

VIA ELECTRONIC SUBMISSION

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Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

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

Dear Ms. Syrek-Jensen,

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

The Duke-Margolis Center generates and analyzes evidence across the spectrum of health policy and supports the triple aim of better care, better health, and lower cost. A core mission of the Center is to focus on increasing the value of biomedical innovation to patients. Center 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 below describe opportunities to ensure the proposed MCIT pathway succeeds in its intended aim of providing Medicare beneficiaries faster and more effective access to innovative medical devices. Our comments are informed by the Center’s independent analyses of the proposed rule, and recent convenings with a broad set of stakeholders. Duke-Margolis is broadly supportive of the proposed rule’s provisions to ensure access to breakthrough device therapies. This rule is a noteworthy step in advancing goals of minimizing coverage gaps and uncertain access for novel technologies from the time of market approval. While we support the intent, Duke-Margolis is concerned that the proposed rule, as written, will have challenges in advancing broad and appropriate access to novel therapies during and after the proposed MCIT period. We outline a series of recommendations to address these challenges, as well as a framework for operationalizing the MCIT program. We also propose regulatory alternatives that include evidence generation components that can ensure long-term sustained access to breakthrough devices.

Our comments are summarized below.

In order to address potential implementation challenges of the proposed MCIT pathway we recommend CMS:

- 1) Include follow-on devices within the MCIT coverage terms.
- 2) Advise manufacturers on how to align requests for new codes and pass through payments prior to the start of the MCIT period.

- 3) Establish a cross-division process within the Agency to assure coding and payment are addressed with coverage in a comprehensive way.
- 4) Provide guidance on what evidence will be evaluated for a coverage determination after the MCIT period.
- 5) Provide guidance on when manufacturers should apply for long-term coverage during the MCIT period to ensure a seamless transition without any gaps in coverage and access.
- 6) Engage with manufacturers during the MCIT period as evidence is being developed to guide and inform downstream coverage assessments, including whether to pursue local or a national determination.
- 7) Establish a framework or standard operating procedures of the MCIT pathway.

In order to ensure the success of the MCIT pathway, and long-term access to breakthrough devices, we recommend CMS:

- 1) Include a clinical evidence development component to the proposed MCIT pathway.
- 2) Identify steps to increase resources and capacity at the Agency to support effective access to breakthrough products, including the development of a statutory user fee program to conduct activities related to MCIT and other traditional coverage pathways.

I. Duke-Margolis comments on specific provisions of the Medicare Coverage of Innovative Technology (MCIT)

Impact to Follow-on Technologies

CMS proposes that, “under the proposed MCIT pathway, an item or service that receives a breakthrough device designation from FDA would be considered “reasonable and necessary” under section 1862(a)(1)(A) of the Act” and thus would qualify them for Medicare coverage under the MCIT pathway.

Premarket Approval (PMA), de-novo, and 510(k) are the traditional regulatory pathways to market for medical devices in the United States. The first two pathways, PMA, and de novo, are for novel technologies that are different than any previously FDA approved device. The PMA track is for devices that sustain or support life with a higher risk-benefit profile and the de novo track is for technologies with a low-moderate benefit risk profile with no equivalent devices. The third track, 510(k), is for devices that are as safe and effective and have the same use and characteristics as a previously approved FDA device. The FDA’s Breakthrough Devices Program is an accelerated pathway for medical devices in an existing regulatory track. To qualify for this program, devices or device led combinations must demonstrate that they are novel, breakthrough, and provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions. The intent of the breakthrough pathway is to provide timely access to novel devices by speeding up their development, assessment, and review within their respective regulatory tracks.¹ To date there have been 16 FDA approved devices that had a breakthrough designation.

While there are many potential benefits from streamlining the process between the FDA breakthrough designation and Medicare coverage, there are several issues that should be considered and resolved for successful implementation. For one, the FDA breakthrough designation is issued on a single technology. In contrast, Medicare coverage is traditionally issued on a procedure with an indication. The current language in the proposed rule suggests that the MCIT coverage will be issued on a single technology. This will have downstream implications for follow-on technologies if they are approved within the four-

year MCIT period. 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. For example, in 2011, the FDA approved the Sapien transcatheter heart valve for transcatheter aortic valve replacement. This technology had received breakthrough designation.² Within four years there was one follow-on technology, two product iterations for the original breakthrough, one product iteration for the follow-on technology, and five label expansions for both technologies.³

The specificity of coverage for a single device may result in restricting coverage to a single technology within the product class. This could result in a class of products with varying levels of coverage for different technologies. Further, if these technologies are included in payment bundles like MS-DRGs, it will be challenging for providers as well as Medicare Administrative Contractors (MACs) to identify devices at the claim level. **We recommend that a follow-on product to a breakthrough therapy that secures FDA approval during the MCIT period, also benefits from the protected coverage afforded by MCIT.** This new follow-on device would not have four full years of protected coverage, but rather will be included in the existing coverage terms. Further, evidence supporting this follow-on device would be considered in the permanent coverage assessment at the end of MCIT for the product class.

Coding and Payment for Breakthrough Devices

In conjunction with coverage, manufacturers of a breakthrough device must also navigate administrative processes with various divisions within and outside CMS to establish new coding and payment for the new technology. For new technologies, especially those that may have a major impact on care and outcomes, it is critical to have reliable codes to be able to track the use and impact of the device in real world settings. Similarly, payment will influence provider decisions to adopt the technology, which will in turn affect how it is used.

For instance, any novel breakthrough device will need to be defined by a HCPCS Level I or Level II code. These codes will facilitate tracking the impact of the device on health outcomes and resource utilization. A HCPCS level I, or CPT, code will identify the procedure involving the new technology and facilitate physician payment. Applications for new HCPCS codes have defined review and implementation cycles and involve both CMS and the American Medical Association (AMA). Novel technologies are usually issued Category III CPT codes which, although allow for tracking, are generally underpaid in Medicare's Physician Fee schedule. Category I CPT codes require a rigorous valuation process to ensure appropriate payment for the procedure. The application criteria for Category I CPT codes include FDA approval and a broad evidence base. The application and implementation cycle for Category I CPT codes can take up to two years after FDA approval. A HCPCS Level II code will identify the device if it is not already identified with a HCPCS Level I code. Applications for these codes also have a defined application and implementation cycle. CMS recently released a proposed rule (CMS 1738-P) that will increase the number of review cycles for new codes throughout a calendar year. If finalized, this rule will allow for faster and more predictable coding decisions. Manufacturers will be able to better align application and implementation cycles for breakthrough devices.

New technology payment applications for prospective hospital payment systems managed by the CMS divisions of New Technology and Pricing also have defined review and implementation cycles. Oftentimes applications for incremental or passthrough payments for new technologies require FDA approval to fulfill "newness" criteria. Consequently, breakthrough devices may not have established payment by FDA approval, which will ultimately impact access.

In the proposed rule, CMS explains that the notification that a manufacturer has opted in to the MCIT pathway would alert CMS to, “point to resources regarding coding and payment, which are key conversations to effectuate coverage upon FDA market authorization.” **We recommend CMS advise manufacturers on how to align requests for new codes and pass through payments prior to the start of the MCIT period.** In addition, we recommend CMS provide guidance on how and when to navigate different application cycles to ensure that coding and payment is established for the new technology at the time of FDA approval. Further, CMS can work with stakeholders to coordinate and streamline new coding and payment processes for new technologies to align with FDA approval. CMS should consider establishing a routine cross-division process with accountability to provide guidance, monitor results, and identify ways to improve performance in addressing the full set of coverage, coding, and payment issues that impact a new breakthrough technology.

Coverage After MCIT

The proposed MCIT pathway is time-limited to four years. Stakeholders are concerned about the uncertainty regarding coverage and access after the time-limited MCIT period. At that juncture, in order to receive long-term Medicare coverage, the technology would have to meet evidentiary standards different from what was required for FDA approval. The proposed rule encourages early manufacturer engagement, “to receive feedback on clinical study designs and endpoints that may produce the evidence needed for a definitive coverage determination after MCIT.” However, the rule doesn’t specify a framework or process by which manufacturers can solicit this guidance. **We recommend CMS provide specific guidance on what evidence will be evaluated for a coverage determination after the MCIT period.**

CMS can expand existing interactions with manufacturers as a starting point to guide evidence development. Breakthrough devices that fit within defined Medicare benefit categories typically use the Clinical Trial Policy (CTP) to apply for Medicare coverage for their early feasibility studies and for their investigational device exemption (IDE) study.⁴ In this coverage pathway, Medicare provides guidance to manufacturers on clinical trial design and endpoints for both sets of studies. For devices in the MCIT pathway, CMS could expand the scope of their guidance and issue recommendations for what evidence can be developed throughout the MCIT period that would allow the device to meet “Reasonable and Necessary” criteria for traditional coverage pathways.

In the proposed rule CMS explains, “four years would allow manufacturers sufficient time to complete FDA required post-approval or other real world collection studies... based on historical experience with studies conducted through coverage with evidence development (CED).” CMS further proposes that manufacturers interested in a National Coverage Decision (NCD) should submit a request at year three of MCIT to allow time for NCD development. There is discrepancy in the implicit timelines that the proposed rule outlines and the actual time required for the sequence of activities needed to design, develop, and assess the evidence needed for an NCD. If a study takes four years to complete, its results may not be available or published for immediate review. Further, the rule doesn’t specify if manufacturers should apply for local coverage determinations through their MACs or request a national assessment.

We recommend that CMS provide more specific guidance on when manufacturers should apply for long-term coverage during the MCIT period to ensure a seamless transition without any gaps in coverage and access. CMS should engage with manufacturers during the MCIT period as evidence is

being developed to guide and inform downstream coverage assessments, including whether to pursue local or a national determination.

Further, as we describe in more detail below, even with better guidance about evidence expectations and the timing to apply for coverage, it is unlikely that a trial, registry, or other post-market study can be quickly and efficiently designed and implemented for a particular breakthrough technology. A more systematic approach to supporting evidence development is needed to assure continuity of coverage and appropriate long-term access.

Establishing an MCIT Framework

The proposed MCIT pathway affords 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. CMS is proposing to provide guidance during the pre-approval phase in clinical study design, during the MCIT period to support evidence generation, and at the end of MCIT to support long-term coverage assessments.

In order to fulfil the intended goals of the MCIT pathway, it will be beneficial for all involved stakeholders to operate under a framework, or standard operating procedures (SOP), that will define roles and expectations for engagement throughout the MCIT pathway. The SOP may facilitate development of guidance on when manufacturers should coordinate with CMS during the pre-approval process, during the MCIT coverage period, and when to apply for a permanent coverage determination. It will also facilitate defined milestones indicating whether evidence development is on track. Milestones can be aligned with critical junctures of the regulatory pathways for breakthrough devices. We outline suggested elements of the SOP as follows:

1. Defined time windows in which a manufacturer opts-in to the MCIT pathway. We recommend that manufacturers notify CMS soon after receiving the breakthrough designation from the FDA.
 - a. In the proposed rule CMS suggests that the manufacturers can submit a notification to CMS shortly before or concurrently with the date of FDA marketing submission, which would allow CMS sufficient time to operationalize MCIT for the device. While the duration of FDA review may afford CMS the time to operationalize MCIT, it will not allow for sufficient coordination between the manufacturer and CMS that will be critical to the success of the program.
2. Cadence of CMS activities following the opt-in notification. These activities can include an evaluation of the breakthrough therapy, their regulatory track and expected lead time, expected benefit category, and existing evidence base. CMS can engage with the FDA and the manufacturer to undertake an assessment of the clinical evidence and context of the therapy. This initial analysis of the breakthrough therapy will allow CMS to inform resources and capacity planning.
3. Defined points *during the pre-approval phase* in which CMS will provide guidance on a clinical evidence plan and how to align coding and payment processes. Guidance on a clinical evidence plan will inform manufacturers on the design of clinical studies and endpoints during the MCIT period. CMS can leverage existing interactions for breakthrough therapies that also use the CTP for Medicare coverage of their investigational device. For example, the SOP can define three meeting times for a breakthrough therapy that is concurrently going through the CTP:

- a. In the first meeting, CMS can provide feedback on the study design and endpoints for their early feasibility study.
 - b. In the second meeting, feedback would focus on study design and endpoints for a pivotal IDE study and guidance on how to align coding application review cycles with the trial.
 - c. A third more substantive meeting would focus on coverage expectations during MCIT, evidence questions that can be answered during MCIT, and guidance on how to align payment application review cycles to FDA approval.
4. Defined junctures *during the MCIT period* in which CMS can provide guidance on ongoing evidence development efforts to support downstream coverage assessments. CMS could request data reports, like FDA post market surveillance reports, that will indicate if evidence being collected is sufficient to satisfy criteria for “Reasonable and Necessary”. Utilization data will allow CMS to determine at the end of MCIT if 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 seamless transition after MCIT.

An MCIT SOP can support CMS partnerships with specialty societies and other organizations to enhance registries and other systems that can further inform evidence development for breakthrough therapies in different therapeutic areas. Given the opt-in design of the MCIT pathway, a formal SOP described above will be beneficial in establishing transparency, time and resource expectations for both manufacturers and CMS. Ultimately, as CMS gains experience in the MCIT pathway, the SOP can establish accountability and identify ways to improve performance.

Ensuring CMS has the Resource Capacity to Implement MCIT

Ensuring CMS has adequate resources and capacity to engage with manufacturers during the MCIT process will be crucial to the MCIT pathway’s success. By encouraging manufacturers to solicit feedback from CMS, the proposed rule is committing 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 set forth in the proposed rule. Over the past decade, CMS resources in areas related to new technology and access have declined.⁵ This mismatch will be exacerbated by the growing number of therapies in the FDA’s breakthrough pathway. Today, there are over 300 breakthrough device therapies in the pre-approval phase. While to date only 16 have reached market approval, this number is expected to grow. Indeed, 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 framework for the MCIT SOP described above identifies existing points of contact between CMS and manufacturers that can be leveraged to fulfill expectations for MCIT. CMS may also leverage existing points of collaboration with the FDA for subspecialty expertise that can inform guidance on 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 offers with subject matter expertise, and a greater number of personnel to manage operational elements of MCIT and downstream coverage assessments. CMS should consider further steps within its administrative authority to make such personnel shifts. Beyond that, there is a need for collaborative action to provide increased resources. CMS could assess the additional resources needed to adequately staff MCIT and the other burgeoning issues related to

innovative technologies. The FDA's substantial progress in supporting breakthrough innovation through a combination of expertise, well-designed processes, and transparency was made possible through additional Congressional appropriations and dedicated user fees. 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).⁶ **We recommend CMS consider 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.

Strengthening MCIT with Coverage with Evidence Development

This proposal underscores the fact that at market approval, breakthrough devices may not have sufficient evidence to meet CMS's criteria for Medicare coverage. Indeed, CMS has historically maintained in preamble language that evidentiary standards between the FDA approval and CMS coverage are different:

"Both CMS and the FDA review scientific evidence, and may review the same evidence, to make purchasing and regulatory decisions, respectively. However, CMS and its contractors make coverage determinations and the FDA conducts premarket review of products under different statutory standards and different delegated authority (67 FR 66755, November 1, 2002). Whereas the FDA must determine that a product is safe and effective as a condition of approval, CMS must determine that the product is reasonable and necessary as a condition of coverage under section 1862(a)(1)(A) of the Act. CMS adopts FDA determinations of safety and effectiveness, and CMS evaluates whether or not the product is reasonable and necessary for the Medicare population. Although an FDA-regulated product must receive FDA approval or clearance (unless exempt from the FDA premarket review process) for at least one indication to be eligible for Medicare coverage, except for Category B devices under an IDE clinical trial (see 60 FR 48417, September 19, 1995), FDA approval/clearance alone does not generally entitle that device to coverage" 68 FR 55634, 55636 (Sept 26, 2003).

"Both CMS and FDA review scientific evidence and will likely review some of the same evidence to meet each agency's mission. Among other things, FDA reviews evidence to determine that a product is safe and effective, that is, it conducts a premarket review of products under a statutory standard and delegated authority (67 FR 66755) different from that of CMS. We also review clinical evidence to determine, among other things, whether the item or service is reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member for the affected Medicare beneficiary population. An FDA-regulated product must receive FDA approval or clearance (unless exempt from the FDA premarket review process) for at least one indication to be eligible for consideration of Medicare coverage (except in specific circumstances). However, FDA approval or clearance alone does not entitle that technology to Medicare coverage." 78 FR 48164, 48165 (Aug. 7, 2013).

Thus, 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 Medicare coverage criteria. The success of the

MCIT pathway will be determined by the extent to which manufacturers and other stakeholders can develop evidence during the breakthrough coverage period, a key component of which will be voluntary data collection at the provider level. While manufacturers can set up clinical studies, data collection from providers will also be needed.

However, the proposed rule provides little motivation or support for providers to collect additional data. Providers currently face many data collection requirements to satisfy quality and performance metrics under other quality and payment frameworks. The prospect of collecting additional data to support permanent coverage for a medical device may prove challenging and discouraging to providers, and manufacturers will likely struggle to establish “one-off” data collection efforts at the provider level. In short, challenges of voluntary data collection present the risk that after the MCIT period there may not be sufficient evidence for a coverage determination, leading to the undesirable choice between continuing coverage despite inadequate evidence or tightening back on access.

These problems can be avoided if MCIT is combined with a clinical evidence component whereby coverage is conditional to data collection. CMS’s CED paradigm can be included in combination to MCIT coverage as a mechanism to motivate data collection at the provider level. MCIT combined with CED can thus ensure more effective and broader long-term coverage for breakthrough devices.

Since 2006, CMS has used its authority under Section 1862(a)(1) (A) and Section 1862(a)(1) (E) of the Social Security Act to mandate evidence development as a condition of coverage for certain medical products in the context of research conducted by the Agency for Healthcare Research and Quality (AHRQ). Under CED, CMS may provide coverage for an item or service as reasonable and necessary for purposes of research conducted under section 1142 of the Social Security Act. See Section 1862(a)(1)(E). Section 1142 directs HHS, acting through AHRQ, to conduct and support research on the outcomes, effectiveness, and appropriateness of health care services and procedures in order to identify the manner in which health care conditions can be best managed and treated. HHS is specifically directed to take into account the needs of Medicare beneficiaries for purposes of this research. CED was developed as a solution to provide access to innovative technology that had insufficient evidence to satisfy certain criteria for Medicare coverage.

While CED has not been codified in regulations, it has been CMS’s policy for over 15 years. CED has been used when there is not sufficient evidence that an item or service is “reasonable and necessary” for Medicare beneficiaries based on available data, and it has been used to assess the impact of a technology in medical decision making. CED has been a crucial tool in ensuring a wide diffusion of innovative technologies to the Medicare population when there may be uncertainty regarding long-term outcomes and durability. It has also been used to assess how well an intervention works in real-world practice settings, and to assess subpopulation effects, and the technology’s impact on medical decision-making.

The CED framework has many advantages that can bolster the reach and impact of an MCIT pathway. Since reimbursement would be conditioned on data collection, the evidence needed for long-term coverage of breakthrough therapies is much more likely to be developed. This includes answers to important CMS questions involving the effects of the technology in different types of Medicare patients, long-term impact, and durability. Follow-on technologies approved within the MCIT period can also be included in the CED registry. A single procedure or therapy-based registry evaluating multiple technologies will facilitate data collection, curation, and evaluation of subpopulation effects by technology which can better inform medical decision making.

The Regulatory Impact Statement of the proposed rule details regulatory alternatives to the proposal that included combining Medicare coverage with clinical evidence development under section 1862(a)(1)(E) of the Act. CMS explains that combining coverage with clinical evidence development would have satisfied the goal of executive order (EO) 13890 of beneficiary access to breakthrough devices. However, under this scenario, “timing of coverage would depend upon the manufacturer being able to initiate a clinical study and provide accessible infrastructure.” CMS’s assessment was that this alternative alone would not have met the goals of EO 13890, to minimize time between FDA market authorization and Medicare coverage, and ensure wide availability of the technology.

Combining MCIT with a CED framework will address all three goals of EO 13890: (1) beneficiary access, (2) timing, and (3) availability. Beneficiary access will be addressed by both MCIT, and CED. Timing and wide availability will be addressed by the MCIT component, as explained in the rule. Furthermore, combining MCIT with a CED framework can address the biggest uncertainty of the MCIT pathway as proposed, which is coverage *after* MCIT. The CED framework is designed to allow manufacturers to develop evidence to satisfy the “reasonable and necessary” criteria for Medicare coverage. During the MCIT period, there could also be reassessment of the need and content of CED to further support long-term coverage. If at the end of the MCIT period the CED study has not yet produced results that satisfy Medicare criteria, a coverage determination can still be issued using the existing CED framework. This would ensure continued access to the device post-MCIT and continued evidence development on the impact of the technology on Medicare beneficiaries.

As CMS points out in the proposed rule, CED requires that providers have the infrastructure necessary to participate in the clinical study. Under MCIT combined with CED, MCIT would allow for immediate access to the technology notwithstanding the timeframe necessary to establish a clinical study. To address operational delays in establishing a CED registry, CMS could allow flexibility in the timing of CED initiation. This will give manufacturers time to establish post-market surveillance registries as required by FDA. It will also give providers time to establish a registry infrastructure. Importantly, during this time, access to the therapy will not be interrupted because of the MCIT coverage component. Further, the added flexibility will allow manufacturers ensure coding and payment is established prior to CED initiation. Coding will be crucial to track the devices, particularly if they are reimbursed through a bundled payment. Similarly, establishing new technology add on payments will further motivate providers to enroll in the CED registry. Another way to address this potential gap is for CMS to support modernized data collection to create a better infrastructure for evidence development as described below. At least in common areas of breakthrough innovation, such as cardiovascular and orthopedic devices, a ready infrastructure could avoid delays and gaps.

Modernizing Data Collection

MCIT combined with CED can address challenges with voluntary data collection, streamline data collection, and ensure that evidence will satisfy Medicare criteria for future coverage. There are currently several ongoing national CED registries whose experience points to areas of improvement that can further strengthen the success of a combined MCIT and CED program. For instance, although they motivate data collection at the provider level, the CED registries can be costly and cumbersome for many hospitals.⁷ Modernizing data collection can address these existing operational challenges of CED, lessen the burden on providers, and streamline data collection.

Opportunities for modernizing data collection include moving towards more innovative real-world data sources that allow for multipurpose use. Registries under the National Cardiovascular Data Registry and those managed by The Society of Thoracic Surgeons offer notable examples on steps towards broadening the use of the data collected.⁸⁹ These national established registries have a ready infrastructure that can be used as a model for further enhancements. The STS/ACC TVT registry is a good example of a multipurpose CED registry that has been used for FDA surveillance, CED, and quality benchmarking. The CathPCI registry has patient reported outcomes incorporated in the case reports to ensure health related quality of like outcomes are captured. A further improvement can be auto-populating data from electronic medical records (EMRs) to reduce the burden of manual data entry and enhance data linkages across other databases to further maximize data analysis capabilities.

Other refinements to directly address challenges with data collection can be to adopt innovative real-world data (RWD) systems that move away from prospectively collected data that overburdens providers. These systems could be developed as a single, near real-time and continuously monitored national registry that converges pre- and post-market datasets. The registry would include variables of interest for FDA and CMS and link to other relevant data sets such as EMRs and claims data. In the midst of a national pandemic, there have been many innovative approaches to rapid evaluation of real-world performance of diagnostic tests. For example, the COVID-19 Evidence Accelerator has been studying the ability to link devices, diagnostics, EMRs, and claims data.¹⁰ These initiatives are also opportunities to evaluate other innovative mechanisms to facilitate efficient data collection.

Impact of a successful MCIT program

Finally, there is potential benefit for CMS to consider how the principles of the MCIT proposal, such as streamlined coverage and concurrent evidence development, could apply to other breakthrough technologies. CMS can consider this strategic option as part of the evaluations of the MCIT program while it is focused specifically on devices. Many of breakthrough technologies require extensive long-term outcome monitoring programs that can track patients longitudinally for extended periods of time. If a successful MCIT program merited limited expansion to other technologies, CMS could also coordinate a public-private partnership dedicated to developing clinical evidence of shared interest for payers and manufacturers and develop standards for a shared registry for longitudinal data.

II. Duke Margolis comments on the proposed definition of “Reasonable and Necessary”

In addition to the topics raised above, CMS is also proposing to modify the longstanding definition of “Reasonable and Necessary”. Currently, a “Reasonable and Necessary” Medicare item or service has been defined in the Program Integrity Manual as an item or service that is (1) safe and effective, (2) not investigational, and (3) appropriate, including the duration and frequency that is considered appropriate for the item or service in terms of:

- Furnished in accordance with accepted standards of medical practice for the diagnosis
- or treatment of the patient's condition or to improve the function of a malformed body member;
- Furnished in a setting appropriate to the patient's medical needs and condition;
- Ordered and furnished by qualified personnel;

- One that meets, but does not exceed, the patient's medical need; and
- At least as beneficial as an existing and available medically appropriate alternative.

CMS proposes to add a separate basis of what is considered “appropriate” based on the private payer market. Stakeholders are concerned with the prospect of applying private payer policies to Medicare beneficiaries as the respective patient populations are distinct. CMS proposes to base coverage decisions on the current criteria for “appropriate” when evidence supports that differences between Medicare beneficiaries and commercially insured individuals are clinically relevant. Given stakeholder concerns about these being distinct populations, **we recommend that CMS only evaluate commercial insurance policies when there is evidence that supports similarities between the commercially insured population and Medicare beneficiaries.**

Specifically, CMS proposes to initiate a commercial market analysis “if an item/service *fails* to fulfil the existing factor (3) criteria defining appropriate for Medicare patients” but fulfils (1) and (2). Factor (3) criteria defining “appropriate” for Medicare patients has been the basis of by which all items and services have been evaluated for Medicare coverage. A proposal to consider an “appropriate” item or a service that fails established criteria could result in two tiers of items or services covered. Instead **we recommend that CMS view coverage policies in the commercial market as a source of information that can be taken into consideration during evidence reviews.**

The proposed rule offers many alternatives to the quantitative criteria by which they should select plans and their individual policies (e.g. geographic subsets, subsets based on number of enrollees, subsets based on plan type; if item or service is covered for a majority or a plurality). We suggest that there should be an equal, if not greater, consideration for how plans inform coverage policies, how they determine what is medically necessary, how they conduct their evidence reviews and technology assessments, and how they 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.¹¹

The evidentiary threshold to determine a coverage policy also varies considerably across plans.¹² 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 beneficiaries. Medicare coverage assessments can benefit from a wider range of evidence sources. However, evidence sources should be transparent and all ensuring proposed policies should be public comment. We recommend that CMS use a systematic approach to evaluate commercial coverage decisions so that decisions are based on an evaluation of commercial policies that assess the evidence used by commercial plans to make coverage determinations.

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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