curative

TITLE:	GLUCOSE MONITORING POLICY
POLICY #:	MM-PNP-041
VERSION #:	01
DEPARTMENT:	MEDICAL MANAGEMENT
ORIGINAL EFFECTIVE DATE:	05/01/2022
CURRENT REVISION DATE:	N/A

1. PURPOSE

Provides guidelines regarding the medical necessity review of glucose monitoring systems/devices

2. SCOPE

Medical and Pharmacy UM Departments

3. DEFINITIONS

N/A

4. RESPONSIBILITIES

N/A

5. POLICY

PRIOR AUTHORIZATION CRITERIA FOR APPROVAL

Target Agent(s) (as determined by client) will be approved when ONE of the following is met:

1. The patient's medication history includes use of a rapid acting insulin (e.g. Admelog, Afrezza, Apidra, Fiasp, Humalog, Novolog) OR regular insulin within the past 90 days

   OR

2. Information has been provided that the patient is currently being treated with the requested agent within the past 90 days

Length of approval: 12 months

NOTE: If Quantity Limit program also applies, please refer to Quantity Limit documents.

Medical Necessity

Curative considers the following medically necessary for persons with diabetes:

Diabetic Supplies

The following diabetic supplies:

- Alcohol swabs;

- Blood glucose monitors;
- Blood glucose test strips;
- Control solutions;
- Insulin pens;
- Lancets;
- Needles and syringes for insulin administration; *and*
- Urine test tablets/strips.

Glutamic Acid Decarboxylase (GAD) Autoantibodies

- Measurement of autoantibodies to GAD for distinguishing type 1 from type 2 diabetes when the clinical history is ambiguous and the results of testing will influence patient management;
- Measurement of anti-GAD antibodies in diagnosing stiff-person syndrome.

Anti-GAD antibody measurement is considered experimental and investigational for predicting the onset of diabetes and for all other indications.

Jet Injectors

Jet injectors (e.g., Vita-Jet II, Advanta Jet, Freedom Jet, Medi-Jector EZ, Biojector 2000) as durable medical equipment (DME) when the member or the member's caregiver is physically unable to use a conventional needle-syringe.

The use of jet injectors for other reasons is considered a matter of preference and convenience.

Continuous Glucose Monitoring Devices

Short-Term CGM

Short-term CGM use (3-14 days) by a healthcare provider for diagnostic purposes is proven and medically necessary for managing individuals with diabetes.

Long-Term CGM

Note: Coverage criteria noted below must be met whether the request comes through the UnitedHealthcare prior authorization process (type 2 or gestational diabetes) or a contracted supplier (type 1 diabetes).

Duration of approved authorization:

- Initial CGM authorization will be for up to six months.
- Reauthorization will be for up to 12 months.

For initial use, CGM is proven and medically necessary for managing individuals with diabetes in the following circumstances:

- Long-term use (greater than 14 days) for personal use at home for managing individuals with diabetes during pregnancy when certain criteria are met.
- Long-term use (greater than 14 days) for personal use at home for managing individuals with type 1 or type 2 diabetes when certain criteria are met. Medical Equipment, Continuous Glucose Monitors (Custom) - UHG.

For continuous long-term use, CGM is proven and medically necessary for managing individuals with diabetes who meet all of the following criteria:

- Clinical criteria noted above for initial use must be met.
- Individuals are assessed by a provider every six months for adherence to the prescribed CGM regimen and treatment plan.

CGM using the Eversense implantable glucose sensor is proven and medically necessary for managing individuals with type 1 or insulin-requiring type 2 diabetes when all of the following criteria are met:

- When used according to U.S. Food and Drug Administration (FDA) labeled indications, contraindications, warnings and precautions.
- Clinical criteria noted above for initial long-term (greater than 14 days) CGM use are met.

Due to insufficient evidence of efficacy, CGM using a noninvasive device is unproven and not medically necessary for managing individuals with diabetes

- The short-term (72 hours to 1 week) diagnostic use of continuous glucose monitoring devices for persons with diabetes who have either of the following problems in controlling blood glucose level, unresponsive to conventional insulin dose adjustment:
    - Hypoglycemia unawareness; *or*
    - Repeated hypoglycemia (less than 50 mg/dL) and hyperglycemia (greater than 150 mg/dL) at the same time each day;
- The short-term (72 hours to 1 week) diagnostic use of continuous glucose monitoring devices to diagnose primary islet cell hypertrophy (nesidioblastosis) or persistent hyperinsulinemic hypoglycemia of infancy (PHHI) (congenital hypoglycemia) in persons with symptoms suggestive of recurrent hypoglycemia. For short-term (72 hours to 1 week) diagnostic use, no more than 2 continuous glucose monitoring periods within a 12-month period.
- The long-term (greater than 1 week) therapeutic use of continuous glucose monitoring devices for adults aged 18 years and older with type 1 or type 2 diabetes using intensive insulin regimens (multiple (3 or more) daily injections or insulin pump therapy) who are either not meeting glycemic targets or experiencing hypoglycemia (including hypoglycemic unawareness); and persons with glycogen storage diseases;
    - CGMS for younger persons with type 1 diabetes or type 2 diabetes using intensive insulin regimens;
    - Continued use of CGMs for adults aged 18 years and older who are either 1) experiencing improved glycemic control or decreased hypoglycemia episodes while using a CGM, or 2) are being assessed every six months by the prescriber for adherence to their CGM regimen and diabetes treatment plan.;
    - Continued use of CGMs for children and adolescents less than 18 years of age with type 1 or type 2 diabetes.

The long-term use of continuous glucose monitoring devices is considered experimental and investigational for all other indications.

Curative considers experimental and investigational the long-term (therapeutic) use of continuous glucose monitors for persons with type 2 diabetes not using intensive insulin regimens, nesidioblastosis (primary islet cell hypertrophy), neonatal hypoglycemia, and for

monitoring blood glucose in non-diabetic persons following gastric bypass surgery because there is insufficient evidence of the clinical benefits of this approach for these indications.

Artificial Pancreas Device Systems

- A continuous glucose monitor and insulin pump with a low glucose suspend feature (e.g., MiniMed 630G) as an equally acceptable alternative to a standard insulin pump and continuous glucose monitor for medically necessary indications;
- A continuous glucose monitor and insulin pump with closed loop system (programmed to automatically adjust delivery of basal insulin based on continuous glucose monitor sensor glucose values) (e.g., Medtronic MiniMed 670G/MiniMed 770G, Tandem t:slim X2 insulin pump with Basal-IQ Technology) as an equally acceptable alternative to a standard insulin pump and continuous glucose monitor for medically necessary indications.

Note: For Trina Health artificial pancreas treatment, see CPB 0742 - Intermittent Intravenous Insulin Therapy.

Blood Glucose Meters for Persons with Visual Impairment

Reflectance meters with an electronic voice, automatic timers, and specially designed arrangements of supplies and materials to allow the visually impaired to use the equipment without assistance as DME only for legally blind (best corrected visual acuity less than 20/200) persons with diabetes.

Blood Glucose Monitors with Integrated Lancing/Blood Sample

Blood glucose monitors with integrated lancing/blood sample as DME in persons with diabetes who meet *either* of the following criteria:

- Persons who are legally blind (best corrected visual acuity less than 20/200); *or*
- Persons with impairment of manual dexterity severe enough to require the use of this special monitoring system.

Alternate Site Blood Glucose Monitors

- Alternate site blood glucose monitors as DME for the following persons with diabetes, when an alternate site blood glucose monitor is recommended by their physician:
    - Children below age of 12 years; *or*
    - Persons who have used conventional blood glucose meters for at least 1 month (more than 30 days) and who have been non-compliant with blood glucose testing because of pain sensitivity or heavily callused fingertips.

Alternate site blood glucose monitors have no proven value over standard blood glucose monitors for other indications.

Disposable Blood Glucose Monitor

A disposable blood glucose monitor (e.g., the ReliOn NewTek (Hypoguard USA, Inc., Edina, MN)) is an acceptable alternative to a standard blood glucose monitor.

Insulin Infusion Pumps

For clinical policy on insulin infusion pumps, please see CPB 0161 - Infusion Pumps.

Flash Glucose Monitoring Systems

Intermittently scanned "flash" continuous glucose monitoring systems (FreeStyle Libre Flash Glucose Monitoring System) are an equally acceptable alternative to other continuous glucose monitoring systems for medically necessary indications.

Implantable Glucose Sensors

Continuous glucose monitors with implantable glucose sensors (e.g., the Eversense E3 implantable CGM sensor) are an equally acceptable alternative to standard continuous glucose monitors for medically necessary indications.

I-Port

Curative considers the I-Port Injection Port (Patton Medical) a non-covered convenience item.

Combinational Items

Curative considers combination devices that include a home blood glucose monitor combined with a blood pressure monitor, cholesterol screening analyzer, or other devices (e.g., cellular telephone) not specifically indicated for the management of diabetes mellitus as not medically necessary convenience items.

Hypoglycemic Wristband Alarms

Curative considers hypoglycemic wristband alarms (e.g., Sleep Sentry) a noncovered convenience item.

Cellular Glucometry

Curative considers a feature that allows wireless transmission of blood glucose test results (cellular-enabled glucometer) as an integral part of the glucometer and not separately reimbursed.

Experimental and Investigational

The following interventions are considered experimental and investigational because the effectiveness of these approaches has not been established:

Lasette™ Laser Blood Glucose Monitoring Device

The Lasette laser blood glucose monitoring device (Cell Robotics International Inc., Albuquerque, NM) uses a laser instead of a lancet to perforate the skin to obtain a blood sample for glucose measurement. There is insufficient evidence in the peer-reviewed medical literature that laser skin perforation offers clinically significant advantages over standard lancets.

Glycated Serum Proteins (GSP)

The clinical utility of monitoring glycated serum proteins with devices to measure glycated serum proteins (fructosamine) (e.g., Duet™ Glucose Control System by LXN Corporation) has not been established.

PreDX Test

The PreDx Test has inadequate evidence in the published peer-reviewed clinical literature regarding its effectiveness.

Biostator® Artificial Pancreas

There are insufficient data in the published peer-reviewed medical literature documenting the safety and effectiveness of the Biostator System, a device which functions as an artificial pancreas.

GlucoWatch® Biographer Monitor

The GlucoWatch Biographer (Cygnus Inc, Redwood City, CA.), a glucose meter that is worn on the wrist.

Home Glycated Hemoglobin Monitors

For home glycated hemoglobin (HbA1c or A1C) monitors (e.g., A1cNow Diabetes Monitor, Metrika Inc., Sunnyvale, CA) there are no prospective clinical studies demonstrating improvements in compliance or other clinically significant benefits of home A1C testing over laboratory A1C testing. Individual-case exceptions to this policy may be made upon medical review for members who are unable to access laboratory A1C testing.

Diabetes Management Software

Curative considers mobile application software (e.g., BlueStar, d-Nav) for self-management of diabetes experimental and investigational because its effectiveness has not been established.

Note: Curative considers computer software for analyzing blood glucose monitor test results as an integral part of a blood glucose monitor and not separately reimbursed. In addition, software or hardware required for downloading data from a blood glucose monitor to a computer are considered an integral part of the blood glucose monitor and not separately reimbursed.

For mobile application software for self-management of diabetes, see CPB 0999 - Prescription Digital Therapeutics.

Personal Digital Assistant-Based Blood Glucose Monitor

A personal digital assistant-based blood glucose monitoring device (e.g., TheraSense FreeStyle Tracker, Accu-Check Advantage Module) and module have not been shown in published clinical studies to improve clinical outcomes over standard blood glucose monitors. **Note:** A personal digital assistant (PDA) does not meet Curative's definition of covered DME in that the PDA can be used in the absence of illness or injury.

Infrared Thermometer Device

There is insufficient evidence for the effectiveness of an infrared thermometer device (e.g., TempTouch) for the intermittent measurement and monitoring of skin surface temperature in reducing the risk for diabetic foot ulceration.

Measurement of Advanced Glycation End Products by Skin Autoflourescence

There is insufficient evidence of the effectiveness of measurement of advanced glycation end products by skin autofluorescence compared to the oral glucose tolerance test.

Remote Glucose Monitoring

There is insufficient published evidence of the impact of remote glucose monitoring on clinical outcomes by remote wireless glucose monitoring devices (e.g., mySentry) for managing persons with diabetes. Curative does not cover an attachment to allow wireless transmission from a continuous glucose monitor to a smart phone or computer (e.g., MiniMed Connect) because it is considered a convenience feature. Curative provides no additional reimbursement for a wireless transmission feature that is integrated into a continuous glucose monitor (e.g., Dexcom SHARE) because it is considered a convenience feature.

Cellular Activation Therapy

Cellular activation therapy by means of the Bionica Microdose infusion pump (Diabetic Innovations, Franklin lakes, NJ).

Policy Limitations and Exclusions

Note: Except for Medicare plans and where coverage is mandated by state law, generally coverage for diabetic supplies would be provided under a pharmacy rider and not as part of medical coverage. Certain diabetic supplies may also be covered under the medical plan if no pharmacy or diabetic supplies rider is available. Please check plan benefits.

Note: Coverage of diabetic supplies varies by medical and pharmacy plan. Please check plan documents for details.

6. PROCEDURE

N/A

7. TRAINING REQUIREMENT

7.1. All Medical and Pharmacy UM associates responsible for reading and comprehending this procedure. Employees are also responsible for contacting management or Privacy and Compliance with any questions or concerns regarding the information contained within this procedure.

8. ENFORCEMENT

Violations of this controlled document will cause the imposition of sanctions in accordance with the Curative sanctions controlled document. This may include verbal/written warning, suspension, up to termination of employment or volunteer, intern, contractor status with Curative. Additional civil, criminal and equitable remedies may apply.

9. DOCUMENTATION

N/A

10. REFERENCE DOCUMENTS AND MATERIALS

N/A

11. COLLABORATING DEPARTMENTS

11.1. Medical and Pharmacy

12. DOCUMENT CONTROL

APPROVED BY:		
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REVISION HISTORY			
Date	**Author**	**Version**	**Comments**
			Initial Version

APPENDICES

N/A