

## Drug **Policy**

Policy:	Diabetic Test Strips Preferred Step Therapy Policy	Annual Review Date: 11/16/2023
		Last Revised Date: 11/16/2023

### **OVERVIEW**

There are a variety of blood glucose meters available on the market with varying features. However, most meters generally offer a small sample size, the ability to test at alternate sites (besides the finger tips), and have easily readable screens. For visually impaired patients, speaking meters are available from select manufacturers. There are a small number of blood glucose meters that interact wirelessly with a specific insulin pump providing data for basal and bolus insulin needs based on the blood glucose measurement. Various sources, including device manufacturers and the American Diabetes Association (ADA), maintain updated lists of available products, including their features and compatibility.<sup>1-7</sup>

Diabetic test strips are measured for accuracy using standards set forth by the International Organization for Standardization and/or FDA.<sup>8-10</sup> Currently marketed monitors must meet the standard under which they were approved.<sup>1</sup> The ADA Standards of Care (2023) acknowledge that monitoring of accuracy is left to the manufacturer and is not routinely checked by an independent source; there may be variation in accuracy of blood glucose monitoring systems. However, a preference is not made in the ADA Standards for any particular brand of test strip over others.

#### **POLICY STATEMENT**

This program has been developed to encourage the use of a Step 1 Product prior to the use of a Step 2 Product. If the Preferred Step Therapy rule is not met for a Step 2 Product at the point of service, coverage will be determined by the Preferred Step Therapy criteria below. All approvals are provided for 1 year in duration.

**Automation:** A patient with a history of one Step 1 Product within the 130-day look-back period is excluded from Step Therapy. Also, a patient with a history of one step 1 AND one step 2 product in last 365-day look-back period is excluded from Step therapy.

#### **Preferred Products (Step 1)**

- Abbott (e.g., Freestyle, Freestyle Lite, Freestyle InsuLinx, Precision Xtra)
- Lifescan (e.g., OneTouch Ultra, OneTouch Verio)

#### **Non-Preferred Products (Step 2)**

- Abbott (e.g., Freestyle Precision Neo)
- Nipro (e.g., TRUEtrack, TRUEmetrix)
- **Bayer** (e.g., Contour, Contour Next)

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- Roche (e.g., Accu-Chek Guide, Accu-Chek Aviva Plus, Accu-Chek Smartview)
- National Medical/Diabetic Supply (e.g., Advocate, Advocate Redi-Code)
- **Omnis Health** (e.g., Embrace, Embrace Evo, Embrace Pro)
- **Unistrip** (e.g., Unistrip)
- Medicore (PIP Test Strips)
- Other products Note: Examples provided in the Step 2 list are not all-inclusive

#### Initial Approval/ Extended Approval.

A) Initial Approval:1 year (365 days)

**B**) Extended Approval: 1 year (365 days)

#### PREFERRED STEP THERAPY CRITERIA FOR THE BASIC/BASIC PLUS FORMULARIES

- 1. If the patient has tried a preferred diabetic test strip product, then authorization for a non-preferred diabetic test strip product may be given.
- 2. For patients who use an insulin pump/meter system that is not compatible with a preferred diabetic test strip product, then authorization for a non-preferred diabetic test strip product may be given (e.g., MiniMed 530 G/ Contour Next, MiniMed 630G/Contour Next, MiniMed 670G/Contour Next, Omnipod/FreeStyle).
- **3.** For patients with significant visual impairment according to the prescribing physician authorization for a National Medical/Diabetic Supply or Omnis Health test strip may be given (e.g., Advocate Redi-Code, Embrace).

#### **Step Therapy Exception Criteria**

Approve for 1 year if the patient meets the following (A, B, or C):

- A. The patient has an atypical diagnosis and/or unique patient characteristics which prevent use of all preferred agents. If so, please list diagnosis and/or patient characteristics [documentation required]; **OR**
- B. The patient has a contraindication to all preferred agents. If so, please list the contraindications to each preferred agent [documentation required]; **OR**
- C. The patient is continuing therapy with the requested non-preferred agent after being stable for at least 90 days [verification in prescription claims history required] or, if not available, [verification by prescribing physician required] AND meets ONE of the following:
  - 1. The patient has at least 130 days of prescription claims history on file and claims history supports that the patient has received the requested non-preferred agent for 90 days within a 130-day look-back period AND there is no generic equivalent available for the requested nonpreferred product (i.e. AA-rated or AB-rated to the requested nonpreferred product); OR

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2. When 130 days of the patient's prescription claims history file is unavailable for verification, the prescriber must verify that the patient has been receiving the requested non-preferred agent for 90 days AND that the patient has been receiving the requested non-preferred agent via paid claims (i.e. the patient has NOT been receiving samples or coupons or other types of waivers in order to obtain access to the requested non-preferred agent) AND there is no generic equivalent available for the requested nonpreferred product (i.e. AA-rated or AB-rated to the requested nonpreferred product).

#### **Documentation Requirements:**

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

#### REFERENCES

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- 3. Resources: Test Strip Compatibility. Ascensia Diabetes Care. Available at: <u>https://www.contournextpro.com/resources/test-strip-compatibility/</u>. Accessed on September 13, 2023.
- 4. One Touch® Test Strips. LifeScan. Available at: <u>http://www.onetouch.com/our\_products</u>. Accessed on September 13, 2023.
- 5. Accu-Chek<sup>®</sup> Test Strips. Roche Diabetes Care. Available at: <u>https://www.accu-chek.com/products/blood-glucose-monitoring/test-strips</u>. Accessed on September 15, 2022.
- 6. Blood Glucose Monitoring Systems. Trividia Health. Available at: <u>https://trividiahealth.com/products/blood-glucose-meters-test-strips/</u>. Accessed on September 13, 2023.
- 7. American Diabetes Association. Consumer Guide. Available at: <u>https://consumerguide.diabetes.org/collections/meters</u>. Accessed on September 13, 2023.
- 8. Krouwer JS and Cembrowski GS. A review of standards and statistics used to describe blood glucose monitor performance. J Diabetes Sci Technol. 2010;4(1):75-83.
- 9. Lazarte M. More accurate self-testing results for diabetes patients with new ISO standard. June 19, 2013. Available at: http://www.iso.org/iso/home/news\_index/news\_archive/news.htm?refid=Ref1749. Accessed on September 13, 2023.
- US Department of Health and Human Services. Food and Drug Administration. Center for Devices and radiological health Office of In Vitro Diagnostic Device Evaluation and Radiological health. Division of Chemistry and Toxicology Devices. Self-monitoring blood glucose test systems for over-the-counter use. Guidance for industry and Food and Drug Administration Staff. September 2020. Available at: <u>http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM380327.pdf</u>. Accessed on September 13, 2023.

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