INDIAN HEALTH SERVICE
National Pharmacy and Therapeutics Committee
Formulary Brief: ***Continuous Glucose Monitors***
-August 2024-

Background:

The Indian Health Service (IHS) National Pharmacy and Therapeutics Committee (NPTC) performed a review of the Continuous Glucose Monitors (CGM) during the Summer 2024 NPTC meeting. This review marks the first for the CGMs. The NPTC views CGMs as medical devices and, as such, **took no voting action(s)** towards potential National Core Formulary (NCF) inclusion.

Discussion:

The NPTC based its review around the notable increase in both interest and use of CGMs in the IHS, with goals of evaluating both CGM benefits and limitations for use. CGM technology has continued to evolve every year since the availability of the first commercial CGM in 1999, named the Glucowatch.[1] Today's CGMs have the ability to operate in tandem with insulin pumps and communicate with receivers, including smart phones. Accuracy, measured by the Mean Absolute Relative Difference which calculates the difference between the CGM value and a referenced laboratory measure, continues to improve with new iterations of CGMs.

The selection of CGM can be cumbersome for providers and patients alike due to the availability of numerous CGM types and iterations, with varying technological options. Additionally, in March and June 2024, the U.S. Food and Drug Administration approved two device manufacturers to begin producing over-the-counter CGMs, which are intended for patients who do not require insulin.[2,3] Once selected, CGMs require individualized patient education, training, and follow-up monitoring to maximize use potential. The variety in CGM subclasses can add to this, with classifications as "intermittent scanning" versus "real time". While in general these devices are placed by patient self-insertion, most require intensive training and counseling and, in some cases, specialized provider training for implanted versions.

The information collected by CGMs can improve the management and care of patients with diabetes. The patient (as the driver) is able to see live information and make therapeutic decisions based on guidance received from their care team. This becomes crucial in conditions of hypoglycemia unawareness. Most CGMs have the ability to notify both the patient and caretaker of abnormal values via receiver and phone notifications. A potential limitation identified by providers and health care systems is the inability to review the collected data. CGMs mostly store data either on the device or in the cloud (server), depending on user settings. As for the latter, healthcare systems may be apprehensive about retrieving data from cloud-based systems while ensuring that patient information is secure. Provider access to this information can be invaluable to understanding the patient's dietary patterns and other relevant factors to allow for better assessment of the patient's condition.

Effectiveness of CGMs has been evaluated among different populations and subsets of individuals including those with type 1, type 2, and gestational diabetes. A 2022 systematic review of 2188 individuals in the community with type 1 diabetes were more likely to benefit from CGM vs. traditional self-monitoring, especially in those with uncontrolled glycemia (A1c >8%), mean difference -0.43%, 95% CI: -6.04 to -3.30, $p<0.00001$.[4] However, no differences were noted in the number of severe hypoglycemia or diabetic ketoacidosis events between groups. Two other recently published meta-analyses found similar results in patients with type 1 diabetes.[5,6]

In patients with type 2 diabetes, a meta-analysis published in 2024 (12 open-label trials, N=1248) noted improved glycemic control (mean difference in A1c: -0.31%; 95% CI: -4.75 to -2.11, $p<0.00001$) with CGMs compared to self-monitoring of blood glucose.[7] No differences were reported between groups in the incidence of severe hypoglycemia or macrovascular complications. For patients with gestational diabetes, a 2017 Cochrane Review of 11 randomized, controlled trials (N=1272) evaluated the use of CGMs to traditional self-monitoring of blood glucose and concluded that there were no differences between groups for the primary or any secondary outcomes.[8]

Diabetes guidelines from both the American Diabetes Association and the American Association of Clinical Endocrinology (AACE) offer strong recommendations for diabetes technology, including CGM, be offered to patients with diabetes.[9,10]

Findings:

In summary, a broad overview of the types, differences and benefits of CGMs was reviewed by the committee. The review found greatest evidence for use for patients with type 1 diabetes and an association of benefits for those with type 2 and gestational diabetes. It was noted that a vast number of CGM options are available, with technological differences varying from continuous to intermittent scanning, and sensor placement from self-placement to implantable.[9,11] The CGMs collect

sufficient data to assist patients, caretakers, and providers in the management of diabetes with live glucose readings, trends, reports, alarms, and notifications. Over the past two decades, CGMs have become more accurate and can interface and operate with other electronic devices (phones, insulin pumps, etc.) to further assist in disease management.

If you have any questions regarding this document, please contact the NPTC at IHSNPTC1@ihs.gov . For more information about the NPTC, please visit the NPTC website.

References:

1. Hirsch IB. Introduction: History of Glucose Monitoring. 2018 Aug. In: Role of Continuous Glucose Monitoring in Diabetes Treatment. Arlington (VA): American Diabetes Association; 2018 Aug.
2. U.S. Food and Drug Administration. FDA NEWS RELEASE. FDA Clears First Over-the-Counter Continuous Glucose Monitor. Mar 5, 2024.
3. Abbott Pharmaceuticals, 2024. Abbott Receives U.S FDA Clearance for Two New Over-The-Counter Continuous Glucose Monitoring Systems. June 10, 2024.
4. Teo E, Hassan N, Tam W, et al. Effectiveness of continuous glucose monitoring in maintaining glycaemic control among people with type 1 diabetes mellitus: a systematic review of randomised controlled trials and meta-analysis. Diabetologia. 2022; 65:604–19.
5. Dicembrini I, Cosentino C, Monami M, et al. Effects of real-time continuous glucose monitoring in type 1 diabetes: a meta-analysis of randomized controlled trials. Acta Diabetologica. 2021; 58:401–10.
6. Evans M, Welsh Z, Ells S, et al. The Impact of Flash Glucose Monitoring on Glycaemic Control as Measured by HbA1c: A Meta-analysis of Clinical Trials and Real-World Observational Studies. Diabetes Ther. 2020; 11:83–95.
7. Jancev M, Vissers T, Visseren F, et al. Continuous glucose monitoring in adults with type 2 diabetes: a systematic review and meta-analysis. Diabetologia. 2024; 67:798–810.
8. Raman P, Shepherd E, Dowswell T, et al. Different methods and settings for glucose monitoring for gestational diabetes during pregnancy. Cochrane Database Syst Rev. 2017; 10(10):CD011069.
9. American Diabetes Association. Continuous Glucose Monitors. Retrieved June 27, 2024.
10. American Association of Clinical Endocrinology. AACE GUIDE TO CONTINUOUS GLUCOSE MONITORING (CGM). Retrieved July 20, 2024.
11. UpToDate. Glucose monitoring in the ambulatory management of nonpregnant adults with diabetes mellitus. Retrieved July 20, 2024.