Effective Date: 01/01/2022
Last P&T Approval/Version: 1/2022
Last Review Date: 4/26/2023
Next Review Date: 4/2024
Policy Number: Pending

Continuous Glucose Monitoring (CGM) Illinois Medicaid Only

PRODUCTS AFFECTED

Dexcom G4, Dexcom G5, Dexcom G6, Dexcom G7, Enlite, Eversense, Freestyle Libre 14 day, Freestyle Libre 2, Freestyle Libre 3, Guardian Real-Time, Guardian, Minilink Real-Time transmitter, MiniMed 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

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, or Freestyle Libre 2, or Dexcom G6, or Dexcom G7 unsafe, inaccurate or otherwise not feasible
      AND
      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 is less than 21 years old and meets BOTH of the following:
      a. Member has been trained on the use of the requested CGM system
         AND
      b. Requires an intensive insulin regimen (1 dose per day of basal insulin and 2 or more shorter or rapid acting insulin injections per day) or utilizes an insulin pump.
      OR
   3. Member is 21 years of age and older and meets ALL of the following:
      a. Member has been trained on the use of the requested CGM system
         AND
      b. Requires an intensive insulin regimen (1 dose per day of basal insulin and 2 or more shorter or rapid acting insulin injections per day) or utilizes an insulin pump.
         AND
      c. Documentation has been provided showing member has failed to achieve glycemic goals

C. Type 2 Diabetes
   1. Member has a diagnosis of Type 2 Diabetes
      AND
   2. Member is currently receiving an intensive insulin therapy (1 dose per day of basal insulin and 2 or more shorter or rapid acting insulin injections per day
   3. ANDMember has at least ONE of the following:
      a. Emergency room visits
         OR
      b. Recurrent documented hypoglycemia including hospitalizations
         OR
      c. Recurrent nocturnal hypoglycemia
         OR
      d. Recurrent ketoacidosis
         OR
      e. Suboptimal glycemic control including wide glycemic swings
         OR
      f. Hyperglycemia
      AND
   4. Member has been 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
      AND
   3. Member has been trained on the use of the requested CGM system.

E. Cystic Fibrosis-Related Diabetes
   1. Documentation that member has a diagnosis of cystic fibrosis-related diabetes
      AND
   2. Documentation that member has suboptimal glycemic control, including wide glycemic swings contributing to exacerbations

CONTINUATION OF THERAPY:

A. ALL INDICATIONS:

1. Documentation of compliance with the CGM is required for continued authorization
   AND
2. Improved HbA1c or time-in-range glucose values compared to baseline.
   AND
3. Clinical benefit as determined by the prescriber.

DURATION OF APPROVAL:
Initial authorization: 12 months, Continuation of Therapy: 12 months

PRESCRIBER REQUIREMENTS:
Ordering provider is a licensed physician specializing in endocrinology, diabetes, and metabolism,or nurse practitioner/physician assistant working with that specialist. Other prescribers, e.g., PCPs, must consult with a licensed physician specializing in endocrinology, diabetes, and metabolism or nurse practitioner/physician assistant working with an endocrinologist.

AGE RESTRICTIONS:
None

QUANTITY:

Sensors	Quantity Limit
Freestyle Libre (14 day)	2 per 28 days
Freestyle Libre 2	2 per 28 days
Freestyle Libre 3	2 per 28 days
Dexcom G4 (7 days)	4 per 28 days2 per 28 days
Dexcom G5 (7 days)	4 per 28
Dexcom G6 (10 days)	3 per 30 days
Dexcom G7 (10 days)	3 per 30 days
Medtronic Guardian Connect (7 days)	5 per 35 days3 (1 box) per 30 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
Dexcom G7 receiver	1 receiver
FreeStyle Libre Flash Glucose Monitoring System	1 receiver
Freestyle Libre 2 Reader	1 receiver

Note: Freestyle Libre 3 and Guardian Connect do not require receivers. Member's smart device acts as receiver.
QL apply across models/generations/systems. Change in model does not constitute need for QL override.

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.

COMPENDIAL APPROVED OFF-LABELED USES:
None

APPENDIX

None

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:
None

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 SPECIAL CONSIDERATIONS:
None

CODING/BILLING INFORMATION

Note: 1) This list of codes may not be all-inclusive. 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

HCPCS CODE	DESCRIPTION
A9276	Sensor; invasive, disposable, for use with interstitial continuous glucose monitoring system, 1unit=1-daysupply
A9277	Transmitter; external, for use with interstitial continuous glucose monitoring system
A9278	Receiver (monitor); external, for use with interstitial continuous glucose monitoring system
A4238	Supply allowance for adjunctive, non-implanted continuous glucose monitor (cgm), includes all supplies and accessories, 1 month supply = 1 unit of service
A4239	Supply allowance for non-adjunctive, non-implanted continuous glucose monitor (cgm), includes all supplies and accessories, 1 month supply = 1 unit of service

E2102	Adjunctive, non-implanted continuous glucose monitor or receiver
E2103	Non-adjunctive, non-implanted continuous glucose monitor or receiver

Note: The term “therapeutic” may be used interchangeably with the term “non-adjunctive.” Likewise, the term “non-therapeutic” may be used interchangeably with the term “adjunctive.”

AVAILABLE DOSAGE FORMS:

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 MISC
Eversense 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 Sensor MISC
FreeStyle Libre Reader DEVI
FreeStyle Libre Sensor System MISC
Guardian Connect Transmitter MISC
Guardian Link 3 Transmitter MISC
Guardian REAL-Time Charger MISC
Guardian REAL-Time Replace Ped DEVI
Guardian REAL-Time Replacement DEVI
Guardian REAL-Time Starter KIT
Guardian REAL-Time System KIT
Guardian REAL-Time System Ped KIT
Guardian REAL-Time Test Plug MISC
Guardian RT Software MISC
Guardian RT Starter KIT
Guardian RT System KIT
Guardian Sensor (3) MISC
Guardian Sensor 3 MISC
Guardian Transmitter MISC
MiniLink REAL-Time Transmitter MISC
MiniMed 630G Guardian Press MISC
Paradigm REAL-Time Starter KIT
Paradigm REAL-Time Transmitter MISC
Sof-Sensor MIS

REFERENCES

1. Illinois HFS Drugs with Stipulated PA Language per Contract for MCOs 4.01.23
2. Illinois Medicaid Preferred Drug List, Effective April 1, 2023
3. Illinois Department of Healthcare and Family Services (HFS) University of Illinois at Chicago – College of Pharmacy, Prior Authorization Continuous Glucose Monitor (CGM), version 3/2019, accessed on March 23, 2023 at https://www2.illinois.gov/hfs/SiteCollectionDocuments/CGMCriteriaApril2019.pdf
4. https://www.fda.gov/news-events/press-announcements/fda-authorizes-first-fully-interoperable-continuous-glucose-monitoring-system-streamlines-review

SUMMARY OF REVIEW/REVISIONS	DATE
ANNUAL REVIEW COMPLETED- No coverage criteria changes with this annual review.	Q4/2023