



## Glucose Test Strips Step Therapy Criteria

This step therapy program will target ALL blood glucose test strips and disks EXCEPT those that are on formulary.

For Blue Cross and Blue Shield of Illinois, formulary products are the Abbott and Roche product lines which include: Accu-Chek (Active, Advantage, Aviva, Comfort Curve, Compact, Instant), Freestyle/Freestyle Lite, and Precision (QID, Sof-Tact, Xtra).

Brand	Generic	Dosage Form
<b>NOTE: This step therapy program includes ALL glucose test strips and disks available on the market at time of implementation, including but not necessarily limited to the products listed below.</b>		
Accu-Chek <sup>®</sup> products Advance <sup>®</sup> products Advocate <sup>®</sup> products Ascensia <sup>®</sup> products Assure <sup>®</sup> products DuoCare <sup>®</sup> products Easypro <sup>®</sup> products Exactech <sup>®</sup> products Freestyle <sup>®</sup> products Glucocard <sup>®</sup> products Glucocom <sup>®</sup> products Glucostix <sup>®</sup> products Nova Max <sup>®</sup> products OneTouch <sup>®</sup> products PocketChem EZ <sup>®</sup> products Precision <sup>®</sup> products Prestige Smart System <sup>®</sup> products Prodigy <sup>®</sup> products ReliOn <sup>®</sup> products TrueTest <sup>®</sup> products TrueTrack <sup>®</sup> products WaveSense <sup>®</sup> products	Blood glucose test strip	test strip
Ascensia AutoDisc <sup>®</sup> Ascensia Breeze 2 AutoDisc <sup>®</sup>	Blood glucose test disk	test disk

### INTENDED USE<sup>1,2</sup>

Glucose Test Strips are indicated to be used with appropriate meters for quantitatively measuring glucose in indicated blood samples. Strips and associated meters are intended for use outside the body by people with diabetes for self monitoring of blood glucose (SMBG) at home and healthcare professionals in the clinical setting, as an aid to monitor the effectiveness of diabetes control.

**RATIONALE FOR STEP THERAPY**

The intent of the step therapy criteria for the Glucose Test Strips step therapy program is to encourage the use of cost-effective preferred glucose test strip products before the nonpreferred products.

The American Diabetes Association (ADA) and the American Association of Clinical Endocrinologists (AACE) recommend self monitoring of blood glucose (SMBG) three or more times daily for patients using multiple insulin injections or insulin pump therapy.<sup>3,4</sup> American Association of Clinical Endocrinologists guidelines suggest that patients whose glycemic levels are above target or who experience frequent hyperglycemia should monitor levels more frequently; monitoring should include both preprandial and 2-hour postprandial glucose levels and occasional 2:00 AM to 3:00 AM glucose levels.<sup>4</sup> For patients whose glycemic levels are above target while on oral agents only, oral agents plus once-daily insulin, or once-daily insulin only, monitoring of glucose levels at least twice daily is recommended.<sup>4</sup> Patients who are meeting target glycemic levels should monitor levels at least once daily.<sup>4</sup>

The accuracy of SMBG is instrument and user dependent; it is important to evaluate each patient’s monitoring technique, both initially and at regular intervals thereafter. In addition, optimal use of SMBG requires proper interpretation of the data. Patients should be taught how to use the data to adjust food intake, exercise, or pharmacologic therapy to achieve specific glycemic goals, and these skills should be reevaluated periodically.<sup>3</sup> Because patients may have different needs for SMBG, based on visual impairment or other physical or mental limitations and including alternate site testing, the PA criteria will include evaluation of these issues.

Patients who are currently using nonpreferred glucose test strip products will be allowed to continue using these products without meeting the edit requirements if a claim for the requested product is identified within 90 days prior to the new claim. The claims system is designed to identify any claim with a days supply that ends within the 90-day look-back period.

**ELECTRONIC EDITS**

The overall process for step therapy requires that another product or product be tried in a specific previous time period before the claim drug. If the patient has met any of the requirements outlined below, the requested step therapy medication will be paid under the patient’s current prescription benefit.

**Table 1: Summary of Glucose Test Strips Step Therapy**

Targeted Agent(s)	ALL nonpreferred Glucose Test Strips and/or Disks [as determined by client] (preferred products listed as prerequisite agents) GPI 94100030006100, 94100030009800
Is auto-grandfathering implemented? (with look-back time frame)	Yes (90 days <sup>a</sup> )
Prerequisite Agent(s)	Preferred Glucose Test Strips and/or Disks [as determined by client] GPI 94100030006100, 94100030009800
Number of prerequisites required	1
Prerequisite look-back time frame	90 days <sup>a</sup>

a - The system searches for a claim with a days supply that begins or ends in the past 90 days. For claims with a 30 day supply the system would be able to identify a claim processed for payment between 1 and 120 days prior to the new claim. For claims dispensed as an extended days supply (90 days), the system would identify a claim processed between 1 and 180 days.

If the patient does not meet the step therapy criteria, then the system will reject with the message indicating that prior authorization is necessary. The *Prior Authorization (PA) Criteria for Approval* would then be applied to requests submitted by the patient’s practitioner for evaluation.

## **PRIOR AUTHORIZATION CRITERIA FOR APPROVAL**

The intent of the *Prior Authorization (PA) Criteria for Approval* is to provide a manual review process for claims that do not meet the electronic edit criteria and are not automatically paid. The criteria for approval through the PA process are identical to those set up in the electronic edit.

The intent of the *PA Criteria for Approval* for nonpreferred glucose test strips subject to step therapy is to ensure that patients who have been unable to use the preferred glucose test strips (and monitor) have the option to use another glucose test strip (and monitor). Approval will be given to patients who have a history of trial and failure of a preferred glucose test strip outside of the 90-day look-back period or outside of the current benefit plan. A nonpreferred product may also be approved if the patient has tried a required preferred glucose test strip and discontinued due to inability to use it accurately; if the patient has a requirement for alternate site testing not accommodated with a preferred glucose test strip and monitor; if the patient requires a nonpreferred glucose test strip and monitor due to visual impairment or other physical or mental disability or use of an insulin pump requiring a special blood glucose monitor; or if the physician has submitted other documentation to support the use of the nonpreferred glucose test strip in the patient. Patients who are currently using nonpreferred glucose test strips will be allowed continuation of their use without meeting the edit requirements.

### **Step Therapy PA Criteria for Approval**

#### ***Nonpreferred Glucose Test Strips***

##### **Initial and Renewal Evaluation**

1. Is the patient currently using a nonpreferred glucose test strip?  
[nonpreferred glucose test strips to be determined by client upon implementation of program.]  
If yes, approve for 12 months. If no, continue to 2.
2. Does the patient's medication history indicate previous use of a preferred glucose test strip?  
[preferred glucose test strips to be determined by client upon implementation of program.]  
If yes, approve for 12 months. If no, continue to 3.
3. Does the patient require a nonpreferred glucose test strip due to visual impairment?  
If yes, approve for 12 months. If no, continue to 4.
4. Does the patient have a requirement for alternate site testing?  
If yes, continue to 5. If no, continue to 6.
5. Has the patient tried and failed at least one preferred glucose test strip and meter that will accommodate alternate site testing?  
If yes, approve for 12 months. If no, continue to 6.
6. Does the patient have a requirement for a specific nonpreferred glucose test strip based on his/her use of an insulin pump?  
If yes, approve for 12 months. If no, continue to 7.
7. Has the prescriber documented that the patient requires a nonpreferred glucose test strip due to other physical or mental disability?  
If yes, approve for 12 months. If no, continue to 8.
8. Has the prescriber submitted documentation that the member would reasonably not be able to use a preferred glucose test strip?  
If yes, pharmacist must review and may approve for 12 months based on review of information provided. If no, deny.

## SUMMARY

The intent of the Glucose Test Strips Step Therapy program is to encourage the use of cost-effective preferred glucose test strip products before the nonpreferred products. The PA criteria review for use of nonpreferred products when the preferred glucose test strips cannot be used due to patient inability to use them accurately, or special requirements such as the requirement of an insulin pump (not accommodated with a preferred glucose test strip), alternate site testing (not accommodated with a preferred glucose test strip and monitor), visual impairment, or other physical or mental disability. PA criteria will also review requests for nonpreferred products if the patient is currently using a nonpreferred glucose test strip or if the physician has submitted other documentation to support the use of the requested nonpreferred glucose test strip in the patient. The PA process provides a member-specific review process where practitioner provided patient-specific parameters are taken into consideration when reviewed.

## REFERENCES

1. Drug Facts and Comparisons (online version), Glucose Blood Tests. Available at: <http://online.factsandcomparisons.com>. Accessed February 11, 2009.
2. Buyers Guide 2009, Home Glucose Monitoring. Diabetes Forecast. 2009;62(1). Available at: <http://www.forecast.diabetes.org/magazine/resource-guide/2009-resource-guide>. Accessed February 11, 2009.
3. American Diabetes Association. Standards of Medical Care in Diabetes—2009. *Diabetes Care* 2009;32(suppl 1):S13-S61.
4. AACE Diabetes Mellitus Clinical Practice Guidelines Task Force. American Association of Clinical Endocrinologists Medical Guidelines for Clinical Practice for the management of Diabetes Mellitus. *Endocrine Practice* 2007;13(suppl 1):4-67.

### **Document History**

Original Prime Standard criteria approved by P&T UM Committee 05/2009  
Initial Client Specific Review, Client specific criteria, approved by HCSC Corporate Clinical Committee 11/2009  
Administrative Addition (textbox with BCBSIL formulary products) 04/2010