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August 28, 2023

Chiquita Brooks-LaSure, Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS–3421–NC
Mail Stop C4–26–05
7500 Security Boulevard
Baltimore, MD 21244–1850

Submitted electronically via www.regulations.gov

Subject: Notice with Comment - Transitional Coverage for Emerging Technologies (CMS-3421-NC)

Dear Administrator Brooks-LaSure:

On behalf of the American Association of Neurological Surgeons (AANS) and the Congress of Neurological Surgeons (CNS), representing more than 4,000 neurosurgeons in the United States, we appreciate the opportunity to comment on the above-referenced Notice with Comment for Transitional Coverage for Emerging Technologies.

Transitional Coverage for Emerging Technologies (TCET) Pathway

Neurosurgeons are at the cutting edge of advances in treating diseases and disorders of the brain, spine and peripheral nerves — including stroke, back pain, traumatic brain injury, epilepsy, Parkinson's disease and tumors. Drugs, devices and biologics regulated by the Food and Drug Administration (FDA) are essential elements of neurosurgical treatments. As such, access to breakthrough technology is crucial for our specialty and the patients we serve. **We, therefore, support Medicare coverage for breakthrough technology and urge the agency at the same time to safeguard high-quality and real-world evidence development for the technologies**. To that end, the AANS and CNS support the proposed TCET pathway to expand access to the rapidly evolving health technology landscape, providing coverage of breakthrough products while they make their way through the permanent coverage process.

Evidence Development

The proposed TCET pathway is specifically for Medicare coverage of designated devices as part of the FDA Breakthrough Devices Program. We note that manufacturers of Breakthrough Devices will be subject to coverage with evidence development. We support this and recommend that CMS require manufacturers to collect and regularly report data on outcomes under the TCET pathway to inform decision-making and treatment recommendations. These data should be prospectively collected and include relevant functional and patient-reported outcome measures. Given that devices in the TCET pathway will not have long-term evidence of safety and efficacy, it is essential that this information be obtained as a condition for inclusion in the TCET program and that the data be reviewed at regular intervals so that determination of suitability for Medicare National Coverage Determinations (NCDs) can be made. Encouragement and facilitation of innovation must also be accompanied by sunsetting those

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devices whose results do not meet their promise. **We urge CMS and FDA to collaborate with manufacturers of Breakthrough Devices to devise an evidence development plan that provides the outcome measures that both agencies find relevant to their processes, including using established and validated physician-led clinical data registries.**

Such collaboration should also involve the relevant physician specialty societies and their experts, and we recommend that the agency consider the valid scientific data provided by specialty society-sponsored registries. The neurosurgery-led NeuroPoint Alliance has worked closely with the FDA and other stakeholders on several important initiatives to explore "real world" data sources and alternatives to costly, time-consuming, randomized controlled trials. Examples include multispecialty projects such as the American Spine Registry (a collaborative project with the American Academy of Orthopaedic Surgeons) and an initiative with the Society of NeuroInterventional Surgery (NeuroVascular Quality Initiative-Quality Outcomes Database, or NVQI-QOD) to establish a single registry for neurovascular surgical procedures. In the case of the neurovascular registry, we are working with the FDA to use the data to evaluate thrombectomy devices to treat stroke.

The AANS and the CNS are confident that these registries are precisely the kind of collaborative effort that will lead to better patient care. Thus, as CMS moves forward with efforts to improve access to innovative technology for Medicare beneficiaries, we urge you to foster a regulatory environment that supports and encourages using real-world practice data to give patients access to life and ability-saving devices more quickly and affordably.

Device Eligibility

While we understand that CMS plans to limit the annual number of TCET devices to five, **we request that the agency establish a transparent process that includes patients with unique neurological diseases rather than arbitrarily limiting the number and defaulting to a small set of common medical conditions and treatment options**. This process merits allocating adequate financial and personnel resources to increase the annual number of devices accepted into the TCET program.

Appropriate candidates for the TCET pathway would include the following:

- FDA-designated Breakthrough Devices;
- Devices determined to be within a Medicare benefit category;
- Devices not already the subject of an existing Medicare NCD; and
- Devices not otherwise excluded from coverage through law or regulation.

Regarding devices determined to be within a Medicare benefit category, we encourage the agency to work with stakeholders to select the appropriate benefit category for their product. For example, manufacturers of cutting-edge technology for brain/computer interface (BCI) devices have encouraged the agency to assign these devices to the "Prosthetic" benefit category. In addition, the agency should consider new benefit categories, such as revolutionary technology such as BCI, which may not fit neatly into the current categories.

Nominations for the TCET Pathway

The program proposes that manufacturers of FDA-designated Breakthrough Devices may self-nominate for participation in the TCET pathway approximately 12 months before the anticipated FDA approval decision. We urge CMS to extend flexibility to this aspect of the program. The FDA approval process is not always smooth and linear and can be saltatory, with jumps forward and backward. This makes it difficult to approximate the timeline for the FDA to reach an approval decision. We do not want these interactions to deter a worthy device from being nominated for TCET.

TCET and other FDA/CMS Innovation Programs

We are encouraged that both CMS and FDA have taken steps to introduce programs intended to facilitate the approval and coverage of innovative medical devices. However, we are concerned that the proposed programs could overlap, interfere with each other, and cause confusion among physicians and manufacturers. Moreover, we do not want the limited resources available for these programs to be spread too thin, resulting in insufficient funding for any of them, defeating the overall initiative. We are particularly interested in whether and how CMS plans to address coverage issues for FDA-designated devices participating in the FDA Total Product Life Cycle Advisory Program (TAP). The FDA recently expanded this program to include neurological devices, so this issue is of particular concern to our members and patients. As with TCET, TAP is a voluntary program for manufacturers, and we would imagine a company could participate in both initiatives but would want CMS and FDA to reduce any duplication of effort. In addition, **we encourage CMS to work with the FDA to make the list of pending and authorized FDA Breakthrough Devices more transparent and easily accessible to stakeholders**.

Transparency of TCET and the NCD process

If a device that is accepted into the TCET pathway receives FDA marketing authorization, CMS will initiate the NCD process by posting a tracking sheet following FDA market authorization pending a CMS and Agency for Healthcare Research and Quality (AHRQ)-approved Evidence Development Plan (EDP) (in cases where there are evidence gaps as identified in the Evidence Preview). The process for Medicare coverage under the TCET pathway would follow the existing NCD statutory timeframes. We commend the agency for setting a goal to finalize a TCET NCD within six months after FDA market authorization. **We urge CMS to create a straightforward, transparent process for tracking the progress of a device through the TCET and NCD pathways to improve confidence in the process**.

Duration of Coverage Under the TCET Pathway

CMS has stated that coverage under the TCET NCD will continue only as long as needed to facilitate the timely generation of evidence informing patient and clinician decision-making. The duration of transitional coverage through the TCET pathway will be tied to the CMS- and AHRQ-approved EDP. The review date specified in the EDP will provide one additional year of coverage after study completion, allowing manufacturers to complete their analysis, draft one or more reports, and submit them for peer-reviewed publication. **We support this process of coverage however long it takes to address evidence gaps and obtain the data necessary for a long-term Medicare coverage determination**.

Transition to Post-TCET Coverage

The agency has stated that it intends to conduct an updated evidence review within six calendar months of the review date specified in the EDP, engaging a third-party contractor to conduct the systematic literature review. The contractor will perform a qualitative evidence synthesis and compare those findings against the benchmarks for each outcome specified in the original NCD. Having had mixed experience with outside contractors, we are glad CMS notes that it will conduct quality assurance on the contractor review. CMS will also review applicable practice guidelines and consensus statements and consider whether the conditions of coverage remain appropriate. While engaging a third party for review could provide improved expertise and impartiality, oversight by the agency will be essential, and feedback from stakeholders on the process must be sought.

CMS has noted that based on this assessment, when appropriate, the agency will open an NCD reconsideration by posting a proposed decision that proposes one of the following outcomes:

1) An NCD without evidence development requirements;

2) An NCD with continued evidence development requirements;
3) A non- coverage NCD; or
4) Rescinding the NCD, resulting in coverage decisions being made by the Medicare Administrative Contractors.

Following a 30-day public comment period, CMS will have 60 days to finalize the NCD reconsideration. **We urge CMS to remain transparent while determining post-TCET CMS coverage and suggest that comments submitted by stakeholder organizations such as ours be seriously considered**.

Coverage of Similar Devices

FDA market-authorized Breakthrough Devices are often followed by similar devices that other manufacturers develop. We are pleased to see the agency state, "CMS believes that it is important to let physicians and their patients make decisions about the best available treatment depending on the patient's individual situation." CMS and FDA should not restrict physician-directed or "off-label" use of devices. We understand that there is substantial discussion about reforming the 510(k) approval pathway for devices substantially similar to those already on the market. We hope that CMS and FDA use the implementation of programs such as TAP and TCET to spur these discussions, and the AANS and CNS plan to participate in this process to ensure that all marketed devices are safe and effective.

The AANS and the CNS appreciate the opportunity to provide feedback on these provisions in the TCET pathway comment notice. We look forward to working with you to develop effective coverage and reimbursement policies to bring critical new treatments to our patients. In the meantime, please contact us if you have any questions or need additional information.

Sincerely,

Anthony L. Asher, MD, President
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