



Drug Coverage Policy

Effective Date9/1/2024
Coverage Policy NumberIP0272
Policy TitleDiabetic Test Strips,
Lancets and Pen Needles

Diabetes – Diabetic Test Strips, Lancets and Pen Needles

INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer’s particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer’s benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer’s benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment and have discretion in making individual coverage determinations. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Cigna Healthcare Coverage Policy

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 fingertips) 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.¹⁻⁷

Diabetic test strips are measured for accuracy using standards set forth by the International Organization for Standardization and/or FDA.⁸⁻¹⁰ Currently marketed monitors must meet the standard under which they were approved.¹ 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.

Medical Necessity Criteria

Coverage criteria are listed for products **in below table:**

Employer Plans:

Product	Criteria
Glucose Test Strips (non-formulary)	<p>Legacy: Glucose Test Strips (non-formulary) are considered medically necessary when ONE of the following is met:</p> <ol style="list-style-type: none"> 1. Patient has tried ONE of the following: <ol style="list-style-type: none"> A. Accu-Chek Test Strips B. Accutrend Test Strips C. OneTouch Test Strips 2. Patients using an insulin pump/meter system that is not compatible with one of the available formulary alternatives 3. If the request is for Freestyle Precision Neo strips for use in a Freestyle Libre reader <p>Standard/Performance/Value/Advantage/Total Savings Glucose Test Strips (non-formulary) are considered medically necessary when ONE of the following is met:</p> <ol style="list-style-type: none"> 1. Patient has tried OneTouch Test Strips 2. Patients using an insulin pump/meter system that is not compatible with one of the available formulary alternatives 3. If the request is for Freestyle Precision Neo strips for use in a Freestyle Libre reader
Pen Needles (non-formulary)	<p>Standard/Performance/Legacy/Value/Advantage/Total Savings: Pen needles (non-formulary) are considered medically necessary when ONE of the following is met:</p> <ol style="list-style-type: none"> 1. Patient has tried BD Pen Needles 2. Patient requires a needle of the requested length and/or gauge which is not available as a BD pen needle product

Individual and Family Plans:

Product	Criteria
Glucose Test Strips (non-formulary)	<p>Glucose Test Strips (non-formulary) are considered medically necessary when ONE of the following is met:</p> <ol style="list-style-type: none"> 1. Patient has tried OneTouch Test Strips 2. Patients using an insulin pump/ meter system that is not compatible with one of the available formulary alternatives

Product	Criteria
	<p>3. If the request is for Freestyle Precision Neo strips for use in a Freestyle Libre reader</p>
<p>Lancets (non-formulary)</p>	<p>Lancets (non-formulary) are considered medically necessary when BOTH of the following is met:</p> <ol style="list-style-type: none"> 1. Patient has tried OneTouch lancets 2. Patient was unable to adhere to a regimen using standard insulin products

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Receipt of sample product does not satisfy any criteria requirements for coverage.

Conditions Not Covered

Any other use is considered experimental, investigational, or unproven (criteria will be updated as new published data are available).

References

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2. Products. Abbott. Available at: <https://www.diabetescare.abbott/products.html>. Accessed on September 13, 2023.
3. Resources: Test Strip Compatibility. Ascensia Diabetes Care. Available at: <https://www.contournextpro.com/resources/test-strip-compatibility/>. Accessed on September 13, 2023.
4. One Touch® Test Strips. LifeScan. Available at: http://www.onetouch.com/our_products. Accessed on September 13, 2023.
5. Accu-Chek® Test Strips. Roche Diabetes Care. Available at: <https://www.accu-chek.com/products/blood-glucose-monitoring/test-strips>. Accessed on September 15, 2022.
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7. American Diabetes Association. Consumer Guide. Available at: <https://consumerguide.diabetes.org/collections/meters>. 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.
10. 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:

Revision Details

Type of Revision	Summary of Changes	Date
Annual Review	<p>Updated preferred product criteria including (1) reducing step through from two preferred products to one preferred product, (2) added using non-compatible insulin pump/meter system option, (3) added criteria option if patient is using Freestyle Libre reader</p> <p>Updated Standard and Performance to include Accu-chek and Accutrend as preferred alternatives</p> <p>Added Diabetic Pen Needles criteria from Pen Needles IP0569</p> <p>Updated title from Glucose Test Strips</p> <p>Added glucose test strips, lancets and criteria for the related IFP non-formulary classes.</p>	9/1/2024

The policy effective date is in force until updated or retired.

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