

Starting January 15, 2022, the <u>federal government requires</u> that **commercial health insurance** companies pay for at-home COVID-19 tests to remove financial barriers and expand access to COVID-19 testing across the United States in an effort to fight the pandemic.

Here is a summary of the plan:

- New requirement applies to commercial/private insurance only NOT Medicare or Medicaid
- OTC COVID-19 diagnostic test must be authorized, cleared, or approved by the FDA (see FDA list here and PAAS list or Product Identifiers)
- Insurance companies and health plans are required to cover 8 free OTC at-home tests per covered individual per month (up to \$12 per test) for tests purchased after January 15, 2022, at network pharmacies or retailers
- OTC tests may be covered up front at point-of-sale or patients may need to get reimbursed by submitting receipts on their own (not all plans will reimburse at point-of-sale)
- OTC tests for employment purposes or travel are NOT required to be covered
- There is theoretically NO LIMIT on the number of tests that are covered if ordered or administered by a health care provider

Starting April 4, 2022, CMS will cover OTC COVID-19 tests for **Medicare** patients at no charge until the end of the Public Health Emergency.

Here are some details:

- Eight (8) OTC COVID-19 tests are covered per patient per calendar month
- No prescription is required
- Providers must be enrolled as a Fee for Service Medicare Part B Provider (not Supplier)
- Pharmacies should only dispense pursuant to a patient request
- HCPCS code K1034 is used to bill for 1 test
- Submit NPI number used when billing for COVID-19 vaccines (Pharmacist Type 1 or Pharmacy Type 2)
- Claims to Medicare are NOT adjudicated in real-time and Providers should ensure that patients have not previously received OTC tests in the same calendar month
- Claims are only paid when submitted by a Provider, patients will not be reimbursed if they buy as OTC items and seek reimbursement
- Reimbursement is lesser of (i) Usual & Customary or (ii) \$12 per test, with no geographic adjustments

There are additional details posted for both providers and patients as of April 4, 2022.





Q1: Do I need a prescription to bill for an OTC COVID-19 test?	
Q2: Who is the prescriber when I haven't initiated a prescription?	3
Q3: Can a pharmacist create a valid prescription for an OTC COVID-19 test?	3
Q4: Who is the prescriber when the pharmacist has initiated a prescription?	3
Q5: What audit risks should I take into consideration?	3
Q6: What documentation should I retain?	4
Q7: What's the appropriate days' supply for a test?	4
Q8: Is my pharmacy required to submit claims to PBMs through the pharmacy dispensing system?	4
Product Identifiers	5
Additional Resources	6
Links to commercial PBM and Insurance Plan websites	6
Please	



Q1: Do I need a prescription to bill for an OTC COVID-19 test?

A: No, section 6001 of the Families First Coronavirus Aid, Relief, and Economics Security Act (FFCRA or CARES Act) specifies that private health plans must cover certain OTC COVID-19 tests obtained without a prescription. Starting on April 4, 2022, CMS will cover tests under the FFS Medicare B benefit.

Q2: Who is the prescriber when I haven't initiated a prescription?

A: Since the emergency order specifies the OTC product does not require a prescription, the Prescriber ID (411 DB) field is not required. In this situation, neither a Prescriber ID nor Prescriber ID Qualifier needs to be sent. However, if the processor requires the submission of a Prescriber ID due to editing rules, NCPDP recommends either the Pharmacist NPI (Type 1) or the Pharmacy NPI (Type 2) with the Prescriber ID Qualifier (466-EZ) of "01" may be submitted as the Prescriber ID. Since a prescription is not required, prescriber enrollment validation should not apply to any prescriber ID value that may be submitted.

Q3: Can a pharmacist create a valid prescription for an OTCCOVID-19 test?

A: The <u>PREP Act</u> gives pharmacists authority to order such tests during the Public Health Emergency (as per April 8, 2020 <u>HHS Guidance for Licensed Pharmacists</u>).

Q4: Who is the prescriber when the pharmacist has initiated a prescription?

A: For prescriptions initiated by a pharmacy, the pharmacist's Type 1 NPI would be submitted as the Prescriber ID (411-DB) and Prescription Origin Code (419-DJ) would be 5 – Pharmacy.

• If pharmacist NPIs are not included within a payer's prescriber data files used for prescriber ID validation, existing NCPDP guidance indicates that a SCC value of 42 (Prescriber ID Submitted is valid and prescribing requirements have been validated) may be used by payers to override prescriber NPI validation and prescriber enrollment rules.

Q5: What audit risks should I take into consideration?

A: The following considerations should be taken into account when adjudicating claims for OTC COVID-19 tests:

- Do not put refills on prescription, subsequent fills should be keyed in as new requests/prescription numbers
- Do not put these prescriptions on auto-refill programs or refill at pre-determined intervals without first obtaining a patient request to fill (consider documenting proof of new/refill request)
- If tests are mailed to patients, PBMs may require the patient pay shipping costs (e.g., Prime Therapeutics)
- Tests covered by commercial payors cannot be used for travel, employment, or resale purposes
- Pharmacies should ensure that patients meet the EUA criteria (e.g., patient is ≥ 2 years of age, when restricted)
- Medicare claims are NOT adjudicated in real-time, and pharmacies are encouraged to ask patients if they have already
 received test in the current calendar month utilize an Advance Beneficiary Notice of Noncoverage (ABN) if a patient has
 already received tests in the current month or cannot remember



Q6: What documentation should I retain?

A: Whether you're initiating a new prescription or billing without one, PAAS recommends that pharmacies create documentation for your records when billing claims through the pharmacy system.

- Prime Therapeutics has indicated that pharmacies must "verify and document" that patients are not using the tests for employment or resale purposes.
- Express Scripts "reserves the right to implement attestation requirements"
- CMS recommends that providers document patient request and that failure to produce such documentation upon request could lead to recoupment and other administrative actions
- CMS recommends that providers utilize an <u>Advance Beneficiary Notice of Noncoverage (ABN)</u> when patients do not know if they have received 8 tests in the current calendar month already
- See PAAS National® <u>Medicare and Commercially Insured Patient Request and Attestation for ONC COVID-19 Test Billing</u>

Q7: What's the appropriate days' supply for attest?

A: NCPDP Emergency Preparedness Guidance version 1.13 section 11.14 recommends that days' supply should be submitted as 1 day per test.

- PBMs may implement point-of-sale quantity limits of 8 tests per 30 days such that you may be forced to bill in this ratio (8 per 30, 4 per 15, etc.).
- With a days' supply of 1 per test, be mindful not to exceed the designed limits of 8 tests per 30 days without a prescription. You may not be able to rely on claim adjudication logic to reject early fills.

Q8: Is my pharmacy required to submit claims to PBMs through the pharmacy dispensing system?

A: Varies based on payer.

- For commercial payers, this may be determined based on plan/PBM requirements.
- For Medicare, you must bill claim at point of sale as CMS will not reimburse patients for OTC tests purchased.





Product Identifiers

Known Authorized Tests

Authorized Tests			
Brand Name	Product ID 407-D7	Quantity Dispensed 442-E7	
BINAXNOW COVID-19 AG CARD HOME TEST	11877-0011-40	2 EA	
CARESTART COVID19 AG HOME TEST	50010-0224-31	2 EA	
CARESTART COVID19 AG HOME TEST	50010-0224-32	4 EA	1
CARESTART COVID19 AG HOME TEST	50010-0224-33	10 EA	
FLOWFLEX KIT HOME TEST	82607-0660-26	1 EA	
FLOWFLEX KIT HOME TEST	82607-0660-27	2 EA	
FLOWFLEX KIT HOME TEST	82607-0660-28	5 FA	
FLOWFLEX KIT HOME TEST	82607-0660-47	25 ÉA	
IHEATLH COVID-19 AG RAPID TEST	56362-0005-89	2 EA	
IHEATLH COVID-19 AG RAPID TEST	56362-0005-90	5 EA	
IHEATLH COVID-19 AG RAPID TEST	56362-0005-96	40 EA	
QUICKVUE AT-HOME COVID-19 TEST	14613-0339-72	2 EA	
QUICKVUE AT-HOME COVID-19 TEST	14613-0339-67	25 EA	

Tests PAAS cannot independently confirm are covered under the OTC EUA

Brand Name	Product ID 407-D7	Quantity Dispensed 442-E7
INTELISWAB COVID-19 RAPID TEST	08337-0001-58	2 EA
QUICKVUE AT-HOME COVID-19 TEST	14613-0339-68	5 EA
ELLUME COVID-19 HOME TEST	56964-0000-00	1 EA
ELLUME COVID-19 HOME TEST	50021-0860-01	1 EA
ON/GO COVID-19 ANTIGEN SELF TEST	60006-0191-66	2 EA
COVID 19 AT KIT	00111-0707-52	1 EA
COVID-19 AT KIT	00111-0707-72	4 EA
CLINITEST KIT SELF-TEST	16490-0025-74	5 EA
BINAX NOW COVID KIT HOME TEST	11877-0011-33	1 EA

^{*}List is not inclusive of all products



Additional Resources

- 1. CMS has a frequently asked questions webpage with information for patients
- 2. NCPA has a Testing for Coronavirus webpage that includes additional details
- 3. NCPDP has Emergency Preparedness Guidance with additional details
- 4. FAQS about Affordable Care Act Implementation Part 51, FFCRA January 10, 2022
- 5. Medicare
 - o April 4, 2022 Fact Sheet
 - o Over-the-Counter COVID-19 Test Demonstration
- 6. Alternatively, patients may request 4 free at-home COVID tests shipped to their home from the U.S. Government from www.covidtests.gov

Links to commercial PBM and Insurance Plan websites

PBMs

- Caremark
- Express Scripts (Network Bulletin issued by email 01-14-2022)
- Humana
- MedImpact
- Navitus
- OptumRx
- Prime Therapeutics (Network Bulletin issued 01-14-2022)

Insurance Plans

- Aetna
- Cigna
- UHC

