CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-03 Medicare National Coverage Determinations	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 189	**Date: February 5, 2016**
	Change Request 9434

SUBJECT: Screening for Cervical Cancer With Human Papillomavirus (HPV) Testing—National Coverage Determination (NCD)

I. SUMMARY OF CHANGES: The purpose of this Change Request (CR) is that CMS has determined that for dates of service on or after effective July 9, 2015, evidence is sufficient to add HPV testing under specified conditions.

This revision to the Medicare National Coverage Determinations Manual is a national coverage determination (NCD). NCDs are binding on all carriers, fiscal intermediaries, contractors with the Federal government that review and/or adjudicate claims, determinations, and/or decisions, quality improvement organizations, qualified independent contractors, the Medicare appeals council, and administrative law judges (ALJs) (see 42 CFR section 405.1060(a)(4) (2005)). An NCD that expands coverage is also binding on a Medicare advantage organization. In addition, an ALJ may not review an NCD. (See section 1869(f)(1)(A)(i) of the Social Security Act.)

EFFECTIVE DATE: July 9, 2015
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: March 7, 2016 - for non-shared MAC edits; July 5, 2016 - CWF analysis and design; October 3, 2016 - CWF Coding, Testing and Implementation, MCS, and FISS Implementation; January 3, 2017 - Requirement BR9434.04.8.2

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	1/210.2.1/Screening for Cervical Cancer with Human Papillomavirus (HPV) Testing

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:

Business Requirements
Manual Instruction

Attachment - Business Requirements

Pub. 100-03	Transmittal: 189	Date: February 5, 2016	Change Request: 9434

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I. GENERAL INFORMATION

A. Background: The Centers for Medicare & Medicaid Services (CMS) currently does not cover Human Papillomavirus (HPV) testing.

Pursuant to §1861(ddd) of the Social Security Act, CMS may add coverage of "additional preventive services" through the National Coverage Determination (NCD) process. The preventive services must meet all of the following criteria:

(1) Reasonable and necessary for the prevention or early detection of illness or disability.

(2) Recommended with a grade of A or B by the United States Preventive Services Task Force (USPSTF).

(3) Appropriate for individuals entitled to benefits under Part A or enrolled under Part B.

CMS reviewed the USPSTF recommendations and supporting evidence for screening for cervical cancer with HPV co-testing and determined that the criteria listed above were met. Therefore, CMS shall cover screening for cervical cancer with HPV co-testing under the conditions specified below.

B. Policy: Effective for claims with dates of service on or after July 9, 2015, CMS has determined that the evidence is sufficient to add HPV testing once every five years as an additional preventive service benefit under the Medicare program for asymptomatic beneficiaries aged 30 to 65 years in conjunction with the Pap smear test. CMS will cover screening for cervical cancer with the appropriate U.S. Food and Drug Administration (FDA)-approved/cleared laboratory tests, used consistent with FDA approved labeling and in compliance with the Clinical Laboratory Improvement Act (CLIA) regulations.

Note: Medicare covers a screening pelvic examination and Pap test for all female beneficiaries at 12- or 24-month intervals, based on specific risk factors. See Publication (Pub) 100-03 NCD Manual, section 210.2.1, and the Pub l00-04, Claims Processing Manual, chapter 18, section 30.2.1.

NOTE: There is no co-insurance or deductible for tests paid under the Clinical Laboratory Fee Schedule (CLFS).

NOTE: This NCD does not change current policy as it relates to screening for pap smears and pelvic exams, Pub 100-03, NCD Manual, section 210.2.

II. BUSINESS REQUIREMENTS TABLE

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

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
9434 - 03.1	Effective for claims with dates of service on and after July 9, 2015, contractors shall pay claims for HPV screening for Medicare beneficiaries subject to the criteria mentioned above and outlined in Pub. 100-03 NCD, section 210.2.1. Please refer to CPM chapter 18, section 30.2.1 for claims processing information.	X	X							

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
9434 - 03.2	MLN Article: A provider education article related to this instruction will be available at http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/ shortly after the CR is released. You will receive notification of the article release via the established "MLN Matters" listserv. Contractors shall post this article, or a direct link to this article, on their Web sites and include information about it in a listserv message within 5 business days after receipt of the notification from CMS announcing the availability of the article. In addition, the provider education article shall be included in the contractor's next regularly scheduled bulletin. Contractors are free to supplement MLN Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly.	X	X			

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

Pre-Implementation Contact(s): Issa Michelle, 410-786-6656 or Michelle.Issa@cms.hhs.gov (Coverage) , Wanda Belle, 410-786-7491 or wanda.belle@cms.hhs.gov (Coverage) , Patricia Brocato-Simons, 410-786-0261 or Patricia.BrocatoSimons@cms.hhs.gov (Coverage) , William Ruiz, 410-786-9283 or William.Ruiz@cms.hhs.gov (Institutional Claims Processing) , Wendy Knarr, 410-786-0843 or Wendy.Knarr@cms.hhs.gov (Supplier Claims Processing) , Ian Kramer, 410-786-5777 or Ian.Kramer@cms.hhs.gov (Practitioner Claims Processing)

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

VI. FUNDING

Section A: 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.

ATTACHMENTS: 0

Medicare National Coverage Determinations Manual
Chapter 1, Part 4 (Sections 200 – 310.1)
Coverage Determinations

210.2.1 Screening for Cervical Cancer with Human Papillomavirus (HPV) Testing

(Effective July 9, 2015)

(Rev.189, Issued: 02-05-16, Effective: 07-05-16; Implementation: 03-07-16 - for non-shared MAC edits; 07-05-16 - CWF analysis and design; 10-03-16 - CWF Coding, Testing and Implementation, MCS, and FISS Implementation; 01-03-17 - Requirement BR9434.04.8.2)

A. General

Medicare covers a screening pelvic examination and Pap test for all female beneficiaries at 12 or 24 month intervals, based on specific risk factors. See 42 C.F.R. § 410.56; Medicare National Coverage Determinations Manual, § 210.2.1 Current Medicare coverage does not include the HPV testing. Pursuant to §1861(ddd) of the Social Security Act, the Secretary may add coverage of "additional preventive services" if certain statutory requirements are met.

B. Nationally Covered Indications

Effective for services performed on or after July 9, 2015, CMS has determined that the evidence is sufficient to add Human Papillomavirus (HPV) testing once every five years as an additional preventive service benefit under the Medicare program for asymptomatic beneficiaries aged 30 to 65 years in conjunction with the Pap smear test. CMS will cover screening for cervical cancer with the appropriate U.S. Food and Drug Administration (FDA) approved/cleared laboratory tests, used consistent with FDA approved labeling and in compliance with the Clinical Laboratory Improvement Act (CLIA) regulations.

C. Nationally Non-Covered Indications

Unless specifically covered in this NCD, any other NCD, by statute or regulation, preventive services are non-covered by Medicare.

D. Other

(This NCD last reviewed July 2015.)