Continuous Glucose Monitor (CGM) Quantity Limit Program Summary

This program applies to Medicaid.

POLICY REVIEW CYCLE

Effective Date	Date of Origin
07-01-2024	05-01-2020

FDA APPROVED INDICATIONS AND DOSAGE

Agent(s)	FDA Indication(s)	Notes	Ref#
Dexcom G6®			
Dexcom G7®			
Freestyle Libre 2®			
Freestyle Libre 3®			
Freestyle Libre®			

See package insert for FDA prescribing information: https://dailymed.nlm.nih.gov/dailymed/index.cfm

CLINICAL RATIONALE

Continuous Glucose Monitoring (CGM)	Glucose measurements are critical to effective diabetes management. While measurement of glycated hemoglobin (HbA1c) has been the traditional method for assessing glycemic control, it does not reflect intra- and interday glycemic excursions that may lead to acute events (such as hypoglycemia) or postprandial hyperglycemia. These events have been linked to both microvascular and macrovascular complications. While self-monitoring of blood glucose (SMBG) has been shown to improve glycemic control and quality of life in patients, it cannot predict impending hypoglycemia or alert for hypoglycemia. Real-time continuous glucose monitoring (rtCGM) and intermittently viewed CGM (iCGM) address many of the limitations inherent in HcA1c testing and SMBG. rtCGM uniformly tracks the glucose concentrations in the body's interstitial fluid, providing near real-time glucose data; iCGM uses similar methodology to show continuous glucose measurements retrospectively at the time of checking. Both rtCGM and iCGM facilitate monitoring of time spent in the target glucose range ("time in range"). However, only rtCGM can warn users if glucose is trending toward hypoglycemia or hyperglycemia. With iCGM, these trends can only be viewed after physically scanning the sensor.(1) CGM affords 2 major benefits over the current standard of SMBG coupled with A1c testing. First, a vast increase in the quantity of blood glucose information, which provides a more comprehensive view of glycemic control. Rather than snapshots in time, continuous information allows us to capture important metrics like time in range, time in hypoglycemia, glucose variability, and many other emerging "glycometrics." These additional metrics cannot be captured with SMBG, even in the most diligent patients. A CGM recording blood glucose every 5 minutes will record 105,120 BG readings per year compared with between just 1000 to 2000 for a person doing frequent SMBG. Second, is the ability of CGM systems to provide real-time biofeedback. With real-time data now seamlessly available on a user's mobile device and the internet, easily visible trends and trajectories can help a person understand their own glycemic response in a more meaningful way. Patients can observe which foods and exercises affect them the most. Iterative exposure to this immediate biofeedback allows patients to learn about their own bodies and physiologic responses.(2) Numerous studies have shown that use of rtCGM improves glycemic control and quality of life in both children and adults with type 1 diabetes treated with either

	continuous subcutaneous insulin infusion or multiple daily insulin injection therapy, improving HbA1c, shortening the time spent in hypoglycemia and hyperglycemia, and reducing moderate-to-severe hypoglycemia. Benefits of rtCGM use have also been reported in individuals with type 2 diabetes who are managed with or without intensive insulin treatment. There is limited data regarding the benefit of rtCGM as an outcome measure for individuals with gestational diabetes mellitus and type 2 diabetes, especially for those who do not use insulin. The benefit of rtCGM is directly correlated to persistence and frequency of use. A meta-analysis found that every 1-day increase of sensor usage per week increased the effect of CGM; the effect on HbA1c is more pronounced the higher the initial HbA1c.(1) High costs and uncertainty over efficacy and necessity have kept CGM from widespread use in people with type 2 diabetes. However, the newest CGM models, the Abbott Freestyle Libre and Dexcom G6, have begun to overcome many of these technical barriers to use of CGM systems. The sensors are inserted painlessly, are small enough to fit easily under clothing, can remain in place for 10 to 14 days, and are FDA approved as sufficiently accurate to use in lieu of fingersticks to make insulin-dosing decisions. Overcoming another significant barrier to use, data can now be seamlessly and continuously uploaded wirelessly to the cloud via a user's smartphone.(2) Technology is rapidly changing, but there is no "one-size-fits-all" approach to technology use in people with diabetes. Patient interest in devices and willingness for adoption can vary. Use of technology should be individualized based on a person's specific needs, preferences, and skill level. In general, no device used in diabetes management works optimally without education, training, and ongoing support.(3) In the 2023 Guidelines, the American Diabetes Association published a recommendation that rtCGM should be offered for diabetes management in adults with diabetes on basal insulin who are capable of using devices safely.(3)

REFERENCES

Number	Reference
1	Danne T, Nimri R, Barrelino T, et al. "International Consensus on Use of Continuous Glucose Monitoring". Diabetes Care 2017 Dec;40(12): 1631-1640. Available at: https://care.diabetesjournals.org/content/40/12/1631.
2	Kompala T, and Neinstein A. "A New Era: Increasing Continuous Glucose Monitoring Use in Type 2 Diabetes". Evidence-based Diabetes Management. March 2019, Volume 25, Issue 4. Available at: https://www.ajmc.com/view/a-new-era-increasing-continuous-glucose-monitoring-use-in-type-2-diabetes.
3	American Diabetes Association Professional Practice Committee; 7. Diabetes Technology: Standards of Care in Diabetes-2024. Diabetes Care 1 January 2024; 47 (Supplement_1): S126–S144. https://doi.org/10.2337/dc24-S007.

POLICY AGENT SUMMARY QUANTITY LIMIT

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Day Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist
Dexcom g6 receiver	*continuous glucose system receiver***		1	Receiver	365	DAYS			08627009111
Dexcom g6 sensor	*continuous glucose system sensor***		3	Sensors	30	DAYS			08627005303

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Day Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist
Dexcom g6 transmitter	*continuous glucose system transmitter***		1	Transmitter	90	DAYS			08627001601
Dexcom g7 receiver	*continuous glucose system receiver***		1	Receiver	365	DAYS			08627007801
Dexcom g7 sensor	*continuous blood glucose system sensor*** ; *continuous glucose system sensor***		3	Sensors	30	DAYS			08627007701
Freestyle libre 14 day/re	*continuous glucose system receiver***		1	Reader	365	DAYS			57599000200
Freestyle libre 14 day/se	*continuous blood glucose system sensor*** ; *continuous glucose system sensor***		2	Sensors	28	DAYS			57599000101
Freestyle libre 2/reader/	*continuous glucose system receiver***		1	Reader	365	DAYS			57599080300
Freestyle libre 2/sensor/	*continuous glucose system sensor***		2	Sensors	28	DAYS			57599080000
Freestyle libre 3/reader/	*continuous glucose system receiver***		1	Reader	365	DAYS			57599082000
Freestyle libre 3/sensor/	*continuous glucose system sensor***		2	Sensors	28	DAYS			57599081800
Freestyle libre/reader/fl	*continuous glucose system receiver***		1	Reader	365	DAYS			57599000021

CLIENT SUMMARY – QUANTITY LIMITS

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Dexcom g6 receiver	*continuous glucose system receiver***		Medicaid
Dexcom g6 sensor	*continuous glucose system sensor***		Medicaid
Dexcom g6 transmitter	*continuous glucose system transmitter***		Medicaid
Dexcom g7 receiver	*continuous glucose system receiver***		Medicaid
Dexcom g7 sensor	*continuous blood glucose system sensor*** ; *continuous glucose system sensor***		Medicaid
Freestyle libre 14 day/re	*continuous glucose system receiver***		Medicaid
Freestyle libre 14 day/se	*continuous blood glucose system sensor*** ; *continuous glucose system sensor***		Medicaid
Freestyle libre 2/reader/	*continuous glucose system receiver***		Medicaid
Freestyle libre 2/sensor/	*continuous glucose system sensor***		Medicaid
Freestyle libre 3/reader/	*continuous glucose system receiver***		Medicaid
Freestyle libre 3/sensor/	*continuous glucose system sensor***		Medicaid
Freestyle libre/reader/fl	*continuous glucose system receiver***		Medicaid

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
QL Standalone	**Quantity limit for the Target Agent(s)** will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. The requested quantity (dose) exceeds the program quantity limit AND ONE of the following: A. BOTH of the following: 1. The requested agent does NOT have a maximum FDA labeled dose for the requested indication **AND** 2. There is support for therapy with a higher dose for the requested indication **OR** B. BOTH of the following: 1. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** 2. There is support for why the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit **OR** C. BOTH of the following: 1. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication **AND** 2. There is support for therapy with a higher dose for the requested indication **Length of Approval**: up to 12 months