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## New CMS proposed rules would cover adjunctive CGM starting in April 2021 - October 28, 2020

*Proposal, if finalized, would enable coverage for Medtronic's Guardian Connect (and MiniMed 670G) and other adjunctive CGMs; proposed reimbursement rate ~20%-25% lower than that of therapeutic CGMs*

Yesterday evening, the Centers of Medicare and Medicaid Services (CMS) [released](#) a new set of proposed rules which would allow for Medicare coverage for adjunctive CGM for the first time. The new rules, if finalized, would take effect starting April 1, 2021, and open up Medicare reimbursement for Medtronic's Guardian CGM, as well as open the pathway for additional CGM competitors if and when they are approved (e.g., Waveform, Nemaura, Biolinq, etc.). Importantly, the change would also enable Medicare coverage for Medtronic's hybrid closed loop MiniMed 670G system, which uses the Guardian Connect 3 sensor. Medtronic had originally filed for non-adjunctive labeling for Guardian Connect 3 back [in July 2019](#), but we haven't heard any updates since then. According to CMS' [press announcement](#), the proposed change is designed to help improve choice for people with diabetes, who make up "one in every three" Medicare beneficiaries. Considering the feature set right at the moment, we'd guess most Medicare beneficiaries would still opt for Dexcom G6 or Abbott FreeStyle Libre 2 (which have non-adjunctive indications) for standalone CGM; however, the availability of MiniMed 670G (and eventually, MiniMed 780G) could bring some Medicare patients into the Medtronic ecosystem. The full 211-page proposed rule is available [here](#).

In classifying adjunctive CGM as DME, CMS argues that adjunctive CGM meet the following criteria: (i) ability to withstand repeated use; (ii) expected life of at least three years; (iii) primarily and customarily used to serve a medical purpose; (iv) generally not useful to a person in the absence of an illness or injury; and (v) appropriate for use in the home. Traditionally, adjunctive CGMs have been considered not "primarily and customarily used for a medical purpose," given that these systems still require a confirmatory fingerstick to make diet or insulin dosing decisions. In the proposed rule, CMS notes that adjunctive CGMs can still be used to alert users about hypoglycemia, particularly while asleep, "primarily and customarily" a medical purpose.

The proposed rules also outline reimbursement rates for adjunctive CGM. By CMS' calculation, the monthly reimbursement for adjunctive CGM would be \$175.62 for class II devices and \$198.77 for class III devices. Those numbers back out to ~\$6-\$7 per day. Medicare would also pay for an additional \$34.35/month of BGM supplies in order to facilitate use of the adjunctive CGM. For comparison, currently, non-adjunctive CGMs are reimbursed at \$222.77 for class II iCGMs and \$259.20 for class III CGMs (~\$7.43 and \$8.64/day, respectively). Of note, this also confirms that class II iCGMs are currently reimbursed at ~15% lower rate than class III CGMs. This has implications for Dexcom, which has [quickly transitioned](#) its Medicare users from G5 (class III) to G6 (class II iCGM), and Abbott, which just [recently launched](#) its own class II iCGM, FreeStyle Libre 2 in Medicare.

- **Medtronic shared with us a quote from Diabetes Group President, Sean Salmon on the proposal:** "On October 27th, the Centers for Medicare & Medicaid Services (CMS) announced proposed new changes that, if finalized, would expand Medicare coverage for Continuous Glucose Monitors (CGMs) that provide critical information on glucose levels to help people with diabetes better manage their disease. We are very encouraged by CMS's proposed rule and commend the agency on taking action to help more people with diabetes. We strongly believe this proposal puts patients first and empowers them to choose the therapies that best meet their diabetes management needs. Importantly, the proposed rule would enable continuity of therapy for people on Medtronic insulin pumps aging into Medicare - including Medtronic hybrid closed loop systems which automatically adjust insulin delivery based on readings from the integrated CGM. We look forward to continuing to engage with CMS and other stakeholders in the finalization of this important rule."

*--by Albert Cai and Kelly Close*