

**VIA ELECTRONIC SUBMISSION**

Liz Richter  
Acting Administrator  
Centers for Medicare and Medicaid Services  
7500 Security Boulevard  
Baltimore, MD 21244

April 16, 2021

**RE: Medicare Coverage of Innovative Technology (MCIT) and Definition of “Reasonable and Necessary” (CMS-3372-IFC)**

Dear Administrator Richter,

The Robert J. Margolis, MD Center for Health Policy at Duke University (the Duke-Margolis Center) appreciates the opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) interim final rule on the Medicare Coverage of Innovative Technology (MCIT) pathway and the definition of “Reasonable and Necessary”.

The Duke-Margolis Center analyzes evidence across the spectrum of health policy and supports the triple aim of better care, better health, and lower cost. A core mission is to increase the value of biomedical innovation to patients. Our experts are engaged in policy research and development efforts to improve the processes and infrastructure needed at CMS to ensure efficient access to new and innovative technologies including challenges related to coding, coverage, and payment.

Our comments are informed by the Center’s independent analyses of the final rule, the interim final rule, and recent convenings with a broad set of stakeholders. Duke-Margolis Center remains supportive of the proposed rule’s provisions to ensure timely access to breakthrough device therapies. While we support the intent of the MCIT pathway, we are concerned that the finalized rule, as written, will still have challenges in advancing broad and appropriate access to novel therapies during and after the proposed MCIT coverage period. We remain concerned that the provisions in the finalized MCIT pathway will present challenges in access for patients in the short and long term. We outline a series of recommendations to address these challenges and a framework for operationalizing the MCIT program to address CMS’s stated concerns in the interim final rule. Our comments describe opportunities to ensure the MCIT pathway succeeds in its intended aim of providing Medicare patients faster and more effective access to innovative medical devices.

Our summary of recommendations to the interim final rule prompts are the following:

1. **Operational Issues:** We recommend CMS establish provisional codes and payment for breakthrough devices as part of the MCIT pathway to ensure availability of codes and payment at the time of FDA approval.
2. **Overlapping Rules:** We recommend that CMS formalize an operational framework with a predictable timeline to conduct evidence reviews, develop benefit category determinations, codes, and payment.
3. **Breakthrough Device Volume:** We recommend CMS consider mechanisms to increase resources through dedicated appropriations or a statutory user fee program.

4. **Medicare Patient Benefit Protection and Other Issues:** We recommend that MCIT coverage is offered to the technological class of the breakthrough device including device iterations and follow-on competitive devices. We recommend that CMS direct an evidence review at the end of MCIT that will determine which coverage route would be most appropriate to ensure the most benefit to Medicare patients.
5. **Public Request for a more Detailed Proposal:** We recommend CMS undergo a separate rule making process regarding the provision of codifying “reasonable and necessary” into regulation and adopting commercial coverage policies.
6. **Adequacy of Rulemaking Process:** We recommend that CMS amend provisions of the January 2021 rule. We also recommend that CMS delay implementation of MCIT while they go through a separate rule making process on codifying “reasonable and necessary” into regulation.

We believe that the success of the MCIT pathway depends on the extent to which CMS can guide evidence development to ensure long term coverage for the breakthrough devices. We believe CMS are uniquely positioned to provide this guidance. We also recommend guardrails to ensure that the MCIT coverage period doesn’t lead to patient harm or disrupt the market. Our comments below detail these recommendations and address CMS’s stated concerns in the interim final rule.

#### *I. Operational Issues*

As CMS note in the interim final rule, the final rule does not directly address operational issues for newly approved devices. Following Food and Drug Administration (FDA) approval, market access for new devices depends on coding, coverage, and payment. The MCIT pathway obviates the time gap between FDA approval and coverage. It does not address the time gaps of establishing coding and payment. The effective date for a new code and payment for a new device can take anywhere from 6 to 24 months from the time of application depending on the complexity of the technology, its clinical evidence base, and benefit category. Furthermore, the majority of code and payment applications require FDA approval as application criteria. For certain codes, application requirements include peer reviewed clinical literature which may not be available for breakthrough devices.

In the final rule, CMS state that the manufacturer’s notification to opt-in to the MCIT pathway would alert CMS to point to resources for coding and payment. They suggest that the transparent process for MCIT would assist manufacturers in developing launch plans earlier so that the four years of coverage could be used more efficiently. Further, CMS recognize that coding and payment may not be available at the time of FDA approval and offer flexibility in the time to start MCIT coverage.

Starting MCIT coverage two years following FDA approval offers manufacturers flexibility to establish coding, payment, and data collection infrastructure. However, it does not meet the goal of the Executive Order (EO) to streamline approval, coverage, and coding processes.<sup>1</sup> Further, it is unlikely that in the span of two years of MCIT coverage, there will be sufficient data collected to meet the evidence thresholds for long term Medicare national coverage. Manufacturers that wait two years to begin MCIT coverage to establish coding and payment will have greater risk of non-coverage or inconsistent coverage across Medicare Administrative Contractor (MAC) jurisdictions.

**We recommend that CMS establish temporary codes and provisional payment for devices that are part of the MCIT pathway to ensure availability of coding and payment at the time of FDA approval. One**

option is for CMS to temporarily waive the requirement for FDA clearance in the HCPCS Level II application for breakthrough devices opted in the MCIT pathway. The temporary code would be valid from the time of FDA approval to the end of the MCIT coverage. During the time of MCIT coverage, manufacturers will continue to pursue permanent codes subject to the regular application requirements. Accordingly, CMS can assign provisional payment amounts based on the information provided about the breakthrough device. Temporary codes will allow providers to issue billing claims which can also inform subsequent payment determinations for permanent codes.

## *II. Overlapping Rules*

In the interim final rule, CMS reference a November 4, 2020 proposed rule that outlined a process to establish benefit category determinations for Durable Medical Equipment Prosthetics and Orthotic Supplies (DMEPOS).<sup>2</sup> CMS solicit comments on whether commenters would have raised additional concerns had there been an opportunity to comment on the DMEPOS and MCIT proposed rules at the same time. We believe an MCIT operational framework can be modeled after the process outlined in the DEMPOS proposed rule and we appreciate the opportunity to comment on the interactions of both rules.

The DEMPOS rule proposes to codify in regulation procedure by which benefit category, coding, and payment determinations are made for new DME items and services. CMS proposed to leverage the HCPCS II code bi-annual application cycle for this process, while acknowledging that public consultations may extend to subsequent application cycles for complex technologies that require more in-depth evidence reviews.

The advantages to this proposed process are that it sets expectations to applicants about the time required to ensure patient access to new DMEPOS items and services. Further, it establishes a process by which CMS can make decisions on elements important to ensure patient access. This process presents a model that can be adapted to facilitate similar evaluations for breakthrough devices in the MCIT pathway. We outline a description of this adapted model which we refer to as the MCIT operational framework:

1. Defined time in which a manufacturer opts-in to the MCIT pathway. We recommend that manufacturers notify CMS after finalizing a Clinical Protocol Agreement with the FDA.
  - a. The Clinical Protocol Agreement is an agreement between the FDA and a manufacturer on the protocol of the IDE clinical trial for the breakthrough device, a step unique to the BDP. This agreement will provide CMS with preliminary information with which it can begin to assess appropriate the benefit category for the breakthrough device.
2. CMS activities following the opt-in notification:
  - a. Evaluation of the breakthrough device and any preliminary clinical evidence
  - b. Evaluation of the clinical protocol agreement to elucidate expected regulatory review time and expected benefit category. During this this step, CMS can engage with the FDA and the manufacturer to undertake an assessment of the preliminary clinical evidence and clinical context of the breakthrough device. This initial analysis will allow CMS to inform resources and capacity planning to operationalize MCIT coverage.
3. Defined points *during the pre-IDE application phase* in which CMS can provide guidance on how to addresses key evidence concerns for Medicare patients in the clinical evidence plan.

CMS can expand existing interactions with manufacturers that request Medicare coverage for IDE studies. We can identify two possible meetings between CMS and a manufacturer that requests Medicare coverage for their IDE study:

- a. In the first meeting, CMS can provide feedback on the preliminary study design to ensure that outcomes relevant to the Medicare population are being addressed. CMS's preliminary evidence review following the opt-in notification can inform these discussions.
  - b. A second meeting could focus on the temporary billing codes to facilitate tracking and billing *during* the IDE trial and subsequent MCIT coverage period.
  - c. At this point, the manufacturer will have received FDA approval for the IDE trial and submitted a formal request for Medicare coverage for the IDE trial.
4. *IDE trial results submission*: We recommend that manufacturers share IDE trial results with CMS at the same time they share them with FDA. FDA can host joint agency meetings. This will allow CMS to provide guidance on evidence development during the MCIT period. CMS can also determine if they need to include guardrails through data collection based on the safety profile of the breakthrough device.
  5. *MCIT coverage comment period*: As we detail below, we recommend CMS issue coverage to the technological class of the breakthrough device. This will prevent shutting out competition during the four years of MCIT coverage and having inconsistent coverage for follow-on competitive devices post-MCIT. CMS can undertake similar actions as it does with traditional coverage pathways and issue proposed decision memos on the scope of coverage before the start of the MCIT period. CMS can outline the scope of coverage for the technological class, detail expected evidence plans, and, as needed, list data to be collected to ensure patient safety and benefit. A public comment period will give stakeholders, including specialty societies and patient advocates, an opportunity to identify evidence questions most relevant to them.
  6. Defined junctures *during the MCIT period* in which CMS can provide guidance on ongoing evidence development. CMS can request data reports, similar to FDA post market surveillance reports, that will indicate if evidence being collected is sufficient to satisfy criteria for "reasonable and necessary" for long term coverage, and whether coverage determination will be better suited at the national or local level through MACs. Moreover, this data will inform CMS's guidance to manufacturers on when to request a coverage determination to ensure a seamless transition of coverage after MCIT.

The MCIT pathway gives manufacturers protected coverage during which they have an opportunity to develop evidence that meets Medicare evidentiary standards, which include data on long-term durability and subpopulation effects. The pathway assumes regular and sustained engagement between CMS and the manufacturer, which can be formalized in this operational framework. This framework can direct CMS and manufacturer engagement at regular intervals:

- the pre-approval phase to inform clinical study design;
- the MCIT period to support evidence generation; and,
- at the end of MCIT to support long-term coverage assessments.

The framework defines milestones for CMS to evaluate whether evidence development is on track. Milestones can be aligned with critical junctures of the regulatory pathways for breakthrough devices. **We recommend that CMS formalize an operational framework with predictable timelines to conduct evidence reviews and develop benefit category determinations, coding, and payment.**

Given the opt-in design of the MCIT pathway, a formal operational framework as described will be beneficial in establishing transparency, time, and resource expectations for both manufacturers and CMS. As CMS gain experience in the MCIT pathway, the framework can establish accountability and identify ways to improve performance.

### *III. Impact of Breakthrough Device Volumes*

In the interim final rule, CMS solicit comments on whether the assumption about the potential volume of breakthrough designations was flawed such that the public did not have meaningful opportunity to comment. We note that breakthrough designation is proprietary and manufacturers may opt to withhold this information. It is unlikely that the public can be aware of the scope of the program at any given time unless the FDA shares aggregated information. As such, we do not think CMS's assessment was flawed. However, the growing breakthrough device volume underscores the need for CMS to engage with the FDA on a regular basis to plan and allocate resources to support the MCIT pathway and downstream coverage assessments.

The FDA's Breakthrough Devices Program (BDP) has grown significantly since it was first established in 2016. Their announcement of over 400 breakthrough designations as of February 2021 indicates almost a 100% increase from the total designations between December 2016-Janary 2020.<sup>3</sup> We expect that the MCIT coverage pathway will further motivate technological development such that the BDP will continue to grow. We note that not all breakthrough devices will be eligible for MCIT based on their benefit category. However, given the CMS resources required for the MCIT program, CMS will benefit from periodic updates from the FDA on the BDP. These updates can aggregate the breakthrough designations by clinical area. These updates can inform CMS in how best to address evidence questions relevant for Medicare patients, which in turn, can inform evidence assessments in the pre-MCIT phase.

#### Breakthrough Technology Coverage Forum

Periodic updates from the FDA on aggregate breakthrough device designations present an opportunity for CMS to engage with stakeholders to inform preliminary evidence assessments. Specifically, CMS could engage with manufacturers, clinicians, specialty groups, and other stakeholders that will benefit from MCIT coverage. The focus would not be product specific, but rather clinical areas of expected innovation. CMS can have directed but nonbinding discussions on what are the key evidence questions for Medicare patients that can inform evidence development.

CMS can promote effective use of breakthrough devices absent a broad clinical evidence base through informed guidance on evidence generation. This forum will increase CMS's understanding of the breakthrough device pipeline. CMS will also be better positioned to develop guidance on post-market evidence as well as the appropriate means to generate the evidence. CMS guidance on post-market evidence could be similar as the FDA guidance for industry and FDA staff on regulatory issues for medical devices that inform clinical development. Further, these preliminary discussions can address how to generate data to make data collection efforts least burdensome, efficient and informative. Recommendations from these forums will guide evidence reviews during in the pre-MCIT coverage phase and enable more directed discussions between CMS and manufacturers. By having FDA participate in these forums, it will allow manufacturers to consider how to evaluate outcomes within the IDE clinical trial and post marketing requirements.

One option to do this is by expanding the scope of Medicare Evidence Development and Coverage Advisory Committee (MEDCAC). MEDCAC already has the directives to perform horizon scanning to help identify technologies that may be appropriate for Medicare coverage.<sup>4</sup> MEDCAC can expand this work by assessing the breakthrough device pipeline and conducting preliminary assessments. Importantly, the MEDCAC structure of appointed members would not further constraint CMS resources to perform these functions.

This coverage forum, in conjunction with the MCIT operational framework can increase CMS's engagement with manufacturers, FDA, and other relevant stakeholders. It can support CMS partnerships with specialty societies and other organizations involved in data collection can further inform evidence development in different clinical areas.

#### Increasing CMS Resources to Support MCIT Coverage Activities

Ensuring CMS has adequate resources and capacity to engage with manufacturers during the MCIT process will be crucial to the success of the MCIT pathway. The final MCIT rule already committed CMS's time, capacity, and resources to fulfil the goals of the MCIT pathway. Stakeholders are concerned that CMS is already resource constrained and may not be able to fulfil the expectations. Over the past decade, CMS resources in areas related to new technology and access have declined.<sup>5</sup> As noted in the interim final rule, this mismatch will be exacerbated by the growing number of therapies in the BDP. Programs like the MCIT pathway are likely to generate manufacturer interest in developing breakthrough therapies.

In the short-term, CMS could rely on existing interactions to coordinate with FDA and manufacturers. The operational framework is based on existing points of contact between CMS and manufacturers that can be used to fulfill expectations for MCIT. CMS may also leverage existing collaboration with the FDA for subspecialty expertise to inform evidence development. However, short term considerations may not be sufficient for long-term sustained success for this pathway. As the pipeline of breakthrough therapies grows, existing resources and mechanisms may not be sufficient. CMS will need medical officers with subject matter expertise, and a greater number of personnel to manage operational elements of MCIT and downstream coverage assessments. Coverage forums through MEDCAC may inform evidence assessments. However, CMS should consider further steps within its administrative authority to make such personnel shifts to support all MCIT activities.

Beyond that, there is a need for collaborative action to provide increased resources. Congressional appropriations and dedicated user fees have driven the FDA's substantial progress in supporting breakthrough innovation. Since 2002, the FDA has had the authority to collect user fees from device manufacturers to help increase the efficiency of its regulatory processes and reduce the time to bring safe and effective medical devices to market through the Medical Device User Fee and Modernization Act (MDUFMA).<sup>6</sup> **We recommend CMS consider similar mechanisms to increase resources through dedicated appropriations or a statutory user fee program** to fulfil activities related to MCIT and other coverage pathways that are critical for innovative technologies.

#### IV. Medicare Patient Benefit & Protection

The EO that formed the basis of the MCIT pathway also included the directive to make coverage of breakthrough devices widely available, consistent with the principles of market-based policies, patient safety, and value.

There are two revisions to the final rule that appear to be contrary to the EO directives. The first revision was about extending MCIT coverage to device iterations that were submitted as supplements under the original Premarket Approval Application (PMA). Breakthrough devices represent rapid innovation, not just in part of one manufacturer. Breakthrough devices, especially those in the de novo and PMA tracks establish regulatory standards and characteristics by which follow-on devices are evaluated. It is expected that follow-on technologies will receive market approval after the breakthrough technology. Device iterations or similar devices can be submitted for FDA approval outside the original PMA after FDA approval of the original breakthrough device. For example, in 2011, the FDA approved the Sapien transcatheter heart valve for transcatheter aortic valve replacement. This technology had received breakthrough designation.<sup>7</sup> Within four years there were two product iterations under the original PMA, one competitive follow-on device with a subsequent iteration, and five label expansions for both technologies.<sup>8</sup>

Extending MCIT coverage only to device iterations approved as supplements to a PMA will create an unfair advantage to a single manufacturer and will restrict competition during MCIT coverage. Further, if the original device fails to develop adequate data, the entire technological class will be at a disadvantage until a subsequent device can undergo traditional coverage assessments. This creates the risk of disrupting the market for follow on competitive devices. **We recommend that CMS extend MCIT coverage to the technological class of the breakthrough device, and include device iterations and follow-on devices.**

A second revision to the final rule was the terms in which MCIT coverage sunsets. The revised MCIT policy no longer included the terms that CMS will automatically open a national coverage determination (NCD) within six months of the end of the MCIT period absent an open local coverage determination (LCD) request. The revised policy relies on the manufacturer to select a permanent coverage route, with the default option of claim by claim adjudication by MACs. This revision may result in uneven coverage across MAC jurisdictions, which can mean uneven access for Medicare patients across the US. Also, for devices paid through bundled payments, this policy can result in coverage and payment for a technology that may not have met reasonable and necessary thresholds, which can result in Medicare waste or even patient harm. **We recommend that CMS direct an evidence review prior to the end of MCIT to inform manufacturers which coverage route would be most appropriate to ensure the most benefit to Medicare patients.** Without this evidence review, manufacturers will not be motivated to develop evidence during the MCIT period, which is contrary to the intent of the pathway. CMS can inform manufacturers on *when* it would be most appropriate to go through the coverage route best suited for the device.

The EO also highlights the principles of patient safety and value. In the interim final rule, CMS solicit comments on whether the revisions in final rule adequately addressed the public's concern of safety and clinical benefit to the Medicare population.

The BDP represents an expedited approval pathway on the basis of preliminary clinical data. Breakthrough devices are often approved on short-term effectiveness surrogate endpoints which may not be indicative

of device performance on clinical outcomes.<sup>3</sup> Further, the FDA has indicated that for breakthrough devices, they will accept greater uncertainty on the risks and benefits during pre-market review under the condition that manufacturers meet post-market controls and studies.<sup>3</sup> Breakthrough devices are treated as such for the potential benefits in treatment outcomes and addressing unmet needs. However, it cannot be understated that at FDA approval there is great uncertainty about the clinical outcomes and treatment benefits. These evidence questions are meant to be addressed in the post market setting with FDA oversight.

The final rule gives CMS the authority to remove a breakthrough device from MCIT following a medical safety communication or warning letter from FDA or if the FDA revokes market authorization. We note that safety warnings and letters have been issued for products that have been deemed “reasonable and necessary” by Medicare. Further, safety concerns can be due to many issues including operator training, batch manufacturing issues, etc. We believe there are alternative ways to ensure the safety and clinical benefit of Medicare patients through CMS directed actions during the pre-MCIT phase, during MCIT coverage, and post-MCIT coverage.

#### Ensuring Safety and Benefit during the Pre-MCIT Phase:

Evidence assessments through the breakthrough device coverage forums and the MCIT operational framework allow CMS to set guardrails or criteria by which they can ensure safety and outcomes of Medicare patients. Evidence reviews during pre-MCIT phases in can include safety assessments based on clinical trial patient selection criteria, expected co-morbidities, device mechanism of action and risk profile. In addition, the operational framework can include discussions of safety ahead of coverage assessments. The final rule outlines three activities to ensure safety of patients:

- 1) CMS will indicate publicly available clinical evidence related to the device,
- 2) CMS will engage with stakeholders – notably specialty societies with expert knowledge of the available treatments, and
- 3) CMS will coordinate with FDA to receive regular feedback on important safety signals and concerns.

We agree with all these safety measures and encourage CMS to formalize them in the operational framework described above. The evidence assessments during the pre-MCIT phase afford CMS and stakeholders the opportunity to evaluate two key questions:

- 1) Which outcomes are most relevant to meet Medicare’s reasonable and necessary evidence threshold, and
- 2) What data collection model would best address the evidence questions.

Pre-MCIT evidence assessments in the coverage forum can be an opportunity to engage with health technology companies that develop data collection models that incorporate real world data sources and facilitate data linkages. These mechanisms can ensure that key outcomes are captured with minimal provider burden. CMS, by including data collection considerations in preliminary evidence reviews, can encourage and drive investments in data collection methodologies that minimize provider and administrative burdens.

#### Ensuring Safety and Benefit during MCIT Coverage:

The MCIT pathway is designed as a bridge between FDA approval and Medicare coverage that allows manufacturers to fill the gaps in evidence to satisfy the standard for “reasonable and necessary” in order

to secure favorable coverage. The success of the MCIT pathway depends on the extent to which manufacturers and other stakeholders can develop evidence during the MCIT coverage period. CMS can ensure success of the pathway by guiding and directing evidence generation before and during the MCIT coverage period. Through the coverage forums and operational framework, CMS has many points of engagement with manufacturers and stakeholders to identify their evidence questions that need to be addressed during the MCIT coverage period. However, as detailed above, CMS also has a role in upholding safety and benefit of Medicare patients. CMS can uphold the safety and benefit of Medicare patients during the MCIT period by ensuring quality of care, and, should the need arise, evaluate effectiveness and treatment outcomes from breakthrough devices with higher risk profiles. We recommend that during the pre-MCIT evidence assessments, CMS evaluate how they can ensure safety and benefit of Medicare patients during the MCIT coverage period. Specifically, CMS's review of preliminary clinical evidence, manufacturers' evidence development plans, and stakeholder input can inform their assessment of what guardrails can be included during MCIT coverage to ensure patient safety and benefit.

Since 2006, CMS have used its authority under Section 1862(a)(1) (A) and Section 1862(a)(1) (E) of the Social Security Act (the Act) to require data collection as a condition of coverage for certain medical products. Breakthrough devices by virtue of their designation, will be provisionally treated as "reasonable and necessary" under Section 1862(a)(1)(A) of the Act under the MCIT pathway. Accordingly, under this section of the Act CMS is able to require data collection on patient criteria. This form of data collection can be used to ensure quality of care by setting patient, operator or facility criteria.

For breakthrough devices with higher safety risk profiles, CMS can consider alternative means to issue coverage while maintaining guardrails to ensure patient safety and benefit. CMS can still provide coverage through section 1862(a)(1)(E) of the Act. By invoking this section of the Act, CMS can apply their longstanding Coverage with Evidence Development (CED) policy to evaluate effectiveness and outcomes of breakthrough devices on Medicare patients. The CED policy was developed to provide access to technology that had insufficient evidence to satisfy criteria for Medicare coverage and thus has the same goals and objectives of the MCIT policy. In these cases, CMS can issue a CED policy for a defined term, with the intent of generating evidence to meet the "reasonable and necessary" standard for Medicare coverage.

We note that not all breakthrough devices may require data collection or formal evidence development through a CED policy. However, given the clinical uncertainties of breakthrough devices, **we recommend CMS consider data collection through Section 1862(a)(1) (A) and Section 1862(a)(1) (E) as options to extend access to patients while ensuring their safety and benefit from higher risk devices.**

#### Ensuring Safety and Benefit Post-MCIT

As detailed above, we recommend CMS undertake an evidence review prior to the end of the MCIT period for the breakthrough device to determine whether there is sufficient evidence to meet the "reasonable and necessary" standard for Medicare coverage. This will ensure patient safety and benefit, and avoid Medicare waste. This juncture presents another opportunity to evaluate relevant safety concerns from the FDA and other stakeholders. For devices with outstanding evidence questions post-MCIT that fail to meet the "reasonable and necessary" standards codified in regulations, CMS can maintain coverage under section 1862(a)(1)(E) with continued evidence development.

## V. *Public Requests for a More Detailed Proposal*

### Codifying “Reasonable and Necessary” into Regulation

CMS finalized the proposal to codify into regulation the long-standing sub-regulatory definition of “reasonable and necessary”. It will be important for CMS to clarify *how* CMS or MACs will determine the threshold for “reasonable and necessary” for breakthrough devices, which may necessitate regulatory guidance on what type of evidence supports a “reasonable and necessary” determination.

CMS can develop guidance on the evidentiary threshold for technological classes of breakthrough devices from discussions in the coverage forums described above. Following these coverage forums, CMS can release guidance on key evidence questions or areas that should be addressed to satisfy formal definitions of “reasonable and necessary”. Manufacturers can then incorporate CMS’s guidance about reasonable and necessary evidence in their clinical trial plans.

Our comments about codifying “reasonable and necessary” into regulation are limited in scope to breakthrough devices. We note, however, that codifying “reasonable and necessary” into regulation has far reaching consequences beyond breakthrough devices. In the interim final rule, CMS requests comment on whether the public had opportunity to comment on the proposed rule and whether interested parties had fair opportunities to present contrary facts and arguments to improve the rule. We believe that a separate rule making process will garner greater opportunities for the public to comment on this significant proposal. **We recommend CMS undergo a separate rule making process regarding its proposal of codifying the Reasonable and Necessary definition into regulation.**

### Adopting Commercial Coverage Policies

The final rule gives provides for the review of commercial insurance policies in the assessment of the “appropriateness” criterion of the “reasonable and necessary” definition. Specifically, CMS proposes to allow for a commercial market analysis “if an item/service *fails* to fulfil the existing factor (3) criteria defining appropriate for Medicare patients”.

In the interim final rule, CMS solicits comment on whether the public had opportunity to comment on the proposed rule and whether interested parties had fair opportunities to present contrary facts and arguments to improve the rule. CMS indicated that they would move forward with the provision, and would accept public input on their methodology. We appreciate CMS’s willingness for public input and postpone implementation of this provision at this time. However, we note that CMS did not directly address commenters concerns regarding the implications of adopting any commercial coverage policy.

Commenters expressed concern with the prospect of applying private payer policies to Medicare patients as the respective patient populations are distinct. Commenters also expressed concerns that by considering “appropriate” an item or a service that failed to meet established criteria defining “appropriate” can result in two tiers of Medicare coverage:

- First tier: items and services that did not fail the established criteria defining appropriate, and

- Second tier: items and services that failed to meet the established criteria, but are covered in commercial policies.

There are many considerations to evaluating commercial coverage policies. In addition to a draft methodology of how CMS will evaluate commercial policies for certain items and services, we suggested that there should be an equal, if not greater, consideration for how plans

- inform coverage policies,
- determine what is medically necessary,
- conduct their evidence reviews and technology assessments, and
- determine the scope, breadth, and depth of coverage.

These processes are heterogeneous and not always transparent across the private payer market. There is a high degree of variability in how plans cover medical interventions. A study by Chambers and colleagues suggest that private plans' coverage for Medicare covered items vary and can be more or less restrictive than in Medicare.<sup>9</sup> The evidentiary threshold to determine a coverage policy also varies considerably across plans.<sup>10</sup> Further, unless plans post their coverage policies publicly, the information is sensitive and may not be easily accessible. There might be even less coverage for technology that is perceived as emerging. Private payers may also consider cost effectiveness data to inform their coverage decisions and have medical management measures, such as step therapy and prior authorization, built into coverage. These implementation conditions differ from Medicare and can complicate the use of private payer policies for Medicare patients.

As we detailed earlier in our comments about codifying “reasonable and necessary,” the impact of this provision will have far reaching impact beyond breakthrough devices. We believe that a separate rule making process will garner greater opportunities for the public to comment on this significant proposal. **We recommend CMS undergo a separate rulemaking process regarding the Reasonable and Necessary definition, including the proposal to evaluate commercial policies for the purposes of informing Medicare coverage.**

## VI. *Adequacy of Rulemaking Process*

In the interim final rule, CMS requests comments on whether there were any procedural issues with the rulemaking process. They also ask if the January 2021 MCIT rule be allowed to go into effect, amended, rescinded, or further delayed pending review by CMS. We find that there were no procedural issues with the rule making process.

**We recommend that CMS amend provisions of the January 2021 rule. We also recommend that CMS delay implementation of MCIT while they go through a separate rule making process on codifying “reasonable and necessary” into regulation. During this delay, CMS can address the operational concerns of the MCIT pathway that remain outstanding.** The MCIT pathway presents an opportunity to ensure rapid patient access to breakthrough devices which can have meaningful impacts on patient care and outcomes. However, the success of this pathway depends on the extent to which it can be operationalized and ensure the safety and health outcomes of Medicare patients.

## Conclusion

The MCIT pathway has the potential to provide broad and timely access to innovative medical devices. Our recommendations describe opportunities in which CMS can succeed in the intended goals. The Duke-Margolis Center appreciates CMS's consideration of our comments, and the Administration's support for advancing high-value, affordable healthcare. We and our colleagues would be pleased to provide more information on these issues if that would be helpful.

Sincerely,

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<sup>1</sup> Executive Order on Protecting and Improving Medicare for Our Nation's Seniors. E.O. 13890 of Oct 3, 2019. <https://www.federalregister.gov/documents/2019/10/08/2019-22073/protecting-and-improving-medicare-for-our-nations-seniors>. Accessed 4/16/2021

<sup>2</sup> Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Policy Issues and Level II of the Healthcare Common Procedure Coding System (HCPCS). 85 FR 70358.

<sup>3</sup> Johnston, J.L., Dhruva, S.S., Ross, J.S. et al. Early experience with the FDA's Breakthrough Devices program. *Nat Biotechnol* 38, 933–938 (2020). <https://doi.org/10.1038/s41587-020-0636-7>

<sup>4</sup> CMS. Factors CMS considers in referring topics to the Medicare Evidence Development and Coverage Advisory Committee. 2006. Accessed 4/10/2021. <https://www.cms.gov/medicare-coverage-database/details/medicare-coverage-document-details.aspx?MCDId=10>

<sup>5</sup> "Access For 21st Century Cures: Updating Medicare's Approach To Coverage And Payment," Health Affairs Blog, December 18, 2019. DOI: 10.1377/hblog20191217.27121

<sup>6</sup> Medical Device User Fee Amendments. <https://www.fda.gov/industry/medical-device-user-fee-amendments-mdufa/background-mdufma> Accessed 10/28/2020

<sup>7</sup> Summary of Safety and Effectiveness Data. [https://www.accessdata.fda.gov/cdrh\\_docs/pdf11/P110021b.pdf](https://www.accessdata.fda.gov/cdrh_docs/pdf11/P110021b.pdf)

<sup>8</sup> Proposed Decision Memo for Transcatheter Aortic Valve Replacement (TAVR) (CAG-00430R). CMS. March 16, 2019. Accessed 11/2/2020

<sup>9</sup> Chambers J, Chenoweth M, et al. Private Payers Disagree With Medicare Over Medical Device Coverage About Half The Time. *Health Affairs* 2015 34:8, 1376-1382

<sup>10</sup> Chambers J, Chenoweth M, and Neumann P. Mapping US Commercial Payers' Coverage Policies for Medical Interventions. *Am J Manag Care*. 2016;22(9):e323-e328