For Commercial, GenPlus and Health Insurance preferred products are Bayer products.

Quantity limits are dictated through benefit design and are not included in this program.

**OBJECTIVE**
The intent of the Glucose Test Strips/Disks and Meters Step Therapy program is to encourage the use of cost-effective preferred test strip/disk and meter products before the more expensive nonpreferred products. (Continuous blood glucose monitors are not included in this program.) The prior authorization (PA) process will accommodate for the use of nonpreferred test strip/disk or meter products when the preferred glucose test strips/disks or meters 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 DRUGS**
- **Preferred products**: Bayer® test strips and disks
- **Non-preferred products**: All remaining test strips and disks

**PRIOR AUTHORIZATION CRITERIA FOR APPROVAL**
A *nonpreferred glucose test strip/disk or meter product* will be approved when **ONE** of the following is met:

1. The patient’s medication history includes use of any preferred glucose test strip/disk or meter product in the past 90 days
   OR
2. **ONE** of the following:
   a. Patient has visual impairment
   OR
   b. Patient uses an insulin pump that is not accommodated with a preferred glucose test strip/disk or meter
   OR
   c. Patient has a physical or a mental disability

**Length of approval**: 12 months
**INDICATIONS AND DOSAGE**

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.

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

**CLINICAL 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.

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).

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.²

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.³

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.⁹

• 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.²

**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.⁵ 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.  
• 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).  
• TRUEtrack, TRUEBalance, TRUEread, and Sidekick utilize glucose oxidase (GO) chemistry which does not interfere with the above mentioned substances. 

GDH-PQQ glucose test strips should not be used on the following patients:
• Patients who are receiving interfering product 
  o Extraneal (icodextrin) peritoneal dialysis solution 
  o Some immunoglobulins: Octagam 5% Gamimune N 5%, WinRho SDF Liquid, Vaccinia Immune Globulin Intravenous (Human), and HepaGamB 
  o Orencia (abatacept) 
  o Adept adhesion reduction solution (4% icodextrin) 
  o BEXXAR radioimmunotherapy agent 
  o 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.

**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.

**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.

For additional clinical information see the Prime Therapeutics Formulary Chapter 15.3: Glucose Meters/Strips.

**REFERENCES**