Effective Date: 01/01/2022
Last Approval/Version: 01/2024
Next Review Due By: 01/2025
Policy Number: C22081-A

Continuous Glucose Monitoring (CGM) Illinois Medicaid Only

PRODUCTS AFFECTED

Dexcom G4 Platinum Pediatric, Dexcom G4 Platinum, Dexcom G4, Dexcom G5, Dexcom G6, Enlite sensor, Eversense, Eversense E3, Freestyle Libre, Freestyle Libre 14 day, Freestyle Libre 2, Freestyle Libre 3, Guardian, Guardian Connect, Guardian Link 3, Guardian Real-Time, Guardian 4, Minilink Real-Time transmitter, Minimed 630G Guardian, Paradigm Real-Time, SOF-sensor

COVERAGE POLICY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any. This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:
Type 1 Diabetes, Type 2 Diabetes, Gestational Diabetes

REQUIRED MEDICAL INFORMATION:

A. FOR NON-PREFERRED OR NON-FORMULARY PRODUCTS ONLY:
   1. Member meets one of the following [Documentation Required]:
      a. Member has a physical or mental limitation that makes utilization of the preferred (Freestyle Libre, Dexcom G6, Dexcom G7) unsafe, inaccurate or otherwise not feasible
      OR
      b. Provider has demonstrated that use of a NON-FORMULARY/NON-PREFERRED MONITORING SYSTEM is medically necessary for this member.
   AND
   2. Member meets diagnosis-specific criteria below.

B. TYPE 1 DIABETES
   1. Member has a diagnosis of Type 1 Diabetes
   AND

2. Member meets BOTH of the following:
    a. Provider attests that member will be trained on the use of the requested CGM system.
    AND
    b. Requires an intensive insulin regimen (defined as: at least 1 per day dose of basal insulin and 2 or more shorter or rapid acting insulin injections per day) or utilizes an insulin pump.

C. TYPE 2 DIABETES
1. Member has a diagnosis of uncontrolled Type 2 Diabetes
AND
2. Member is currently receiving an intensive insulin therapy (defined as: at least 1 per day dose of basal insulin and 2 or more rapid or shorter acting insulin injections per day)
AND
3. Provider attests that the member has a recent history of emergency room visits or hospitalizations related to hypoglycemia or ketoacidosis.
4. Provider attests that member will be trained on the use of the requested CGM system.

D. GESTATIONAL DIABETES
1. Documentation that member has a current diagnosis of gestational diabetes.
AND
2. Documentation that member has suboptimal glycemic control which is likely to harm the mother or the fetus.
AND
3. Provider attests that member will be trained on the use of the requested CGM system.

CONTINUATION OF THERAPY:

A. ALL INDICATIONS:
1. Provider attests to member's compliance with the CGM and diabetes treatment.
AND
2. Provider attests to member's improved HbA1c or time-in-range glucose values compared to baseline.
AND
3. Provider attests to member's clinical benefit.

DURATION OF APPROVAL:

Sensors and Transmitters: 6 months
Receiver: 12 months
Gestational Diabetes: approval for the remaining duration of that pregnancy and up to 12 months post-partum
Continuation of Therapy: 12 months

PRESCRIBER REQUIREMENTS (Not required for continuation of therapy):

Ordering provider is an Illinois licensed physician specializing in Endocrinology, Diabetes, and Metabolism, or a nurse practitioner/physician assistant working under supervision of that specialist. Other prescribers must consult with a specialist in Endocrinology, Diabetes and Metabolism. That consult may take place through either an in-person or a telehealth visit. Documentation of that consultation will be required for prior approval requests from primary care physicians.

AGE RESTRICTIONS:

None

QUANTITY:

*Sensors	Quantity Limit
Freestyle Libre (10day)	3 per 30 days
Freestyle Libre (14 day)	2 per 28 days
Dexcom G4 (7 days)	4 per 28 days
Dexcom G5 (7 days)	4 per 28 days
Dexcom G6 (10 days)	3 (1 box) per 30 days
Medtronic Guardian Connect (7 days)	5 per 35 days

*Transmitters	Quantity Limit
Dexcom G4	1 transmitter per 180 days
Dexcom G5	1 transmitter per 90 days
Dexcom G6	1 transmitter per 90 days
Medtronic Guardian Connect	1 transmitter per 365 days

*Receiver	Quantity Limit per 365 days
Dexcom G4 Receiver	1 receiver
Dexcom G5 Receiver	1 receiver
Dexcom G6 Receiver Kit	1 receiver per 360 days
FreeStyle Libre Flash Glucose Monitoring System	1 receiver

*Devices not listed must comply with FDA approved quantities based on diagnosis.

PLACE OF ADMINISTRATION:
The recommendation is that CGM supplies in this policy will be for pharmacy benefit coverage and patient self-administered.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Subcutaneous

DRUG CLASS:
Glucose Monitoring Test Supplies

FDA-APPROVED USES:
Indicated for detecting trends and tracking patterns and glucose level excursions above or below the desired range, facilitating therapy adjustments in persons with diabetes.

OTHER CONSIDERATIONS

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
All other uses of Continuous Glucose Monitoring systems are considered experimental/investigational and therefore, will follow Molina's Off- Label policy.

OTHER CONSIDERATIONS:
Only those CGMs meeting the below standards will be approved:

1. An alarm when glucose levels are outside the pre-determined range
2. Capacity to generate predictive alerts in case of impending hypoglycemia
3. Ability to transmit real time glucose values and alerts to patient and designated others

AVAILABLE DEVICES

Dexcom G4 Plat Ped Rcv/Share DEVI
Dexcom G4 Plat Ped Receiver DEVI
Dexcom G4 Platinum Rcv/Share DEVI
Dexcom G4 Platinum Receiver DEVI
Dexcom G4 Platinum Transmitter MISC
Dexcom G4 Sensor MISC
Dexcom G5 Mob/G4 Plat Sensor MISC
Dexcom G5 Mobile Receiver DEVI
Dexcom G5 Mobile Transmitter MISC
Dexcom G5 Receiver Kit DEVI
Dexcom G6 Receiver DEVI
Dexcom G6 Sensor MISC
Dexcom G6 Transmitter MISC
Dexcom G7 Receiver DEVI
Dexcom G7 Sensor MISC
Enlite Glucose Sensor MISC
Eversense Sensor/Holder MISC
Eversense E3 Sensor/Holder MISC
Eversense Smart Transmitter MISC
FreeStyle Libre 14 Day Reader DEVI
FreeStyle Libre 14 Day Sensor MISC
FreeStyle Libre 2 Reader DEVI
FreeStyle Libre 2 Sensor MISC
FreeStyle Libre 3 Reader DEVI
FreeStyle Libre 3 Sensor MISC
FreeStyle Libre Reader DEVI
Guardian Connect Transmitter MISC
Guardian Link 3 Transmitter MISC
Guardian REAL-Time Charger MISC
Guardian REAL-Time Replace Ped DEVI
Guardian REAL-Time Test Plug MISC
Guardian Sensor (3) MISC
Guardian Sensor 3 MISC
Guardian 4 Sensor MISC
MiniLink REAL-Time Transmitter MISC
MiniMed 630G Guardian Press MISC
MiniMed Guardian Link 3 MISC
Paradigm REAL-Time Transmitter MISC

REFERENCES

1. Illinois HFS Drugs with Stipulated PA Language per Contract for MCOs 1.01.24
2. Illinois Medicaid Preferred Drug List, Effective January 1, 2024
3. Illinois Department of Healthcare and Family Services (HFS), Continuous Glucose Monitor (CGM) Prior Authorization Criteria, version 2021, accessed on December 28, 2023 at https://hfs.illinois.gov/content/dam/soi/en/web/hfs/sitecollectiondocuments/cgmcriteria2021final.pdf

SUMMARY OF REVIEW/REVISIONS	DATE
ANNUAL REVIEW - Notable revisions: Products Affected Available Devices Required Medical Information Prescriber Requirements Other Considerations References	01/2024
Annual updates	04/2023
New	12/2021