

SCOPE STATEMENT FOR HERC COVERAGE GUIDANCE

GENETIC TESTING OF THYROID NODULES

Population description	Adults with cytologically indeterminate thyroid nodules after fine needle aspiration (FNA) <i>Population scoping notes: None</i>
Intervention(s)	Multigene expression assay performed on FNA specimens <i>Intervention exclusions: None</i>
Comparator(s)	Usual care
Outcome(s) (up to five)	Critical: Mortality, thyroid cancer-related morbidity, quality of life Important: Change in management, harms resulting from testing (including overtreatment and undertreatment) <i>Considered but not selected for GRADE Table: None</i>
Key questions	<ol style="list-style-type: none">1. Are multigene expression assays performed on thyroid nodule FNA specimens analytically valid?2. Are multigene expression assays performed on thyroid nodule FNA specimens clinically valid?<ol style="list-style-type: none">a. Do these tests predict the likelihood of thyroid cancer?b. Do these tests offer prognostic information when thyroid cancer is present?c. Do these tests predict responsiveness to certain treatments?3. Are multigene expression assays performed on thyroid nodule FNA specimens clinically useful?<ol style="list-style-type: none">a. Do these tests change the management plans selected by physicians and patients?b. Do these tests result in changes in patient-important clinical outcomes?