

AMERICAN ASSOCIATION OF
NEUROLOGICAL SURGEONS

KATHLEEN T. CRAIG, *CEO*
5550 Meadowbrook Drive
Rolling Meadows, IL 60008
Phone: 888-566-AANS
Fax: 847-378-0600
info@aans.org



American
Association of
Neurological
Surgeons



Congress of
Neurological
Surgeons

CONGRESS OF
NEUROLOGICAL SURGEONS

REGINA SHUPAK, *CEO*
10 North Martingale Road, Suite 190
Schaumburg, IL 60173
Phone: 877-517-1CNS
FAX: 847-240-0804
info@cns.org

President
JOHN A. WILSON, MD
Winston-Salem, North Carolina

President
BRIAN L. HOH, MD
Gainesville, Florida

November 2, 2020

Seema Verma, MPH, Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Submitted electronically via www.regulations.gov

Subject: CMS-3372-P Medicare Program: Medicare Coverage of Innovative Technology (MCIT) and Definition of “Reasonable and Necessary”

Dear Administrator Verma:

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 of proposed rulemaking.

Medicare Coverage of Innovative Technology (MCIT) 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 particularly important for our specialty and the patients we serve. We, therefore, support Medicare coverage for breakthrough technology but 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 believe an MCIT pathway should allow for expanded access to the rapidly-evolving health technology landscape, providing for automatic temporary coverage of breakthrough products while they make their way through the permanent coverage process. We note that there may be cases where new technology is granted coverage under MCIT, but that corresponding reimbursement is not available for the physician service required to furnish or deliver the product. This would create a coverage gap that would undermine CMS’ goals and ultimately restrict beneficiaries’ access to the novel technologies the MCIT pathway is intended to support. To address this gap, we recommend that CMS align Medicare physician coverage and payment policies to ensure that the MCIT pathway increases access to innovative products.

Evidence Development

The proposed MCIT 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 not be obligated or mandated by CMS to conduct clinical studies during coverage under the proposed MCIT pathway. However, we strongly recommend that CMS incentivize manufacturers to collect and regularly report data on outcomes under the MCIT pathway to inform decision-making and treatment

recommendations. As such, we urge the agency to consider the valid scientific data provided by specialty society registries. The neurosurgery-led NeuroPoint Alliance (NPA) has worked closely with the FDA and other societies on several important initiatives to explore “real world” data sources and alternatives to costly and time-consuming randomized controlled trials. As you move forward with efforts to improve access to innovative technology for Medicare beneficiaries, we urge you to enhance the use of registry data to help bring potentially life and ability-saving medical products to patients more quickly and affordably.

Organized neurosurgery has several registries, including 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 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 efforts that will lead to better care for our patients. Therefore, we urge CMS to foster a regulatory environment that supports and encourages the use of real-world practice data to get life and ability-saving devices to patients.

Defining “Reasonable and Necessary”

CMS proposes to codify its longstanding definition of “reasonable and necessary” with modifications. An item or service could be considered “appropriate for Medicare patients” if commercial insurers cover it unless evidence supports the differences between Medicare beneficiaries and commercially insured individuals are clinically relevant. Allowing determinations of whether an item or service is “appropriate for Medicare patients” to be based on commercial coverage would expand Medicare beneficiaries’ access to new technologies, strengthen incentives for medical innovation, provide greater autonomy to physicians to exercise discretion and judgment in developing patients’ care plans, and remove unnecessary administrative burden. We also appreciate the agency’s proposal to adopt the least restrictive coverage policy for a given item or service among the commercial offerings examined. If adopted, this proposal would limit the use of utilization management tools like step therapy or prior authorization that might otherwise restrict patients’ access to a broad array of accepted medical technologies and would avoid imposing significant burdens on physician practices.

The AANS and the CNS appreciate the opportunity to provide feedback on these provisions in the MCIT pathway proposed rule. We look forward to working with you to develop effective coverage and reimbursement policies to bring critical new treatments to our patients.

Sincerely,



John A. Wilson, MD, President
American Association of Neurological Surgeons



Brian L. Hoh, MD, President
Congress of Neurological Surgeons

Staff Contact:

Catherine Jeakle Hill
Senior Manager, Regulatory Affairs
AANS/CNS Washington Office
25 Massachusetts Ave., NW
Washington, DC 20001
Phone: 202-446-2026
E-mail: chill@neurosurgery.org