OTC Covid-19 Test Kits
BinaxNow
FlowFlex
IHealth
Inteliswab
QuickVue
On-Go
Carestart
CVS COVID-19
Genabio
Effective 03/01/2023

Plan	☒ MassHealth ☐ MH UPPL ☐Commercial/Exchange	**Program Type**	☐ Prior Authorization ☒ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☐ Medical Benefit (NLX)		
Specialty Limitations	N/A		
Contact Information	**Specialty Medications**		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	Non-Specialty Medications		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	Medical Specialty Medications (NLX)		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
Exceptions	N/A		

Overview

The Food & Drug Administration (FDA) has granted emergency use authorization to several rapid at-home antigen tests for COVID-19 that allow individuals to test themselves without presenting to medical care or a testing site. Antigen tests detect the presence of a specific viral antigen, which implies current viral infection. Antigen tests are very specific for the virus but are not as sensitive as molecular tests (polymerase chain reaction [PCR] tests). This means that while positive results from antigen tests are generally as accurate as from molecular tests, there is a higher chance of false negatives compared to molecular tests.

To increase the testing accessibility for MassHealth members through the pharmacy program, select OTC COVID-19 at-home antigen self-test kits have been added to the MassHealth Non-Drug Product List and will be covered through the pharmacy benefit without prior authorization within the quantity limit of eight tests per 28 days (i.e., four test kits with two tests per kit or eight test kits with one test per kit per member per 28 days). The list of covered tests is provided in the table below:

Product	Availability*
BinaxNow	Box of 2
FlowFlex	Box of 1
	Box of 2
IHealth	Box of 2
On-Go	Box of 2
Carestart	Box of 2
	Box of 4
Inteliswab	Box of 2
QuickVue	Box of 2
CVS COVID-19	Box of 2
Genabio	Box of 1
	Box of 2

*The billing unit is per test.

No PA	PA required
BinaxNow (COVID-19 antigen self-test) ≤8 tests/28 days	BinaxNow (COVID-19 antigen self-test) >8 tests/28 days
FlowFlex (COVID-19 antigen self-test) ≤8 tests/28 days	FlowFlex (COVID-19 antigen self-test) >8 tests/28 days
IHealth (COVID-19 antigen self-test) ≤8 tests/28 days	IHealth (COVID-19 antigen self-test) >8 tests/28 days
Inteliswab (COVID-19 antigen self-test) ≤8 tests/28 days	Inteliswab (COVID-19 antigen self-test) >8 tests/28 days
QuickVue (COVID-19 antigen self-test) ≤8 tests/28 days	QuickVue (COVID-19 antigen self-test) >8 tests/28 days
BinaxNow (COVID-19 antigen self-test) ≤8 tests/28 days	BinaxNow (COVID-19 antigen self-test) >8 tests/28 days
FlowFlex (COVID-19 antigen self-test) ≤8 tests/28 days	FlowFlex (COVID-19 antigen self-test) >8 tests/28 days
Carestart (COVID-19 antigen self-test) ≤8 tests/28 days	Carestart (COVID-19 antigen self-test) >8 tests/28 days
On-Go (COVID-19 antigen self-test) ≤8 tests/28 days	On-Go (COVID-19 antigen self-test) >8 tests/28 days
CVS COVID-19 At-Home Test (COVID-19 antigen self-test) ≤8 tests/28 days	CVS COVID-19 At-Home Test (COVID-19 antigen self-test) >8 tests/28 days
Genabio COVID-19 Rapid At-Home Test ≤8 tests/28 days	Genabio COVID-19 Rapid At-Home Test >8 tests/28 days

Coverage Guidelines

Authorization may be granted for members when all the following criteria are met, and documentation is provided:

1. Medical necessity for increased testing (see Appendix)

Continuation of Therapy

Reauthorization requires physician documentation of continued medical necessity (see Appendix) for increased testing.

Limitations

1. Initial approvals and reauthorizations will be granted for 1 week up to 1 month based on medical necessity

Appendix

Medical Necessity for Quantity Limit Exceeding of 8 Tests/28 days

Certain populations may require increased COVID testing due to extenuating circumstances. Guidance on reviewing common scenarios for exceeding quantity limit of 8 tests/28 days is provided in the table below. Reasonable accommodations will be provided while ensuring appropriate use that discourages stockpiling of tests. An approval can generally be issued for up to 1 week; however, approvals for up to 1 month may be appropriate in some cases consistent with the period of increased testing required based on a case-by-case review.

Rationale for Exceeding Quantity Limit	Guidance on Reviewing Requests
High risk for infection (e.g., immunocompromised)	Members at a high risk of infection may require more frequent testing. Request may be approved for additional 8 tests/28 days.
Travel	Reasonable accommodations can be provided to allow for additional testing for travel while ensuring that COVID test kits are not being stockpiled. Requests may be approved to allow for testing prior to travel (2 tests), during travel (up to 2 tests/week), prior to returning home (2 tests), and/or upon return home (2 tests).
Work requirement	If member's place of work requires frequent testing (e.g., for each day reporting to work) and the place of work does not provide or cover the cost of COVID testing, request can be approved for up to 1 test/day for up to 1 month.
Known exposure with a negative test, but showing symptoms	With a known exposure to COVID where member tests negative, additional testing may be required that would exceed quantity limit. Request may be approved for up to 1 test/day for up to 1 week.
Test and Stay (close contact testing)	A close contact of someone who is infected with COVID-19 may require more frequent testing (e.g., a child may require daily testing for several days to stay in daycare). Requests can be approved for daily use (e.g., one test/day for up to a week).
Chronic exposure with a negative test requiring frequent testing	With chronic exposure to COVID (e.g., member is a close contact at a facility with multiple positive tests or close contact of a household member who has tested positive) and member tests negative, additional testing may be required that would exceed quantity limit. Request may be approved for additional 8 tests/28 days.
Test was not performed correctly/user error	A phone override or prior authorization approval should be issued as a replacement for the test(s)

References

1. Centers for Disease Control and Prevention (CDC). Overview of Testing for SARS-CoV-2 (COVID-19) [webpage on the internet]. Atlanta, GA: CDC; Oct 22, 2021 [cited 2021 Dec 27]. Available from: https://www.cdc.gov/coronavirus/2019-ncov/hcp/testing-overview.html.
2. Caliendo AM, Hanson KE. COVID-19: Diagnosis. In: Hirsch MS (Ed). UpToDate [database on the internet]. Waltham (MA): UpToDate; 2021 [cited 2021 Dec 27]. Available from: https://www.uptodate.com/contents/search.
3. BinaxNow COVID-19 Antigen Self Test [package insert on the internet]. Scarborough (ME): Abbott Diagnostics Scarborough, Inc.; 2021 Nov [cited 2021 Dec 28]. Available from: https://www.fda.gov/media/147255/download.

4. FlowFlex COVID-19 Antigen Home Test [package insert on the internet]. San Diego (CA): ACON Laboratories, Inc; 2021 Oct [cited 2021 Dec 28]. Available from: https://www.fda.gov/media/152699/download.
5. IHealth COVID-19 Antigen Rapid Test [package insert on the internet]. Sunnyvale (CA): iHealth Labs, Inc.; 2021 Dec [cited 2022 Jan 13]. Available from: https://www.fda.gov/media/152699/download.
6. Inteliswab COVID-19 Antigen Rapid Test [package insert on the internet]. Bethlehem (PA): Orasure Technologies, Inc; 2021 Oct [cited 2022 Jan 13]. Available from: https://www.fda.gov/media/149911/download
7. QuickVue At-Home OTC COVID-19 Test [package insert on the internet]. San Diego (CA): Quidel Corporation; 2021 Oct [cited 2021 Dec 28]. Available from: https://www.fda.gov/media/147250/download.

Review History

03/16/2022 – Created and Reviewed March P&T Mtg; created to match MH for select OTC COVID-19 at-home antigen self-test kits. Effective 03/01/2022.
01/11/23 – Reviewed and updated for Jan P&T. Added CVS COVID-19 At-Home Test and Genabio COVID-19 Rapid At-Home Test. Effective 3/1/23.

Disclaimer

AllWays Health Partners complies with applicable federal civil rights laws and does not discriminate or exclude people on the basis of race, color, national origin, age, disability, or sex.