

VIA ELECTRONIC SUBMISSION

Chiquita Brooks-LaSure
Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244
August 28, 2023

RE: Medicare Program; Transitional Coverage for Emerging Technologies (CMS-3421-NC)

Dear Administrator Brooks-LaSure,

The Robert J. Margolis, MD Center for Health Policy at Duke University (“the Duke-Margolis Center” or “the Center”) appreciates the opportunity to comment on the Center for Medicare and Medicaid Services (CMS) procedural notice for the Transitional Coverage for Emerging Technologies (TCET), published on June 27, 2023.¹

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. The Duke-Margolis Center commends CMS for proposing an expedited Medicare coverage pathway and supports their goals for increasing predictability, transparency, and efficiency of Medicare coverage processes. Our comments are informed by an independent analysis of the procedural notice and engagement with a diverse group of stakeholders, including manufacturers, real-world evidence experts, providers, researchers, and payers including CMS. Our comments describe steps that CMS can take both to strengthen the TCET pathway proposal and in future guidance. We recommend that CMS:

- Clarify circumstances when CMS will convene a Medicare Evidence Development & Coverage Advisory Committee (MEDCAC) panel or solicit broad stakeholder input to align on evidence gaps in the evidence preview stage, and clarify how this might affect evidence preview timelines.
- Include mechanisms for manufacturers interested in the TCET pathway to engage with CMS when developing pivotal trial designs, to reduce postmarket evidence issues.
- Clarify whether CMS will prioritize TCET candidates in disease areas for which Clinical Guidance Documents have been developed.
- Clarify how Medicare Administrative Contractors (MACs) can evaluate the Evidence Preview to identify applications for reasonable and necessary use of the technology by clarifying the relevance of the Evidence Preview to the MACs as the manufacturer engages with the MACs.
- Keep the current approach that TCET duration be contingent upon the evidence review milestones outlined in the Evidence Development Plan (EDP).
- Require follow-on device manufacturers to create an EDP, but the existing endpoint guidance and public TCET information may support data standards and infrastructure that reduces the cost of needed CED studies for follow-on devices with similar evidentiary questions

- Provide additional clarity on how they intend to coordinate coding and payment efforts in the TCET pathway.
- Provide recommendations through the Fit-For-Purpose (FFP) Guidance and the Clinical Guidance on the type of data collection that would be best suited for given therapeutic areas, including guidance on data sources and data infrastructures.
- Support better evidence development infrastructure through aligning TCET activities with CMS's overall strategy to advance the use of interoperable electronic health data.
- Clarify how additional resources could expand the scope and breadth of the TCET pathway, as well as support other Medicare coverage pathway processes.

Our comments below detail these recommendations.

Principles for Expedited Medicare Coverage

Medicare coverage is one of several factors that are required for reimbursement of items and services, which include benefit category determinations, coding and payment. Absent reimbursement, there is a low likelihood that providers and hospitals will furnish items or services for most beneficiaries who need them. CMS provides Medicare coverage based on a determination that an item or a service is “reasonable and necessary” to improve Medicare patients’ health outcomes.² Medicare coverage decisions aim to ensure patient access to items and services that improve healthcare outcomes and fall within statutory Medicare benefit categories. Most breakthrough devices do not require formal coverage policies, as they are reasonably captured within established reimbursement structures. But manufacturers of potentially important novel technologies intended for Medicare populations may face greater uncertainties and challenges in establishing coding, coverage, and payment to ensure patient access. If processes to establish these components for reimbursement are unclear during development, less investment in such technologies may occur; if these reimbursement issues are not resolved until well after FDA authorization, substantial delays and gaps in patient access will occur.

There have been several efforts to address the coverage and ensuing reimbursement gap that delays patient access: the coverage with evidence development (CED) program, of the Food and Drug Administration (FDA)/CMS parallel review program, new technology add-on payment, outpatient pass through payments, and shorter application cycles for certain product codes.^{3, 4, 5, 6, 7} While these reforms have resulted in more expedient paths to patient access, there are still significant gaps in the pace and clarity of coverage determinations for important novel technologies. This is further exacerbated by the growing pace of regulatory authorizations for novel technologies resulting from FDA’s “breakthrough” designation and other regulatory process reforms. The FDA’s Breakthrough Devices Program is an expedited regulatory pathway for devices that are novel, breakthrough, and provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions.⁸ The intent of this pathway is to provide timely commercial access to novel devices by speeding up their development, assessment, and regulatory review. At the time of device authorization, there may be limited evidence on the device’s effects on health outcomes, its long-term adverse events, and the treatment durability in Medicare beneficiaries. The evidence needed for FDA’s determination of safety and effectiveness may not address questions related to whether an innovative technology is reasonable and necessary for many Medicare beneficiaries – for example, those in care settings different from the academic settings of most pivotal clinical trials, and those with characteristics (demographics,

comorbidities, etc.) that differed from patients well-represented in the trials. Though breakthrough devices promise to provide Medicare patients with much-needed treatments or diagnostics, limited substantive evidence are a concern for CMS which may cause delays in coverage, and thus, patient access.

In the last few years, as part of efforts to modernize Medicare coverage processes, CMS has made several iterative proposals to develop an expedited Medicare coverage pathway for novel technologies, namely, devices with a breakthrough designation that reach FDA authorization. Medicare has used the longstanding policy of CED to provide early access to novel technologies, including breakthrough devices, when there is insufficient evidence to substantiate reasonable and necessary determination for Medicare coverage. A CED policy requires data collection as a condition for Medicare coverage in order to develop the evidence to support reasonable and necessary coverage. In 2016, FDA and CMS formalized the Parallel Review pilot program, which allows manufacturers to engage with both FDA and CMS at the pivotal clinical trial design phase, and allows both agencies to review evidence simultaneously to reduce the gap between FDA authorization and coverage.⁹ In September 2020, CMS proposed the Medicare Coverage for Innovative Technologies (MCIT), a pathway that would provide four years of automatic national coverage for FDA authorized breakthrough devices. At the end of the four years, the device would be subject to local or national coverage determinations. During the four years of coverage, manufacturers would be encouraged to develop real world evidence (RWE) to support Medicare coverage. After multiple iterations, CMS eventually repealed the MCIT rule in November 2021, citing concerns regarding the ability of CMS to ensure safety of Medicare beneficiaries and the failure to include both a requirement for evidence development in the postmarket setting, as well as a path to minimize gaps in access form coding and payment.¹⁰

The multiple iterative proposals for an expedited Medicare coverage pathway afforded CMS and stakeholders to further assess the best approaches to providing timely access while assuring CMS' reasonable and necessary standards are met, that is, the technology is safe and effective and appropriate for use in the covered beneficiary population. As part of this process, the Duke-Margolis Center identified three guiding principles for the development of a Medicare coverage pathway to ensure the goal of providing timely access to novel technologies while developing evidence-based coverage policies. The three guiding principles are:

1. **Early stakeholder engagement prior to FDA authorization can inform and enable a more effective and efficient evidence generation strategy.** Early engagement between manufacturers, CMS, FDA and other key stakeholders will allow CMS to clarify evidence gaps relevant to Medicare beneficiaries and provide guidance on relevant pre-market evidence development to help assure timely and predictable coverage. In cases where additional postmarket evidence generation is still warranted, earlier engagement will allow manufacturers and other stakeholders to develop a data collection infrastructure and minimize operational delays following FDA approval.
2. **The coverage pathway should have predictable and transparent operating procedures with opportunities for public comment and stakeholder engagement.** A new coverage process should be predictable, reliable, and include opportunities for public input. A predictable and reliable process will be beneficial in establishing transparency, as well as time and resource expectations for both manufacturers and CMS.

3. **FDA and CMS should provide early clarity about postmarket evidence generation requirements to minimize provider and product developer burden and products.** 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 breakthrough device may prove challenging and potentially discouraging to providers. Higher costs and delays in conducting such studies add to the time and cost of product development, which is likely to be particularly challenging for smaller companies. Clear opportunities for early engagement between manufacturers and both agencies will enable more efficient study design and data collection infrastructure to satisfy all evidence generation requirements while minimizing provider burden.

On June 22nd CMS announced the proposed Transitional Coverage for Emerging Technologies pathway, reflecting insights from this iterative evaluation process with broad stakeholder feedback.¹¹ At the same time, CMS published three proposed guidance documents, the CMS National Coverage Analysis Evidence Review Proposed Guidance, the CED Proposed Guidance, and a Proposed Clinical Endpoints Guidance for Knee Osteoarthritis (KO).^{12, 13, 14} These proposed guidance documents are supportive to the TCET proposal, but may have implications for general Medicare coverage processes. Accordingly, the guiding principles detailed above are goals for any coverage process that can aim to provide more timely, efficient, evidence-based patient access to novel technologies.

We commend CMS on developing a framework for an expedited coverage pathway that broadly aligns with the guiding principles identified above. CMS released this proposal through a procedural notice, citing ease of implementation and modification. Given the flexibility built into a procedural notice approach, these guiding principles will allow CMS to ensure a core foundation for evidence-based coverage while they implement initial TCET applications and evaluate opportunities to improve and potentially expand the TCET pathway.

Early Stakeholder Engagement to Inform on an Evidence Generation Strategy

The proposed TCET pathway incorporates multiple stages of engagement across manufacturers, CMS, FDA, and AHRQ designed to facilitate an iterative process of identifying evidence gaps and informing an EDP to address them. While these points of engagement facilitate a process of identifying evidence gaps, there remain opportunities to strengthen these processes (see figure 1).

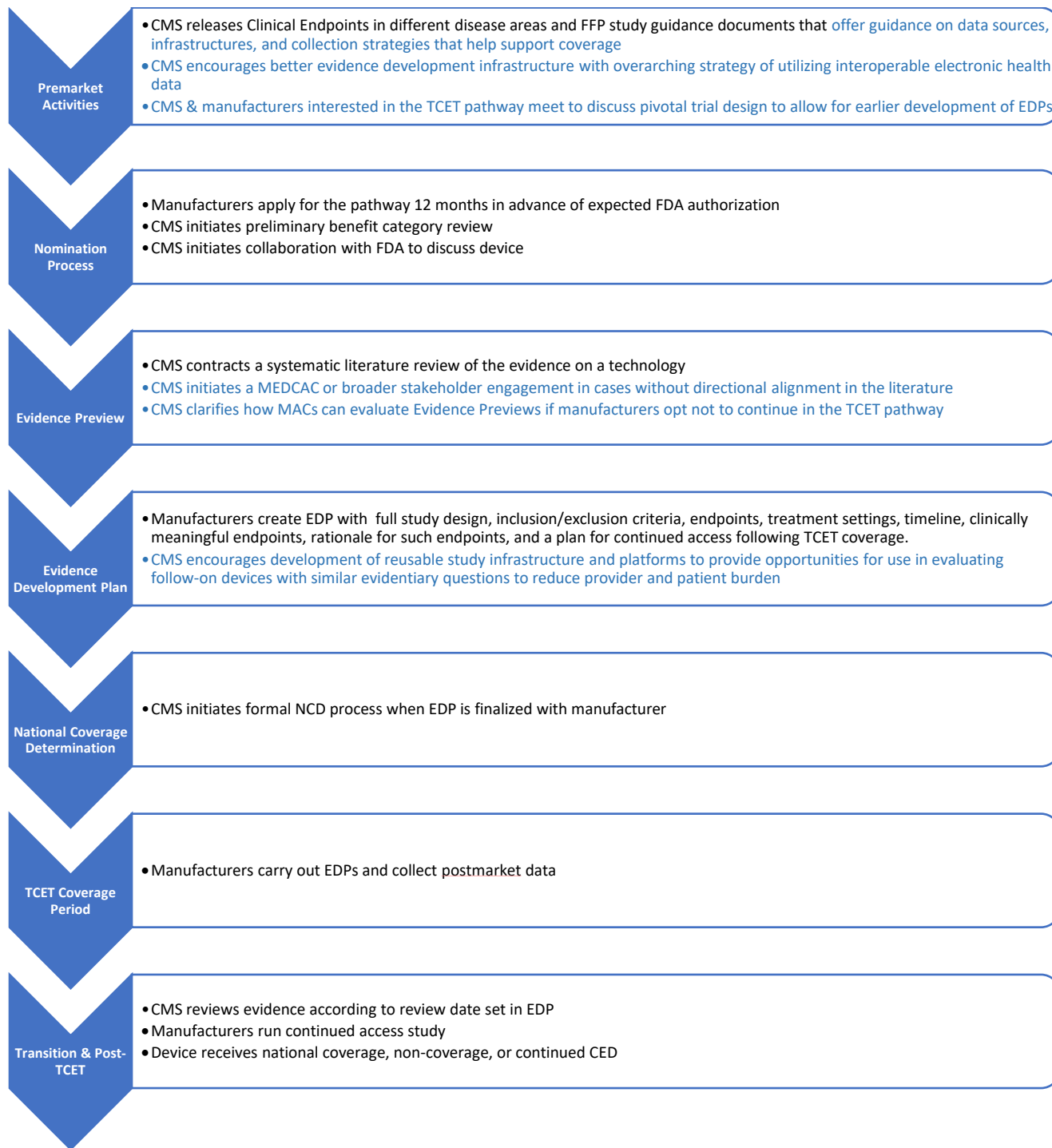


Figure 1: TCET Pathway Operational Framework, with Recommended Additions Highlighted

One these stages in the proposed pathway is through the Evidence Preview, whereby CMS contracts out a systematic literature review to identify evidence gaps to support a reasonable and necessary determination for Medicare coverage. CMS incorporates input from FDA, AHRQ, and the manufacturer on the findings of the preview, which forms the basis of the subsequent EDP. In the case of truly novel technologies, for which there is little prior literature on the benefits and risks of the product, and

uncertainty about the relevant clinical outcomes that are most important to patients a conclusive Evidence Preview may be challenging to develop. CMS indicated that there is a possibility for conflicting evidence that may impact the timelines of this stage.

If issues related to limited or conflicting evidence significantly impacts an Evidence Preview, there is an opportunity to solicit broader stakeholder input to inform the state of evidence and relevant evidence gaps. To obtain such input, CMS could convene the Medicare Evidence Development & Coverage Advisory Committee (MEDCAC) panel, or engage directly with variety of stakeholders (e.g., in collaboration with expert organizations, specialty societies, and patient groups). The Evidence Preview is a material step to inform overall candidacy and applicability of the TCET pathway thus it is important to establish a comprehensive review of the evidence which may include stakeholder input. **CMS should clarify circumstances where they can convene a MEDCAC or otherwise solicit broad stakeholder input to align on evidence gaps in the evidence preview stage, and clarify how this might affect evidence preview timelines.**

Clinical Endpoint Guidance Documents provide another opportunity to facilitate early stakeholder engagement to ensure a comprehensive approach to identify and inform addressing evidence gaps. As detailed in Duke-Margolis comments on the guidance, the Clinical Endpoints Guidance offers an opportunity for CMS to engage with stakeholders to identify health outcomes of interest for disease areas¹⁵. Particularly for emerging disease areas where they may not be substantive literature, engaging with stakeholders such as clinicians, societies, researchers, and developers may yield substantial insight that can inform manufacturers design robust clinical studies. Devices with a breakthrough designation and truly innovative technology may address disease risks in novel ways, such as earlier in the disease course or through a new kind of intervention. Consequently, there may be limited literature to inform Clinical Endpoints Guidance. In these cases, an effective mechanism for broader stakeholder engagement can help CMS focus its Clinical Endpoints Guidance on meaningful outcomes or indicators related to long-term outcomes, and feasible and efficient ways to obtain the data needed to obtain these measures.

Predictable and Transparent Operating Procedures with Opportunities for Public Comment and Stakeholder Engagement

Per the proposed notice, the TCET pathway is designed to facilitate early, predictable, and safe access to new technologies, reduce coverage uncertainties, and encourage evidence development. CMS has proposed a multistage operational framework that begins with a manufacturer's "self-nomination" around 12 months prior to expected FDA authorization. During this timeframe, CMS proposes to initiate a benefit category review, conduct an Evidence Preview, engage with manufacturers, FDA, and AHRQ, and provide guidance to manufacturers on key evidence gaps in the postmarket setting. As the TCET pathway is built off the National Coverage Determination (NCD) pathway, at the time of FDA authorization, manufacturers are then able to submit a formal NCD request along with an EDP that outlines the evidence generation strategy to develop reasonable and necessary evidence. The EDP will also outline study milestones and plan for study finalization and continued access until NCD reconsideration.

These steps should help device manufacturers reduce delays in coverage. However, in some cases, stakeholders may benefit from *earlier* feedback ahead of the described timeline to ensure that both the Evidence Preview and EDP are completed in a timely manner, and to reduce the cost and time of developing needed evidence. First, having feedback from CMS on pivotal trial development may be particularly useful for some promising but new technologies. CMS already provides substantial feedback to manufacturers that apply for Medicare coverage for the clinical trials coverage through the Medicare Clinical Trials Policy.¹⁶ As part of the CTP process, CMS is able to provide feedback on clinical trial design which could anticipate evidence needs to substantiate reasonable and necessary assessments. **CMS should include mechanisms for manufacturers interested in the TCET pathway to engage with CMS when developing pivotal trial designs, to reduce postmarket evidence issues.** CMS and manufacturers can then discuss pivotal trial protocol to ensure more representative data and better inform manufacturers on their EDPs.

Second, the EDP is a critical to achieving timely coverage within the TCET proposal, and may benefit from further guidance. Manufacturers create an EDP for postmarket studies that can support filling evidentiary gaps, with the goal of submitting a complete EDP with their NCD submission as soon as they receive FDA authorization. As CMS can only post a tracking sheet with an NCD request, and CMS can only propose a coverage determination with a finalized EDP, the EDP is the key part of the TCET pathway that determines the speed with which a technology can receive coverage. Manufacturers have the time between when the evidence preview is finalized to FDA authorization to develop a complete EDP, which should include a full study design, inclusion/exclusion criteria, treatment settings, study timeline, and clinically meaningful endpoints. Manufacturers must also plan the sites at which they will collect data, the providers who will be responsible for data collection, and the methods for assuring appropriate data collection. Thus, guidance both on meaningful clinical endpoints and sources of data in the Clinical Endpoints Guidance can be instrumental for manufacturers to develop finalize an EDP within expected timelines. **CMS should clarify how the Clinical Endpoints Guidance Documents will interact with and facilitate the TCET pathway, as well as clarifying whether CMS will prioritize TCET candidates in disease areas for which Clinical Guidance Documents have already been developed.**

Through the Clinical Endpoints Guidance Documents, CMS also has the opportunity encourage innovative data collection efforts in real-world settings that can reduce provider burden. Through a process for obtaining manufacturer and other stakeholder input on clinical endpoints guidance in advance of expected TCET proposals where such gaps are expected to occur, CMS could promote innovative data collection strategies that can support coverage with high-quality data, including utilization of RWE, data from wearables and digital health technologies, or point-of-care trials. Importantly, these guidance documents could then inform manufacturers how best to structure EDPs. This process could build on prior CMS advance collaborations with manufacturers and other stakeholders to create needed evidence development infrastructures in advance of innovative device approvals, such as for implantable cardioverter defibrillators and transcatheter valve replacement and repair.^{17, 18}

The operational framework of the TCET pathway reduces uncertainties through early and sustained engagement with product sponsors throughout the process, as well as by providing earlier insights about possible coverage outcomes at the end of the TCET coverage period. Having clear expectations and milestones for the program with clear eligibility criteria will help manufacturers have confidence in

the steps they need to take to receive TCET coverage. Since the pathway utilizes the existing NCD processes, the overall path to coverage should be familiar and predictable for manufacturers.

The current proposal allows manufacturers to opt out of the TCET pathway following the Evidence Preview meetings. Should the manufacturer opt out at that time, and not develop an EDP, they could work with MACs, who can support individual claim-by-claim adjudication. CMS proposes to share the findings from the Evidence Preview with the local Medicare Administrative Contractors. During a recent multi-stakeholder convening hosted by the Center, manufacturers articulated the concern that opting out from the TCET pathway following a determination from the Evidence Preview that the technology in question did not have reasonable and necessary evidence could negatively impact the impression MACs would have of the value of the technology and result in claim denials. To minimize concern for manufacturers who may not have the resources to develop and implement an EDP, **CMS can clarify how MACs can evaluate the Evidence Preview to identify applications for reasonable and necessary use of the technology by clarifying the relevance of the Evidence Preview to the MACs as the manufacturer engages with the MACs.**

The TCET pathway framework provides predictability around when manufacturers can expect an NCD reconsideration following TCET coverage through the EDP which specifies the study completion dates and publication plans. This adds accountability to both CMS and manufacturers to ensure a timely TCET coverage reconsideration. **We recommend CMS keep the current approach that TCET duration be contingent upon the evidence review milestones outlined in the EDP.** This will allow manufacturers to have a clearer idea of when an NCD reconsideration would be possible, and holds manufacturers accountable for completing relevant studies.

In the proposed notice CMS solicits feedback on how follow on devices with breakthrough designations should be incorporated into the TCET pathway. Applying the same nomination and evidence preview processes for follow-on devices as the first device will ensure that sponsors and CMS are up to date with the current state of the evidence. **Follow-on device manufacturers should still create an EDP, but the existing endpoint guidance and public TCET information may support data standards and infrastructure that reduces the cost of needed CED studies for follow-on devices with similar evidentiary questions.** As we have noted above, CMS should work with stakeholders in its guidance process for clinical areas where multiple TCET-relevant products may be developed to advance existing data infrastructures to minimize burden of data collection on providers and patients. This would enable all relevant products to have an easier transition to permanent coverage and allow for a seamless development of a coverage-to-class NCD.

Finally, as detailed earlier, reimbursement and patient access for novel technologies includes a coverage determination, as well as benefit category, coding, and payment determinations. CMS indicates that following a nomination, they would initiate a benefit category review and incorporate that into the assessment for pathway candidacy. However, the proposed TCET framework does not describe how it would be coordinated with coding and payment determinations for the new technology. **We recommend that CMS provide additional clarity around how they intend to coordinate coding and payment efforts in the TCET pathway.**

FDA and CMS should provide early clarity about postmarket evidence generation requirements to minimize provider and product developer burden and products

There are several ways CMS can support minimizing provider burden through the TCET pathway and proposed guidance documents. First, the TCET pathway design incorporates multiple potential points of engagement between CMS and FDA, which will help both agencies to align on postmarket evidence generation expectations and methods. Accordingly, FDA and CMS guidance during the EDP finalization process will allow manufacturers to align CED study requirements with FDA postmarket data collection requirements, which ultimately supports the principle of minimizing provider burden.

Second, as described above, the TCET process and the relevant clinical guidance that precedes it can support the development of innovative data collection capabilities in time to support CED and reduce its costs. Both the TCET proposal and CED Proposed Guidance indicate that CED studies could be conducted with FFP study designs that could include leveraging secondary uses of RWD. Advance planning to develop RWD capabilities has the potential to significantly reduce provider and patient burden. Duke-Margolis has submitted comments on the CED proposed guidance and welcomes the forthcoming FFP Study guidance. As detailed in the Duke-Margolis comments on the CED Proposed Guidance, through forthcoming FFP guidance, CMS can provide specific guidelines and examples on the types of data generation strategies, data sources, and study designs that support CMS Medicare coverage. This type of information will help manufacturers and collaborating organizations develop a robust and valid CED study as part of their TCET pathway requirements.

CMS has constructed the TCET pathway based on NCD statutory authorities, which incorporates a CED paradigm to develop reasonable and necessary evidence to support coverage. The TCET pathway offers more advance planning and predictability than traditional NCD pathway to give manufacturers clearer expectations for postmarket evidence generation before they submit a request for an NCD. This should allow the development of a postmarket evidence generation strategy that better addresses both CMS and FDA data collection requirements—resulting in a more efficient and less burdensome data collection approach. However, in order to receive TCET coverage, manufacturers have to develop the EDP with a comprehensive evidence generation plan before CMS can open the NCD tracking sheet. Thus, in conjunction with the responsibility of developing the evidence generation plan, manufacturers also face time pressures to do so. The urgency to finalize an EDP may complicate finding innovative ways of addressing CED questions using RWD sources.

We commend CMS in formally considering FFP studies to support CED requirements. However, the success of this effort will depend on the extent to which CMS working with other stakeholders can provide guidance on topical FFP studies including data sources and infrastructure which can be implemented in the TCET context and time frame. Such guidance and stakeholder engagement could be provided through a combination of the FFP guidance and the Clinical Guidance Documents. Absent clarity on the type of evidence and evidence thresholds CMS will accept, manufacturers may be deterred from developing more effective and less costly EDP approaches. For example, national registries developed to satisfy CED and FDA postmarket requirements such as the STS/ACC TVT Registry and the National Oncologic PET Registry, resulted from broad stakeholder engagement including specialty societies, FDA, and manufactures.^{19, 20} Such platforms for effective data collection may face

difficulties for breakthrough devices that go through the TCET pathway because the manufacturer is envisioned to develop an evidence generation strategy in consultation with CMS. As mentioned, the time pressures associated with the EDP may deter manufacturers from engaging broadly with other stakeholders. However, Clinical Guidance Documents can prioritize therapeutic areas with potential for breakthrough innovation that could benefit from innovative, collaborative data collection, CMS can highlight such opportunities in its clinical guidance, which could provide a stronger foundation for their implementation in any particular TCET applications that follow. **Through the FFP Guidance and the Clinical Guidance Documents, CMS can provide recommendations on the type of data collection that would be best suited for given therapeutic areas, including guidance on data sources and data infrastructures.** Ultimately, the FFP guidance, in combination with the Clinical Endpoints guidance in key product development areas can encourage a better ongoing evidence infrastructure and simplify the execution of TCET for particular products.

Third, as detailed in the Duke-Margolis comments on the Clinical Guidance Document on KO, CMS also has the opportunity to align its clinical endpoints guidance with broader CMS quality and performance metrics. This would allow for sponsors to design EDPs with outcomes and endpoints that are already collected in routine care, or utilize data sources such as electronic health records, registries, or claims data for FFP studies. Such aligned guidance for data and measures in FFP study designs could help streamline and leverage the effective use of electronic data by providers, sponsors, and patients.

In addition to providing additional guidance on endpoints of interest, the data types, and data sources that could be utilized in TCET studies, **CMS could support better evidence development infrastructure through aligning TCET activities with its overall strategy to advance the use of interoperable electronic health data.** CMS has the opportunity to promote studies that build on adoption of Health Level 7's Fast Healthcare Interoperability Resources in different sites, for example by advancing the use of USCDI+ use cases in key areas of emerging technology.²¹ Standardized, interoperable electronic health data in areas relevant for major TCET studies will reduce the cost and increase availability of more comprehensive, longitudinal data on breakthrough device impacts on important health outcomes – and in turn support better care coordination and use involving these technologies. This approach would facilitate the ability for manufactures to design FFP studies that leverage interoperable sources of RWD such as EHRs, claims data, registry data, among others.

Increasing Resources to Support Medicare Coverage Processes

The extent of proposed TCET activities – 5 breakthrough devices per year – was determined not by an assessment of the number of innovative devices that would likely benefit from TCET participation, but rather by the available level of resources for the Coverage and Analysis Group. Increased resources would enable CMS could expand the scope of the TCET pathway to additional breakthrough devices and perhaps other types of emerging technologies that could be used more quickly and effectively in Medicare beneficiaries as a result of TCET participation. For example, advanced diagnostics and cell and gene therapies may face similar evidentiary gaps as breakthrough devices, and may benefit from an expedited coverage pathway that ensures evidence development. There appears to be considerable stakeholder support for legislative proposals to increase CMS appropriations to enable the agency to

increase the impact of TCET. **CMS should clarify how additional resources could expand the scope and breadth of the TCET pathway, as well as support other Medicare coverage pathway processes.**

Our guiding principles and specific recommendations provide a foundation upon which CMS can pilot the TCET pathway and iteratively engage with stakeholders to improve the scope and breadth of the program. Early experiences in the TCET pathway will highlight areas where the TCET pathway could be clarified and made more effective. To better inform public input, CMS can identify performance metrics for the TCET pathway, such as the extent to which manufacturers with suitable products are participating in the program, and the time to NCD, breadth of coverage, and extent of evidence development for TCET products in comparison to a historical or other control group. Evaluation of early TCET experience will help CMS both adjust the TCET pathway as needed to support its goals and provide better guidance on resource needs to support and expand the pathway, both by the number of medical products evaluated per year and the types of medical products included.

Conclusion

The Duke-Margolis Center supports the development and goals of the procedural notice for the TCET pathway. The Center encourages CMS to consider adding additional clarity around critical TCET milestones, additional specificity in future guidance documents, and broader stakeholder engagement. Adequate resourcing will ensure CMS is equipped to support these changes and ensure the impact of the proposed pathway and guidance documents are all the more effective. The Duke-Margolis Center appreciates CMS's consideration of our comments, and the Administration's support for advancing high-value, affordable healthcare.

Sincerely,

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Hannah Graunke – Senior Policy Analyst, Duke-Margolis Center

Mark McClellan – Director, Duke-Margolis Center

Disclosures

Beena Bhuiyan Khan is a former employee of Abbott Laboratories and Boston Scientific Corporation and a shareholder of the respective parent companies.

Mark B. McClellan, MD, PhD, is an independent director on the boards of Johnson & Johnson, Cigna, Alignment Healthcare, and PrognomiQ; co-chairs the Guiding Committee for the Health Care Payment Learning and Action Network; and receives fees for serving as an advisor for Arsenal Capital Partners, Blackstone Life Sciences, and MITRE.

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