Editorial

SCAI Position Statement Concerning Coverage Policies for Percutaneous Coronary Interventions Based on the Appropriate Use Criteria

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The Appropriate Use Criteria for Coronary Revascularization (AUC) were created in 2009 [1,2] and updated in 2012 [3] through a rigorous process and then endorsed by major cardiovascular societies. The AUC were developed from a limited set of carefully defined clinical scenarios; they were not envisioned as covering every clinical situation, but rather, descriptive of common ones. The AUC have become widely accepted as one component of decision making, along with published clinical guidelines, physician experience, and patient preference. Regrettably, they have also come to be seen as an instrument for directing insurance coverage policy. While the original AUC document [1,2] noted "it is hoped that payors would use these criteria as the basis for the development of rational payment management strategies to ensure that their members receive necessary, beneficial, and cost-effective cardiovascular care," denial of coverage in individual cases based on the AUC category was not an intended purpose. In addition, the 2012 update [3] explicitly states that some inappropriate indications should be reimbursed and that the uncertain rating does not justify denial of payment.

Policymakers and payors must be good stewards of the insurance system, and are increasingly challenged to find innovative ways to curb expenditures. Thus, it is tempting for them to view the AUC as a professionally mandated tool for "cost-cutting" [4]. SCAI and its members recognize the essential need for prudent cost management but are very concerned with this unanticipated and detrimental approach to coverage determinations. This SCAI position statement addresses our members' apprehension that the application of AUC by many payors without consideration of other features of the patient's medical condition is far beyond the intent of the AUC, and has the potential for significant unintended consequences for patients and hospitals. Accordingly, this position statement outlines SCAI's recommendations regarding the use of AUC in making coverage determinations for percutaneous coronary intervention (PCI) procedures.

SCAI and its members have several concerns. First, although the AUC may be useful in helping to guide insurance coverage, the AUC classification should not be the solitary reason used to deny coverage. Such unjustifiable application of AUC might be harmful to patients, and could be contrary to shared decision-

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making. For example, it is conceivable that a payor may decide that only those procedures classified by AUC criteria as "appropriate" will be covered; yet unquestionably, that is not the intent of the AUC. Second, individual third party payors should not develop their own "appropriateness criteria" for insurance coverage that are not based on guidelines and that are not subject to peer review. Finally, coverage determinations should take into account reasonable decisions by health care providers who are following accepted clinical guidelines. Outside expert review should be available prior to any determination of denial of coverage. These concerns are not unique to interventional cardiology [5].

When decisions for coverage of medical care are based strictly on categories or algorithms, opportunities for physician–patient interaction that lead to shared decision-making and patient-centered care are limited. In particular, the weight of patient preference would be at the discretion of payors. Exclusions based on inflexible adherence to AUC that were never intended to be rigid categorizations may harm patients. We are concerned that lower income and less well-insured patients may ultimately receive disproportionately reduced access to necessary cardiovascular care, because they are less likely to have advocates willing to appeal coverage determinations.

It is sensible for payors to consider AUC as one of several elements in pre-authorization of treatment options, and to encourage the use of AUC at the point of care [6]. For stable patients for whom a procedure is rated as "rarely appropriate", it is reasonable to expect physicians to document the medical justification for that patient and their particular situation. It is rational to require physicians to document the process of shared decision-making and patient preference for situations where PCI "may be appropriate". However, denial of coverage based solely on a categorization of "rarely appropriate" or "may be appropriate" without a process that involves review by experts and consideration of patient preference and detailed condition may not be in the patients' best interest and therefore is not acceptable. Physicians must be able to use their experience and best judgment to interpret clinical guidelines and to apply them to individual patients, particularly when there is no definite right or wrong.

SCAI believes that AUC developed by professional societies should be implemented, interpreted, and utilized as they were intended. We therefore propose that coverage policies for PCI adhere to the following principles:

1. Coverage decisions for PCI procedures should be made based on scientific evidence and expert consensus using criteria constructed by professional medical societies. Additional individual considerations not taken into account by AUC should also be considered (Table I), as is standard in clinical practice. Mechanisms to assure that these factors are fully addressed in each case must be developed and closely followed before coverage is denied.
2. Coverage decisions should not be made based only on relative cost differences. When two or more strategies offer particular benefits and risks that may not be directly comparable, and which may be unquantifiable, or when the evidence base suggests equipoise, cost should not be the sole determinant.
3. Patient preference and shared decision-making, using a heart team approach when pertinent, should have a central role in revascularization decisions [7], especially when the evidence base does not identify a superior strategy. Payors should recognize the importance of patient input into decisions, as well as the merit of improvement of quality of life and pain relief, not only improved survival.
4. Automatic denial of coverage for specific AUC categories such as "rarely appropriate" should not occur. Clinicians should document why, for that patient, the procedure was reasonable. If questions arise, the case should be evaluated through an independent peer review process to determine whether special circumstances are documented indicating that the procedure was reasonable for that individual.
5. Criteria used to determine coverage policy should be transparent, available for review, and their use contingent on endorsement by professional societies. Outsourcing such eligibility evaluations to private companies, particularly when measures of appropriateness are to be obtained only from administrative data from an electronic health record is not acceptable.

TABLE I. Factors Influencing Selection of Revascularization Method

- Age & activity/stress levels in everyday life
- Frailty: physical, cognitive
- Exercise duration
- Anginal triggers
- Co-morbid conditions/Life expectancy
- Prior bypass surgery or PCI
- Complete vs. incomplete revascularization
- Presence of left ventricular dysfunction; Presence of viable myocardium; Substantial myocardium at jeopardy
- Availability of conduits for bypass surgery
- Risk of procedure – real & perceived
- Desire and ability to be compliant with medications
- What are the patient's short and long-term goals? (e.g., elderly)
- Which outcomes/benefits can be anticipated? (e.g., survival, improved quality of life, diminished angina, less heart failure)

6. Decisions regarding denial of coverage for revascularization procedures should be made only after consultation with the physician involved and a full review of documentation. An outside independent expert review based on pre-determined criteria may be warranted and should be an option for patients or health care providers.
7. Coverage determinations based upon an AUC case-by-case review is conceptually incorrect and inconsistent with the context of how the AUC were developed. An evaluation of AUC was intended to be within the framework for evaluation of hospital or physician *total* population of PCIs rather than on an individual case basis. Assessing hospital/clinician practice patterns, benchmarked against peers, might have valid meaning and could demonstrate "opportunities for improvement" in case selection; but, how and whether to apply these findings to create differential coverage strategies has never been tested provisionally on any scale.

In summary, SCAI is concerned that implementation of policies of coverage for PCI based solely on AUC nomenclature, or a non-peer reviewed set of arbitrary criteria, either prospectively or retrospectively, could compromise care of patients. SCAI is driven by our vision and mission to transform the treatment of expensive cardiovascular diseases by providing innovative solutions that improve care and reduce the economic burden of costly diseases on the healthcare system overall. SCAI is committed to seeking effective strategies to promote proper utilization of effective procedures while minimizing both overuse and underuse of PCI, and to assure patient access to optimal quality cardiovascular care.

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