



## **Durable Medical Equipment Update - CGM January 2017 Issue**

### **Medicare Acknowledges Dexcom's Continuous Glucose Monitor is a Covered Medicare Benefit**

On Thursday night, the Centers for Medicare and Medicaid Services issued a Ruling declaring continuous glucose monitors that can be used without confirmatory fingersticks to be durable medical equipment covered under the Medicare benefit. Effective immediately, Medicare beneficiaries seeking coverage of their CGM should ensure they have a prescription for the Dexcom G5. The Ruling indicates Medicare will not cover other CGMs. See <https://www.cms.gov/Regulations-and-Guidance/Guidance/Rulings/Downloads/CMS1682R.pdf>

The CMS Ruling comes after numerous efforts by Congress, advocacy organizations, professional organizations, industry and individual Medicare beneficiaries and their physicians, to align Medicare's position with the consensus of experts, and peer-reviewed literature in recognizing CGM as reasonable and medically necessary for individuals with Type 1 diabetes and hypoglycemic unawareness. The CMS Ruling also comes after more than **40 favorable Medicare Administrative Law Judge decisions** found CGMs reasonable and medically necessary for T1Ds, **five Federal District Court actions** were filed (two of which vacated the Medicare Appeals Council decisions that asserted CGM was precautionary), and Medicare's Civil Remedies Division found that the statement that CGM is simply precautionary is **invalid** under the reasonableness standard.

Last summer, when a Medicare beneficiary challenged the Medicare policy that held CGMs are "precautionary" and did not serve a medical purpose, CMS tried to argue that even if a CGM did not require a confirmatory fingerstick before making an insulin adjustment (many Medicare beneficiaries testified they made insulin adjustments based on CGM readings without performing a confirmatory test), because CGM sensors did not last three years, a CGM would not meet the durability requirements to be considered durable medical equipment and covered by Medicare. CMS has abandoned that logic and now holds that the receiver performs the medically necessary function of a CGM by informing a user of his or her glucose level.

The CMS Ruling found that the Dexcom G5 (1) is a replacement of blood glucose monitors; (2) is a glucose monitoring system for the management of diabetes; (3) it provides trend information; (4) aids in the detection of hyperglycemia and hypoglycemia; and (5) is prescribed for a single patient. The CMS Ruling **acknowledges the multiple medical purposes** a CGM fulfills. All CGMs provide trend information, are used to monitor diabetes, are prescribed for a single patient and detect hyperglycemia and hypoglycemia. Nonetheless, CMS stated that despite CGMs service of such medical purposes, effective January 12, 2017, CMS will only cover those CGMs that do not require confirmatory fingerstick testing.

Medicare's denial of some CGM claims on the basis that it is precautionary riled the T1D community and underscored that Medicare coverage decisions are not based on scientific and clinical evidence, the consensus of experts or the standard of care. Medicare's denial of CGM claims forced numerous T1D Medicare beneficiaries through the **multi-step, often multi-year,** Medicare appeals process as they sought Medicare coverage for their CGMs and supplies. Although most of Medicare's Administrative Law Judges found CGM was not "precautionary" for such individuals, the process was grueling and often had to be repeated when subsequent CGM supplies were ordered (at least one Medicare beneficiary was forced to go through the process **SEVEN** times despite repeatedly winning coverage decisions). Hopefully the Ruling will bring an end to these Sisyphus appeals.