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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 transmitter, Freestyle Libre 14 day, Freestyle Libre 2, Guardian Real-Time, Guardian, Minilink Real-Time transmitter, Paradigm Real-Time

### 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 unsafe, inaccurate or otherwise not feasible  
AND
  - b. Member has a physical or mental limitation that makes utilization of the preferred Dexcom G6 unsafe, inaccurate or otherwise not feasible  
OR
  - c. 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.

## Drug and Biologic Coverage Criteria

### 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 (2 or more 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 (2 or more 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 and frequently tests blood glucose  
AND
3. Member has at least ONE of the following:
  - a. Hypoglycemic unawareness  
OR
  - b. Recurrent documented hypoglycemia  
OR
  - c. Recurrent nocturnal hypoglycemia  
OR
  - d. Recurrent ketoacidosis  
OR
  - e. Suboptimal glycemic control including wide glycemic swings

### D. Gestational Diabetes

1. Documentation that member has a current diagnosis of gestational diabetes  
AND
2. Documentation that member has suboptimal glycemic control

### 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

## DURATION OF APPROVAL:

Initial authorization: 12 months, Continuation of Therapy: 12 months

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## Drug and Biologic Coverage Criteria

### PRESCRIBER REQUIREMENTS:

Ordering provider is an endocrinologist or nurse practitioner/physician assistant working with an endocrinologist. Other prescribers, e.g., PCPs, must consult with an endocrinologist or nurse practitioner/physician assistant working with an endocrinologist. If such consult is not feasible, the provider may submit the request and note that specialist consult is not available.

### 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

### 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*

<b>HCPCS CODE</b>	<b>DESCRIPTION</b>
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

**AVAILABLE DOSAGE FORMS:**

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

## REFERENCES

1. Illinois HFS Drugs with Stipulated PA Language per Contract for MCOs 1.01.22
2. Illinois Medicaid Preferred Drug List, Effective January 1, 2022
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 November 23, 2021 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>

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