CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-20 One-Time Notification	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 12214	**Date: August 18, 2023**
	Change Request 13336

SUBJECT: OTC COVID-19 Tests

I. SUMMARY OF CHANGES: The purpose of this Change Request (CR) is to implement an edit that will deny more than eight COVID-19 OTC tests billed in a calendar month for the same beneficiary.

EFFECTIVE DATE: May 12, 2023
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: August 14, 2023 - CWF SSM Testing and Implementation; August 15, 2023 - FISS SSM Testing and Implementation; August 28, 2023 - MACs to Release and Process Held Claim Lines with the OTC Test Kit Code (K1034)

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated)
R=REVISED, N=NEW, D=DELETED-*Only One Per Row.*

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
N/A	N/A

III. FUNDING:

For Medicare Administrative Contractors (MACs):
The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

IV. ATTACHMENTS:

One Time Notification

Attachment - One-Time Notification

Pub. 100-20	Transmittal: 12214	Date: August 18, 2023	Change Request: 13336

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EFFECTIVE DATE: May 12, 2023
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I. GENERAL INFORMATION

A. Background: As part of the Biden-Harris Administration's ongoing efforts to expand access to free COVID-19 testing, CMS launched a demonstration project under the authority of Section 402(a)(1)(B) of the Social Security Amendments of 1967. The demonstration, beginning on April 4, 2022, allowed Medicare beneficiaries to get up to eight COVID-19 OTC tests per month for free. Tests were available through eligible pharmacies and other participating entities. This policy applied to COVID-19 OTC tests approved or authorized by the U.S. Food and Drug Administration (FDA). The demonstration ended on May 11, 2023 with the end of the public health emergency (PHE).

Tests were assigned the following HCPCS code:

K1034 – Provision of COVID-19 test, nonprescription self-administered and self-collected use, FDA authorized, cleared or approved, one test count.

While the MACs implemented regional edits to limit the number of COVID-19 OTC tests to eight per beneficiary per month at the start of the demonstration, CMS is now seeing evidence of likely fraud in the form of suspicious entities skirting the regional edits on a large scale. A nation-wide edit is needed to enforce the eight tests per month limit and stem the substantial amount of overpayments. While the demonstration has ended, providers have up to a year to submit claims, and CMS has already observed a considerable amount of back-billing of COVID-19 OTC tests since the end of the PHE.

This edit will deny more than eight over-the-counter COVID-19 tests billed in a calendar month for the same beneficiary, regardless of MAC jurisdiction.

B. Policy: Section 402(a)(1)(B) of the Social Security Amendments of 1967.

II. BUSINESS REQUIREMENTS TABLE

"Shall" denotes a mandatory requirement, and "should" denotes an optional requirement.

Number	Requirement	Responsibility								
		A/B MAC			DME	Shared-System Maintainers				Other
		A	B	HHH	MAC	FISS	MCS	VMS	CWF	
13336.1	The contractor shall add the K1034 HCPCS code to COVID-19 Auxiliary file and accumulate the test kit count								X	

Number	Requirement	Responsibility								
		A/B MAC			DME	Shared-System Maintainers				Other
		A	B	HHH	MAC	FISS	MCS	VMS	CWF	
	in COVID-19 auxiliary file.									
13336.2	The contractor shall modify filler (:XX:-FILLER-2) area of existing CABCCOVD copybook to track the test kit count for HCPCS code K1034.								X	
13336.3	The contractor shall add a new 88 level in CABCCOVX copybook to accommodate HCPCS code K1034 as a valid COVID-19 HCPCS for COVDAUX processing.								X	
13336.4	The contractor shall set a new edit if K1034 test kits count is more than 8 per month and will populate trailer 39 (for HUBC claims) or trailer 43 (for HUOP and HUHC claims) for this new edit.								X	
13336.5	The contractors shall modify HIMR/COVID-19 Auxiliary detail screen to display the test kit count for HCPCS Code K1034 per claim.								X	
13336.6	Contractors shall accept new overridable line level CWF reject edit U5729, along with the associated Trailer 43.					X				
13336.7	Contractors shall apply reject code U5729 to the line item date of service associated with Trailer 43.					X				
13336.8	Contractors shall perform the required maintenance to accept and adjudicate CWF edit(s).	X	X							
13336.9	Contractors shall deny the rejected line items with K1034.	X	X							
13336.9.1	Contractors shall ensure Beneficiary Liability is	X	X			X				

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	applied to the rejected line and use the following messaging when denying claim lines with HCPCS code K1034: CARC 96 - Non-covered charge(s). At least one Remark Code must be provided (may be comprised of either the NCPDP Reject Reason Code, or Remittance Advice Remark Code that is not an ALERT.) Usage: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present. RARC N640 - Exceeds number/frequency approved/allowed within time period. Grp Code PR MSN 16.25 - Medicare does not pay for this much equipment, or this many services or supplies. Spanish Translation - Medicare no paga por tantos servicios o suministros.									

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
	None					

IV. SUPPORTING INFORMATION

Section A: Recommendations and supporting information associated with listed requirements: N/A

"Should" denotes a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:

Section B: All other recommendations and supporting information: N/A

V. CONTACTS

Post-Implementation Contact(s): Contact your Contracting Officer's Representative (COR).

VI. FUNDING

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ATTACHMENTS: 0