

MTF Formulary Management for Self-Monitoring Blood Glucose Systems (SMBGS) Test Strips

Defense Health Agency Pharmacy Operations Division

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Bottom Line

- **Precision Xtra test strips remain on the Basic Core Formulary (BCF). FreeStyle Lite test strips were added to the BCF.** These two products are the most cost-effective strips.
- **Patients currently using Precision Xtra test strips should continue to receive them.**
- **Use FreeStyle Lite** for patients who currently use a nonformulary test strip, newly diagnosed patients, or patients with dexterity issues.
- All other test strips except for FreeStyle Lite and Precision Xtra are nonformulary and non-preferred. Prior Authorization (Step Therapy) now applies to new and current test strip users; see Prior Authorization Criteria listed below.
- MTFs that are not currently using an Abbott test strip have the highest priority for converting patients to FreeStyle Lite.
- ACCU-CHEK Aviva Plus is the most common Roche test strip purchased at the MTFs; non-Abbott test strips are now NF. The price/strip of Roche's most popular NDC will roughly double as the price converts to its Federal Supply Schedule price.
- New Quantity Limits apply: #100 strips/30 days and #300 strips/90 days; see below.

Uniform Formulary Decision: The Director, DHA, approved the recommendations from the November 2014 DoD P&T Committee meeting on February 3, 2015. Implementation will occur by August 5, 2015.

Uniform Formulary (UF) test strips		Nonformulary (NF) test strips
BCF test strips MTFs are required to have on formulary	SMBGS not on BCF MTFs <u>may</u> have on formulary	MTFs <u>must not</u> have on formulary
<p><u>Step-preferred:</u></p> <ul style="list-style-type: none"> • Precision Xtra (Abbott) for the Precision Xtra meter • FreeStyle Lite (Abbott) for the FreeStyle Freedom Lite meters 	N/A	<p><u>Non step-preferred:</u>*</p> <ul style="list-style-type: none"> • ACCU-CHEK Aviva Plus (Roche) • GLUCOCARD 01-Sensor (ARKRAY) • GLUCOCARD Vital (ARKRAY) • CONTOUR NEXT (Bayer) • FreeStyle InsuLinx (Abbott) • Nova Max (Nova) • OneTouch Ultra Blue (LifeScan) • OneTouch Verio (LifeScan) • TRUEtest (Nipro) • Plus any test strip other than BCF selections, including earlier versions of FreeStyle Lite and Precision test strips (e.g., Precision QID)
* Step therapy applies to all new users and current users of a test strip		

NDCs

NDC numbers for the Abbott preferred test strips are included in this table.

Test Strip	NDC
Precision Xtra Strips Pkg Size 50	57599-9695-04
Precision Xtra Strips Pkg Size 100	57599-9694-05
FreeStyle Lite Strips Pkg Size 50	99073-0710-26

Test Strip/Blood Glucose Meters

- **Precision Xtra test strips remain BCF. There is no need to switch patients from Precision Xtra to FreeStyle Lite.** Patients newly diagnosed with diabetes or those with dexterity issues receiving a nonformulary test strip can be transitioned over to the FreeStyle platform.
 - The Precision Xtra meter does not require coding (since March 2012). Ketone testing is available with a separate test strip.
 - Abbott Diabetes Care will **not** be phasing out the Precision Xtra test strip or meters.
- **FreeStyle Lite test strips** were chosen for the BCF due to improved technology, including a “ZipWik” tab on the strip that allows easier blood sample application and faster uptake.
 - The strips are packaged in vials and do not require the dexterity needed to open the Precision Xtra foil wrapping.
 - Only a 0.3 microliter blood sample size is required. A second drop of blood can be reapplied within 60 seconds, if needed. The test will not start if there is insufficient blood on the test strip.
 - **FreeStyle Freedom Lite meters are the “workhorse” meters for the FreeStyle Lite test strips.** Abbott Diabetes Care will have maximum quantities of Trade Agreements Act (TAA)-compliant meters available to convert MTFs where non-Abbott meters are used.
 - The meter does not require coding and has a large visual display. The meter is easy to operate with only two buttons. Up to 400 results can be stored. The meter is easy to hold (ergonomically designed). Ketone testing is not available with this meter.

Meter Replacement

- The BCF decision is for the test strips, **not** the glucometers. However, Abbott Diabetes Care will continue to provide glucometers at no charge to the MTFs.
- New meters should only be provided to the following patients: patients not already using an existing Abbott Diabetes Care meter (Precision Xtra or FreeStyle Freedom Lite) or newly diagnosed patients.
- Abbott Diabetes Care will provide one no-charge meter per patient to MTFs during the three-year meter warranty period. Patients whose meter malfunctions during the warranty period must call the Abbott Diabetes Care Technical Support phone number (located on the reverse of the meter or on the meter package) to acquire a new meter.
- MTFs will continue to be supplied with no-charge meters for newly diagnosed patients or patients currently on a nonformulary test strip. For all other circumstances, such as a lost meter or request for an additional meter, etc., patients will be required to purchase a meter at a retail pharmacy.
- Your local Abbott Diabetes Care representative or the Inside Sales Team can provide assistance.

Prior Authorization

- FreeStyle Lite and Precision Xtra are the preferred test strips. All other test strips are nonformulary and non-preferred, which means the patient must try one of the Abbott products before using a nonformulary test strip.
- “No grandfathering” applies: current users of the nonformulary non-preferred test strips **must** try FreeStyle Lite or Precision Xtra, unless they meet Prior Authorization criteria. Valid patient-specific factors when a nonformulary test strip is warranted include the following:
 - The patient is blind/severely visually impaired and requires a test strip used in a talking meter:
 - Prodigy Voice
 - Prodigy AutoCode
 - Advocate Redi-Code
 - The patient uses an insulin pump and requires a specific test strip that communicates wirelessly with a specific meter:
 - CONTOUR NEXT strip with CONTOUR NEXT LINK Meter for Medtronic pump
 - Nova Max strip with Nova Max Link meter for Medtronic pump

- OneTouch Ultra Blue test strips with OneTouch UltraLink Meter for Medtronic MiniMed Paradigm insulin pump (for the Retail Network only, due to TAA non-compliance)
- OneTouch Ultra Blue test strips with OneTouch Ping meter and using the OneTouch Ping insulin pump (for the Retail Network only, due to TAA non-compliance)
- ACCU-CHEK Aviva Plus test strips for patients using the ACCU-CHEK Aviva Combo meter or ACCU-CHEK Aviva Spirit Combo meter
- The patient has a documented physical or mental health disability and requires a special strip or meter.

Quantity Limits (QLs)

QLs were lowered to #100 strips/30 days and #300 strips/90 days due to recent guidance from the Centers for Medicare & Medicaid Services showing no benefit in Type 2 diabetics (T2DM) for testing more than once per day. The guidance is available at <http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/SE1008.pdf>.

- QLs may be exceeded in appropriate clinical circumstances. Examples include:
 - Patients receiving insulin
 - Patients using an insulin pump
 - Patients with gestational diabetes
 - Patients that require more frequent testing due to endocrine disorders (e.g., insulinoma, endogenous hyperinsulinism, or non-islet cell tumor)
 - Patients with a history of poorly controlled blood glucose levels, resulting in a history of adverse outcomes (e.g., ketoacidosis, hypoglycemic episode) and requiring medical intervention

Software

- Abbott meters use the Co-Pilot system for reporting. USB cables can be obtained from your local Abbott Diabetes Care contact.
- The Co-Pilot software is approved by the United States Army, Navy, and Air Force. For information, contact Tom Tveit, Senior Account Manager (contact information above). The Department of Defense Information Assurance Certification and Accreditation Process (DIACAP) certification for Defense Health Agency facilities is being pursued.

Patients using the Retail Network or Mail Order Pharmacy

- Patients receiving a nonformulary test strip in the Retail Network or Mail Order Pharmacy will receive letters mailed from Express Scripts. If a patient brings a letter to the MTF, supply them with the FreeStyle Lite test strips and meter and inform them that they can fill their prescriptions at the MTFs. Meters will not be dispensed from the Mail Order Pharmacy; only test strips are available.

Clinical Information

- Test strips that were candidates for inclusion on the Uniform Formulary met the minimum technical standards, as outlined in the May 2013 and August 2013 DoD P&T Committee meeting minutes.
- New ISO standards (ISO 15197:2013) were published on May 15, 2013.¹ However, personal communication with the FDA stated that the FDA has not recognized ISO 15197:2013 and will not be recognizing it in the future.
- Abbott Diabetes Care has several accuracy studies for both the FreeStyle and Precision brands that show test strip accuracy well within the current standards (glucose concentrations < 75mg/dL within ±15 mg/dL and ≥ 75 mg/dL within ± 20% for 95% of all readings versus reference). Additionally, there are studies available that show enhanced performance

References

1. International Organization for Standardization. In vitro diagnostic test systems — Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus. ISO 15197:2013.
- DoD P&T Committee minutes: <http://www.health.mil/About-MHS/Other-MHS-Organizations/DoD-Pharmacy-and-Therapeutics-Committee/Meeting-Minutes>
 - Current/future drug classes under review by the DoD P&T Committee: <http://www.health.mil/About-MHS/Other-MHS-Organizations/DoD-Pharmacy-and-Therapeutics-Committee>
 - TRICARE Formulary Search Tool: <http://www.express-scripts.com/tricareformulary>
 - Prior Authorization/Medical Necessity forms: See TRICARE Formulary Search Tool above.
 - Point of contact for additional information: usarmy.jbsa.medcom-ameddcs.list.pecuf2@mail.mil

SMBGS Test Strip Price Comparison at MTF	
Test Strip	MTF Weighted Average cost (Nov 2014) ^{ab}
Basic Core Formulary (preferred)	
Precision Xtra	Most Cost-Effective
FreeStyle Lite	Most Cost-Effective
Nonformulary (non-preferred)	
FreeStyle InsuLinx	Not Cost-Effective
GLUCOCARD 01-Sensor GLUCOCARD Vital	Not Cost-Effective
TRUEtest	Not Cost-Effective
ACCU-CHEK Aviva Plus	Not Cost-Effective
Prodigy No Coding	Not Cost-Effective
CONTOUR NEXT	Not Cost-Effective
Nova Max	Not Cost-Effective
^a Actual price may vary slightly due to MTF-specific Prime Vendor fees/discounts or Retail vendor rebates (mandated by Section 703 or voluntary additional rebates). ^b MTFs are prohibited from entering into any incentive pricing agreements in any form with SMBGS manufacturers to receive additional discounts.	