AAOS
American Association of Orthopaedic Surgeons

November 2, 2020

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-3372-P
P.O. Box 8013
Baltimore, MD 21244-8013

Submitted electronically via http://www.cms.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 over 34,000 orthopaedic surgeons and residents represented by the American Association of Orthopaedic Surgeons (AAOS) and the orthopaedic specialty societies that agreed to sign on, we are thankful for the opportunity to provide comments on the Medicare Program: Medicare Coverage of Innovative Technology (MCIT) and Definition of "Reasonable and Necessary" Proposed Rule (CMS-3372-P) published in the Federal Register on September 1, 2020.

The Centers for Medicare and Medicaid Services (CMS) is proposing the voluntary MCIT pathway to afford up to four years of national Medicare coverage to newly FDA market authorized breakthrough devices. Within the proposal, CMS solicits stakeholder feedback on numerous aspects of the MCIT pathway, including the time frame for coverage, opt-in/opt-out process for manufacturers, application of the National Coverage Analysis process, and indications for use. The AAOS appreciates the ongoing efforts of the CMS to make innovative medical devices available to Medicare beneficiaries and the orthopaedic surgeons who treat them. Our recommendations are described below.

Time Frame for Coverage

In order to provide immediate national coverage for breakthrough devices, CMS proposes setting a timeframe for coverage under the MCIT pathway. The timeframe is intended to establish a limit to newness of the devices much like the existing New Technology Add-On Payment policy. CMS is asking stakeholders if an appropriate length of time for coverage under the MCIT pathway is four years from the date of FDA market approval.

The AAOS believes that four years is the **minimum** necessary time from the date of FDA market approval under the MCIT pathway. The reason is the relationship between the MCIT coverage and the existing CMS coverage mechanisms already discussed in the proposed rule. CMS notes the National Coverage Determination (NCD) process can take "9 to 12 months" as part of the rationale for the MCIT pathway coverage period,

opining that modifying existing CMS coverage determination pathways would be less consistent with Executive Order 13890. However, for sponsors, commercial success is driven by a complex process involving Medicare Administrative Contractor (MAC) Local Coverage Determinations (LCDs), possible NCDs, commercial payer coverage policies, and the attempted adoption of new technology in a complex healthcare landscape involving providers, hospitals, patients and payor stakeholders. Adoption of innovative and breakthrough technology does not necessarily happen at breakthrough pace due to these competing factors. Sponsors require time to successfully support the adoption of new technology regardless of how impactful the technology may be to patients as a breakthrough. Simultaneously, execution of the necessary studies supporting further decisions has become more difficult due to multiple factors, including COVID-19. Though CMS has noted that "from our experience with clinical studies conducted as part of an NCD, four years is approximately the amount of time it takes to complete a study", this interval is likely to lengthen.

At the conclusion of MCIT coverage, CMS believes a device will be subject to one of three possible outcomes: "(1) NCD (affirmative coverage, which may include facility or patient criteria); (2) NCD (non-coverage); or (3) MAC discretion (claim-by-claim adjudication or LCD)".[1] CMS is seeking comment on whether a National Coverage Analysis (NCA) should be performed if an LCD does not exist for a breakthrough device six months after the MCIT coverage period ends.

The AAOS supports NCA supporting an NCD whenever the evidence and resources exist. We agree that the MCIT pathway is a reasonable trigger for NCA under the circumstances described. Though the LCD mechanism has its merits, it has demerits too including the substantial heterogeneity of coverage noted by CMS within the proposed rule. Therefore, NCA remains a gold-standard mechanism supporting NCD.

Opt-In versus Opt-Out Process

Within two weeks of receiving breakthrough device designation from the FDA, CMS proposes manufacturers emailing CMS to show interest in coverage for their device through the MCIT pathway. The email box will be set up and monitored by the CMS Coverage and Analysis Group, who will provide guidance and resources to manufacturers. CMS is interested in stakeholder feedback on whether an opt-out process would be less burdensome to manufacturers than the proposed opt-in process. They also request feedback on the process for how a manufacturer could opt-in/out and if a manufacturer should be allowed to opt-in after previously opting out of the MCIT pathways.

The AAOS feels that an opt-out process is likely to be less burdensome for most sponsors pursuing breakthrough designation for orthopaedic devices. A similar email process to request opt-out could be utilized.

Expansion of pathway to non-device products

As proposed, only devices would be eligible for coverage through the MCIT pathway. In recognition of the potential applicability of the pathway to other medical products, CMS is soliciting comments on whether the MCIT pathway should also apply to drugs, diagnostics, and/or biologics subject to breakthrough or expedited FDA approval mechanisms.

The AAOS feels strongly that the MCIT pathway should also apply to drugs, diagnostics, and/or biologics subject to expedited FDA approval mechanisms for three complementary reasons. First, many innovations in

[1] Medicare Program; Medicare Coverage of Innovative Technology (MCIT) and Definition of "Reasonable and Necessary", 80 Fed. Reg. 54327-54339 (proposed September 1, 2020) (to be codified at 42 CFR Part 405)

musculoskeletal patient care have historically been surgical and related to medical devices; however, the current and future trends point towards biologics in a broader sense. Biologics could be drugs regulated by Center for Drug Evaluation and Research (CDER) or human cells, tissues, and cellular and tissue-based products (HCT/P's) regulated by the Center for Biologics Evaluation and Research (CBER). Simultaneously, combination products have become the new normal. Several of the most important orthopaedic "biologics" are drug/device combinations regulated by the Center for Devices and Radiological Health (CDRH) as lead regulator, but these distinctions are likely to become increasingly blurred. Finally, the impetus behind expedited FDA approval mechanisms is common across musculoskeletal disease as few non-surgical breakthroughs have occurred for major disease such as osteoarthritis within the past regulatory framework prior to expedited reviews.

Off-Label Indications

Though CMS acknowledges that use of the device for a condition or population that is not FDA authorized will not be covered in the Proposed Rule, they seek stakeholder feedback on whether "off-label" indications should be covered and what evidence should be required to support these coverage determinations under the MCIT program.

Inclusion of "off-label" indications raises certain safety concerns. The approval or clearance of these devices is predicated on specific indications so that a "reasonable assurance of safety and effectiveness" can be determined. Specifically, with the Breakthrough Devices program the FDA will accept "greater uncertainty in the benefit-risk profile under appropriate circumstances" per their final guidance document. [2] This is warranted considering the nature and intent of these devices, however, expansion into "off-label" usage leads to increased uncertainty and unpredictability. This was seen with Infuse, which became a multibillion-dollar device, and according to some reports, 85% of its usage was off label.[3] After years of rapid market growth, significant safety concerns arose, and ultimately a congressional hearing on it was performed.

The AAOS firmly believes that "off-label" indications **should not** be covered. Instead, the sponsor should seek to provide adequate evidence to support a label sufficiently broad to match the evidence-based indications for the device under the existing FDA Breakthrough Device review program. By doing so, the sponsor would activate consideration of MCIT coverage for the appropriate patient population and indications reflected in the sufficiently broad breakthrough device labeling.

Thank you for your time and attention to the concerns of the American Association of Orthopaedic Surgeons (AAOS) on the important proposals made in the Medicare Coverage of Innovative Technology (MCIT) and Definition of "Reasonable and Necessary" Proposed Rule. The AAOS looks forward to working closely with CMS on further improving access to innovative medical technologies, and to enhancing the care of musculoskeletal patients in the United States. Should you have questions on any of the above comments, please do not hesitate to contact Shreyasi Deb, PhD, MBA, AAOS Office of Government Relations at deb@aaos.org.

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[2] US Food and Drug Administration. (2018, December 18). *Breakthrough Devices Program Guidance for Industry and Food and Drug Administration Staff.* Retrieved from https://www.fda.gov/media/108135/download

[3] Spencer, J. (2015, May 2). *Appeals court rejects case claiming Medtronic's Infuse device harmed patient*. Star Tribune. Retrieved from https://www.startribune.com/appeals-court-rejects-case-claiming-medtronic-s-infuse-device-harmed-patient/302227781/

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Sincerely,

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American Association for Hand Surgery

American Orthopaedic Foot & Ankle Society

American Orthopaedic Society for Sports Medicine

American Shoulder and Elbow Surgeons

American Society for Surgery of the Hand

Arthroscopy Association of North America

Musculoskeletal Tumor Society

Pediatric Orthopaedic Society of North America

Ruth Jackson Orthopaedic Society

Scoliosis Research Society