

## Medicare Evidence Development & Coverage Advisory Committee Meeting Recap

ASNR participated virtually in the Medicare Evidence Development & Coverage Advisory Committee Meeting (MEDCAC) that took place on Wednesday, September 22nd. The MEDCAC panel examined relevant health outcomes in studies for cerebrovascular disease treatment with a particular focus on new technologies of interest to CMS. Given the increased emphasis on new and innovative medical products for treating diseases that have few proven therapies, studies on certain medical technologies have focused on intermediate and surrogate outcomes rather than longer-term data. As a result, there are more frequent evidence gaps with respect to the clinically meaningful health outcomes for CMS beneficiaries, and these gaps impact our assessments of medical technologies. The MEDCAC panel examined the growing challenges associated with the decreased level of evidence of certain new and innovative technologies.

James Milburn, MD, FACR who is section Director of Neurointerventional Services, Vice Chair for academic affairs and program director at Ochsner represented ASNR as a subject matter expert along with a team of collaborative societies who presented at the meeting. Rahul Bhala, MBA, MPH attended as ASNR staff. Additionally, ASNR members, Josh Hirsch, MD, FACR, FSIR, Mahesh Jayaraman MD, and Sameer Ansari, MD, PhD participated in the meeting as the subject matter experts for ACR, SNIS and DASIS respectively. Other presenters included NINDS director Walter Koroshetz, neurologist Jeffrey Saver from UCLA, SNIS President Michael Chen MD, and neurosurgeons Adnan Siddiqui MD, PhD and Clemens Schirmir MD from AANS/CNS CV Section.

The speakers presented eloquent responses to a series of questions posed by the MEDCAC panel on which research outcomes measures were most valid and meaningful in neurovascular research. The panel explored primary outcomes measures, secondary outcomes measures, and patient reported outcomes. Pertinent research on outcomes assessments was reviewed by the speakers. Regarding standalone primary outcomes, mRS  $\geq 3$  and mRS  $\leq 2$  or equal to pre-stroke score were awarded the highest level of confidence by the presenters, and the use of mRS also received high confidence scores in the MEDCAC vote. NIHSS within 1 week was presented as an important and readily available early outcome measure to assess procedural success, but it is less useful to assess long term disability status compared to mRS. The panel vote was widely split on NIHSS as a primary outcome measure. Length of follow-up of 90 days was agreed upon as the most appropriate by the presenters and panel.

Regarding secondary outcomes, the presenters were more confident in discharge disposition and less confident hospital length of stay and unscheduled re-admissions. The panel voted with low to intermediate confidence in each of these measures. On the subject of patient/family reported outcomes using standardized questionnaires, most presenters were less confident in these as outcome measures because they are not specific to stroke, did not have questions about speech, and were more biased. The panel voted that to say that these serve as an important way to measure patient experience, but they were less meaningful as a standalone measurement. The panel voted with high confidence that these questionnaires should be included as secondary outcomes measures, but they should not be used as primary measures.

As a result of this daylong meeting consisting of expert testimony, discussion, and final voting, the MEDCAC panel members will advise CMS on the best health outcomes in research studies of cerebrovascular disease treatment technologies, appropriate measurement instruments and follow-up durations to help to provide clarity and transparency of National Coverage Analyses (NCAs). MEDCAC

panels do not make coverage determinations, but CMS benefits from their advice. The ASNR will continue to support and provide guidance in this important MEDCAC process.