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President
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VIA ELECTRONIC TRANSMISSION

October 13, 2026

The Honorable Mehmet Oz, MD, MBA
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
P.O. Box 8010
Baltimore, MD 21244-8010

RE: Medicare Program; Regulatory Alignment for Predictable and Immediate Device (RAPID) Coverage Pathway

Dear Administrator Oz,

On behalf of the American Association of Neurological Surgeons (AANS) and the Congress of Neurological Surgeons (CNS), representing more than 4,000 neurosurgeons nationwide, we appreciate the opportunity to submit comments to the Centers for Medicare & Medicaid Services' (CMS) Regulatory Alignment for Predictable and Immediate Device (RAPID) Coverage Pathway notice published in the *Federal Register* on August 11, 2026.

The notice addresses several issues of significant importance to neurosurgical patients and providers. In particular, the AANS and CNS comment on RAPID Pathway eligibility criteria, the participation of devices that have advanced beyond the Investigational Device Exemption (IDE) pre-submission stage, identifying clinical outcomes that are meaningful to Medicare beneficiaries, and evidence development for RAPID National Coverage Determination (NCD).

In summary, the AANS and CNS:

- Support CMS efforts to align RAPID eligibility with participation in the FDA Breakthrough Devices Program and the Total Product Life Cycle Advisory (TAP) Program to ensure evidence generation aligns with regulatory and coverage expectations from the beginning of the product development process;
- Call on CMS to establish a transition pathway for devices beyond the IDE pre-submission stage to be eligible for RAPID;
- Call on CMS to establish a mechanism for Breakthrough Devices supported by appropriately designed Non-Significant Risk (NSR) studies to participate in RAPID;

- Support CMS efforts to identify clinical outcomes that reflect what matters most to Medicare beneficiaries, including symptom burden, quality of life, and the ability to maintain independence, and that are appropriate for the specific technology under review;
- Encourage CMS to use independent, clinician-led registries when additional postmarket evidence is necessary under Coverage with Evidence Determination (CED);
- Call on CMS to define the process, evidence expectations, and review milestones that would support extension of RAPID coverage when sponsors are generating meaningful evidence toward a permanent Medicare coverage determination; and
- Call on CMS to ensure that implementation of RAPID does not inadvertently delay consideration of other technologies waiting for coverage review through existing NCD pathways.

The AANS and CNS appreciate CMS's consideration of these comments and look forward to continued engagement on policies that accelerate patient access to innovative and safe medical devices that improve long-term health outcomes and strengthen quality of care.

II B. RAPID COVERAGE PATHWAY GENERAL PRINCIPLES

Eligibility through Breakthrough and TAP

The AANS and CNS support CMS's decision to align RAPID eligibility with participation in the FDA Breakthrough Devices Program and the Total Product Life Cycle Advisory Program (TAP). This approach creates an important opportunity for CMS engagement much earlier in the product development process, while clinical studies are still being designed, rather than only after a device is approaching FDA authorization. Earlier coordination between CMS, FDA, and manufacturers can help ensure that evidence-generation plans are better aligned with both regulatory and coverage expectations from the beginning.

In doing so, the RAPID proposal addresses a longstanding concern raised by stakeholders during discussions of the Transitional Coverage for Emerging Technologies (TCET) pathway, which is the misalignment between the evidence needed for FDA review and the evidence required to support Medicare coverage.¹ Manufacturers faced the risk of investing substantial resources in studies that satisfied FDA requirements but fell short of CMS's evidence expectations. Earlier engagement through RAPID can help reduce this uncertainty and promote more efficient development of innovative technologies.

RAPID also addresses another significant challenge identified during stakeholder discussions of Medicare coverage for innovative technologies, which is the timing of NCDs. Historically, manufacturers have often faced substantial delays between FDA authorization and a final Medicare coverage determination, creating uncertainty for providers, patients, and innovators. For example, research has found a median of 5.7 years from FDA authorization to Medicare coverage for novel technologies requiring a new reimbursement pathway.² By allowing CMS to engage with developers earlier in the product development process and issue a proposed NCD concurrent with FDA marketing authorization, RAPID can help narrow the gap between regulatory approval and coverage decision-making.

The value of this earlier CMS engagement is reflected in RAPID's reliance on the FDA Breakthrough Devices Program and TAP, which provide a framework for coordinating evidence development and coverage discussions before market authorization. RAPID's reliance on participation in the FDA

¹ Dave Muoio, "CMS, FDA Unveil RAPID Program for Breakthrough Medical Devices," Fierce Healthcare, April 26, 2026, <https://www.fiercehealthcare.com/health-tech/cms-fda-announce-new-program-speed-medicare-coverage-breakthrough-medical-devices>.

² Stanford Biodesign, Response to CMS Proposed Transitional Coverage for Emerging Technologies (TCET) (Aug. 28, 2023)

Breakthrough Devices Program and TAP is also supported by the growing use of these pathways. As of June 30, 2026, FDA's Center for Devices and Radiological Health (CDRH) and Center for Biologics Evaluation and Research (CBER) had granted 1,320 Breakthrough Device designations, and 133 devices were enrolled in the TAP Pilot as of July 1, 2026.^{3,4} TAP has expanded across all Offices of Health Technologies (OHTs) for eligible Breakthrough-designated devices, reflecting increasing interest from manufacturers developing technologies for serious or life-threatening conditions. These programs provide earlier and more frequent interactions with FDA and engagement throughout the product development process. As medical technologies become increasingly complex, these pathways can accelerate patient access to important innovations.

Certain neurosurgical technologies are well suited to this framework. Innovations such as brain-computer interfaces (BCIs), deep brain stimulation systems, stroke technologies, and neurovascular devices often address serious or life-threatening conditions and have significant potential to improve patient outcomes.^{5,6} As a result, these technologies are frequently candidates for FDA Breakthrough Device designation and TAP participation, making them strong examples of the types of innovations that could benefit from earlier CMS engagement under RAPID.

Recent examples illustrate the relevance of these pathways to the neurosurgical field. In 2026, CorTec received FDA Breakthrough Device designation for a BCI device and was formally accepted into the FDA TAP program, demonstrating how developers of neurotechnology can engage with regulators early in the development process.⁷ In February of 2026, Sentante was accepted into the FDA TAP program following its 2025 Breakthrough Device designation for an endovascular robotic system to address needs in stroke care.⁸ These examples show that many emerging neurosurgical technologies are already utilizing the FDA programs that form the basis for RAPID eligibility and can benefit from better coordination between FDA review and Medicare coverage planning.

While only a limited number of neurosurgical technologies currently participate in the FDA Breakthrough Devices Program and TAP, the neurosurgical community nevertheless strongly supports RAPID's use of these pathways as eligibility criteria. The value of RAPID extends beyond the number of devices currently enrolled. By fostering earlier coordination among CMS, FDA, and manufacturers, the program can help ensure that innovative technologies are developed with both regulatory and coverage considerations in mind from the beginning.

II C. APPROPRIATE CANDIDATES

IDE Presubmission Stage

CMS proposes to limit RAPID participation to devices that have not advanced beyond the IDE pre-submission stage. The AANS and CNS appreciate CMS's goal of engaging with manufacturers as early as possible in the product development process, but remain strongly concerned that this restriction

³U.S. Food and Drug Administration (FDA), "Breakthrough Devices Program," <https://www.fda.gov/medical-devices/how-study-and-market-your-device/breakthrough-devices-program>.

⁴U.S. Food and Drug Administration (FDA), "Total Product Life Cycle Advisory Program (TAP)," <https://www.fda.gov/medical-devices/how-study-and-market-your-device/total-product-life-cycle-advisory-program-tap>.

⁵NeuroPace, "NeuroPace Receives FDA Breakthrough Device Designation for RNS System for Idiopathic Generalized Epilepsy," <https://www.neuropace.com/press-release/fda-breakthrough-device-designation-for-rns-system/>

⁶Practical Neurology, "FDA Grants Breakthrough Device Designation to Aurenar's Investigational V-Link System for Cerebral Vasospasm After Aneurysmal Subarachnoid Hemorrhage," <https://practicalneurology.com/news/fda-grants-breakthrough-device-designation-to-aurenars-investigational-v-link-system-for-cerebral-vasospasm-after-aneurysmal-subarachnoid-hemorrhage/2487686/>

⁷CorTec, "Brain Interchange Accepted into FDA TAP Program," <https://cortec-neuro.com/news/brain-interchange-fda-tap-third-patient>

⁸Sentante, "Sentante Accepted into FDA Total Product Life Cycle Advisory Program Following Breakthrough Device Designation," <https://sentante.com/news/sentante-accepted-into-fda-total-product-life-cycle-advisory-program-following-breakthrough-device-designation/>

would exclude innovative Breakthrough Devices that are already generating clinical evidence under an IDE and would benefit from FDA-CMS engagement.

Excluding devices that have progressed beyond the IDE pre-submission stage would prevent these manufacturers from receiving the joint FDA-CMS feedback that RAPID is designed to provide and would deny them access to the issuance of a proposed National Coverage Determination (NCD) on the same day as FDA marketing authorization. As a result, manufacturers that have already invested substantial resources in clinical evidence generation may face a less predictable path to Medicare coverage than similarly situated products that happen to be at an earlier stage of development.

We urge CMS to align eligibility for devices beyond the IDE pre-submission stage with the broader eligibility criteria proposed for RAPID participants. Specifically, CMS should establish a limited transition pathway for eligible Breakthrough Devices that, as of the date the agency publishes the final RAPID notice, have already progressed beyond the IDE pre-submission stage and are either being studied under an FDA-approved IDE or have an IDE application pending before FDA. This approach would preserve CMS's goal of encouraging early engagement while ensuring that manufacturers are not unfairly excluded from participation solely because they advanced their development programs before RAPID became available.

Innovative devices that address serious unmet medical needs are already undergoing clinical evaluation under IDEs and could benefit from coordinated FDA-CMS engagement. For example, investigational therapies being evaluated in studies for conditions such as contained herniated lumbar discs may present important opportunities for early alignment between FDA and CMS regarding evidence expectations.⁹ Including these and other similar technologies in a transitional eligibility process would help ensure that RAPID fulfills its purpose of reducing uncertainty, supporting evidence development, and facilitating timely patient access to breakthrough innovations.

Non-Significant Risk Studies

CMS's IDE coverage framework is built around FDA-assigned Category A and Category B designations for IDE studies.¹⁰ Therefore, devices studied through an NSR pathway may fall outside the framework RAPID proposes to use, despite otherwise satisfying the goals of the program. Limiting eligibility to devices supported by Category A or B IDE studies could inadvertently exclude Breakthrough Devices, including those participating in TAP, solely because their evidence-generation strategy relies on an NSR study rather than a significant-risk IDE. To ensure that RAPID remains focused on accelerating patient access to promising technologies, the AANS and CNS recommend that CMS establish a mechanism for Breakthrough Devices supported by appropriately designed NSR studies to participate in RAPID. These studies can generate clinically meaningful evidence regarding device performance, clinical utility, and, where applicable, safety and effectiveness, and should not be excluded solely because they do not require a significant-risk IDE.

This issue may become increasingly important as software- and AI-enabled medical technologies continue to emerge. FDA's risk-based framework distinguishes between significant-risk and non-significant-risk device studies based on the potential risk posed to study subjects, and some software-based technologies that analyze existing patient data, medical imaging, or pathology slides may be

⁹ *MedPath Trial*, "SpinaFX Medical Receives FDA IDE Approval for Triojection Pivotal Trial in Contained Herniated Lumbar Discs," available at: <https://trial.medpath.com/news/spinafx-medical-receives-fda-ide-approval-for-triojection-pivotal-trial-in-contained-herniated-lumbar-discs>

¹⁰ U.S. Food and Drug Administration, FDA Categorization of Investigational Device Exemption (IDE) Devices to Assist the Centers for Medicare and Medicaid Services (CMS) with Coverage Decisions: Guidance for Sponsors, Clinical Investigators, Industry, Institutional Review Boards, and Food and Drug Administration Staff (Dec. 5, 2017), available at <https://www.fda.gov/media/98578/download>

appropriately evaluated through NSR studies when they do not present a potential for serious risk.¹¹ For example, in neurosurgery, AI-enabled software may be developed to analyze brain CT scans for findings suggestive of intracranial hemorrhage, predict surgical outcomes using existing clinical datasets, or automate the review of neuropathology slides.^{12,13,14} Because these technologies can often be evaluated using retrospectively collected or routinely generated clinical data without altering patient treatment or exposing patients to additional procedural risk, a NSR study may be the appropriate regulatory pathway. Excluding these devices from RAPID solely because they are supported by NSR studies could prevent CMS from engaging early with some of the very technologies that RAPID is intended to help advance toward Medicare coverage and patient access.

II 3. TRANSITION FROM IDE TO COVERAGE

A. IDE Completion and Manufacturer Next Steps

Clinical Outcomes

The AANS and CNS support CMS's approach of working collaboratively with the FDA and manufacturers to identify clinical outcomes that are meaningful to Medicare beneficiaries and appropriate for the specific technology under review. Alignment between CMS and FDA can help ensure that evidence development efforts focus on outcomes that are clinically relevant, and reflective of real-world patient needs. This CMS-FDA coordination may also reduce unnecessary duplication and provide more predictability for innovators developing technologies intended to address serious neurological conditions.

The FDA already has a well-established framework for evaluating clinically meaningful outcomes across a broad range of therapeutic areas, including neurological and neurosurgical conditions.¹⁵ FDA's assessment of clinical benefit extends beyond survival and includes outcomes that directly reflect how a patient feels, functions, or survives. These outcomes may be reported by healthcare providers, patients themselves through patient-reported outcome measures, non-clinical observers such as caregivers or family members, or through performance-based assessments that evaluate a patient's ability to complete tasks or activities. This framework recognizes that the impact of neurological disease is often reflected in changes in function, cognition, independence, and quality of life that may not be fully captured through mortality outcomes alone.

For example, in stroke recovery and other movement disorders, clinically meaningful improvements may be demonstrated through measures of motor recovery, physical function, and activities of daily living.¹⁶ Even the smallest improvements in motor performance can translate into significant improvements in a patient's ability to live independently and participate more fully in daily life. These outcomes are often of substantial value to Medicare beneficiaries despite not being reflected in traditional survival outcomes.

¹¹ U.S. Food and Drug Administration, Significant Risk and Nonsignificant Risk Medical Device Studies: Information Sheet Guidance for IRBs, Clinical Investigators, and Sponsors (Jan. 2006), <https://www.fda.gov/media/75459/download>

¹² Yueh-Tsae Lee et al., Real-world Performance Evaluation of a Commercial Deep Learning Model for Intracranial Hemorrhage Detection, <https://pmc.ncbi.nlm.nih.gov/articles/PMC12823562>

¹³ Amit Agrawal et al., Decision Support Systems in Neurosurgery: Current Applications and Future Directions, *Brain Sciences* (2025), <https://pmc.ncbi.nlm.nih.gov/articles/PMC12736516/>

¹⁴ David J. Foersch et al., *Validation of Machine Learning Models to Detect Amyloid Pathologies Across Institutions*, 8 *Acta Neuropathologica* Commc'ns 78 (2020), <https://link.springer.com/article/10.1186/s40478-020-00927-4>

¹⁵ U.S. Food and Drug Administration (FDA), *Clinical Outcome Assessments (COAs) in Medical Device Decision Making*, <https://www.fda.gov/about-fda/division-patient-centered-development/clinical-outcome-assessments-coas-medical-device-decision-making>

¹⁶ Gladstone DJ, Danells CJ, Black SE. The Fugl-Meyer Assessment of Motor Recovery After Stroke: A Critical Review of Its Measurement Properties. *Neurorehabil Neural Repair*. 2002;16(3):232-240. doi:10.1177/154596802401105171. PMID: 12234086

For patients with brain tumors, meaningful benefit may extend beyond survival and include preservation of neurological function, cognitive abilities, speech, mobility, and independence.¹⁷ Treatments that reduce tumor burden, delay neurological deterioration, or preserve a patient's ability to communicate, work, or perform activities of daily living can provide substantial value to patients and caregivers.

For neurodegenerative diseases such as early-stage Alzheimer's disease, meaningful clinical benefit may center on slowing cognitive and functional decline rather than reversing disease progression.¹⁸ Delaying deterioration in memory, communication, or the ability to perform daily activities can meaningfully extend a patient's independence and quality of life while reducing the burden on family caregivers. As emerging therapies increasingly target earlier stages of disease, CMS should ensure that evidence requirements account for the value of slowing progression in conditions where a cure or full restoration of function is not currently achievable.

D. Evidence Development for RAPID NCDs

Coverage with Evidence Development

The AANS and CNS support CMS's efforts to collaborate closely with FDA and device manufacturers to ensure that Medicare evidence development requirements are aligned with existing regulatory expectations and do not create unnecessary burden on innovators, providers, or patients. As technologies move from FDA authorization into clinical practice, it is important that CMS and FDA coordinate their evidence needs to avoid duplicative data collection.

Furthermore, AANS and CNS support the use of the CED framework in circumstances where available evidence is insufficient to support broad Medicare coverage. CED can serve as an important mechanism for ensuring beneficiary access to promising technologies while additional evidence is generated to address remaining clinical questions. For De Novo Class II and Class III devices in particular, robust clinical studies and trials should continue to play a central role in evidence generation. These technologies are often associated with higher levels of complexity and risk, making clinical evaluation critical to understanding safety and effectiveness.

Registries

When additional postmarket evidence is necessary under a CED, the AANS and CNS strongly support the use of independent registries that are capable of producing high-quality, objective, and clinically meaningful data. Registries can help improve transparency and provide stakeholders with confidence that coverage decisions are informed by reliable evidence.

Where registry-based evidence development or postmarket surveillance is appropriate, CMS should consider whether existing clinical data infrastructure can meet evidence-generation needs. Leveraging established registries can reduce unnecessary administrative burden, avoid duplicative data collection, accelerate evidence generation, and maximize the value of existing investments in clinical quality infrastructure. CMS should also ensure that registry participation requirements are streamlined and operationally feasible for hospitals and clinicians. Participation processes should leverage existing

¹⁷ Salans M, Tibbs MD, Huynh-Le MP, et al. Quality of life is independently associated with neurocognitive function in brain tumor patients: analysis of a prospective clinical trial. *International Journal of Radiation Oncology, Biology, Physics*. 2021;111(3):754-763

¹⁸ Alireza Atri et al., "Clinical Meaningfulness of Donanemab in Early Symptomatic Alzheimer Disease: Data From the Randomized Phase 3 TRAILBLAZER-ALZ 2 Trial," *Neurology Clinical Practice* 16, no. 3 (2026): e200621, <https://doi.org/10.1212/CPJ.0000000000200621>

clinical workflows, electronic health record data, and established reporting systems whenever possible and avoid unnecessary reporting or data submission requirements. Reducing barriers to participation will encourage broader provider engagement and improve data completeness. For these reasons, AANS and CNS recommend that CMS give preference to clinician-led clinical data registries over vendor-led registries.

Clinician-led registries are uniquely positioned to support the goals of CED because they are governed by clinical experts with direct experience caring for the patient populations being studied. These registries operate as tax-exempt entities and are devoted to the care of a population defined by a specific disease, condition, exposure, or therapy. Additionally, these registries collect detailed, standardized data on an ongoing basis, provide feedback to participants, maintain standards for data quality, and provide ongoing training and support for participants. To ensure accuracy and integrity, clinician-led clinical data registries also are required to use standardized data elements, verify data completeness and validity, and ensure regular data audits. In contrast, vendor-led registries do not have clinical expertise or in-depth understanding about quality measurement.

Clinician-led registries can serve as a valuable complement to clinical trials by providing real-world evidence on device safety, effectiveness, and utilization in broader patient populations. For example, while a clinical trial evaluated the safety of Transcarotid Artery Revascularization (TCAR) devices in a limited patient cohort, the Society for Vascular Surgery's Vascular Quality Initiative (VQI) Carotid Artery Stent Registry enabled assessment of TCAR performance in routine clinical practice, generating evidence that may not have been possible through clinical trials alone.¹⁹

In addition, many specialty societies also operate Qualified Clinical Data Registries (QCDRs), which CMS has long recognized within the Quality Payment Program as valuable tools for collecting specialty-specific clinical information and supporting quality improvement efforts. Unlike traditional registries used solely for reporting, QCDRs can develop and report specialty-specific quality measures that address clinical areas not otherwise captured in CMS measure sets, demonstrating the ability to generate meaningful, clinically nuanced information.²⁰ While AANS and CNS recognize that QCDRs are not designed to serve as a universal solution for postmarket evidence generation, they demonstrate that substantial clinical data infrastructure and expertise already exist within the specialty community.

Electronic Health Record Integration and Interoperability

Clinical data registries continue to face significant operational and financial barriers in obtaining timely access to electronic health information (EHI) due to ongoing information blocking practices. The AANS and CNS recommend The Office of the National Coordinator for Health Information Technology (ONC) reevaluate the effectiveness of its existing information blocking framework and address exceptions that are being misused in ways that impede data sharing with registries.

In particular, the ONC should examine whether the fees exception is being applied consistently with the intent of the 21st Century Cures Act and consider additional guardrails to prevent excessive or unjustified charges that prevent participation in quality improvement and outcomes research

¹⁹ Goodney et al., *Transcarotid Artery Revascularization Versus Transfemoral Carotid Artery Stenting in the Society for Vascular Surgery Vascular Quality Initiative*, 69 *Journal of Vascular Surgery* 92-103.e2 (2019), available at [https://www.jvascsurg.org/article/S0741-5214\(18\)31054-1/fulltext](https://www.jvascsurg.org/article/S0741-5214(18)31054-1/fulltext).

²⁰ Centers for Medicare & Medicaid Services (CMS), *A Brief Overview of Qualified Clinical Data Registries (QCDRs)*, Measures Management System (Oct. 2018), available at <https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/mms/downloads/a-brief-overview-of-qualified-clinical-data-registries.pdf>

initiatives.²¹ Although the fees exception was intended to recover reasonable costs associated with data exchange, AANS and CNS are concerned that some actors may be relying on this exception to impose charges that discourage or prevent registry participation.

In addition, the Office of Inspector General (OIG) and CMS should utilize their existing authority to enforce existing regulations against EHR vendors and hospital systems that continue to prevent data exchange to clinical data registries. Congress expressly authorized OIG to investigate claims of information blocking and impose civil monetary penalties on applicable entities found to have engaged in prohibited conduct.²² The OIG should respond to complaints of information blocking within a reasonable timeframe and provide stakeholders with greater transparency regarding the investigation and enforcement actions.

Adverse-Event Surveillance

The AANS and CNS urge CMS and FDA to continue developing a coordinated postmarket evidence infrastructure that allows registries and FDA adverse-event data to complement one another rather than operate in separate silos. For many implantable and other high-risk devices, specialty society registries provide clinically meaningful information that is not available through traditional claims data or adverse event reporting systems alone. While adverse event reports play a critical role in identifying potential safety concerns, they often lack the clinical context necessary to fully assess device performance and patient outcomes.²³ Registries can help address some of these limitations by providing information regarding the population actually receiving a device, patient characteristics and indications, device utilization, and longitudinal outcomes.²⁴ Registries can also facilitate long-term follow-up and evaluation of device performance across diverse patient populations and care settings.

The FDA already recognizes registries as potentially valuable real-world data sources for postmarket evaluation and has recognized the value of incorporating Unique Device Identifiers into these sources.²⁵ Improved device identification would strengthen the ability to link utilization, outcomes, and safety information across data systems, facilitating timely evaluation of emerging safety signals and postmarket performance. This would provide essential context regarding patient characteristics, enabling regulators to more effectively evaluate potential safety signals and device performance over time. As RAPID evolves, interoperable data systems that connect coverage and clinical evidence-generation activities will be critical to achieving the pathway's goal of accelerating patient access to innovative devices while maintaining rigorous standards for safety and effectiveness.

E. Duration of Coverage Under the RAPID Coverage Pathway

The AANS and CNS support the principle that RAPID-generated NCD coverage policies are not intended to last indefinitely without reassessment. Consistent with CMS's longstanding NCD framework, reconsideration may be appropriate when new evidence emerges that could support a material change in

²¹ U.S. Department of Health and Human Services, Office of the National Coordinator for Health Information Technology, *Information Blocking Exceptions Fact Sheet* (Apr. 2024), https://healthit.gov/wp-content/uploads/2024/04/IB_Exceptions_Fact_Sheet_508.pdf.

²² 42 U.S.C. § 300jj-52, Information Blocking, Public Health Service Act, available at <https://www.law.cornell.edu/uscode/text/42/300jj-52>

²³ Shuren J, Califf RM. *Need for a National Evaluation System for Health Technology*. *JAMA*. 2016;316(11):1153-1154. doi:10.1001/jama.2016.8708

²⁴ AHRQ, *Registries for Evaluating Patient Outcomes: A User's Guide*, Chapter 23: Registries for Medical Devices

²⁵ U.S. Food and Drug Administration. *National Evaluation System for Health Technology (NEST)*. FDA. Updated October 29, 2019. Available at: <https://www.fda.gov/about-fda/cdrh-reports/national-evaluation-system-health-technology-nest>.

coverage.²⁶ Further, CMS's 2024 Coverage with Evidence Development Guidance states that coverage associated with evidence development should be time-limited and structured to facilitate the timely generation of sufficient evidence to support a Medicare coverage determination.²⁷

At the same time, because RAPID NCDs would remain in effect until reconsidered, CMS should establish a predictable mechanism for extending RAPID coverage when sponsors are generating evidence that meaningfully addresses the evidentiary gaps identified at the time of coverage. This framework would help ensure continued beneficiary access to promising technologies while evidence generation remains ongoing and would provide greater certainty regarding the pathway from RAPID coverage to a permanent Medicare coverage determination.

Because RAPID is built upon early alignment between FDA and CMS regarding clinically meaningful outcomes for Medicare beneficiaries, the agencies are uniquely positioned to identify the key evidence gaps. Manufacturers should understand from the outset what real-world data, registry participation, longer-term follow-up, or additional clinical studies may be expected to demonstrate durability of benefit, safety, and effectiveness within the Medicare population, as well as the factors CMS will consider when determining whether an extension of RAPID coverage is warranted.

In addition, CMS should establish clear evidence-development milestones and a transparent process for reviewing post-RAPID evidence. Consistent with the 2024 CED guidance, manufacturers should understand in advance the objectives of evidence generation, the anticipated timelines, and the circumstances under which CMS may reconsider coverage. Establishing predictable review milestones specific to the RAPID pathway would provide reassurance that coverage decisions remain evidence-based while avoiding situations in which coverage continues indefinitely without updated assessment. This approach would promote accountability while preserving the certainty needed for innovators to invest in evidence generation and ensuring that Medicare beneficiaries continue to have access to technologies that demonstrate meaningful clinical benefit.

H. RAPID Coverage Pathway Prioritization

The AANS and CNS recognize that the RAPID pathway is intended to expedite Medicare coverage decisions for certain innovative technologies. However, CMS should ensure that implementation of RAPID does not inadvertently delay consideration of other technologies waiting for coverage review through existing NCD pathways.

We encourage CMS to allocate sufficient personnel, expertise, and operational resources to the RAPID program to support timely review of participating technologies while maintaining progress on pending NCD requests and other coverage activities. Establishing a dedicated expedited pathway without the appropriate corresponding resources could create bottlenecks in the coverage review process, potentially delaying beneficiary access to other clinically important technologies.

To that end, AANS and CNS recommend that CMS clarify how RAPID reviews will be prioritized relative to other coverage activities and should dedicate adequate resources to ensure that expedited review under RAPID does not come at the expense of timely consideration of other NCD matters.

²⁶ Medicare Program; Revised Process for Making National Coverage Determinations</Federal Register>, 78 Fed. Reg. 48164, 48167-68 (Aug. 7, 2013)

²⁷ Centers for Medicare & Medicaid Services, *Coverage with Evidence Development* (Aug. 7, 2024), <https://www.cms.gov/files/document/ced-guidance2024pdf.pdf>

CONCLUSION

The AANS and CNS appreciate the opportunity to comment on the RAPID Coverage Pathway notice and look forward to continued engagement with CMS on these important issues. If additional information would be helpful or questions arise regarding these comments, please contact Natalie Torentinos, MPS, Manager of Regulatory Policy for the AANS/CNS Washington Office, at ntorentinos@neurosurgery.org. Thank you for considering these recommendations and for your continued efforts to improve care for Medicare beneficiaries.

Sincerely,



E. Antonio Chiocca, MD, PhD
President
American Association of Neurological Surgeons



Martina Stippler, MD
President
Congress of Neurological Surgeons