

DHA Considers Expanding Continuous Glucose Monitoring Coverage to Type 2 Diabetes

By Annette M. Boyle

Results of a range of studies are conclusive: Continuous glucose monitoring can improve glycemic control and reduce hypoglycemia risks in patients with both Type 1 and Type 2 diabetes. Now, the Defense Health Agency, which tightly controls use of the technology primarily in Type 1 diabetes patients, is reviewing a draft of a new policy to allow CGM to be used by certain patients with Type 2 diabetes prescribed insulin.

The devices use sensors placed on the arm or abdomen to read interstitial glucose levels at regular intervals. A transmitter wirelessly sends the results to a monitor, which may be imbedded in an insulin pump, a separate device or a smartphone or other mobile device. Results can be downloaded to observe trends and shared with physicians and others. Sensors can be used for up to 14 days, though some new implantable versions can be used for up to 90 days.

If blood glucose levels go too high or too low, some CGMs sound an alarm that can alert a caregiver or spouse to awaken a sleeping diabetic. Some send results and alerts to a second phone to permit monitoring from a distance, say, for a sleeping child or an elderly parent at home alone.

CRITERIA FOR USE

While most commercial insurers initiated coverage for CGMs several years ago, the Centers for Medicare and Medicaid Services drove more rapid adoption when it began covering therapeutic CGMs in January 2017. Coverage criteria for CMS, which has become the basis for most insurance policies, currently includes:

- Have a diagnosis of diabetes, either Type 1 or Type 2.
- Use a home blood glucose monitor and conduct four or more daily BGM tests.

BETHESDA, MD—Despite rapidly accumulating evidence supporting the benefits of continuous glucose monitors in improving glycemic control among both Type 1 and Type 2 diabetics, the Defense Health Agency has continued to tightly control use of the devices to patients, even among those with Type 1 diabetes. That may be about to change.

“A draft of a policy allowing Type 2 diabetics to use CGMs is under review,” DHA spokesman Kevin Dwyer told *U.S. Medicine*.

In Fiscal Year 2018, 16,813 DHA beneficiaries used the devices, Dwyer said. If the current restrictions are relaxed, many more people will be eligible for CGMs.

DoD physicians have already started embracing the devices. “Endocrinologists are moving toward CGMs as opposed to finger stick tests

for diabetics on an insulin regimen, but not for patients on diet restriction or metformin,” Dwyer noted.

That split in use is in line with the research. While studies show that CGMs provide a benefit to a wide range of patients with diabetes, the advantages are particularly clear and have been building for longer for those who take insulin.

How CGMs Work

Continuous glucose monitors permit constant tracking of blood glucose levels, in contrast to the traditional finger prick, which assess glucose levels at a particular point in time. Most also indicate trends, so people with diabetes can see whether they are heading toward dangerous hypoglycemia or need to increase insulin to avert very high blood sugar levels.

- Be treated with insulin with multiple daily injections or a constant subcutaneous infusion pump.
- Require frequent adjustments of the insulin treatment regimen, based on therapeutic CGM test results.

The current TRICARE criteria for CGMs is far more restrictive, generally limiting their use to Type 1 diabetics who demonstrate significant difficulty regulating their glucose levels and demonstrate severe consequences for out-of-range blood glucose levels. First established in 2008, when the devices were bulky and not particularly reliable, the policy has had no significant updates for more than a decade.

According to the policy, Type 1 diabetics may use a CGM for up to 72 hours on an intermittent basis, not more than six times per year, if their physician documents:

- Glycosylated hemoglobin level (HbA1c) is greater than 9.0% or less than 4.0%;
- History of unexplained large fluctuations in daily glucose values before meals (greater than 150 mg/dl);
- History of early morning fasting hyperglycemia (“dawn phenomenon”);
- History of severe glycemic excursions; or
- Hypoglycemic unawareness.

Use of a CGM for more than 72 hours or on a continuous or periodic basis may be covered for patients who meet the above criteria and have documentation showing:

- A history of recurrent, unexplained, severe hypoglycemic events or hypoglycemic unawareness (i.e., blood glucose less than 50 mg/dl);
- A history of recurrent episodes of ketoacidosis;

- Hospitalizations for uncontrolled glucose levels; or
- Frequent nocturnal hypoglycemia.

The policy also allows extended use if the beneficiary is pregnant and has poorly controlled Type 1 diabetes or gestational diabetes.

Tricare West’s website says that CGMs may also be covered for Type 2 diabetes “when there is documentation by the physician of poor diabetic control and the patient has failed to achieve glycemic control after six months of multiple daily injection therapy.” A physician should document the need for CGM using the Letter of Attestation.

THE BENEFITS OF CGM

Still, the barriers to use appear to run contrary to evidence that has accumulated over the past several years, showing that the devices help patients stay in range for a greater proportion of the day and reduce episodes of hypoglycemia. The risk of hypoglycemia increases in patients with both Type 1 and Type 2 diabetes with the duration of the disease and use of insulin.

A real-world study presented at the American Diabetes Association 78th Scientific Sessions last summer found that individuals with Type 1 diabetes who used CGMs had better glycemic control, spent longer time in range and had lower risk for hypoglycemia than those who used a traditional glucometer. Patients using a CGM had a mean HbA1c of 7.5% compared to 8.5% for the glucometer users. Two-thirds of those using the traditional finger stick method of monitoring experienced one or more clinically significant episode of hypoglycemia, nearly twice the rate seen in those using a CGM.¹

Patients with Type 2 diabetes achieve similar benefits. A study in 139 patients

with Type 2 diabetes on intensive insulin therapy determined that use of factory-calibrated, flash CGM reduced the time patients were in hypoglycemia by 50% over 12 months, even as back-up self-monitored blood glucose testing declined from nearly four times a day to 0.2 times per day.²

The greater accuracy of the latest generation of CGMs has reduced or eliminated the need for verification of results with glucometer readings or frequent calibration by patients. As a result, the FDA has approved several devices that eliminate the need for finger sticks entirely.

The update to DHA policy will reflect this improvement in the technology. “The newer CGMs no longer require this calibration and our policy will reflect this soon,” Dwyer noted.

The latest consensus statement on treatment of Type 2 diabetes care issued by the American Association of Clinical Endocrinologist and the American College of Endocrinology reflects the new data. Updated in February 2019, it notes that CGM “has become more available for people with T2D and has added a considerable degree of clarity for the patient’s and clinician’s understanding of the glycemic pattern.”

Greater use of the monitors has also revealed that more patients with Type 2 diabetes experience hypoglycemia than previously understood, up to 49% of those on insulin, according to the statement.

The risks associated with hypoglycemia should not be underestimated. “Several large RCTs found that T2D patients with a history of one or more severe hypoglycemic events have an approximately two- to four-fold higher death rate,” the groups said. “One possible safety measure for prevention of hypoglycemia is the

FIGURE 1. Incidence rates of diabetes mellitus (DM), by type, active component, U.S. Armed Forces, 2008–2015

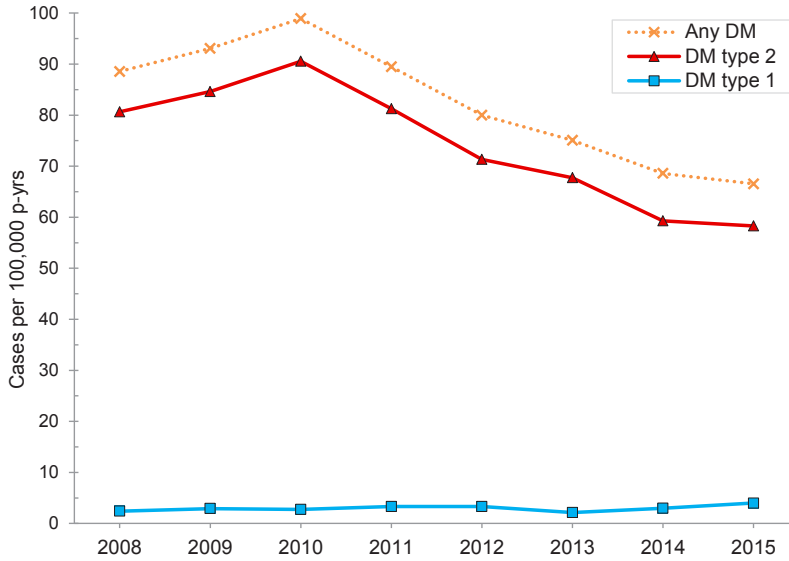
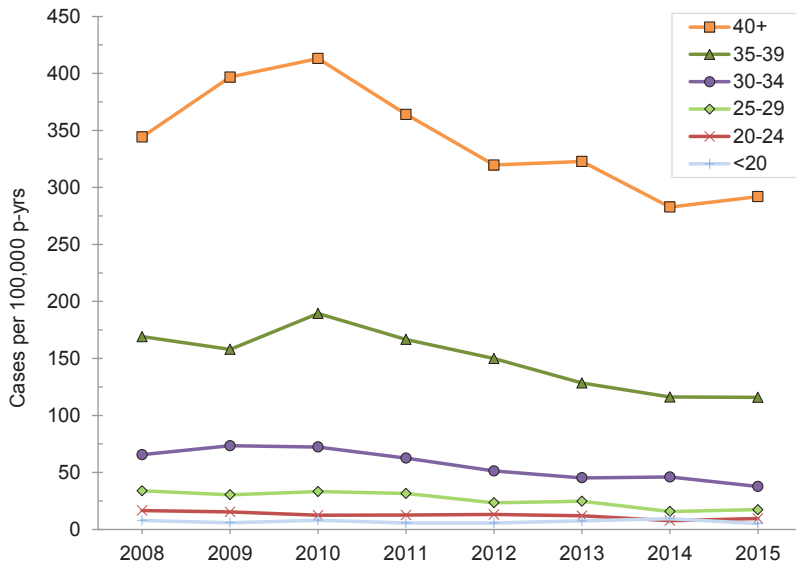


FIGURE 2. Incidence rates of type 2 diabetes mellitus, by age group, active component, U.S. Armed Forces, 2008–2015



Source: Diabetes Mellitus, Active Component, U.S. Armed Forces, 2008-2015; Medical Surveillance Monthly Report; January 2017, Volume 24, Number 1

use of CGM that provides real-time glucose data with or without alarms for hyper- and hypoglycemic excursions and events.”

The expert panel also said that the devices should be “considered for those patients who are on intensive insulin therapy (three to four injections/day

or on insulin pump), for those with history of hypoglycemia unawareness, or those with recurrent hypoglycemia. While these devices could be used intermittently in those who appear stable on their therapy, most patients will need to use this technology on a continual basis.”

WHAT’S COVERED

The FDA has approved four continuous glucose monitoring systems: Abbott’s Freestyle Libre/Libre 14 Day/Libre Pro, Medtronic’s Guardian Connect, Dexcom G5/G6 and Senseonics’ Eversense implantable CGM.

The TRICARE policy says U.S. Food and Drug Administration approved devices are covered, but it specifically lists only two, the MiniMed CGMS System Gold and the MiniMed Guardian Real Time System, neither of which is still on the market.

According to Dwyer, “FDA-approved CGMs are covered by TRICARE when the patient meets the conditions listed” in the Tricare policy manual. “The list is not all inclusive; it just lists models that were out at the time that this regulation was written. The Medical Benefits and Reimbursement Section is in the process of updating this policy and will remove the names of the devices in the new version.”

¹ Munshi M, Toschi E, Slyne C, et al. Use of real time continuous glucose monitoring (CGM) in real life clinical practice compared with finger-stick glucose monitoring. Poster presentation at: ADA 2018 78th Scientific Sessions; June 22-26, 2018; Orlando, FL. Poster 959.

¹ Haak T, Hanaire H, Ajjan R, Hermanns N, Rivelino JP, Rayman G. Use of flash glucose-sensing technology for 12 months as a replacement for blood glucose monitoring in insulin-treated type 2 diabetes. *Diabetes Ther.* 2017;8:573-586.