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DXCM vs ABT in Updated ADA Guidelines

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DexCom Inc (DXCM)

Price:	$79.34
52-Week High:	$142.00
52-Week Low:	$62.34

Abbott Laboratories (ABT)

Price:	$116.00
52-Week High:	$121.64
52-Week Low:	$99.71

We view **ABT** as likely better positioned than **DXCM** following updated guidelines from the American Diabetes Association (ADA) that clinicians "consider" the use of continuous glucose monitors (CGM) in "adults with type 2 diabetes treated with glucose-lowering medications other than insulin." However, any near-term Medicare coverage gains for the companies' over-the-counter (OTC) products will more likely come from the 74% of Medicare Advantage (MA) plans offering these supplemental benefits rather than Fee-for-Service (FFS), which continues to require a physician order / prescription. That said, ~54% of beneficiaries are now enrolled in MA rather than FFS.

Current Coverage Policy

Recall that the existing Medicare FFS coverage policy for CGM under the Part B Durable Medical Equipment (DME) benefit requires that beneficiaries meet *all* of the below criteria [1-5], with our own emphasis added. We also note that this does ***not*** currently extend to OTC products acquired without a prescription.

CGM COVERAGE POLICY (L33822)

(1) The beneficiary **has diabetes mellitus**; and

(2) The treating practitioner has concluded that the beneficiary (or their caregiver) has sufficient training using the CGM prescribed as evidenced by **providing a prescription**; and

(3) The CGM is prescribed in accordance with its **FDA indications for use**; and

(4) The beneficiary meets **at least one** of the criteria below:

- (a) Is **insulin-treated**; ***or***
- (b) Has a **history of problematic hypoglycemia** with documentation of at least one of the following:
  - Recurrent (more than one) level 2 hypoglycemic events that persist despite multiple (more than one) attempts to adjust medication(s) and/or modify the diabetes treatment plan; or
  - A history of one level 3 hypoglycemic event characterized by altered mental and / or physical state requiring third-party assistance for treatment of hypoglycemia.

(5) Within six months **prior to ordering the CGM**, the treating practitioner has an in-person or Medicare-approved telehealth visit to determine that criteria 1-4 are met.

Source: Medicare Local Coverage Determination L33822 – Glucose Monitors

This policy was most recently updated in April 2023 to remove what had previously been a requirement that beneficiaries be taking "multiple (three or more) daily administrations of insulin," replacing it with the criteria that they merely be "insulin treated" ***or*** have "a history of problematic hypoglycemia."

The policy maintains its condition that CGMs be "prescribed in accordance with its FDA indications for use," which is relevant when we consider the 510(k) clearance documents for DXCM's Stelo and ABT's Rio / Lingo:

Over-the-Counter CGM Indications

	DXCM STELO	ABT RIO
Indications for Use	The Stelo Glucose Biosensor is an **over-the-counter (OTC)** integrated Continuous Glucose Monitor (iCGM) intended to continuously measure, record, analyze, and display glucose values in people age **18 years and older not on insulin**. The system helps detect normal (euglycemic) and low or high (dysglycemic) glucose levels.	The Libre Rio Continuous Glucose Monitoring System is an **over-the-counter (OTC)** integrated continuous glucose monitoring system (iCGM) device indicated for **non-insulin using persons age 18 and older**. The system detects trends and tracks patterns and aids in the detection of euglycemia, hyperglycemia, and **hypoglycemia**.
Special Conditions for Use	**Do not use if you have problematic hypoglycemia**. The Stelo Glucose Biosensor system hasn't been designed for these populations.	Do not use the Libre Rio Continuous Glucose Monitoring System if you are on dialysis or critically ill. It is not known how different conditions or medications common to these populations may affect performance of the System.

Source: Stelo 510(k) Clearance (K234070); Libre Rio 510(k) Clearance (K23386)

As shown above, DXCM's Stelo includes a specific prohibition on use by those with "problematic hypoglycemia," whereas ABT's Rio is intended to "aid in the detection of euglycemia, hyperglycemia, and hypoglycemia."

In other words, Rio could theoretically meet the *existing* standards for coverage, so long as the patient has (A) either type 1 or type 2 diabetes, and (B) a documented history of problematic hypoglycemia. Coverage in Medicare FFS would nevertheless still require a valid prescription following consultation with a physician to ensure these criteria are met, which would seem to preclude OTC utilization.

FFS Versus MA

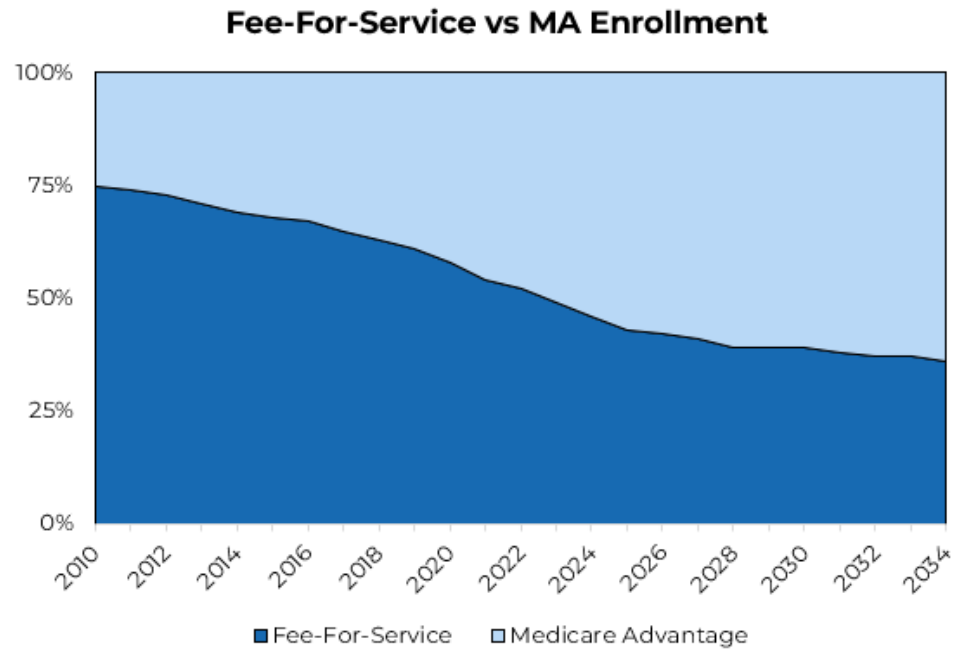
While ADA's updated guidance is certainly a positive step and could lay the groundwork for a Medicare FFS coverage expansion into non-insulin-treated individuals, we would be surprised to see this in the near-term.

- Not only is the April 2023 update of the current FFS coverage policy fairly recent as far as Medicare coverage goes, but even the ADA guidelines themselves stop short of an outright *recommendation* for use in non-insulin patients, instead suggesting only that clinicians "consider" CGM use in this population.
- Moreover, the recommendation still presupposes the involvement of a clinician, which is little reason for CMS to lift its long-standing practice of requiring a prescription for DME equipment and supplies. Indeed, even during the COVID-19 pandemic, CMS had to create a special demonstration project to allow FFS coverage of OTC test kits, which was ended along with the Public Health Emergency (PHE) declaration in May 2023.

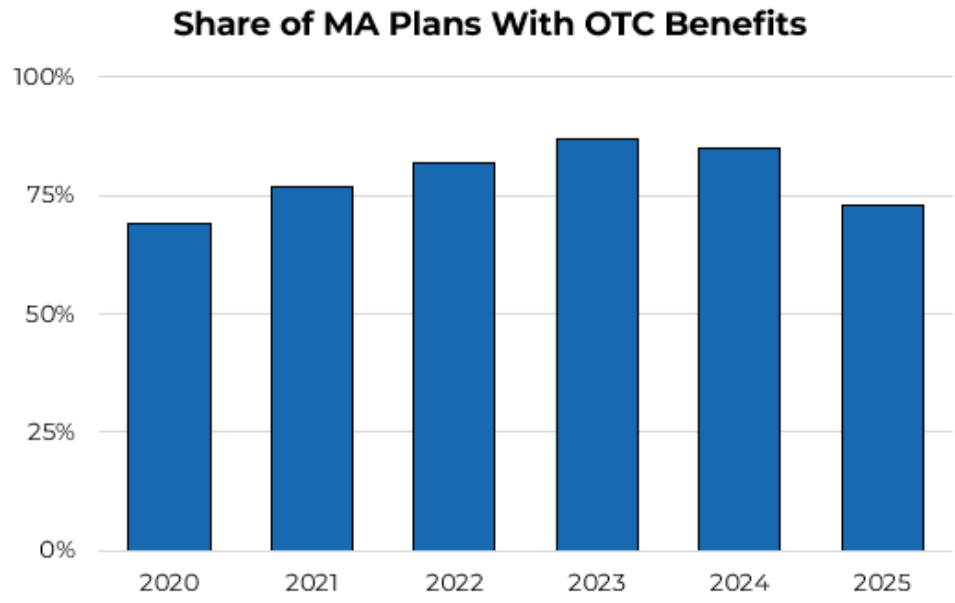
ADA – DIABETEST TECHNOLGOY: STANDARDS OF CARE IN DIABETES – 2025
Consider using real-time CGM (rtCGM) and intermittently scanned CGM (isCGM) in adults with type 2 diabetes treated with glucose-lowering medications other than insulin to achieve and maintain individualized glycemic goals. The choice of device should be made based on the individual's circumstances, preferences, and needs.

Source: ADA Standards of Care in Diabetes – 2025

The Medicare Advantage (MA) population is a somewhat different story. While the *baseline* for coverage must be no less generous than whatever is provided for in FFS, MA plans are free to go beyond such standards to better attract customers. An analysis of 2025 plan offerings shows that nearly three-quarters will provide supplemental OTC coverage benefits, and with CBO projecting that the share of MA beneficiaries will only grow over time from today's 54%, this is a potentially meaningful patient group.



Source: CMS Monthly Enrollment & CBO Projections



Source: KFF, CMS Landscape and Benefit Files, Capitol Policy Partners

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