MCIT INTERIM FINAL RULE AND DMEPOS/HCPCS PROPOSED RULE

CMS-3372-IFC
CMS-1738-P

MEDTRONIC MEETING WITH WHITE HOUSE DOMESTIC POLICY COUNCIL AND OFFICE OF MANAGEMENT AND BUDGET

MAY 13, 2021

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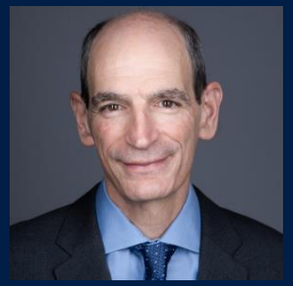
Further, Together

INTRODUCTIONS
SPEAKERS & ATTENDEES

Carrie Bullock

Senior Director, Health Economics, Policy, and Reimbursement; Medtronic Corporate



Jeff Farkas

Vice President, Global Health Economics, Reimbursement, and Government Affairs; Medtronic Diabetes

Christine Jackson

Senior Director, Health Economics, Policy, and Reimbursement; Medtronic Corporate

Sean Salmon

Executive Vice President, Diabetes , President Cardiovascular Portfolio

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Lauren Aronson, Partner, Mehlman Castagnetti Rosen & Thomas

Todd Gillenwater, Senior Director, Government Affairs, Medtronic Corporate

Bonnie Handke, Vice President, Health Economics, Policy, and Reimbursement; Medtronic Endovenous & Peripheral, Structural Heart & Aortic, Coronary & RDN, Cardiac Surgery

PURPOSE AND AGENDA
FOR TODAY'S METING

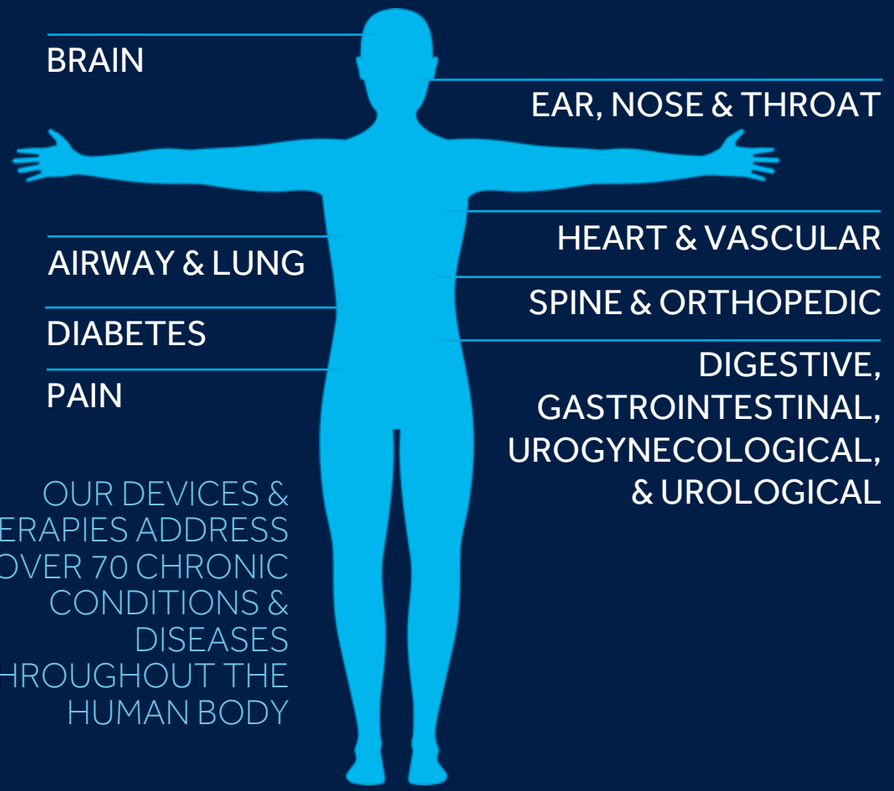
Medtronic seeks the finalization of two Medicare rules with critical implications for patient access to innovative, beneficial medical technologies – the MCIT IFC and the DMEPOS/HCPCS proposed rule. MCIT expedites Medicare coverage for FDA-designated Breakthrough Devices while providing incentives for ongoing evidence generation, and the DMEPOS rule expands DME benefit classification to all CGMs, including adjunctive CGM, which is a critical component of hybrid closed-loop artificial pancreas device systems that automate the delivery of basal insulin to people with type 1 diabetes. We ask the Administration to finalize and implement these rules as quickly as possible.

AGENDA

- Introductions
- Medtronic Positions on:
  - MCIT Interim Final Rule with Comment
  - DMEPOS/HCPS Proposed Rule – Expansion of DME Benefit Category to Include All CGMs
- Discussion/Next Steps

MEDTRONIC'S ONGOING COMMITMENT TO CLINICAL RESEARCH
GENERATING MEANINGFUL EVIDENCE ON IMPROVED OUTCOMES FOR PATIENTS

IMPROVE QUALITY AND EFFICIENCY OF CARE THROUGH MEDICAL TECHNOLOGY AND DEEP CLINICAL EXPERTISE



STRONG FOCUS ON RESEARCH
THROUGH CLINICAL EXPERTISE & INVESTMENTS

10,700+
SCIENTISTS & ENGINEERS*

1,700+
CLINICAL PROFESSIONALS*

350+
ONGOING CLINICAL TRIALS*

* Numbers are representative of CY 2020.

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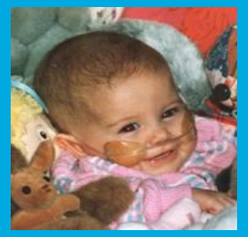
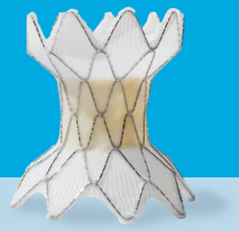
MEDTRONIC BREAKTHROUGH DEVICES AND CGM TECHNOLOGY
FULFILL IMPORTANT AND UNMET NEEDS FOR CRITICAL PATIENT POPULATIONS

CONGENITAL HEART DISEASE



~1 IN 100 BIRTHS

~22% RVOT Dysfunction



HARMONY™ TRANSCATHETER PULMONARY VALVE SYSTEM

The use of the Harmony TPV system may afford patients more time before needing additional open-heart surgery and can also potentially reduce the total number of open-heart surgeries required over an individual's lifetime.

BDD

HYPERTENSION

SYMPLICITY SPYRAL™ CATHETER

A different approach to lower blood pressure

LEADING PREVENTABLE CAUSE OF HEART ATTACK, STROKE, AND DEATH[2]

2X **AS LIKELY TO DIE FROM COVID-19 IF HAVE HIGH BLOOD PRESSURE[3]**

>75% **U.S. ADULTS ≥60 YEARS HAVE HYPERTENSION[4]**

DISPROPORTIONALY AFFECTS COMMUNITIES OF COLOR[5]

$131B **INCREMENTAL COSTS TO U.S. HEALTHCARE SYSTEM EACH YEAR[6]**

DIABETES

DME WITH ADJUNCTIVE CGM

MEDTRONIC'S MINIMED™ 670G AND 770G HYBRID CLOSED-LOOP SYSTEMS

Adjunctive CGM is critically important when used in conjunction with automated insulin delivery systems, which automatically adjust or stop basal insulin delivery based on readings from the CGM sensor.

2. Bundy JD, et al. JAMA Cardiol. 2018 Jul 1;3(7):572-581. doi: 10.1001/jamacardio.2018.1240
3. Chao Gao, et al. EHJ. 2020; 41: 2058-2066. doi: doi:10.1093/eurheartj/ehaa433
4. HHS. Office of Minority Health. Accessed Oct 2020. https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=4&lvlid=19
5. CMS Office of Minority Health. June 2020. Accessed Oct 2020. https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/OMH_Dwnld-DataSnapshot-Hypertension.pdf
6. Kirkland EB, et al. JAHA. 2018;7(11):ee008731. doi:10.1161/JAHA.118.008731

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MEDICARE COVERAGE OF INNOVATIVE TECHNOLOGIES (MCIT)
BALANCES PATIENT ACCESS WITH INCENTIVES FOR EVIDENCE GENERATION

MCIT FULFILLS CRITICAL UNMET NEED	Creates pathway to address coverage gaps that limit or delay patient access to many new devices.
BREAKTHROUGH DEVICES OFFER UNIQUE ADVANTAGES FOR PATIENTS	By definition, FDA Breakthrough Devices provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions. [1]
STRONG INCENTIVES FOR EVIDENCE DEVELOPMENT	Risk of coverage loss after temporary coverage period creates strong evidence incentives for manufacturers, which CMS can enhance at the sub-regulatory level.
OPERATIONAL ISSUES ARE NOT UNIQUE TO MCIT & CAN BE OVERCOME	CMS Technology, Coding, and Pricing Group was designed to harmonize coding and payment for new products and increase the agency's focus on driving innovation.
NUMBER OF DEVICES IN MCIT WILL BE LESS THAN TOTAL BDDs	Several factors will limit the number of devices in MCIT – whether device is ultimately approved; has a benefit category; is used consistent with labeling; has no existing Medicare national coverage; or is ultimately used in a Medicare patient.

1. See section 515B(b)(2)(C) of the FD&C Act (21 U.S.C. 360e-3(b)(2)(C)).

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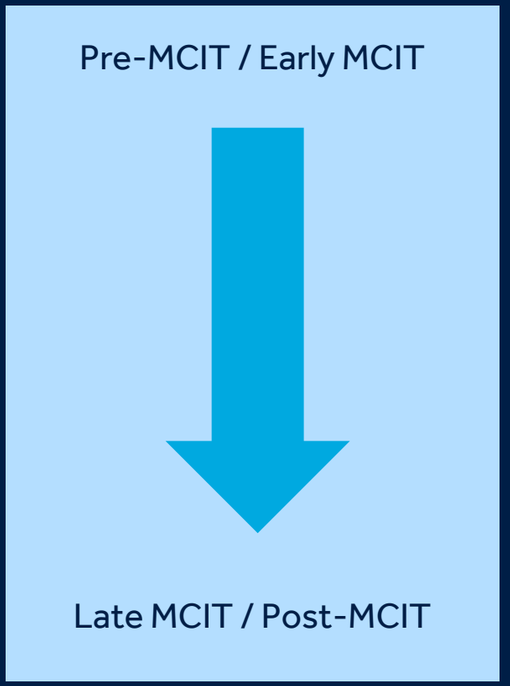
EVIDENCE DEVELOPMENT UNDER MCIT

SUB-REGULATORY ACTIONS THAT CAN GUIDE EVIDENCE DEVELOPMENT FURTHER

- General Guidance Documents
  - Issue general guidance documents on the types of evidence CMS considers useful when considering coverage (may be useful more broadly than MCIT)
- Opt-In Process Requirements Under MCIT
  - Upon entry to MCIT, recommend manufacturers to submit evidence plans to be carried out during the 4-year provisional coverage period
- MEDCAC Meetings
  - Convene condition-specific MEDCAC meetings to identify evidence gaps and outcome measures of importance for disease states targeted by BDDs
- AHRQ Technology Assessments
  - Commission condition-specific AHRQ Technology Assessments to evaluate beneficiary outcomes and clinical evidence base



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DMEPOS/HCPCS PROPOSED RULE (CMS-1738-P)
INCLUDES ALL CGM IN DME BENEFIT CATEGORY

Medtronic applauds and supports the CMS proposal to expand recognition of adjunctive CGM as DME under Medicare Part B

- Adjunctive CGM is critically important when used in conjunction with automated insulin delivery systems such as Medtronic's MiniMed™ 670G and 770G hybrid closed-loop systems, which automatically adjust or stop basal insulin delivery based on readings from the CGM sensor.
- Closed-loop systems typically consist of an insulin pump, CGM, and a control algorithm to monitor blood sugar and deliver insulin based on blood glucose readings from the patient's CGM sensor.
- Medicare benefit classification and coverage for both the insulin pump and the adjunctive CGM are critical to ensure Medicare beneficiaries can benefit from hybrid closed-loop artificial pancreas device technology.

April 26 Federal Register notice extended the review period for 2018 DME IFC until May 2022 and indicated that finalization of 2020 DMEPOS/HCPCS proposed rule would be incorporated into that review process. We are concerned about this delay.

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MEDTRONIC RECOMMENDATIONS
ON PROPOSED RULE PROVISIONS FOR CONTINUOUS GLUCOSE MONITORS

Medtronic deeply appreciates the change in benefit classification for CGM devices in the proposed rule. The inclusion of adjunctive CGM will ensure that Medicare beneficiaries with diabetes who rely on hybrid closed-loop systems have access to necessary CGM supplies. **We ask the Administration to finalize the benefit classification as soon as possible and to clarify details of coding, coverage, and payment of all CGMs to assure timely implementation upon finalization**.

Topic	Medtronic Recommendation to CMS
Benefit Category	Specify that devices physically incorporating insulin pumps and CGM monitors together may serve as the durable component of a CGM system.
Coding	Issue codes or publish coding guidance (including temporary codes if needed) for all proposed categories of CGM (automatic non-adjunctive, automatic adjunctive, manual non-adjunctive).
Coverage	Provide early guidance to DME MACs to implement coverage for all CGMs on a timely basis (LCDs, policy articles, PDAC verification).
Payment	Clarify data sources and methodology used to determine payment rates for all CGM categories. Proposed rates are not consistent with publicly available data and could impact patient access.

The proposed rule CGM provisions had an effective date of April 1, 2021. We ask the Administration to make the effective date of the final rule as early as possible so that Medicare patients can benefit from this policy immediately.

RECOMMENDATIONS
ON MCIT IFC AND DMEPOS/HCPCS PROPOSED RULE

Medtronic seeks the finalization of two Medicare rules with critical implications for patient access to innovative, beneficial medical technologies – the MCIT IFC and the DMEPOS/HCPCS proposed rule.

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QUESTIONS / DISCUSSION

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