Policy and Procedure	
PHARMACY PRIOR AUTHORIZATION POLICY AND CRITERIA ORPTCOTH017.1024	**MISCELLANEOUS PRODUCTS** **DIABETIC DURABLE MEDICAL EQUIPMENT (DME)** Non-preferred diabetic DME products/supplies and quantity limit exceptions
Effective Date: 1/1/2025	**Review/Revised Date**: 01/17, 05/18, 09/18, 11/18, 02/19, 09/19, 09/20, 09/21, 09/22, 08/23, 09/23, 09/24 (JLS)
Original Effective Date: MM/YY	**P&T Committee Meeting Date**: 02/17, 06/18, 09/18 (cv), 12/18, 04/19, 10/19, 10/20, 10/21, 10/22, 08/23, 10/23, 10/24
Approved by: Oregon Region Pharmacy and Therapeutics Committee	

SCOPE:
Providence Health Plan, Providence Health Assurance, Providence Plan Partners, and Ayin Health Solutions as applicable (referred to individually as “Company” and collectively as “Companies”).

APPLIES TO:
Commercial
Medicare Part B
Medicaid

POLICY CRITERIA:

COVERED USES:
Providence Health Plan and Providence Health Assurance as applicable (referred to individually as “Company” and collectively as “Companies”).

Medicare Part B: Coverage criteria are based on the Noridian Local Coverage Determination (LCD) L33822

REQUIRED MEDICAL INFORMATION:
Preferred test strips, blood glucose meters (manufactured by Roche and LifeScan) are covered without prior authorization. Continuous glucose monitors require prior authorization and are reviewed according to the continuous glucose monitors policies (ORPTCOTH020, ORPTCOTH020M).

Non-preferred test strips and/or blood glucose meter:
1. Patient is using an insulin pump that requires the requested meter that synchronizes with their pump.
   OR
2. Patient has physical or mental limitations that makes utilizing BOTH of the preferred products (manufactured by Roche and LifeScan) unsafe, inaccurate, or otherwise not feasible.

Test strip quantity exceptions:

1. For patients using a **continuous glucose monitoring systems for personal use:** Patients that have been approved for use of a continuous glucose monitor for personal use will be restricted to the following:
    a. Dexcom or Freestyle Libre: 150 test strips per 30-day supply.
    b. Requests above this quantity are not considered medically necessary. Coverage may be allowed with discontinuation of continuous glucose monitoring system and is subject to test strip quantity criteria below

2. For patients using **traditional "finger-stick" glucose monitors**, quantities up to 10 strips per day may be covered if the patient meets one of the following criteria:
    a. Patient has a diagnosis of Type 1 diabetes mellitus (T1DM)
    b. Patient is currently using an insulin pump
    c. Patient has an intensive insulin regimen (more than three insulin injections per day)
    d. Patient is pregnant
    e. Patient is less than 18 years of age
    f. Prescriber provides clinical rationale to support the need for additional testing

3. For patients using **traditional "finger-stick" glucose monitors**, quantities exceeding 10 strips per day are not considered medically necessary and will not be covered

For **reauthorization of quantity exceptions**, all of the following are required:

1. Documentation that the patient continues to need the requested quantity
2. Documentation that there is a clinical benefit associated with the increased quantity.

EXCLUSION CRITERIA: N/A

AGE RESTRICTIONS: N/A

PRESCRIBER RESTRICTIONS: N/A

COVERAGE DURATION:
Initial authorization will be approved for 12 months. Reauthorization will be approved until no longer eligible with the plan, subject to formulary and/or benefit changes

QUANTITY LIMIT:
Test strips will be covered up to five test strips per day without authorization required, unless patient is on a continuous glucose monitor as outlined above.

Requests for indications that were approved by the FDA within the previous six (6) months may not have been reviewed by the health plan for safety and effectiveness and inclusion on this policy document. These requests will be reviewed using the New Drug and or Indication Awaiting P&T Review; Prior Authorization Request ORPTCOPS047.

Requests for a non-FDA approved (off-label) indication requires the proposed indication be listed in either the American Hospital Formulary System (AHFS), Drugdex, or the National Comprehensive Cancer Network (NCCN) and is considered subject to evaluation of the prescriber's medical rationale, formulary alternatives, the available published evidence-based research and whether the proposed use is determined to be experimental/investigational.

Coverage for Medicaid is limited to a condition that has been designated a covered line item number by the Oregon Health Services Commission listed on the Prioritized List of Health Care Services.

Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case.

INTRODUCTION:
Monitoring of blood glucose levels is a critical component of a comprehensive diabetes treatment plan. Providence Health Plan provides coverage of supplies for blood glucose testing, subject to products and limits described in benefit summaries.

There are two primary methods for monitoring glucose response to the recommended treatment plan, for a patient with diabetes: Blood Glucose Monitoring (BGM) and periodic assessment of the hemoglobin A1C. The recommended frequency of BGM depends on several factors, including age, duration of diabetes, current medication therapy, patient experience, and ability of the patient to adhere to the prescribed regimen. Performing BGM alone does not lower blood glucose levels; this information must be integrated into a clinical and self-management plan. The ongoing need for and frequency of BGM should be periodically monitored to avoid overuse.

POSITION STATEMENT:
Blood Glucose Monitoring (BGM) for diabetic patients is an important element of their treatment plan. It allows a means to assess efficacy and safety of a patient's current treatment regimen and facilitates medication dose adjustments. The value of BGM is widely accepted in Type 1 diabetes mellitus (T1DM). The value of BGM in Type 2 diabetes mellitus (T2DM) is still considered controversial in patients not

receiving insulin therapy. Newer studies suggest some benefit for newly diagnosed T2DM patients that are not receiving insulin therapies in terms of providing education to the patient regarding glucose levels around meal-time and at bedtime.

Major clinical practice guidelines support frequent BGM in patients with T1DM. Increased frequency of testing in these patients has been associated with lower A1C and lower risk of complications.

BGM in T2DM patients can provide benefit in some patients. It provides immediate feedback regarding glycemic control and assists in patient education. The use of BGM in this population should be individualized to each patient. For BGM to be of value, the patient must be taught how and when to test. The test results also need to be communicated with the healthcare team. The recommended frequency of tests for these patients varies depending on patient characteristics and treatment regimen.

The 2024 American Diabetes Association Standards of Care recommendations for BGM.

Treatment Regimen	Recommendations
Patients using insulin regimens	• Check when appropriate for insulin regimen • May include checking when fasting, prior to meals and snacks, at bedtime, postprandially, prior to exercise, when they suspect low blood glucose, after treating low blood glucose until they are normoglycemic, and prior to critical tasks such as driving.
Patients on noninsulin therapy	• Routine glucose monitoring may be of limited additional clinical benefit • It may be helpful when making lifestyle changes in combination with adjustments to treatment

The following blood glucose test strip brands are preferred formulary products for Providence Health Plan:

- Johnson & Johnson (OneTouch®)
- Roche (AccuChek®)

All other test strips will require a clinical reason why the preferred test strips cannot be used. The Companies acknowledge that in certain situations, the use of non-preferred products will be advantageous to the patient. The technology associated with insulin pumps and meters has advanced to the point that these devices can sync with each other. Additionally, some patients may have visual or dexterity impairments that make using preferred meter/test strips difficult.

Per the American Diabetes Association (ADA) 2024 Standards of Care, patients on CGM should have access to BGM for the following reasons/situations:

- CGM accuracy concerns (inclusive of clinical settings where rapidly changing glucose levels (>2 mg/dL/min) may result in inaccurate CGM readings
- CGM calibration (when applicable)
- CGM warnings/alerts
- Glucose levels are changing rapidly

REFERENCE/RESOURCES:

1. American Diabetes Association. Standards of Medical Care in Diabetes. Diabetes Care 2024; 47:Issue Supplement 1. Available at https://diabetesjournals.org/care/issue/47/Supplement_1 (Accessed September 16, 2024).
2. Centers for Medicare & Medicaid Services (CMS) Medicare Coverage Database. CGS Administrators, LLC Local Coverage Determination (LCD) L33822 “Glucose Monitors”. Available at https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdId=33822&ver=55 (Accessed September 12, 2023).