

Pharmacy Policy

Diabetic Testing Supplies – Unified Formulary

Policy Number: 9.336

Version Number: 2

Version Effective Date: 9/1/2021

Product Applicability <input type="checkbox"/> All Plan⁺ Products	
<p>Well Sense Health Plan</p> <p><input type="checkbox"/> New Hampshire Medicaid</p>	<p>Boston Medical Center Healthnet Plan</p> <p><input checked="" type="checkbox"/> Masshealth - MCO</p> <p><input checked="" type="checkbox"/> Masshealth - ACO</p> <p><input type="checkbox"/> Qualified Health Plans</p> <p><input type="checkbox"/> Senior Care Options</p>

Note: Disclaimer and Audit Information Is Located At The End Of This Document.

Policy

Reference Table:

Products that require PA	No PA
Freestyle [®] >100 units/month ^{††}	Freestyle [®] ≤100 units/month ^{††}
Freestyle InsuLinx [®] >100 units/month ^{††}	Freestyle InsuLinx [®] ≤100 units/month ^{††}
Freestyle Lite [®] >100 units/month ^{††}	Freestyle Lite [®] ≤100 units/month ^{††}
Freestyle Neo [®] ^{††}	Precision Xtra [®] ≤100 units/month ^{††}
Precision Xtra [®] >100 units/month ^{††}	
All brands other than those listed in column to the right	

^{††}Rebate agreement. MassHealth has a rebate agreement with the manufacturer for this product. Please see below for specific NDCs which are included in the rebate agreement.

The following NDCs are included within the rebate agreement and will usually process and pay at the pharmacy without a prior authorization within quantity limits:

Freestyle[®], Freestyle InsuLinx[®], Freestyle Lite[®]
 99073-0120-50

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99073-0121-01
 99073-0124-50
 99073-0124-01
 99073-0708-22
 99073-0708-27
 99073-0708-19
 99073-0712-27
 99073-0712-30
 99073-0712-31

Precision Xtra®
 57599-9728-04
 57599-9877-05
 57599-9838-04
 57599-9878-05

The following NDCs are included within the rebate agreement and will usually reject at the pharmacy level for prior authorization:

Freestyle Neo®
 57599-1577-01
 57599-1579-04

The following Freestyle® and Precision Xtra® NDCs are not included in rebate agreement and therefore will usually reject at the pharmacy level for prior authorization. All other brands are not included in the rebate agreement and therefore will usually reject at the pharmacy level for prior authorization.

Freestyle®, Freestyle InsuLinx®, Freestyle Neo®, Freestyle Lite®
 99073-0707-92
 99073-0710-26
 99073-0712-29

Precision Xtra®
 57599-9694-05
 57599-9695-04
 93815-0998-77
 93815-0998-78
 93815-0998-38
 93815-0997-28
 93815-0996-94
 93815-0996-95

Procedure

Approval Diagnosis:	<ul style="list-style-type: none"> • Type 1 or Type 2 Diabetes Mellitus, Gestational Diabetes
Approval Criteria: <i>Non-preferred agents</i>	Prescriber provides documentation of the following: <ol style="list-style-type: none"> 1. Medical necessity for a non-preferred product (<i>See appendix for a list of products with features that may be medically necessary in certain populations</i>). Examples of conditions that warrant the use of a non-preferred product may include (depending on the product): <ol style="list-style-type: none"> a. Physical disability (e.g., severe arthritis) b. Visual impairment

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	<p>c. Cognitive impairment</p> <p>2. Quantity requested is ≤ 100 units per month</p> <p><i>Note:</i></p> <ul style="list-style-type: none"> • <i>An attempt should be made to contact the provider to determine the frequency of testing for a non-preferred test strip if it is not indicated on the prior authorization request. If the provider is unable to be reached and the request is otherwise approvable, please enter the approval for up to 100 strips.</i> • <i>*Requests for >100 units per month for non-preferred test strips must meet non-preferred agents' criteria AND all agents above quantity limit criteria</i>
<p>Approval Criteria:</p> <p>Freestyle Neo[®]</p>	<p>Prescriber provides documentation of the following:</p> <ol style="list-style-type: none"> 1. Documentation that member is using compatible continuous glucose monitoring device (i.e., Freestyle Libre 2[®], Freestyle Libre 14 Day[®]) 2. Quantity requested is ≤ 100 units per month <p><i>Note:</i></p> <ul style="list-style-type: none"> • <i>An attempt should be made to contact the provider to determine the frequency of testing for Freestyle Neo[®] test strips if it is not indicated on the prior authorization request. If the provider is unable to be reached and the request is otherwise approvable, please enter the approval for up to 100 strips.</i>
<p>Approval Criteria:</p> <p><i>All agents above quantity limits</i></p>	<p>Prescriber provides documentation of ALL of the following:</p> <ol style="list-style-type: none"> 1. ONE of the following:* <ol style="list-style-type: none"> a. Medical necessity for increased testing[†] b. Treatment plan describing self-testing frequency 2. If request is for Freestyle Neo, prescriber must provide documentation that member is using compatible continuous glucose monitoring device (i.e., Freestyle Libre 2[®], Freestyle Libre 14 Day[®]) <p><i>Note:</i></p> <ul style="list-style-type: none"> • <i>*If member is utilizing a continuous glucose monitoring device, member must meet BOTH of the following.</i> • <i>† Examples of medical necessity include type 1 diabetes, gestational diabetes, insulin pump use, multiple daily insulin injections</i>
<p>Denial Criteria:</p>	<p>Cases that do not meet the approval criteria will be denied.</p> <p>If a request is denied and the prescriber has additional clinical documentation, a new prior authorization request must be submitted.</p>
<p>Duration/Quantity of Authorization:</p>	<p>Prior authorization may be issued for 1 year.</p>
<p>Recertification Criteria:</p>	<p>Prescriber provides documentation of the following:</p> <ul style="list-style-type: none"> • Continued medical necessity for increased testing or continued medical necessity for the use of non-preferred testing supplies

Appendix:

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Stability

Stability on a non-preferred meter is not medical necessity for approval.

Increased Testing per Day

Certain populations may require increased daily blood glucose monitoring. Treatment guidelines recommend testing a minimum of two times and as much as six to ten (or more) times daily for patients on insulin, although individual needs may vary. These requests should be approved if the prescriber describes the treatment plan and the frequency of testing.

Non-preferred Products

No meter offers a clear clinical advantage over another; however, there are differences from meter to meter with regards to sample size of blood, alternate site testing, test memory and data management. Medical necessity should be evaluated case by case. Compelling requests may be reviewed with the clinical reviewer of the day.

In addition, if a prescriber documents that a member has a condition that may present a barrier to adopting a new preferred meter (learning disability without a care giver present, dementia, obsessive compulsive disorder); this should be taken into consideration. A 3 month approval can be granted to allow members to be trained on how to use a preferred meter. The following sentence should be included in the outgoing messaging of approvals.

“A short term approval is granted to allow for the member to be trained on a meter compatible with diabetic test strips covered by MassHealth without prior authorization.”

Insulin Pumps: Certain insulin pumps are compatible with meters that allow them to connect through WiFi. This allows the insulin reading to be forwarded directly to the pump without a risk of dose entry errors. Any request for a non-preferred test strip for a member with an insulin pump and accompanying meter should be approved.

Glucometer and personal electronic device interface:

Certain glucometers may interface with computers, phones or other personalized electronic devices. One such device, the BG star meter is capable is syncing with smart phones. Requests for test strips that are used in meters with this functionality should generally be denied. However, if the member has a compelling indication for the use of this product (e.g. cognitive impairment and documented difficulty managing diabetes with other glucometers), the request may be forwarded to clinical review. Consideration could be given for approval in this case.

Bolus dose calculator:

The Accu-Chek Aviva[®] meter has a functionality that allows it to calculate bolus doses based upon patient specific factors (e.g. insulin sensitivity) and the amount of carbohydrate consumed. If the prescriber documents this as a medical necessity, this should generally not be considered to meet approval criteria. However, the request may be forwarded to clinical review for a member who has difficulty managing diabetes with other glucometers. Consideration could be given for approval in this case.

Point of Sale (POS) Criteria

Criteria:

1. Claims for preferred diabetic test strips at less than or equal to 100 strips per 30 days will usually process and pay at the pharmacy.
2. Claims for Freestyle Neo[®] test strips at less than or equal to 100 strips per 30 days of will usually process and pay at the pharmacy, if the member has a claim for Freestyle Libre 2[®], Freestyle Libre 14 Day[®] sensors within the last 90 days.

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3. Claims for non-preferred diabetic test strips will usually reject at the pharmacy requiring prior authorization regardless of quantity.
4. Claims for preferred diabetic test strips at greater than 100 strips per 30 days but less than or equal to 200 strips per 30 days will usually pay at the pharmacy if the member has a claim for injectable insulin or a prenatal vitamin within the last 90 days.*

*Please note: a 50 day supply will be allowed on all claims for test strips. The ratio of 100 strips/30 days (or 200 strips/30 days if insulin or prenatal vitamins in claims history) applies to these requests.

Original Approval Date	Original Effective Date	Policy Owner	Approved By
1/1/2021	1/1/2021	Pharmacy Services	Pharmacy & Therapeutics (P&T) Committee

Policy Revisions History			
Review Date	Summary Of Revisions	Revision Effective Date	Approved By
1/1/2021	Created policy to align with Diabetic Testing Supplies PUF guidelines	1/1/2021	P&T Committee
5/13/2021	Updated policy for 3/16/21 changes from MH: Appendix added for Precision Neo test strips. Updated policy for 4/8/21 changes from MH: Appendix for Freestyle Precision Neo test strips removed and guidance for reviewing requests added in PA criteria under Procedure table. The reference table and POS criteria were updated to reflect Freestyle Neo as a preferred product. Lastly, minor verbiage changes to criteria for non-preferred agents and requests above quantity limits.	7/1/2021	P&T Committee
7/23/2021	Updated policy for 6/14/21 changes from MH: Two NDCs removed for Freestyle Precision Neo test strips as they were UPCs	9/1/2021	P&T Committee

Next Review Date

5/2022

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Other Applicable Policies

Reference To Applicable Laws And Regulations, If Any

Disclaimer Information

Medical Policies Are The Plan's Guidelines For Determining The Medical Necessity Of Certain Services Or Supplies For Purposes Of Determining Coverage. These Policies May Also Describe When A Service Or Supply Is Considered Experimental Or Investigational, Or Cosmetic. In Making Coverage Decisions, The Plan Uses These Guidelines And Other Plan Policies, As Well As The Member's Benefit Document, And When Appropriate, Coordinates With The Member's Health Care Providers To Consider The Individual Member's Health Care Needs.

Plan Policies Are Developed In Accordance With Applicable State And Federal Laws And Regulations, And Accrediting Organization Standards (Including NCQA). Medical Policies Are Also Developed, As Appropriate, With Consideration Of The Medical Necessity Definitions In Various Plan Products, Review Of Current Literature, Consultation With Practicing Providers In The Plan's Service Area Who Are Medical Experts In The Particular Field, And Adherence To FDA And Other Government Agency Policies. Applicable State Or Federal Mandates, As Well As The Member's Benefit Document, Take Precedence Over These Guidelines. Policies Are Reviewed And Updated On An Annual Basis, Or More Frequently As Needed. Treating Providers Are Solely Responsible For The Medical Advice And Treatment Of Members.

The Use Of This Policy Is Neither A Guarantee Of Payment Nor A Final Prediction Of How A Specific Claim(S) Will Be Adjudicated. Reimbursement Is Based On Many Factors, Including Member Eligibility And Benefits On The Date Of Service; Medical Necessity; Utilization Management Guidelines (When Applicable); Coordination Of Benefits; Adherence With Applicable Plan Policies And Procedures; Clinical Coding Criteria; Claim Editing Logic; And The Applicable Plan – Provider Agreement.

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