



## Insulin Pump and Continuous Glucose Monitoring Systems

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### Policy

The Medical Management Department reviews referral requests for authorization of the purchase of insulin pumps, continuous glucose monitoring systems and related supplies.

**NOTE: Requests for Insulin Pumps and Continuous Glucose Monitoring (CGM) Systems for patients who have received their initial device prior to coverage with Quartz, will be reviewed using the replacement criteria.**

This Medical Policy does not constitute medical advice. When deciding coverage, the enrollee's specific plan document must be referenced. The terms of an enrollee's plan document (Certificate of Coverage (COC) or Summary Plan Description (SPD)) may differ from this Medical Policy. In the event of a conflict, the enrollee's specific benefit plan document supersedes this Medical Policy. All reviewers must first identify enrollee eligibility, any federal or state regulatory requirements, and the plan benefit coverage prior to use of this Medical Policy. Other Policies and Coverage Determination Guidelines may apply. Quartz reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary.

### Procedure

#### **A. Documentation Required:**

In order to facilitate the authorization process, referral requests **MUST** include the following:

1. Evidence of the patient's adherence to an intensive insulin therapy regimen; **AND**
2. History of the patient's pattern of hypoglycemic episodes, symptoms reported and measures required as treatment for low blood glucose events; **AND**
3. An order from the Endocrinologist or Diabetes specialist; **AND**
4. The ordered device is FDA approved for use by the age group of the patient.

#### **B. Criteria for Medical Necessary for Specific Glucose Management Devices:**

##### **1. Authorization of Initial Insulin Pump:**

External insulin pump devices are considered medically necessary if **ALL** of the following criteria are met:

- a. The insulin pump is prescribed by an Endocrinologist or Diabetes specialist who has expertise in the management of insulin pumps; **AND**
- b. The patient has been established on an intensive insulin therapy of at least 3 insulin injections per day with frequent self-adjustments of insulin dose and **ONE** of the following:
  - i. Has been established on an Intensive insulin therapy regimen for at least 6 months; **OR**
  - ii. Has been established on intensive insulin therapy regimen for less than 6 months during pregnancy to avoid fetal and maternal complications; **OR**
  - iii. For children aged 6 months to 6 years of age;

- c. The patient demonstrates compliance with a diabetic education program that meets **ONE** of the following:
  - i. documented blood glucose testing at least three (3) times per day for a minimum of three (3) months;
  - ii. the 3-month time period may be waived during pregnancy to avoid fetal and maternal complications); **AND**
- d. The patient meets at least **ONE** of the following criteria while on the intensive insulin therapy regimen:
  - i. Hemoglobin A1C greater than 7.0%
    - Hemoglobin A1C requirement may be waived during pregnancy;
    - Hemoglobin A1C requirement may be waived for children 6 months to 6 years of age); **OR**
  - ii. History of recurring severe hypoglycemia (*less than 50mg/dL*); **OR**
  - iii. Dawn phenomenon with fasting blood sugars frequently exceeding 200mg/dl; **OR**
  - iv. History of severe glycemic excursions; **OR**
  - v. Recurrent nocturnal hypoglycemia **OR**
  - vi. Extreme sensitivity to insulin; **OR**
  - vii. wide fluctuations in blood glucose before mealtimes;

**NOTE:** Insulin pumps must be FDA approved for the age of the infant/child.

## 2. Authorization of a Replacement of Insulin Pump:

**In compliance with Wisconsin Statue 632.895, replacement of an insulin pump determined to be medically necessary is limited to one pump per year.**

Exception to Wisconsin Statue 632.895: Members with Diabetes managed with an insulin pump obtained prior to coverage with Quartz must meet the initial pump criteria 1a, 1b, and 1c above for approval of an insulin pump replacement.

**Note:** If a member is currently approved for a CGM and their existing CGM is not compatible with the replacement insulin pump, the CGM may be approved for replacement.

## 3. Indications Considered Experimental, Investigational or not Medically Necessary for Insulin Pumps: (*Not all inclusive*)

- a. Clinical use in pediatric patients under the age of 6 months.
- b. Implantable pumps for the infusion of insulin to treat diabetes.
- c. Insulin pumps that are not FDA approved for use by the age group of the patient.

## 4. Authorization of Initial Continuous Glucose Monitor (CGM)

Continuous glucose monitoring systems are considered medically necessary when **BOTH** of the following are met:

- a. The CGM is prescribed by an Endocrinologist or Diabetes specialist who has expertise in the management of CGM systems; **AND**
- b. The patient meets **ONE** of the following criteria (i or ii):

- i. Type 1 diabetes with a current insulin pump and **BOTH** of the following:
  - 1) Documented compliance with blood glucose testing at least three (3) times per day; **AND**
  - 2) The patient is unable to achieve optimum glycemic control index (defined as an Hgb A1C of  $\leq 7\%$ ); **OR** is having frequent severe hypoglycemic events (less than 50 mg/dL) to maintain optimum glycemic control index (defined as an Hgb A1C of  $\leq 7\%$ ); **OR**
  
- ii. Type 1 diabetes with **ALL** of the following criteria:
  - 1) The patient has been established on an intensive insulin therapy regimen with at least three (3) insulin injections per day; with frequent self-adjustments of insulin dose; for at least six (6) months; **AND**
  - 2) The patient demonstrates compliance with a diabetic education program including documented blood glucose testing at least three (3) times per day for a minimum of three (3) months; **AND**
  - 3) The patient meets at least **ONE** of the following criteria while on the intensive insulin therapy regimen:
    - a) Hemoglobin A1C greater than 7.0%; **OR**
    - b) History of recurring severe hypoglycemia (*less than 50 mg/dL*);
    - c) Dawn phenomenon with fasting blood sugars frequently exceeding 200mg/dl; **OR**
    - d) History of severe glycemic excursions; **OR**
    - e) Recurrent nocturnal hypoglycemia **OR**
    - f) Extreme sensitivity to insulin; **OR**
    - g) Wide fluctuations in blood glucose before mealtimes.
  
- iii. Type 2 diabetes with recurrent, severe hypoglycemic events (less than 50mg/dL) despite appropriate modifications in insulin therapy and **ALL** of the following criteria:
  - 1) Documented compliance with blood glucose testing at least three (3) times per day; **AND**
  - 2) The patient has been established on an intensive insulin therapy regimen with at least three (3) insulin injections per day; with frequent self-adjustments of insulin dose; for at least six (6) months; **AND**
  - 3) The patient is unable to achieve optimum glycemic control index (defined as an Hgb A1C of  $\leq 7\%$ ); **OR** is having frequent severe hypoglycemic events (less than 50 mg/dL) in order to maintain glycemic control.

**5. Authorization of a Replacement Continuous Glucose Monitor:**

CGM replacement is considered medically necessary if **ALL** of the following criteria are met:

- a. Patient has used the device an average of at least 5 days per week during the month prior to the request for replacement; **AND**
  
- b. Patient has been evaluated annually by an Endocrinologist or Diabetes specialist; **AND**

- c. Patient's current CGM is out of warranty and the equipment is malfunctioning or damaged/inoperable (excludes misuse, abuse or neglect as determined by the service provider).

**6. Indications Considered Experimental, Investigational or not Medically Necessary for Continuous Glucose Monitoring Systems: (Not all inclusive)**

- a. Additional software or hardware required for downloading data to a device such as personal computer, smart phone, or tablet to aid in self-management of diabetes mellitus.
- b. Combination devices that include a home blood glucose monitor combined with a cellular telephone or other device not specifically indicated for the management of diabetes mellitus (e.g., blood pressure monitor, cholesterol screening analyzer).
- c. Remote glucose monitoring device (e.g., mySentry).
- d. Continuous Glucose Monitoring systems that are not FDA approved for use by the age group of the patient.
- e. Freestyle Libre System is not a covered device under the medical benefit.

**CPT/HCPCS Codes:**

E0784	External Ambulatory Infusion Pump, Insulin
A9277	Transmitter; External, For Use With Interstitial Continuous Glucose Monitoring System
A9278	Receiver (Monitor); External, For Use With Interstitial Continuous Glucose Monitoring System
A9276	Sensor; Invasive (e.g., Subcutaneous), Disposable, For Use With Interstitial Continuous Glucose Monitoring System, One Unit = 1-day Supply
A9274	External Ambulatory Insulin Delivery System, Disposable, Each, Includes All Supplies and Accessories

**REFERENCES:**

Agency for Healthcare Research and Quality (AHRQ), Methods of Insulin Delivery and Glucose Monitoring Comparative Effective Review, No. 57, 2012.

American Diabetes Association. Standards of medical care in diabetes - 2019. Diabetes Care. 2019;42(Suppl 1):S1-193. Available at: <http://professional.diabetes.org/ResourcesForProfessionals.aspx?cid=84160>.

CMS Pub 100-03 National Coverage Determination for Infusion Pumps, Section 280.14. Available at <https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=40&fromdb=true> Accessed May 22, 2019.

Garber AJ, Abrahamson MJ, Barzilay JI, et al. Consensus statement by the American Association of Clinical Endocrinologists/American College of Endocrinology on the comprehensive type 2 diabetes mellitus management algorithm – 2019. *Endocrine Practice*. 2019;25(1):69-100.

Grunberger G, Abelseth JM, Bailey TS, et al. Consensus statement by the American Association of Clinical Endocrinologists/American College of Endocrinology insulin pump management task force. *Endocrine Practice*. 2014;20(5):463-489.

Hayes, Inc. Medical Technology Directory. Continuous glucose monitoring systems. Publication date August 13, 2015. Annual review July 31, 2018. Accessed May 15, 2019.

Moy F, Ray A, Buckley BS, West HM. Techniques of monitoring blood glucose during pregnancy for women with pre-existing diabetes. *Cochrane Database of Systematic Reviews* 2017, Issue 6. Art. No.: CD009613. DOI: 10.1002/14651858.CD009613.pub3.

Raman P, Shepherd E, Dowswell T, Middleton P, Crowther CA. Different methods and settings for glucose monitoring for gestational diabetes during pregnancy. *Cochrane Database of Systematic Reviews* 2017, Issue 10. Art. No.: CD011069. DOI: 10.1002/14651858.CD011069.pub2.

Sundberg F, Barnard K, Cato A, et al. Managing diabetes in preschool children. *Pediatric Diabetes*, 2017;18(7), 499–517.

WI Medicaid Forward Health. Forward health coverage and prior authorization policy for personal continuous glucose monitoring devices and accessories. No. 2016-48. October 2016. Available at <https://www.forwardhealth.wi.gov/kw/pdf/2016-48.pdf> Accessed May 22, 2019.

Yeh HC, Brown TT, Maruthur N, et al. Comparative Effectiveness and Safety of Methods of Insulin Delivery and Glucose Monitoring for Diabetes Mellitus – A Systematic Review and Meta-analysis, *Ann Intern Med*. 2012;157:336-347.