

Clinical Pharmacy Program Guidelines for Test Strips

Program	Prior Authorization
Medication	Blood Glucose Test Strips
Issue Date	12/2012
Pharmacy and Therapeutics Approval Date	3/2018
Effective Date	5/2018

1. Background:

Intended Use:

Blood glucose monitoring systems are intended to be used for quantitative measurements of glucose in fresh capillary and/or venous whole blood. Various devices are designed for testing by persons with diabetes or by health care professionals in the home or health care facilities.

Off-labeled Use:

Drug therapies must be utilized in accordance with FDA approved indications OR the uses found within the compendia † AND the drug is being prescribed for a medically accepted indication that is recognized as a covered benefit by the applicable health plans' program. Authorization for off-labeled use of medication will be evaluated on an individual basis. Review of an off-labeled request by the UnitedHealthcare Community Plan Medical Staff will be predicated on the appropriateness of treatment, scientific evidence and full consideration of medical necessity.

†-Compendia: • American Hospital Formulary Service Drug Information • National Comprehensive Cancer Network Drugs and Biologics Compendium • Thomson Micromedex DrugDex • Clinical Pharmacology

2. Coverage Criteria:

A.	<p><u>Non-Preferred Test Strips</u></p> <p>1. Non-preferred test strip products will be approved based on the following criteria:</p> <p style="padding-left: 40px;">a. History of failure, contraindication, or intolerance to OneTouch Ultra Test Strips and OneTouch Verio Test Strips</p> <p style="text-align: center;">-OR-</p>
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- b. Patient is on an insulin pump.

Authorization will be issued for 12 months.

B. Quantity Limit Overrides

NOTE: The quantity limit for insulin-dependent and pregnant patients is 6 test strips/day. The quantity limit for non-insulin dependent and non-pregnant patients is 3 test strips/day.

1. **One** of the following:

- a. **Insulin Dependent or Pregnant Patients** will be approved based on all of the following:

- (1) Quantity requests exceeding the limited amount will be approved based on physician confirmation that the patient requires a greater quantity because of more frequent blood glucose testing (e.g., patients on intravenous insulin infusions)^a

-OR-

- b. **Non-Insulin Dependent Patients**^b will be approved based on **one** the following:

- (1) The patient is experiencing postprandial hyperglycemia and requires additional postprandial testing in addition to fasting blood glucose testing
(2) The patient's physician is adjusting medications and the patient requires additional blood glucose testing during this time
(3) The patient's physician is adjusting MNT (medical nutrition therapy) and the patient requires additional blood glucose testing during this time
(4) The patient requires additional testing due to fluctuations in blood glucose due to physical activity/exercise
(5) Other circumstances where prescribing physician confirms that the patient requires a greater quantity because of more frequent blood glucose testing (**clinical review required by UnitedHealthcare reviewing pharmacist and/or medical director**)

Authorization will be issued for 12 months.

3. Endnotes:

- a. In patients who are receiving continuous enteral or parenteral nutrition, glucose
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monitoring is optimally performed every 4 – 6 hours. In patients who are receiving cycled enteral or parenteral nutrition, the schedule for glucose monitoring can be individualized but should be frequent enough to detect hyperglycemia during feedings and risk of hypoglycemia when feedings are interrupted. More frequent blood glucose testing ranging from every 30 minutes to every 2 hours is required for patients on intravenous insulin infusion. Continuous glucose monitoring in conjunction with intensive insulin regimens can be a useful tool to lower A1c in selected adults (age \geq 25 years) with type 1 diabetes.^{1,2}

- b. The optimal frequency and timing of SMBG for patients with type 2 diabetes on noninsulin therapy is unclear. A meta-analysis of SMBG in non-insulin-treated patients with type 2 diabetes concluded that some regimens of SMBG were associated with a reduction in A1C of 20.4%. However, many of the studies in this analysis also included patient education with diet and exercise counseling and, in some cases, pharmacologic intervention, making it difficult to assess the contribution of SMBG alone to improved control.³ Several randomized trials have called into question the clinical utility and cost-effectiveness of routine SMBG in non-insulin-treated patients.⁴⁻⁶

4. References:

1. American Diabetes Association. Standards of Medical Care in Diabetes – 2010 (position statement). Available at: http://care.diabetesjournals.org/content/33/Supplement_1. Accessed on March 19, 2010.
2. American Diabetes Association. Standards of Medical Care in Diabetes – 2010 (position statement). Available at: http://care.diabetesjournals.org/content/34/Supplement_1/S11.full.pdf+html. Accessed on September 26, 2011.
3. Welschen LM, Bloemendal E, Nijpels G, et al. Self-monitoring of blood glucose in patients with type 2 diabetes who are not using insulin: a systematic review. *Diabetes Care* 2005;28:1510–1517
4. Farmer A, Wade A, Goyder E, et al. Impact of self-monitoring of blood glucose in the management of patients with non-insulin treated diabetes: open parallel group randomized trial. *BMJ* 2007;335:132
5. O’Kane MJ, Bunting B, Copeland M, Coates VE; ESMON study group. Efficacy of self-monitoring of blood glucose in patients with newly diagnosed type 2 diabetes (ESMON study): randomized controlled trial. *BMJ* 2008;336: 1174–1177
6. Simon J, Gray A, Clarke P, Wade A, Neil A, Farmer A; Diabetes Glycemic Education and Monitoring Trial Group. Cost effectiveness of self-monitoring of blood glucose in patients with non-insulin treated type 2 diabetes: economic evaluation of data from the DiGEM trial. *BMJ* 2008; 336: 1177–1180.

Program	Program type – Prior Authorization
Change Control	

Date	Change
12/06/2012	New clinical policy
2/20/2015	Updated list of preferred products to include OneTouch Verio
9/17/2015	Removed Roche products from criteria for non-preferred test strip
4/29/2016	Enhanced clarity of the requirement in Section A for operational execution.
8/2016	Updated policy template. Added authorization durations.
8/2017	Added pregnant patients to QL override criteria to match language in PDL book.
3/2018	Added note to outline QLs