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# Support Medicare Coverage of Continuous Glucose Monitors

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Diabetes technologies have the potential to transform the care of people with diabetes. The continuous glucose monitor (CGM) has been shown to improve glucose control—preventing dangerous high and low blood sugars—and is recommended by national diabetes clinical guidelines and covered by private health plans. However, Medicare does not yet cover CGM devices, leaving seniors with diabetes vulnerable. Medicare beneficiaries with insulin-dependent diabetes have disproportionately high rates of hospitalization and emergency room use. Severe low blood sugar causes seizures or episodes of unconsciousness in 16 percent of older Americans with type 1 diabetes each year. It's time for us to change that.

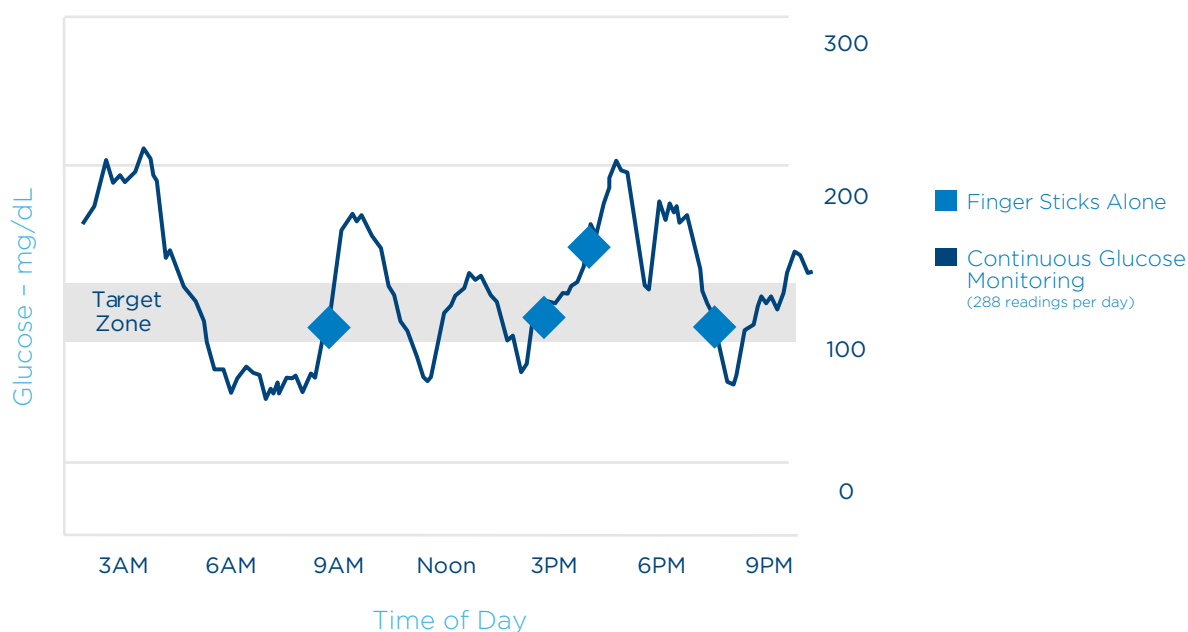
**It's time for Medicare to cover CGMs.**



## CGM: A Cornerstone of Quality Diabetes Care

People with insulin-dependent diabetes have to test their blood glucose and give themselves insulin injections or infusions via a pump 24 hours a day every day in order to stay alive. Too much insulin can result in seizures, comas, or death from hypoglycemia, or low glucose levels. Too little insulin leads to devastating kidney, heart, nerve, and eye damage from hyperglycemia, or high blood sugar.

A CGM is an FDA-approved, physician-prescribed device that helps people with diabetes manage this difficult disease and prevent its life-threatening complications. The device consists of a glucose sensor, a transmitter, and a small external monitor (which may be built into an insulin pump or stand-alone device). A CGM detects and displays blood glucose levels continuously, and reveals trends in glucose levels that often go unnoticed by using finger-stick measurements alone. By viewing continuous data, and by responding to alerts from the CGM, patients can react to rising or falling glucose levels before they become dangerous. Trends over time can also provide insight into underlying causes of high and low blood glucose levels, enabling therapy adjustments to further improve outcomes.



## Clinical Evidence, Clinical Guidelines, and Private Health Plans Support Use of a CGM

Extensive clinical evidence shows use of a CGM improves diabetes outcomes.

A JDRF-funded clinical trial, published in *The New England Journal of Medicine*<sup>1</sup> and *Diabetes Care*,<sup>2</sup> found adults using a CGM had improved glucose control (reduced A1c) and reduced rates of severe hypoglycemia.

Many studies since the original trial have shown similar results. A 2012 review of the published literature conducted by the Agency for Healthcare Research and Quality found continuous glucose monitoring is superior to blood glucose monitoring.<sup>3</sup> It also found that insulin pumps with CGM functionality are superior to other available insulin delivery and glucose monitoring methods.

Based on this clinical evidence, diabetes clinical guidelines by all leading diabetes professional societies recommend use of a CGM, including the American Association of Clinical Endocrinologists,<sup>4</sup> the American Diabetes Association,<sup>5</sup> and The Endocrine Society.<sup>6</sup>

In addition, nearly all private health plans cover CGM devices, including Aetna, CIGNA, United Healthcare, Wellpoint, many Blue Cross and Blue Shield plans, and numerous regional plans.

<sup>1</sup> JDRF CGM Study Group, *N Engl J Med* 2008 359:1464-1476

<sup>2</sup> JDRF CGM Study Group, *Diabetes Care* 32:2047-2049, 2009

<sup>3</sup> Golden et. al. Comparative Effectiveness Review No. 57. AHRQ Publication No. 12-EHC036-EF. July 2012

<sup>4</sup> *Endocrine Practice* Vol 16 No. 5 September/October 2010

<sup>5</sup> *Diabetes Care*, Volume 36, Supplement 1, January 2013, p S17

<sup>6</sup> *J Clin Endocrinol Metab*, October, 2011, 96 (10): 2968-2979

## Medicare Patients Face Significant Risks Without Using a CGM

Medicare beneficiaries with insulin-dependent diabetes have disproportionately high hospitalization, emergency room use, and mortality rates, according to the Agency for Healthcare Research and Quality.<sup>7</sup>

Hypoglycemia, or low blood sugar, is the most frequent complication experienced by older adults with diabetes.<sup>8</sup> A recent study found that 16 percent of elderly patients with long standing type 1 diabetes experienced at least one seizure or episode of unconsciousness in the past year due to severe hypoglycemia.<sup>9</sup> Other studies have found the elderly's high risk of hypoglycemia increases the risks of falls, fractures, and related complications.<sup>10</sup>

Patients over the age of 80 were 2.5 times as likely to visit the ER for an insulin related hypoglycemia event, and nearly 5 times as likely to be admitted versus patients between the ages of 45-64.<sup>11</sup> Among Medicare patients overall, the rate of hospitalization for hypoglycemia has risen by 11.7% since 1999.<sup>12</sup>

## Medicare CGM Coverage Will Help Advance Artificial Pancreas Systems

A CGM is an important component of an artificial pancreas, a system that will combine a CGM with other technology to automate insulin delivery. Research studies funded through the Special Diabetes Program, JDRF, and the private sector are testing innovative artificial pancreas systems which have the potential to transform diabetes care. Medicare coverage for the CGM will help create a pathway for coverage of artificial pancreas systems when they are developed and approved for use in the regular clinical care setting.

## Medicare Is Not Covering the CGM Despite Evidence of Clinical Benefit

While thousands of people with insulin-dependent diabetes benefit from using a CGM, Medicare beneficiaries are excluded.

People with diabetes who are already over age 65 cannot obtain a CGM through Medicare.

People with diabetes who are using a CGM through private plans and turn 65 are suddenly denied coverage for their CGM, even if they have been on successful treatment regimen using it.

**It's time for us to step forward to ensure those with Medicare have access to life-saving CGM technologies.**

### CGM Potential Return on Investment

By reducing hospital admissions for hypoglycemia, a CGM has the potential to improve quality of care while reducing unnecessary expenditures.

In the JDRF CGM trial, the rate of severe hypoglycemic events among adults using a CGM fell by two-thirds over the first year of use.<sup>2</sup>

Currently, costs for a hypoglycemia inpatient admission average \$17,564 per visit.<sup>13</sup>

Diabetes is one of the costliest chronic diseases accounting for \$322 billion in economic costs in 2012, including \$244 billion in direct medical costs and \$78 billion in reduced productivity.<sup>14</sup>

Overall, 42 percent of Medicare fee-for-service spending is attributed to people with diabetes.<sup>15</sup>



<sup>7</sup> Virnig et. al. Use of Diabetes Care. Data Points # 18 AHRQ Publication No. 14-EHC005-EF. January 2014

<sup>8</sup> Seaquist et. al. Diabetes Care, 36 1384-1395 May 2013

<sup>9</sup> Weinstock, et. al. J Clin Endocrinol Metab, 98(8):3411-3419

<sup>10</sup> Chu et. al., Diabetic Hypoglycemia 2012;5;(2)24-28

<sup>11</sup> Geller, et. al., JAMA Intern Med. Published online March 10, 2014. doi:10.1001/jamainternmed.2014.136

<sup>12</sup> Lipska et.al., JAMA Intern Med. Published online May 17, 2014. doi:10.1001/jamainternmed.2014.1824

<sup>13</sup> Quilliam, et. al, Am J Manag Care 2011;17(10):673-680

<sup>14</sup> American Diabetes Association. The Economic Burden of Elevated Blood Glucose Levels in 2012. Diabetes Care Dec 2014 vol. 37 no. 37(12): 3172-3179

<sup>15</sup> Foote, S.M. Population-Based Disease Management Under Fee-For-Service Medicare. Health Affairs, 27 1103-1112.