

MEDTRONIC-OMB MEETING

**COMMENTS ON CONTINUOUS
GLUCOSE MONITORING (CGM)
PROVISIONS IN DMEPOS
PROPOSED RULE (CMS-1738-P)**

**MEDTRONIC DIABETES
NOVEMBER 23, 2021**

Medtronic

INTRODUCTIONS

PRIMARY SPEAKERS



Jeff Farkas

VP Health Economics, Reimbursement,
and Government Affairs, Diabetes



Sean Salmon

EVP & President, Diabetes Operating
Unit, Cardiovascular Portfolio



Dr. Robert Vigersky

Chief Medical Officer, Global Medical and
Clinical Affairs, Diabetes

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- **Carrie Bullock**, Sr. Director, Health Policy & Reimbursement, Corporate
 - **Todd Gillenwater**, Sr. Government Affairs Program Director, Corporate
 - **Danielle Showalter**, Reimbursement Consultant, Diabetes
 - **Lauren Aronson**, Partner, Mehlman Castagnetti Rosen & Thomas
 - **Dr. Thomas Blevins**, Texas Diabetes and Endocrinology, Austin, TX
 - **Dr. James Thrasher**, Arkansas Diabetes and Endocrinology Center, Little Rock, AR

PURPOSE AND AGENDA

FOR TODAY'S MEETING

Medtronic seeks finalization of the CGM benefit category provisions of the Medicare DMEPOS/HCPCS proposed rule (CMS-1738-P), which has critical implications for thousands of patients with insulin-dependent diabetes.

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.

The rule is now pending with OMB before it may be issued in final form by CMS. We ask OMB to clear the rule as soon as possible so that it may be issued as final and implemented at the earliest possible date.

AGENDA

- Introductions
- Benefits and Patient Impacts of Medicare Access to Adjunctive CGM in Automated Insulin Delivery Systems
- Improving Equity in Access to Advanced Diabetes Technologies
- Discussion/Next Steps

BENEFIT CLASSIFICATION OF CGM

PROPOSED RULE INCLUDES ALL CGM IN DME BENEFIT CATEGORY

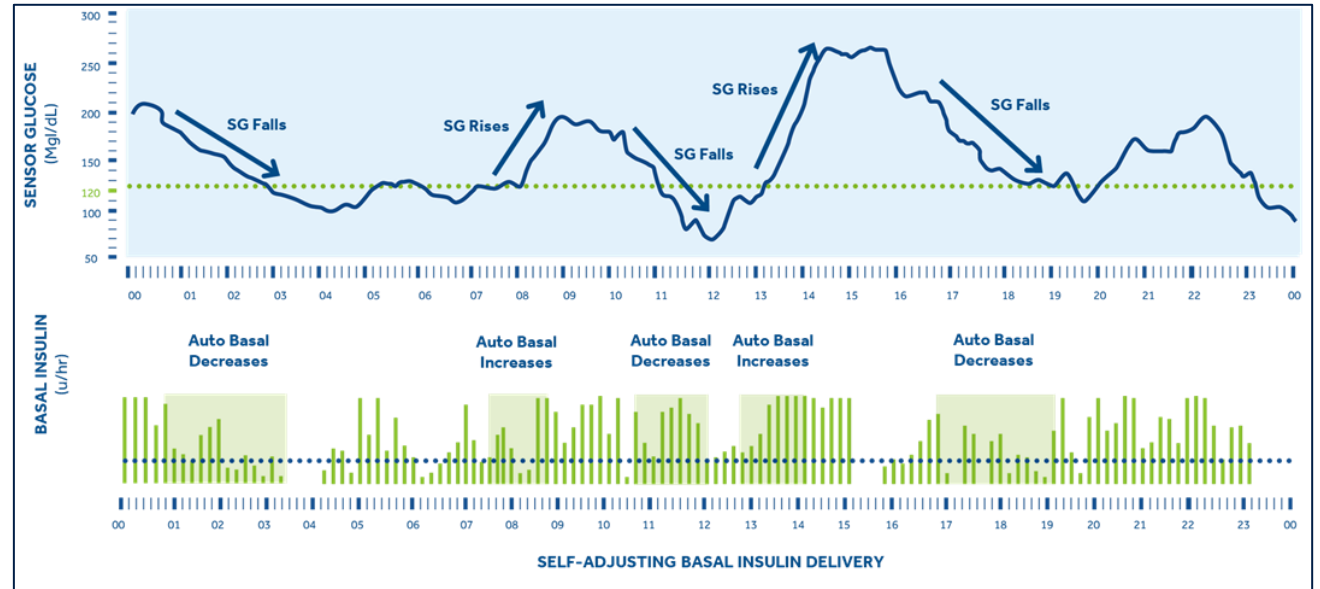
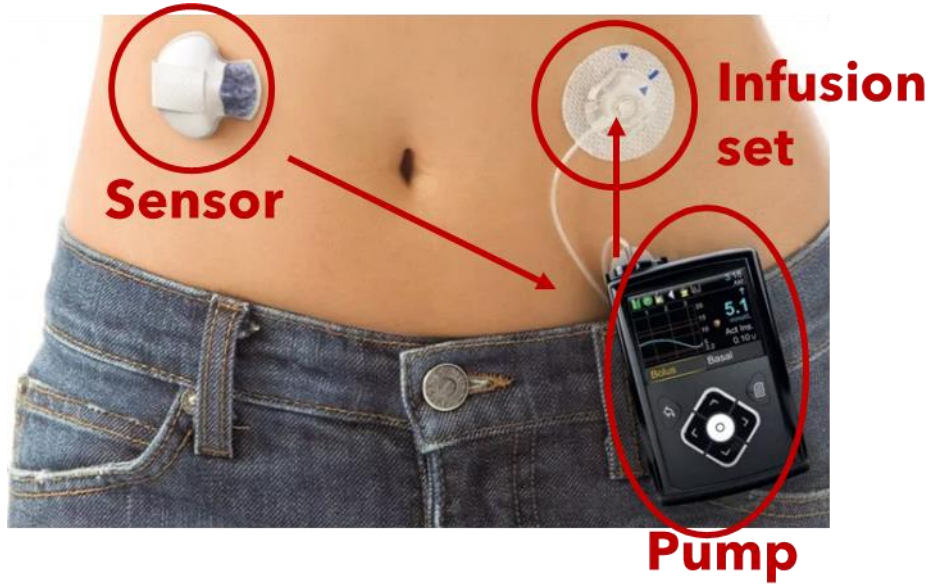
Medtronic applauds and supports the CMS proposal to expand recognition of adjunctive CGM as DME under Medicare Part B

- 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.



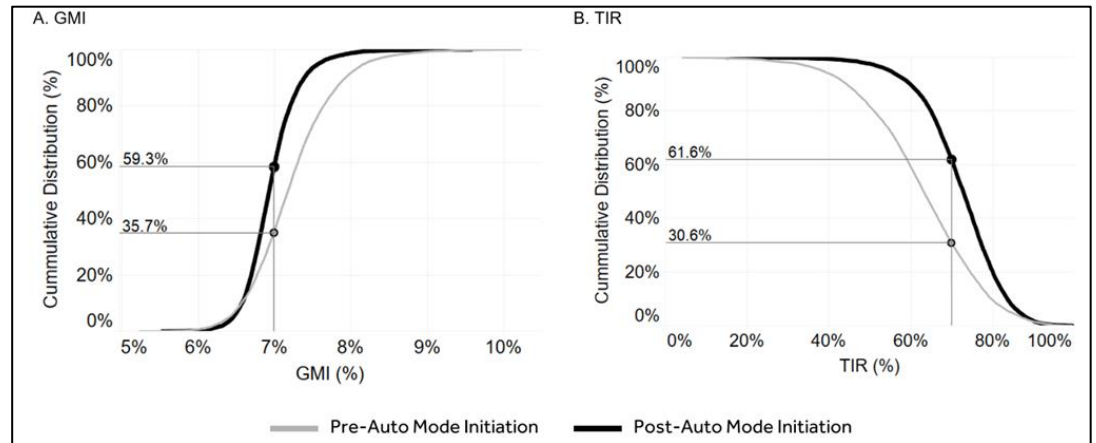
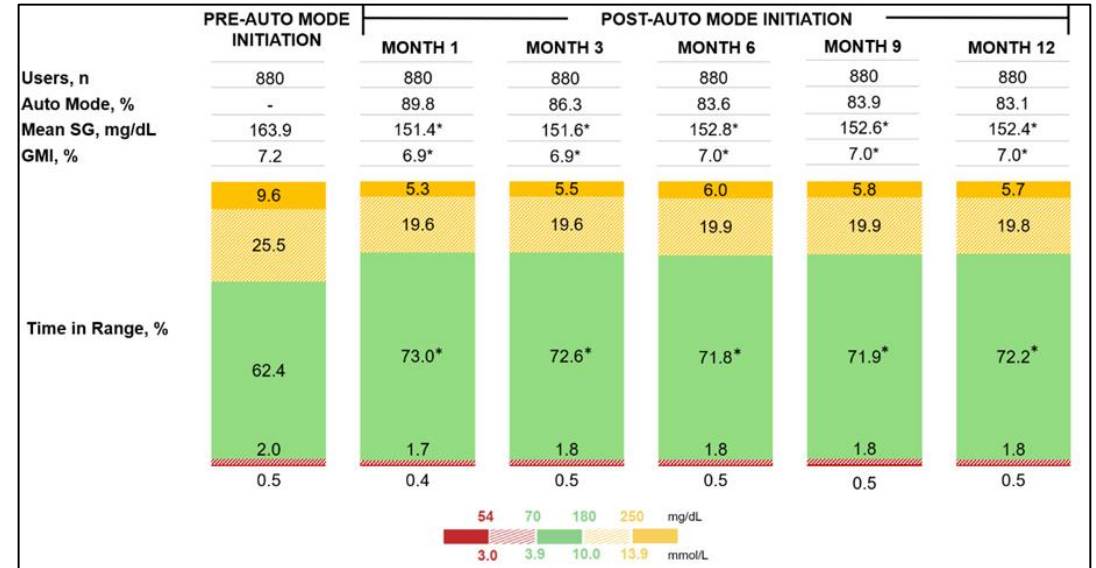
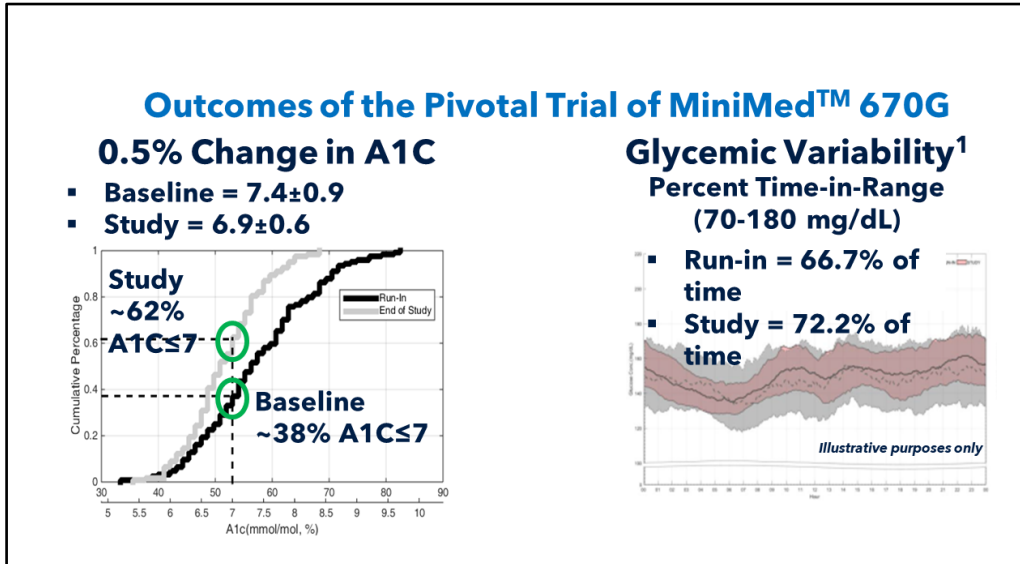
MINIMED 670G/770G SYSTEMS

AUTOMATED DELIVERY AND SUSPENSION OF INSULIN



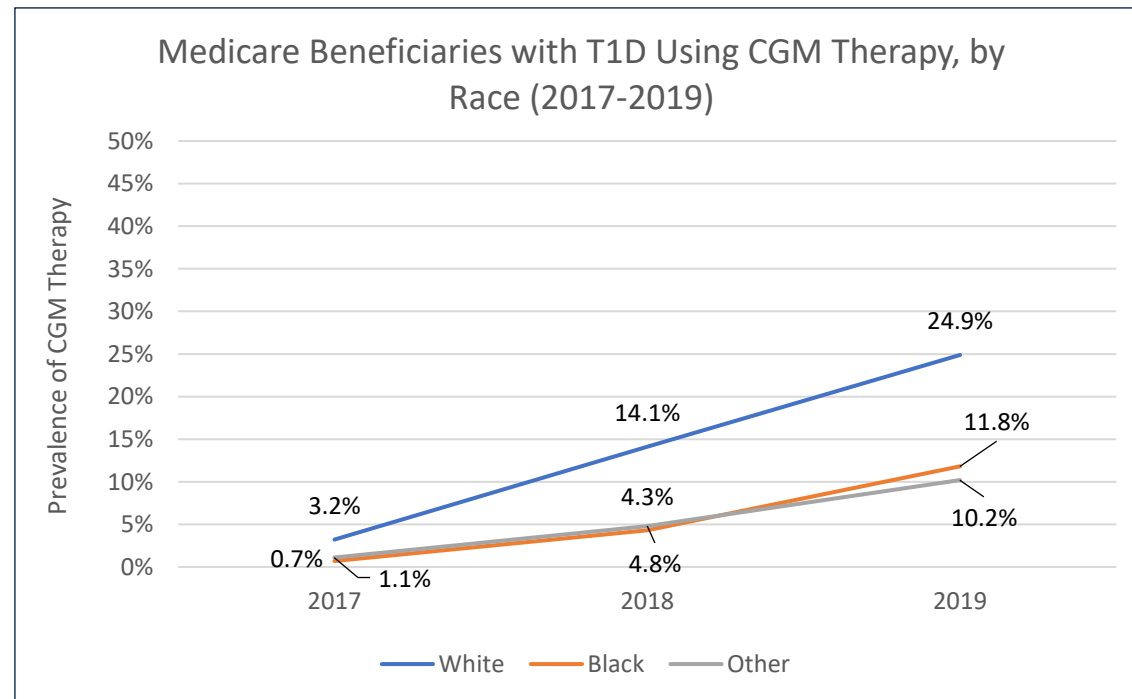
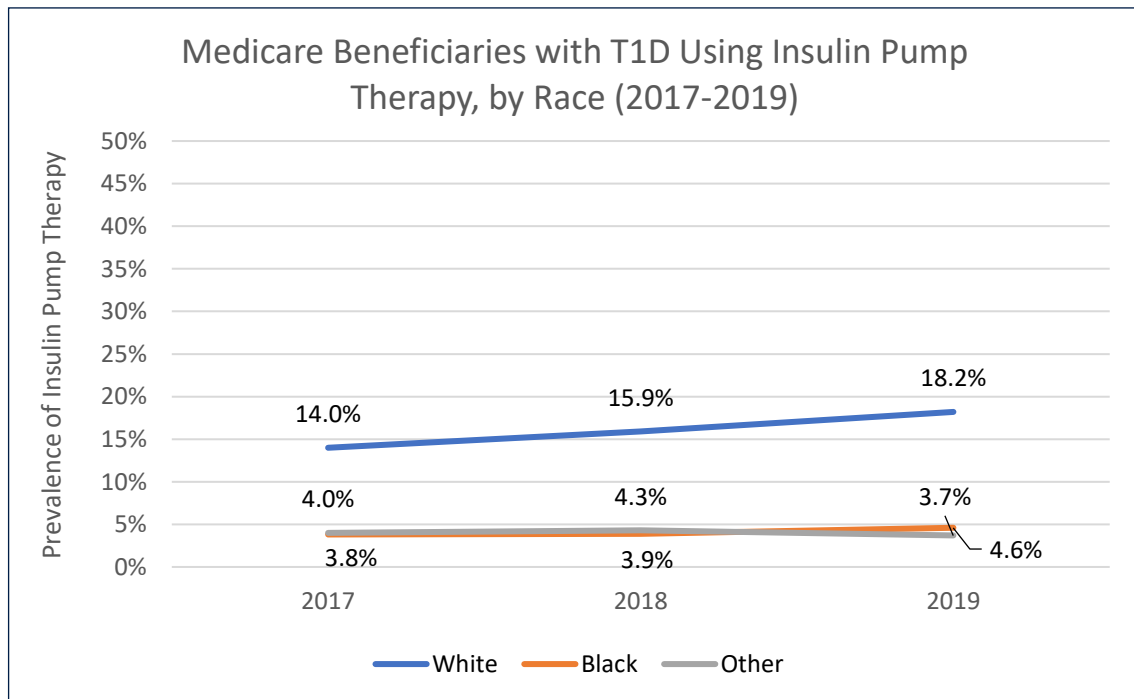
CLINICAL BENEFITS OF MEDTRONIC HYBRID CLOSED-LOOP SYSTEMS

Real-World Data of 670G Confirms Pivotal Trial Data



SIGNIFICANT DISPARITIES IN MEDICARE ACCESS TO DIABETES TECHNOLOGIES AMONG BENEFICIARIES FROM DIFFERENT RACIAL AND ETHNIC GROUPS

Diabetes Technology Use by Race Among Medicare FFS Beneficiaries with Type 1 Diabetes (2017-2019)



Analysis based on Medicare fee-for-service (FFS) 5% Limited Data Set, Jan 1, 2017 – Dec 31, 2019. Enrollees were included in the study if they met enrollment and diagnostic inclusion criteria during the study period. *Race identification in the FFS data is based on self-reported data collected by the Social Security Administration or the Railroad Retirement Board. Other includes Asian, Hispanic, North American Native, and Other and was grouped to meet the Centers for Medicare and Medicaid Services' cell size suppression rule.

MEDTRONIC APPROACH TO BRIDGE THE DIABETES TECHNOLOGY EQUITY GAP

BREAKING DOWN BIAS, INCREASING AWARENESS & ACCESS, IMPROVING TRUST



Key Programs

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| <ul style="list-style-type: none"> ▪ Bi-annual Internal Employee Health Equity Forums ▪ ERGs Advisory Board ▪ Inclusive Product Development ▪ Terminology/language training | <ul style="list-style-type: none"> ▪ ADA Health Equity Now TAP ▪ Spanish Speaking Community Centers ▪ Community Health Worker Training Pilot | <ul style="list-style-type: none"> ▪ Multicultural campaigns & representation ▪ Patient Journey in Spanish ▪ Spanish Community Events (JDRF) | <ul style="list-style-type: none"> ▪ Investigational Site Training ▪ Simplifying subject facing materials ▪ Quality improvement pilot ▪ Publications | <ul style="list-style-type: none"> ▪ Clinical Evidence Webinars ▪ Livestream Panels with Experts ▪ Advisory Boards Feedback ▪ Convention Presentations |
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ASSURING ACCESS TO ADJUNCTIVE CGM AND HYBRID CLOSED-LOOP SYSTEMS

MEDICARE PATIENT IMPACT



MEDTRONIC RECOMMENDATIONS

ON CGM PROVISIONS IN DME PROPOSED RULE (CMS-1738-P)

Medtronic deeply appreciates the change in benefit classification for CGM devices in the proposed DME 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 OMB and CMS to finalize the benefit classification as soon as possible, with an effective date as early as possible, and to clarify details of coding, coverage, and payment of all CGMs to assure timely implementation upon finalization.**

CGM Topic	Medtronic Request 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.

DISCUSSION

THANK YOU