December 9, 2015

Tamara Syrek Jensen, JD
Director, Coverage & Analysis Group
Office of Clinical Standards and Quality
Centers for Medicare & Medicaid Services
Mailstop C1-09-06
7500 Security Blvd
Baltimore MD 21244

RE: Proposed Medicare Coverage Decision Memorandum for Percutaneous Left Atrial Appendage (LAA) Closure Therapy (CAG-00445N)

Dear Ms. Syrek Jensen:

The Advanced Medical Technology Association (AdvaMed) offers the following comments on the Centers for Medicare & Medicaid Services’ (CMS) Proposed CoverageDecision Memorandum for Percutaneous Left Atrial Appendage (LAA) Closure Therapy. In the proposed decision memorandum, CMS proposes to limit Medicare coverage for LAA closure therapy to patients who are contraindicated for warfarin. CMS further proposes that patients be enrolled in a prospective national registry that also includes contemporaneous patients followed on oral anticoagulant (OAC) therapy to serve as non-interventional controls. CMS has specifically requested comments on its use of coverage with evidence development (CED) in this decision. AdvaMed’s comments below address these issues, as well as the use of CED.

AdvaMed’s member companies produce the life-saving and life-enhancing medical devices, diagnostic products and health information systems that are transforming health care through earlier disease detection, less invasive procedures and more effective treatments. AdvaMed members range from the largest to the smallest medical technology innovators and companies.

The proposed NCD contains several issues of concern, which we address in more detail in the comments below. In addition, CMS has specifically requested public comments on the Agency’s use of CED in this proposed coverage determination.

Terms of the Proposed NCD

In the proposed decision, CMS states that coverage for LAAC therapy would be limited to “clinical studies” that meet particular conditions. AdvaMed is specifically concerned with conditions (2) and (6) as described in the decision memorandum.

Condition (2) describes requirements for patients for whom coverage would apply. CMS appears to propose to limit coverage of LAAC therapy under CED for an FDA-approved device (at this time the only FDA approved device is the Watchman LAAC Therapy) to patients who are contraindicated to warfarin. The proposed decision memorandum does not provide additional detail or explanation regarding CMS use of the term “contraindication.”

The FDA-labeled indication is for patients who (among other requirements) are deemed by their physicians to be suitable for warfarin, and who have an appropriate rationale for seeking a non-pharmacologic alternative to warfarin, taking into account the safety and effectiveness of the device compared with warfarin.

CMS’ language could be interpreted to mean that only patients who are not suitable for warfarin would be eligible for the limited coverage under CED described in this proposed decision. This is not only confusing, but seems to result in an unintended consequence. Under this reading of the proposed decision, patients who are not suitable for warfarin (and therefore not included in the FDA label) would be the only patients covered by the policy.

Furthermore, the proposed NCD is not clear as to whether CMS’ current coverage policy for IDE trials or other FDA-approved clinical trials would still apply. The final NCD should make clear that coverage for percutaneous LAAC therapy furnished to all other patients with non-valvular atrial fibrillation enrolled in an FDA-approved IDE trial is provided under the current IDE coverage policy.

Condition (6) of the NCD requires participation in a registry that enrolls LAAC patients as well as patients followed on oral anticoagulant therapy (OAC), to serve as a control arm. AdvaMed has multiple concerns with this proposal. In general, we do not believe that it is necessary or appropriate to include a control arm where CMS requires CED, and the Agency should carefully consider whether a control arm is necessary. CMS should collaborate with stakeholders and seek their input in the decision-making process. With respect to the requirement for a control arm in the proposed NCD, we have a number of specific comments:

First, CMS appears to be seeking a better understanding of the patient population receiving LAAC therapy, and wishes to compare the treatment group with patients on oral anticoagulant therapy. We do not agree that gathering additional data on patients who are well-managed on OAC is the appropriate comparison, as these patients would not be eligible for the Watchman device.
Furthermore, it is not clear that the OAC population is the group CMS is genuinely interested in learning more about, and collecting such data would not appear to answer the clinical questions that are of concern to CMS. A comparison between the patients receiving the Watchman device and patients on OAC would be extremely difficult, if not impossible, to interpret.

Finally, there are numerous operational and logistical issues associated with collecting these data, including very real issues associated with identifying and enrolling those control-arm patients in the registry. The potential number of OAC patients alone could be daunting. In addition, the physicians managing those patients will differ from those managing Watchman patients, and there is little incentive for physicians managing OAC patients, and for the patients themselves, to participate in the registry. For all of these reasons, it would be difficult to comply with the requirements of the registry as contemplated in the proposed decision memo.

AdvaMed has often advocated that CMS should work with stakeholders to identify the appropriate clinical questions to be addressed in order for the Agency to ultimately make a permanent coverage determination. We recommend that CMS meet with stakeholders to work through the clinical questions together to develop appropriate study endpoints that will meet CMS’ needs.

Additionally, with respect to Condition (6), CMS alternately describes this condition as a registry, and as a prospective, randomized, controlled clinical study. The language in the proposed coverage decision has caused confusion and should be clarified. We recommend that in addition to working with stakeholders to determine the appropriate comparator, if any, CMS should make clear whether the continued data collection requirement lies in a registry or a clinical trial.

Use of CED in the Proposed Coverage Determination

In the proposed NCD, CMS specifically asks for public comment on the use of Coverage with Evidence Development in this decision. AdvaMed supports the use of sound evidence to inform medical practice, and has generally believed that CED may be a means to generate additional evidence in cases where the available evidence regarding a promising medical technology or procedure is not sufficient to support national coverage. In these circumstances, coverage contingent on the development of additional evidence can provide beneficiaries with access to innovative medical treatments when the alternative may be non-coverage.

CED allows CMS to provide coverage within the context of studies that conform to standards detailed in Medicare’s Clinical Trial Policy.\textsuperscript{2} The research meeting these standards can include a range of research approaches.

\textsuperscript{2} National Coverage Determination (NCD) for Routine Costs in Clinical Trials (310.1), effective 7/9/2007; see http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=1&ncdver=2&bc=AgAAgAAAAAA&
AdvaMed has submitted comments to CMS regarding its CED guidance generally, and many of the concerns we have raised in that context are relevant with respect to the proposal for coverage of LAAC therapy under CED. AdvaMed strongly believes that Medicare’s coverage policies should encourage innovation, and that CED should expand, not restrict, patient access to new technologies and treatments. We also urge CMS to continue to find avenues in NCDs whereby the Agency may impose certain conditions for coverage (for example, specific provider or institutional requirements) without finding that the evidence is insufficient under §1862(a)(1)(A) of the Act and therefore placing the NCD under §1862(a)(1)(E).

We reiterate that when Medicare coverage is contingent on the collection of additional clinical or scientific evidence (beyond FDA requirements for safety and efficacy), CMS should:

1) collaborate with stakeholders to clearly identify the data collection objectives,
2) consider the minimum data necessary to achieve those objectives, and
3) clearly identify, with input from interested stakeholders, scientifically supported study endpoints and the duration of data collection in advance.

In considering the minimum data necessary, CMS should also consider whether additional data being developed through FDA-mandated post-market studies satisfies CMS’ evidentiary needs for coverage. In addition, coverage policies should be sensitive to the practical challenges associated with generating evidence, and should support patient participation in clinical trials.

If you have questions regarding these comments or if you require additional information, please contact me or Chandra Branham, JD, Vice President, Payment and Health Care Delivery Policy, at (202) 434-7219 or cbranham@AdvaMed.org.

Sincerely,

/s/

Donald May
Executive Vice President
Payment and Health Care Delivery Policy