

Continuous Glucose Monitoring (CGM) Systems

Generic Name: N/A

Therapeutic Class or Brand Name: Continuous Glucose Monitoring (CGM) Systems

Applicable Drugs (if Therapeutic Class):

FreeStyle Libre, Freestyle Libre 14 Day; all Dexcom® CGMs. Guardian Connect® CGM System, Eversense®

GPI Code: Class: 97202012 (Sensors: 97202012046300; Reader Devices: 97202012026200; Transmitters: 97202012066300)

Preferred: Dexcom G6® , Freestyle Libre, FreeStyle Libre 14 Day

Non-preferred: Dexcom G4®, Dexcom G5®, Eversense®, Guardian Connect®

Date of Origin: 5/18/2018

Date Last Reviewed / Revised: 2/20/2020

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I through III are met)

- I. The patient fulfills ONE of the following diagnosis criteria A through C:
 - A. Diagnosis of diabetes mellitus Type I AND ONE of the following:
 1. Requires 4 or more times Self Monitored Blood Glucose (SMBG) checks per day.
 2. Use of an insulin pump.
 - B. Diagnosis of diabetes mellitus Type II requiring SMBG checks 4 or more times per day AND on insulin therapy via ONE of the following methods:
 1. Basal insulin plus mealtime insulin injections.
 2. Use of an insulin pump.
 - C. Diagnosis of diabetes mellitus Type I or II with history of recurrent hypoglycemia (blood glucose 70 mg/dL or lower) and/or hypoglycemia unawareness
- II. The patient fulfills the age requirement for the device requested:
 - A. Dexcom G6: 2 years of age and older
 - B. Eversense: 18 years of age and older
 - C. Freestyle Libre, Freestyle Libre14 Day: 18 years of age and older
 - D. Guardian Connect: 14 years of age and older
- III. Refer to plan document for the list of preferred products. If requested agent is not listed as a preferred product, must have a documented failure, intolerance, or contraindication to a preferred product(s).

EXCLUSION CRITERIA

- Diagnosis of gestational diabetes.

OTHER CRITERIA

- N/A

QUANTITY / DAYS SUPPLY RESTRICTIONS

- Dexcom G6
 - Sensors: 3 per 30 days
 - Receiver: 1 unit per year
 - Transmitter: 1 unit per year
- Freestyle Libre (10 day)
 - Sensors: 3 per 30 days.
 - Reader device: 1 unit per year.
- FreeStyle Libre 14 Day:
 - Sensors: 2 per 28 days
 - Reader device: 1 unit per year
- Eversense
 - Sensor: 1 per 90 days
 - Transmitter: 1 unit per year
- Guardian Connect
 - Sensors: 5 per 30 days
 - Receiver: 1 unit per year
 - Transmitter: 1 unit per year

APPROVAL LENGTH

- **Authorization:** 1 year. Ensure that authorization include applicable sensors, receivers, reader devices and transmitters WITH appropriate quantities and days supply restrictions.
- **Re-Authorization:** An updated letter of medical necessity or progress notes showing that current prior authorization criteria are met and that the medication is effective.

APPENDIX

N/A

REFERENCES

1. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5306122/> .

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2. <https://www.ncbi.nlm.nih.gov/pubmed/27634581> .
3. <https://www.ncbi.nlm.nih.gov/pubmed/29273897> .
4. http://care.diabetesjournals.org/content/42/Supplement_1 .
5. <https://diatribe.org/freestyle-libre-us-now-approved-14-day-wear-and-1-hour-warmup> .
6. <https://integrateddiabetes.com/continuous-glucose-monitor-comparisons-and-reviews/> .
7. <https://diatribe.org/dexcom-g6-review-no-fingersticks-cgm-one-button-insertion-and-10-day-wear> .
8. <https://integrateddiabetes.com/continuous-glucose-monitor-comparisons-and-reviews/> .

HISTORICAL TRACKING OF CHANGES MADE TO POLICY

Date	Notes/Changes
2/20/2020	<ol style="list-style-type: none"> 1. Added "Ensure that authorization include applicable sensors, receivers, reader devices and transmitters WITH appropriate quantities and days supply restrictions under Approval Length authorization."
12/19/2019	<ol style="list-style-type: none"> 1. Updated name of Policy from "Freestyle Libre 14 day Continuous Glucose Monitor" to "Continuous Glucose Monitoring Systems (CGMs)". 2. Changed Generic Name to N/A 3. Added "Class: 97202012" to address all CGMs and/or supplies under GPI Code section. 4. Added Dexcom, Eversense, and Guardian Connect under Applicable Drugs. 5. Added "Continuous Glucose Monitoring Systems (CGMs)" under Therapeutic class 6. Added Dexcom, FreeStyle Libre, and FreeStyle Libre 14 day under Preferred. 7. Added Dexcom G4, Dexcom G5, Eversense and Guardian Connect under Non-preferred. 8. Added the following age limit criteria under Prior Authorization Criteria: <ol style="list-style-type: none"> I. The patient fulfills the age requirement for the device requested: <ol style="list-style-type: none"> A. Dexcom G6: 2 years of age and older B. Eversense: 18 years of age and older C. Freestyle Libre, Freestyle Libre14 Day: 18 years of age and older D. Guardian Connect: 14 years of age and older 9. Added criterion "Refer to plan document for the list of preferred products. If requested agent is not listed as a preferred product, must have a documented failure, intolerance, or contraindication to a preferred product(s). " under Prior Authorization Criteria. 10. Changed organization of the diagnosis criteria under Prior Authorization Criteria <u>FROM</u>:

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- I. Diagnosis of diabetes mellitus Type I AND ONE of the following:
 - A. Requires 4 or more times Self Monitored Blood Glucose (SMBG) checks per day.
 - B. Use of an insulin pump.
- II. Diagnosis of diabetes mellitus Type II requiring SMBG checks 4 or more times per day AND on insulin therapy via ONE of the following methods:
 - A. Basal insulin plus mealtime insulin injections.
 - B. Use of an insulin pump.

Diagnosis of diabetes mellitus Type I or II with history of recurrent hypoglycemia (blood glucose 70 mg/dL or lower) and/or hypoglycemia unawareness

TO:

- I. The patient fulfills ONE of the following diagnosis criteria A through C:
 - A. Diagnosis of diabetes mellitus Type I AND ONE of the following:
 - 1. Requires 4 or more times Self Monitored Blood Glucose (SMBG) checks per day.
 - 2. Use of an insulin pump.
 - B. Diagnosis of diabetes mellitus Type II requiring SMBG checks 4 or more times per day AND on insulin therapy via ONE of the following methods:
 - 1. Basal insulin plus mealtime insulin injections.
 - 2. Use of an insulin pump.
 - C. Diagnosis of diabetes mellitus Type I or II with history of recurrent hypoglycemia (blood glucose 70 mg/dL or lower) and/or hypoglycemia unawareness

11. Changed Quantity/Days Supply Restrictions from sensors: 2 sensors/28 days and reader device 1 unit every 2 years to:

- Dexcom G6
 - Sensors: 3 per 30 days
 - Receiver: 1 unit per year
 - Transmitter: 1 unit per year
- Eversense
 - Sensor: 1 per 90 days
 - Transmitter: 1 unit per year
- Freestyle Libre
 - Sensors: 3 per 30 days.
 - Reader device: 1 unit per year.
- FreeStyle Libre 14 Day:
 - Sensors: 2 per 28 days
 - Reader device: 1 unit per year
- Guardian Connect
 - Sensors: 5 per 30 days
 - Receiver: 1 unit per year
 - Transmitter: 1 unit per year

12. Added items 6 - 8 under References.

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5/9/2019	<ol style="list-style-type: none"> 1. Updated name of product from "Freestyle Libre" to "Freestyle Libre 14 Day" to reflect new product name. 2. Changed number of sensors from "3 sensors per 30 days" to "2 sensors per 28 days" to reflect new FDA approval for 14-day use instead of 10-day use for each sensor under Quantity/Days Supply Restrictions. 3. Added item #5 https://diatribe.org/freestyle-libre-us-now-approved-14-day-wear-and-1-hour-warmup under References. 4. Deleted obsolete URL: https://tuftshealthplan.com/documents/providers/guidelines/medical-necessity-guidelines/cgms under References. 5. Updated URL #3 for 2018 diabetes management guidelines (http://care.diabetesjournals.org/content/42/Supplement_1) to URL for 2019 guidelines under References.
5/18/2018	<ol style="list-style-type: none"> 1. New policy created.

DISCLAIMER: Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgement in providing the most appropriate care for their patients.