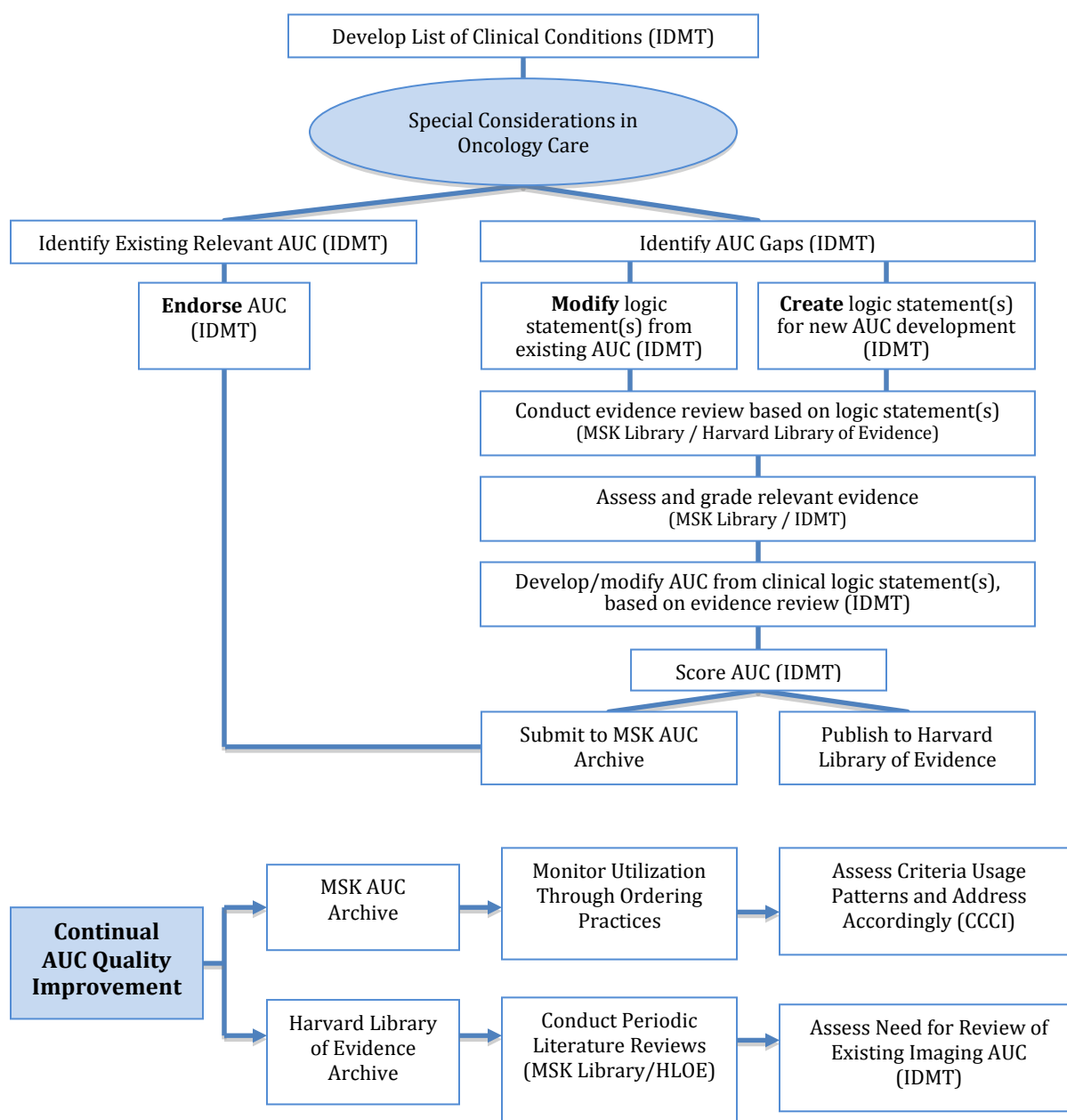


## Evidentiary Review Process: Appropriate Use Criteria Development Methodology

The Evidence-based Cancer Imaging Program (ECIP) at Memorial Sloan Kettering Cancer Center (MSK) has implemented a structured evidentiary review methodology to create, modify, or endorse appropriate use criteria (AUC) for the ordering of advanced diagnostic imaging exams (i.e., CT, MRI, PET, NM). The Clinical Council for Cancer Imaging (CCCI) provides oversight of this process to ensure consistency across Imaging Disease Management Teams (IDMTs). A schematic of this workflow is provided below.

### MSK Evidence-based Cancer Imaging Program Methodology



IDMTs are charged with developing, modifying, or endorsing AUC in subspecialized clinical domains based on clinical practice needs, evidentiary gaps, and Priority Clinical Areas (PCAs). Each IDMT includes at least 7 members, including at least one practicing physician with expertise in the relevant imaging studies who serves as the IDMT leader, at least one practicing physician with expertise in the clinical topic relating to the AUC under consideration, at least one practicing primary care physician or practitioner, at least one expert in clinical trial design and at least one expert in statistical analysis. Some team members may have expertise in more than one of these domains. Each IDMT has autonomous governance, decision-making authority and accountability for the AUC developed, modified or endorsed by that team, independent of the CCCI and MSK.

The process of modifying or creating new AUC utilizes library research informationists assigned by the MSK Director of Library Services to the AUC development process. Two research informationists are assigned to each AUC logic statement identified for investigation by an IDMT. Informationists implement search strategies to identify relevant published papers, guidelines, professional medical specialty society consensus statements, or other published sources of evidence. The MSK Library is working in partnership with the Harvard Library of Evidence (HLoE) to ensure a consistent approach to defining search parameters, leveraging the HLoE-developed information technology platform. The library team uses the Oxford Centre for Evidence-Based Medicine (“OCEBM”) to grade the most relevant and significant documents from systematic literature reviews. Grading is performed separately by two research informationists who then compare their results. After resolving any grading discrepancies, the MSK Director of Library Services forwards the papers and the assigned grading to IDMT leaders. The IDMT reviews the documents to confirm the assigned grades using the OCEBM framework and HLoE technical platform. IDMT members meet to resolve any grading discrepancies, after which an AUC is formatted, incorporating relevant citations and appropriateness score. MSK has defined a scoring system for AUC Appropriateness with three levels: Usually Appropriate; Sometimes Appropriate; or Rarely Appropriate. Fully developed AUC are posted on the MSK Evidence-based Cancer Imaging Program website as well as the HLoE database for publication.

Inherent in the use of the formal and widely recognized OCEBM system is the distinction between criteria that are evidence-based and those that are consensus-based. The OCEBM level 5 grading denotes criteria that are supported based on “expert opinion without critical appraisal.” Through our evidentiary review process, we strive to identify the most relevant literature to support our AUC. However, we also recognize that our internal cancer care expertise and guidelines may serve as the basis for AUC when no relevant literature or studies are available. In those circumstances, logic statements that underlie each AUC will be graded an OCEBM level 5 and AUC scoring will appropriately reflect the degree of available evidentiary support.

Each IDMT will review AUC it has created or modified no less frequently than once per year. Reviews may be performed more frequently when new evidence that seems likely to affect an AUC is published. The systematic literature review process will be repeated and any new publications or consensus statements identified will be reviewed and assessed according to the methodology outlined above, promoting *continual AUC quality improvement*. In reviewing AUC, IDMTs will take into consideration all the available evidence, including newly identified and previously reviewed evidence, and update or modify the AUC if appropriate.

Our experience with this effort to date confirms that imaging AUC development requires an iterative workflow that leverages the vast experience and knowledge of the members of our IDMTs and others throughout our institution. The clinical perspectives provided by IDMT members further confirm published evidence that high quality, well composed, actionable AUC must be specific enough to isolate unique clinical conditions but still parsimonious in approach, adding modifiers to the logic statements only if they will lead to different imaging recommendations.

MSK will endorse AUC developed by other qualified provider-led entities where we determine the quality of evidence provided is consistent with MSK standards of care, clinically relevant and valid for the cancer patient population.

Our methodology may be revised from time to time by the CCCI, within the limits imposed by the statute and implementing regulations, as well as any additional CMS guidance that may become available. When and if revised, the amended process will be published on the MSK Evidence-based Cancer Imaging Program website.