Cancer. <sup>2</sup>

#### Measure Importance

##### Rationale for the Measure:

Thyroid sonography provides the most accurate identification of thyroid nodules compared with physical examination and other imaging modalities. Up to 17% of nodules identified by physical examination are not confirmed to be discrete nodules on sonographic imaging and therefore fine-needle aspiration (FNA) can be avoided. Furthermore, sonography detects additional nonpalpable nodules that often require FNA in up to 15% of patients with an index palpable thyroid nodule.<sup>3</sup>

Thyroid sonographic imaging provides information about the feasibility of FNA performance by either palpation or with ultrasound (US) guidance. Sonographically imaged palpable nodules identified to be either predominantly cystic or located posteriorly in the thyroid gland require US FNA whereas more anteriorly located predominantly solid palpable nodules are amenable to palpation FNA.

In addition to delineation of thyroid nodules, thyroid sonography identifies imaging features associated with different degrees of risk for malignancy, which are used in FNA decision making for patients with either solitary or multiple nodules.

Both the American Thyroid Association and the American Association of Clinical Endocrinologists recommend performance of thyroid sonography for all patients with detected thyroid nodules.<sup>1,2</sup>

**IOM Domains of Health Care Quality Addressed:**

·Safe           ·Effective           ·Efficient

<b>Measure Source</b>	Developed from a nationally recognized clinical guideline
<b>Guideline citation</b>	<sup>1</sup> AACE/AME/ETA medical guidelines for clinical practice and management of thyroid nodules. Endocr Pract 2010;16(Suppl 1).  <sup>2</sup> Cooper DS, Doherty GM, Haugen BR, et al The American Thyroid Association Guidelines Task Force. Revised management guidelines for patients with thyroid nodules and differentiated thyroid cancer. Thyroid 2009.19:1167-1214.
<b>Specific guideline recommendation related to the measure</b>	Thyroid sonography should be performed in all patients with known or suspected thyroid nodules. <sup>2</sup>  US evaluation is recommended for: patients at risk for thyroid malignancy; patients with palpable thyroid nodules or multinodular goiters; patients with lymphadenopathy suggestive of malignant lesion. <sup>1</sup>
<b>Grade of level of evidence for this recommendation</b>	Recommendation rating: A <sup>2</sup> Grade B; BEL * 3 <sup>1</sup>
<b>Comments</b>	None
<b>Type of Measure</b>	Process Measure

## Measure #4: Thyroid Sonogram Characteristics

### Measure Description

The percentage of patients with the diagnosis of thyroid nodule(s) who had a sonogram performed and the sonogram report documented the following characteristics of the nodule(s): location, size (3 dimensions), composition (solid, cystic, mixed solid/cystic), echogenicity, presence of microcalcifications, margins and vascular features.

### Measure Detail

<b>Numerator Statement</b>	Number of patients for whom the sonogram report or the endocrinologist interpretation of the sonogram documented all of the following characteristics of the nodule(s): location, size (3 dimensions must be reported – transverse, anterior-posterior and longitudinal), composition (solid, cystic, mixed solid/cystic), echogenicity, presence of microcalcifications (if present), margins and vascular features
<b>Denominator Statement</b>	All patients with a diagnosis of thyroid nodule(s) who had a thyroid sonogram performed
<b>Denominator Exceptions</b>	Documentation of medical reason for not documenting all of the characteristics of the nodule (e.g., thyroid ultrasound performed by someone other than the endocrinologist and images not available, nodule and/or patient characteristics prevent recording all characteristics i.e. peripheral calcifications, body habitus)
<b>Supporting Guideline</b>	AACE/AME/ETA Medical Guidelines for Clinical Practice and Management of Thyroid Nodules. <sup>1</sup>

### Measure Importance

#### Rationale for the Measure:

Thyroid nodule sonography identifies imaging characteristics that are associated with either increased or decreased risks of malignancy. Thyroid cancers are more likely to be hypoechoic, predominantly solid nodules that have calcifications (especially microcalcifications), increased vascularity, and infiltrative margins. Nodules that appear as either spongiform or pure cysts are highly likely to be benign. Thyroid nodule sonography reports nodule size and location with the thyroid gland, which is required during follow-up for nodule reidentification and direct comparison with prior imaging. FNA decision making requires knowledge of both sonographic features and nodule size.

Both the American Thyroid Association and the American Association of Clinical Endocrinologists recommend documentation of nodule size, location and sonographic features in the ultrasound report.<sup>1,2</sup>

#### IOM Domains of Health Care Quality Addressed:

- Safe
- Effective
- Efficient

<b>Measure Source</b>	Developed from a nationally recognized clinical guideline
<b>Guideline citation</b>	<sup>1</sup> AACE/AME/ETA medical guidelines for clinical practice and management of thyroid nodules. Endocr Pract 2010;16(Suppl 1).
<b>Specific guideline recommendation related to the measure</b>	Describe position, shape, size, margins, content, echogenic pattern, and vascular features of the nodule(s). <sup>1</sup>
<b>Grade of level of evidence for this recommendation</b>	Grade C; BEL* 3 <sup>1</sup>
<b>Comments</b>	None
<b>Type of Measure</b>	Process Measure

## Measure #5: Fine Needle Aspiration Biopsy

### Measure Description

The percentage of patients with a diagnosis of thyroid nodule(s) who had a fine needle aspiration biopsy performed

### Measure Detail

<b>Numerator Statement</b>	Number of patients who had a biopsy performed following a thyroid sonogram
<b>Denominator Statement</b>	All patients with a diagnosis of thyroid nodule(s)
<b>Denominator Exceptions</b>	Documentation of medical reason for not performing biopsy following a thyroid sonogram (e.g., sonogram does not support the need for a FNA biopsy, the nodule does not meet guideline specifications as listed below, more conservative approach is appropriate based on risk/benefit assessment)  Documentation of patient reason for not performing a biopsy following a thyroid sonogram (e. g., patient refused)
<b>Supporting Guideline</b>	AACE/AME/ETA Medical Guidelines for Clinical Practice and Management of Thyroid Nodules. <sup>1</sup>  The American Thyroid Association Guidelines Task Force Revised Management Guidelines for Patients with Thyroid Nodules and Differentiated Thyroid Cancer. <sup>2</sup>

### Measure Importance

#### Rationale for the Measure:

The primary purpose of thyroid nodule evaluation is to determine if cancer is present. Although several clinical and radiologic findings modify the risk any nodule may prove cancerous, fine needle aspiration remains the recommended diagnostic intervention for euthyroid patients. This is because aspiration cytology demonstrating a “benign” result carries a very high negative predictive value (>95%). Similarly, FNA cytology “positive for malignancy” carries a very high positive predictive value (>95%). These findings modify care recommendations. Such high levels of sensitivity and specificity cannot be obtained with clinical or radiologic assessment alone.<sup>1,2,4,5</sup>

Importantly, not all thyroid nodules require FNA. The American Thyroid Association and the American Association of Clinical Endocrinologists recommendations to perform FNA are based on evidence or expert opinion that such interventions would provide meaningful and additive information, thereby reducing risk or eventual harm if discovered. Thyroid nodule size, as well as sonographic appearance, are often used to recommend FNA. Importantly, purely cystic nodules are uniformly benign, and FNA is not recommended. Spongiform nodules are also highly likely to be benign. Therefore, spongiform nodule aspiration is recommended only when the nodule is ≥2.0cm. For patients at average (or low) risk, thyroid nodules should be aspirated if size is beyond 1-2cm in diameter, largely depending upon sonographic characteristics and cystic content. These

cutoffs are supported by data that sonographic features such as cystic fluid strongly correspond to benign nodules, while the presence of microcalcifications, hypoechoic parenchyma, and abnormal cervical lymph nodes corresponds to malignancy. Furthermore, evidence confirms that most thyroid cancer smaller than 1-1.5cm poses minimal future risk if treated effectively. Therefore, the identification of thyroid malignancy smaller than 1cm is of limited additive value and may even create additive harm. Importantly, nodules 5-10mm in diameter should be aspirated only in high-risk individuals.<sup>1,2</sup>

Both the American Thyroid Association and the American Association of Endocrinologists recommend a tiered approach to thyroid nodule aspiration, relying heavily upon sonographic features and nodule size as depicted above. Unless initially non-diagnostic, thyroid nodule FNA is usually performed once for each nodule. A survival benefit has primarily been demonstrated when diagnosis and treatment of patients with stage 3 and 4 thyroid cancer occurs. However, presumptive extrapolation assumes similar (albeit lesser) benefit into those with lower stage disease.<sup>1,2</sup>

**IOM Domains of Health Care Quality Addressed:**

- Safe
- Effective
- Efficient

<b>Measure Source</b>	Developed from a nationally recognized clinical guideline																										
<b>Guideline citation</b>	<sup>1</sup> AACE/AME/ETA medical guidelines for clinical practice and management of thyroid nodules. Endocr Pract 2010;16(Suppl 1). <sup>2</sup> Cooper DS, Doherty GM, Haugen BR, et al The American Thyroid Association Guidelines Task Force. Revised management guidelines for patients with thyroid nodules and differentiated thyroid cancer. Thyroid 2009.19:1167-1214.																										
<b>Specific guideline recommendation related to the measure</b>	<p>FNA biopsy is recommended for nodule(s): of diameter larger than 1.0 cm that is solid and hypoechoic on US; of any size with US findings suggestive of extracapsular growth or metastatic cervical lymph nodes; of any size with a patient history of neck irradiation in childhood or adolescence, PTC, MTC, or MEN 2 in first-degree relatives, previous thyroid surgery for cancer, increased calcitonin levels in the absence of interfering factors; of diameter smaller than 10 mm along with US finding associated with malignancy, the coexistence of 2 or more suspicious US criteria greatly increased the risk of thyroid cancer.<sup>1</sup></p> <p>FNA is the procedure of choice in the evaluation of thyroid nodules. <sup>2</sup></p> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="background-color: #cccccc;">High-risk history</td> <td></td> <td></td> <td></td> </tr> <tr> <td style="background-color: #cccccc;">Nodule WITH suspicious sonographic features**</td> <td style="text-align: center;">&gt;5mm</td> <td></td> <td style="text-align: center;">Recommendation A</td> </tr> <tr> <td style="background-color: #cccccc;">Nodule WITHOUT suspicious sonographic features**</td> <td style="text-align: center;">&gt;5mm</td> <td></td> <td style="text-align: center;">Recommendation I</td> </tr> <tr> <td style="background-color: #cccccc;">Abnormal cervical lymph nodes</td> <td style="text-align: center;">All***</td> <td></td> <td style="text-align: center;">Recommendation A</td> </tr> <tr> <td style="background-color: #cccccc;">Microcalcifications present in nodule</td> <td style="text-align: center;">≥1 0mm</td> <td></td> <td style="text-align: center;">Recommendation B</td> </tr> <tr> <td style="background-color: #cccccc;">Solid nodule</td> <td></td> <td></td> <td></td> </tr> </table>			High-risk history				Nodule WITH suspicious sonographic features**	>5mm		Recommendation A	Nodule WITHOUT suspicious sonographic features**	>5mm		Recommendation I	Abnormal cervical lymph nodes	All***		Recommendation A	Microcalcifications present in nodule	≥1 0mm		Recommendation B	Solid nodule			
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Nodule WITH suspicious sonographic features**	>5mm		Recommendation A																								
Nodule WITHOUT suspicious sonographic features**	>5mm		Recommendation I																								
Abnormal cervical lymph nodes	All***		Recommendation A																								
Microcalcifications present in nodule	≥1 0mm		Recommendation B																								
Solid nodule																											

	AND hypoechoic	>1 cm	Recommendation B
	AND iso- or hyperechoic	≥1–1.5 cm	Recommendation C
	Mixed cystic–solid nodule		
	WITH any suspicious ultrasound features**	≥1.5–2.0cm	Recommendation B
	WITHOUT suspicious ultrasound features	≥2.0 cm	Recommendation C
	Spongiform nodule	≥2.0 cm#	Recommendation C
	Purely cystic nodule	FNA not indicated##	Recommendation E
<p>*High-risk history: History of thyroid cancer in one or more first degree relatives; history of external beam radiation as a child; exposure to ionizing radiation in childhood or adolescence; prior hemithyroidectomy with discovery of thyroid cancer, 18FDG avidity on PET scanning; MEN2=FMTC-associated RET protooncogene mutation, calcitonin &gt;100pg=mL.MEN, multiple endocrine neoplasia; FMTC, familial medullary thyroid cancer.</p> <p>**Suspicious features: microcalcifications; hypoechoic; increased nodular vascularity; infiltrative margins; taller than wide on transverse view.</p> <p>***FNA cytology may be obtained from the abnormal lymph node in lieu of the thyroid nodule.</p> <p>#Sonographic monitoring without biopsy may be an acceptable alternative (see text) (48).</p> <p>##Unless indicated as therapeutic modality (see text).<sup>2</sup></p>			
<b>Grade of level of evidence for this recommendation</b>	Grade B; BEL * 3 <sup>1</sup> Recommendation ratings: See above. <sup>2</sup>		
<b>Comments</b>	None		
<b>Type of Measure</b>	Process Measure		



## Measure #6: Additional Evaluation for Patients with Indeterminate FNA

### Measure Description

The percentage of patients with a diagnosis of thyroid nodule(s) who were referred for either surgery, radionuclide scan, molecular marker analysis, OR repeat FNA, within 3 - 6 months following a fine needle aspiration biopsy classified as indeterminate (defined as: follicular lesion of undetermined significance/atypia of undetermined significance, suggestive of follicular or Hurthle cell neoplasm, or suspicious for papillary thyroid cancer).

### Measure Detail

<b>Numerator Statement</b>	Number of patients who were referred for one of the following therapies: surgery, radionuclide scan, molecular marker analysis, OR repeat fine needle aspiration biopsy, within 3 – 6 months of the fine needle aspiration biopsy
<b>Denominator Statement</b>	All patients with a diagnosis of thyroid nodule(s) who had a fine needle aspiration biopsy classified as indeterminate (defined as: follicular lesion of undetermined significance/atypia of undetermined significance, suggestive of follicular or Hurthle cell neoplasm, or suspicious for papillary thyroid cancer)
<b>Denominator Exceptions</b>	Documentation of patient reason for not referring patient for surgery, radionuclide scan, molecular marker analysis or a repeat fine needle aspiration biopsy within 3 - 6 months (e.g., patient refused)
<b>Supporting Guideline</b>	AACE/AME/ETA Medical Guidelines for Clinical Practice and Management of Thyroid Nodules. <sup>1</sup>  The American Thyroid Association Guidelines Task Force Revised Management Guidelines for Patients with Thyroid Nodules and Differentiated Thyroid Cancer. <sup>2</sup>

### Measure Importance

#### Rationale for the Measure:

Indeterminate fine needle aspirates are adequately cellular, though demonstrate abnormal microscopic features. Though abnormal, such features are unfortunately not diagnostic of benign or malignant disease. Generally, indeterminate cytology conveys a 20-60% risk of cancer, depending on the indeterminate cytology terminology used (atypical of undetermined significance, follicular neoplasm, suspicious for papillary carcinoma). Because the diagnosis is not certain, and because the risk of malignancy is increased, further assessment of cytologically indeterminate nodules is required.<sup>1,2,4,5</sup>

Traditionally, surgical resection is recommended for cytologically indeterminate thyroid nodules. This allows for accurate diagnosis to be confirmed following histopathologic analysis. Furthermore, if a nodule is cancerous, surgical removal is the initial recommended treatment. The Endocrine Society and American Thyroid Association both recommend that such an approach be balanced against other individual comorbidities and surgical risk.<sup>1,2</sup> For patients in whom TSH is suppressed below the reference range, a radionuclide thyroid scan is recommended. This is because

hyperthyroidism may signal the presence of a “hot” nodule. If confirmed via radionuclide scanning, “hot” nodules are uniformly benign.<sup>1,2</sup>

For cytologically indeterminate nodules at low-risk, experts recommend consideration of repeat biopsy. Most often such nodules demonstrate indeterminate cytology that is “atypical of an undetermined significance (AUS)”. Data confirm that approximately 50% of AUS lesions will prove benign on repeat FNA. Separately, molecular analysis of indeterminate nodules has demonstrated the power to clarify cancer risk. Three manuscripts demonstrate that a subsequent aspiration performed for molecular marker analysis can significantly modify clinical care recommendations. This is because the mutational analysis may signal a very high malignancy risk (e.g., BRAF, RAS, RET/PTC mutations) or a mRNA expression analysis may indicate a very low malignancy risk.<sup>1,2</sup>

Both the American Thyroid Association and the American Association of Clinical Endocrinologists recommend additional treatment or diagnostic testing when aspiration reveals indeterminate cytology.<sup>1,2</sup>

**IOM Domains of Health Care Quality Addressed:**

- Safe
- Effective
- Efficient

<b>Measure Source</b>	Developed from a nationally recognized clinical guideline
<b>Guideline citation</b>	<sup>1</sup> AACE/AME/ETA medical guidelines for clinical practice and management of thyroid nodules. Endocr Pract 2010;16(Suppl 1).  <sup>2</sup> Cooper DS, Doherty GM, Haugen BR, et al The American Thyroid Association Guidelines Task Force. Revised management guidelines for patients with thyroid nodules and differentiated thyroid cancer. Thyroid 2009.19:1167-1214.
<b>Specific guideline recommendation related to the measure</b>	The use of molecular markers (e.g., BRAF, RAS, RET/PTC, Pax8-PPARγ, or galectin-3, gene expression classifier) may be considered for patients with indeterminate cytology on FNA to help guide management. <sup>2</sup>  If the cytology reading reports a follicular neoplasm, an I thyroid scan may be considered, if not already done, especially if the serum TSH is in the low-normal range. If a concordant autonomously functioning nodule is not seen, lobectomy or total thyroidectomy should be considered. <sup>2</sup>  Surgical excision is recommended for most follicular thyroid lesions. <sup>1</sup>  Management of FNA biopsy – suspicious nodules – surgery is recommended. <sup>1</sup>
<b>Grade of level of evidence for this recommendation</b>	Recommendation rating: C <sup>2</sup> Recommendation rating: C <sup>2</sup> Grade B; BEL * 3 <sup>1</sup> Grade B; BEL * 3 <sup>1</sup>
<b>Comments</b>	None
<b>Type of Measure</b>	Process Measure

## Guideline Rating Systems

### American Thyroid Association

Rating	Recommendation	Definition
A	Strongly recommends	The recommendation is based on good evidence that the service or intervention can improve important health outcomes. Evidence includes consistent results from well-designed, well-conducted studies in representative populations that directly assess effects on health outcomes.
B	Recommends	The recommendation is based on fair evidence that the service or intervention can improve important health outcomes. The evidence is sufficient to determine effects on health outcomes, but the strength of the evidence is limited by the number, quality, or consistency of the individual studies; generalizability to routine practice; or indirect nature of the evidence on health outcomes.
C	Recommends	The recommendation is based on expert opinion.
D	Recommends against	The recommendation is based on expert opinion.
E	Recommends against	The recommendation is based on fair evidence that the service or intervention does not improve important health outcomes or that harms outweigh benefits.
F	Strongly recommends against	The recommendation is based on good evidence that the service or intervention does not improve important health outcomes or that harms outweigh benefits.
I	Recommends neither for nor against	The panel concludes that the evidence is insufficient to recommend for or against providing the service or intervention because evidence is lacking that the service or intervention improves important health outcomes, the evidence is of poor quality, or the evidence is conflicting. As a result, the balance of benefits and harms cannot be determined.

### American Association of Clinical Endocrinologists

Recommendation Grade	Description
A	Homogenous evidence from multiple well-designed randomized controlled trials with sufficient statistical power Homogeneous evidence from multiple well-designed cohort controlled trials with sufficient statistical power ≥1 conclusive level 1 publications demonstrating benefit >> risk
B	Evidence from at least 1 large well-designed clinical trial, cohort or case-controlled analytic study, or meta-analysis No conclusive level 1 publication; ≥1 conclusive level 2 publications demonstrating benefit >> risk

C	Evidence based on clinical experience, descriptive studies, or expert consensus opinion No conclusive level 1 or 2 publications; ≥1 conclusive level 3 publications demonstrating benefit >> risk  No conclusive risk at all and no conclusive benefit demonstrated by evidence
D	Not rated No conclusive level 1, 2, or 3 publication demonstrating benefit >> risk Conclusive level 1, 2, or 3 publication demonstrating risk >> benefit

**\*BEL – Best evidence level**

Evidence Level	Reference Methods
1	Meta-analysis of randomized controlled trials Randomized controlled trial
2	Meta-analysis of nonrandomized prospective or case-controlled trials Nonrandomized controlled trial Prospective cohort study Retrospective case-control study
3	Cross-sectional study Surveillance study (registries, surveys, epidemiologic study) Consecutive case series Single case reports
4	No evidence (theory, opinion, consensus, or review)

## References

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<sup>1</sup>AACE/AME/ETA medical guidelines for clinical practice and management of thyroid nodules. *Endocr Pract* 2010;16(Suppl 1).

<sup>2</sup>Cooper DS, Doherty GM, Haugen BR, et al The American Thyroid Association Guidelines Task Force. Revised management guidelines for patients with thyroid nodules and differentiated thyroid cancer. *Thyroid* 2009.19:1167-1214.

<sup>3</sup>Marqusee E, Benson CB, Frates MC, Doubilet PM, Cibas ES, Larsen PR, Mandel, SJ.: Utility of ultrasound in the management of nodular thyroid disease. *Annals of Internal Medicine* 133: 696-700, 2000.

<sup>4</sup>Yassa L, Cibas ES, Benson CB, Frates MC, Doubilet PM, et al. Long-term Assessment of a Multidisciplinary Approach to Thyroid Nodule Diagnostic Evaluation. *Cancer (Cancer Cytopathol)*; 111:508-16, 2007.

<sup>5</sup>Wang C, Friedman L, Kennedy GC, Wang H, Kebebew E, et al. A Large Multicenter Correlation Study of Thyroid Nodule Cytopathology and Histopathology. *Thyroid*; 21(3):243-251, 2011.