

## Medical Policy



An independent licensee of the  
Blue Cross Blue Shield Association

### Title: Glucose Test Strips/Disks

- Prime Therapeutics will review Prior Authorization requests

#### Prior Authorization Forms:

<http://www.bcbsks.com/CustomService/Forms/pdf/PriorAuth-6116KS-GLUC.pdf>

#### Link to Drug List (Formulary):

[http://www.bcbsks.com/CustomService/PrescriptionDrugs/drug\\_list.htm](http://www.bcbsks.com/CustomService/PrescriptionDrugs/drug_list.htm)

#### Professional

Original Effective Date: January 1, 2013

Revision Date(s): January 1, 2013;

January 1, 2014; October 28, 2014;

June 10, 2015; June 1, 2016

Current Effective Date: June 1, 2016

#### Institutional

Original Effective Date: January 1, 2013

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State and Federal mandates and health plan member contract language, including specific provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage. To verify a member's benefits, contact [Blue Cross and Blue Shield of Kansas Customer Service](#).

The BCBSKS Medical Policies contained herein are for informational purposes and apply only to members who have health insurance through BCBSKS or who are covered by a self-insured group plan administered by BCBSKS. Medical Policy for FEP members is subject to FEP medical policy which may differ from BCBSKS Medical Policy.

The medical policies do not constitute medical advice or medical care. Treating health care providers are independent contractors and are neither employees nor agents of Blue Cross and Blue Shield of Kansas and are solely responsible for diagnosis, treatment and medical advice.

If your patient is covered under a different Blue Cross and Blue Shield plan, please refer to the Medical Policies of that plan.

**DESCRIPTION**

The intent of the Glucose Test Strips/Disks Therapy program is to encourage the use of cost-effective preferred test strip/disk before the more expensive nonpreferred products. The prior authorization (PA) process will accommodate for the use of nonpreferred test strip/disk when the preferred glucose test strips/disks 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/disk or meter), visual impairment, or other physical or mental disability. Requests for nonpreferred products will be reviewed when patient-specific documentation has been provided.

**Target Supplies**

Preferred	Non-Preferred	
Accu-Chek <sup>®</sup> products Accu-chek <sup>®</sup> Compact Drums Ascensia <sup>®</sup> AutoDisc Bayer <sup>®</sup> products Bayer <sup>®</sup> Breeze	Acura <sup>®</sup> products Advocate <sup>®</sup> products Control AST <sup>®</sup> products EasyGluco <sup>®</sup> products FreeStyle <sup>®</sup> products Glucocard <sup>®</sup> products Infinity <sup>®</sup> products Nova Max <sup>®</sup> products	One Touch <sup>®</sup> products Precision <sup>®</sup> products Prodigy <sup>®</sup> products ReliOn <sup>®</sup> products Sidekick <sup>®</sup> products TrueTest <sup>®</sup> products TrueTrack <sup>®</sup> products WaveSense <sup>®</sup> products

**Indication and Dosage<sup>1,5</sup>**

Glucose Test Strips/Disks and appropriate meters are indicated to be used for quantitatively measuring glucose in indicated blood samples. Strips/disks 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.

**NOTE: This table is not inclusive of all available diabetic test strips or disks.**

Available Brand Products		Generic	Dosage Form
Acura <sup>®</sup> products Accu-Chek <sup>®</sup> products Advocate <sup>®</sup> products Bayer <sup>®</sup> products Control AST <sup>®</sup> products EasyGluco <sup>®</sup> products FreeStyle <sup>®</sup> products Glucocard <sup>®</sup> products Infinity <sup>®</sup> products	Nova Max <sup>®</sup> products One Touch <sup>®</sup> products Precision <sup>®</sup> products Prodigy <sup>®</sup> products ReliOn <sup>®</sup> products Sidekick <sup>®</sup> products TrueTest <sup>®</sup> products TrueTrack <sup>®</sup> products WaveSense <sup>®</sup> products	Blood glucose test strip, Blood glucose test meter	Test strip Meter
Accu-chek <sup>®</sup> Compact Drums Ascensia <sup>®</sup> AutoDisc Bayer <sup>®</sup> Breeze		Blood glucose test disk	Test disk

## **POLICY**

### **Prior Authorization Criteria for Approval**

**A nonpreferred glucose test strip/disk** will be approved when **ONE** of the following is met:

A. The patient's medication history includes use of any preferred glucose test strip / disk product in the past 90 days.

**OR**

B. ONE of the following:

1. Patient has visual impairment

**OR**

2. Patient uses an insulin pump that is not accommodated with a preferred glucose test strip/disk or meter

**OR**

3. Patient has a physical or a mental disability

**Length of approval:** 12 months

## **RATIONALE**

### **Self Monitoring of Blood Glucose (SMBG)**

Major clinical trials of insulin-treated patients that demonstrated the benefits of intensive glycemic control on diabetes complications included SMBG as part of multifactorial interventions, suggesting that SMBG is a component of effective therapy. SMBG allows patients to evaluate their individual response to therapy and assess whether glycemic targets are being achieved. Results of SMBG can be useful in preventing hypoglycemia and adjusting medications (particularly prandial insulin doses), medical nutrition therapy, and physical activity. The frequency and timing of SMBG should be dictated by the particular needs and goals of the patient.<sup>2</sup>

Patients on multiple-dose insulin or insulin pump therapy should do SMBG at least prior to meals and snacks, occasionally postprandially, at bedtime, 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 (around 6-10 times daily).<sup>2</sup>

The evidence base for SMBG for patients with type 2 diabetes (T2DM) on noninsulin therapy is somewhat mixed. Several randomized trials have called into question the clinical utility and cost-effectiveness of routine SMBG in non-insulin-treated patients. A meta-analysis suggested that SMBG reduced A1C by 0.25% at 6 months, while a Cochrane review concluded that the overall effect of SMBG in such patients is small up to 6 months after initiation and subsides after 12 months.<sup>2</sup>

However, there are situations when home blood glucose monitoring may be justified for noninsulin using patients T2DM (e.g., acute illness, unstable glucose levels, new diabetes

diagnosis, changes in medications, hypoglycemia risk, during pregnancy, and if postprandial hyperglycemia is a concern). Patients taking oral sulfonylureas may benefit from SMBG since these agents can cause hypoglycemia.<sup>3</sup>

The American Academy of Pediatrics guideline for management of newly diagnosed T2DM in children and adolescents (2013) suggests all patients with newly diagnosed T2DM, regardless of prescribed treatment plan, should perform finger-stick BG monitoring before meals (including a morning fasting concentration) and at bedtime until reasonable metabolic control is achieved. Once BG concentrations are at target levels, the frequency of monitoring can be modified depending on the medication used, the regimen's intensity, and the patient's metabolic control. Patients who are prone to marked hyperglycemia or hypoglycemia or who are on a therapeutic regimen associated with increased risk of hypoglycemia will require continued frequent BG testing. Expectations for frequency and timing of BG monitoring should be clearly defined through shared goal-setting between the patient and clinician.<sup>9</sup>

- For patients on oral agents only, once treatment goals are met, the frequency of monitoring can be decreased; however, the committee recommends some continued BG testing for all youth with T2DM, at a frequency determined within the clinical context (e.g. medication regimen, HbA1c, willingness of the patient, etc). For example, an infrequent or intermittent monitoring schedule may be adequate when the patient is using exclusively an oral agent associated with a low risk of hypoglycemia and if HbA1c concentrations are in the ideal or non-diabetic range. A more frequent monitoring schedule should be advised during times of illness or if symptoms of hyperglycemia or hypoglycemia develop.
- For patients on an oral agent plus a single injection of long-acting insulin, twice a day BG monitoring (fasting plus a second BG concentration - ideally 2-hour post prandial) often is recommended, as long as HbA1c and BG concentrations remain at goal and the patient remains asymptomatic.

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>2</sup>

### **Test Strips Safety Concerns: Glucose Dehydrogenase Pyrroloquinoline Quinone (GDH-PQQ) Glucose Monitoring Technology**

On August 14, 2009 the FDA released a public health notification regarding the potentially fatal errors with GDH-PQQ glucose monitoring technology. GDH-PQQ glucose monitoring measures a patient's blood glucose value using methodology that cannot distinguish between glucose and other sugars. Certain non-glucose sugars, including maltose, xylose, and galactose, are found in certain drug and biologic formulations, or can result from the metabolism of a drug or therapeutic product. When these non-glucose sugars are present in the patient's blood, using a GDH-PQQ glucose test strip will produce an elevated glucose result.<sup>6</sup> This can lead to inappropriate dosing and administration of insulin, potentially resulting in hypoglycemia, coma, or death. Currently, only Nipro Diagnostics provides GDH-PQQ testing supplies as TRUEresult meters with TRUEtest test strips. Test strips currently on the market may be distributed under multiple trade names (i.e., RiteAid, CVS, Walgreens).

The following are Nipro, Accu-Chek, and Freestyle test strips that use different chemistry than GDH-PQQ:

- Freestyle test strips use the glucose dehydrogenase-flavin adenine dinucleotide (GDH-FAD) monitoring technology which minimizes interference from non-glucose carbohydrates.<sup>5</sup>
- ACCU-CHEK Aviva Plus test strips and Nano meter/SmartView test strips use Mut Q-GDH (glucose dehydrogenase with pyrroloquinolinequinone modified to eliminate maltose interference).<sup>6,8</sup>
- TRUEtrack, TRUEbalance, TRUEread, and Sidekick utilize glucose oxidase (GO) chemistry which does not interfere with the above mentioned substances.<sup>7</sup>

GDH-PQQ glucose test strips should not be used on the following patients:

- Patients who are receiving interfering product
  - Extraneal (icodextrin) peritoneal dialysis solution
  - Some immunoglobulins: Octagam 5% Gamimune N 5%, WinRho SDF Liquid, Vaccinia Immune Globulin Intravenous (Human), and HepaGamB
  - Orencia (abatacept)
  - Adept adhesion reduction solution (4% icodextrin)
  - BEXXAR radioimmunotherapy agent
  - Any product containing, or metabolized into maltose, galactose, or xylose
- Patients whom information regarding concomitant medication use cannot be obtained, e.g., patients who are unresponsive or cannot adequately communicate.

Most blood glucose systems have a special 'correction' electrode that allows the meters to correct for interfering substances and rarely appear to be a problem when levels of the interfering substances are within normal ranges. For example, oral drugs do not appear to cause incorrect glucose readings when taken at FDA approved doses.<sup>7</sup>

### **Ceftriaxone and ACCU-CHEK Compact Plus**

Ceftriaxone may lead to incorrect low results if used with ACCU-CHEK® Compact Plus system: if a patient is undergoing therapy containing the antibiotic ceftriaxone (e.g., Rocephin® or Cefotrix®), DO NOT use the ACCU-CHEK® Compact Plus system throughout the duration of the treatment and for 2 full days after the last treatment. Use an alternate blood glucose monitoring system for testing your blood sugar levels.<sup>10</sup>

### **Comparison of Blood Glucose Meters and Test Strips**

Although there are differences in capabilities and features among blood glucose meters (meter size, time to obtain results, memory size, blood sample size requirement), all meters work by measuring blood glucose levels. The use of blood glucose test strips or disks is meter-dependent. Patients must use the type of test strip or disk specified by the meter in order to correctly operate the meter and obtain results. Because patients may have different needs for SMBG, certain meters are designed to accommodate patients with special needs such as visual impairment, and physical or mental limitations.

### **REVISIONS**

01-01-2013	Policy added to the bcbsks.com web site. (Posted to the web site 11-30-2012)
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01-01-2014	Description section updated
	In Policy section: <ul style="list-style-type: none"> <li>▪ Added the following criteria, "The patient's medication history includes use of any preferred glucose test strip / disk product.</li> </ul> OR ONE of the following:"
	Rationale section reviewed
	References reviewed
10-28-2014	Title revised to "Glucose Test Strips / Disks" from "Glucose Test Strips / Disks and Meters"
	Description section
	Rationale section updated
	References updated
06-10-2015	Rationale section updated
	References updated
06-01-2016	In Policy section: <ul style="list-style-type: none"> <li>▪ In Item A added "in the past 90 days" to read "The patient's medication history includes use of any preferred glucose test strip / disk product in the past 90 days"</li> </ul>
	Rationale section updated
	References updated

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