CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-04 Medicare Claims Processing	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 3460	**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.

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	18/30.2.1/ Screening for Cervical Cancer with Human Palillomavirus Testing
R	18/30.5/Screening Pap Smears: Healthcare Common Procedure Coding System (HCPCS) Codes for Billing
R	18/30.6/Screening Pap Smears: Diagnoses Codes
R	18/30.7/ TOB and Revenue Codes for Form CMS-1450
R	18/30.8 /MSN Messages
R	18/30.9/ Remittance Advice Codes

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. 100-04	Transmittal: 3460	Date: February 5, 2016	Change Request: 9434

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

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

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.

NOTE: A new HCPCS code, G0476, HPV combo assay, CA screen, has been created for this benefit. It will be effective retroactive back to the effective date of this policy, which is July 9, 2015. Code G0476 will be

in the January 2016, Integrated Outpatient Code Editor (IOCE), January 2016 OPPS, and Medicare Physician Fee Schedule Database (MPFSDB). Beginning January 1, 2017, G0476 will be priced and paid according to the CLFS. Code G0476 will be contractor-priced from July 9, 2015 through December 31, 2016 and during this period code G0476 is paid only when it is billed by a laboratory entity.

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 - 04.1	Effective for claims with dates of service on and after July 9, 2015, contractors shall recognize new HCPCS code G0476, HPV screening, as a covered service. Note: HCPCS G0476 will appear in the January 1, 2017, CLFS, in the January 1, 2016, IOCE, and MPFS. HCPCS G0476 TOS -5 NOTE: Refer to Pub. 100-03, Medicare NCD Manual, Chapter 1, Section 210.2.1 for coverage policy, and Pub. 100-04, Claims Processing Manual, Chapter 18, Section 30.2.1 for claims processing instructions.	X	X							IOCE
9434 - 04.2	Contractors shall apply contractor pricing to claims containing HCPCS code G0476 with dates of service July 9, 2015 through December 31, 2016, received on or after January 1, 2016.	X	X							
9434 - 04.3	Contractors shall not apply beneficiary coinsurance and deductibles to claim lines containing HCPCS G0476, HPV screening.	X	X							

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
9434 - 04.4	Contractors shall only accept claims with a Place of Service Code equal to '81', Independent Lab or '11', Office.		X							
9434 - 04.5	Effective for claims with dates of service on or after July 9, 2015, contractors shall deny line-items on claims containing HCPCS G0476, HPV screening, when reported more than once in a 5-year period [at least 4 years and 11 months (59 months total) must elapse from the date of the last screening].	X	X			X			X	
9434 - 04.5.1	When denying a line-item on claim per requirement 9434.5, contractors shall use the following messages: CARC 119: "Benefit maximum for this time period or occurrence has been reached." RARC N386: "This decision was based on a National Coverage Determination (NCD). An NCD provides a coverage determination as to whether a particular item or service is covered. A copy of this policy is available at www.cms.gov/mcd/search.asp. If you do not have web access, you may contact the contractor to request a copy of the NCD." Group Code PR (Patient Responsibility) assigning financial responsibility to the beneficiary (if a claim is received with a GA modifier indicating a signed ABN is on file). Group Code CO (Contractual Obligation) assigning financial liability to the provider (if a claim is received with a GZ modifier indicating no signed ABN is on file).	X	X							

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
9434 - 04.5.1.1	(Continuation of 9434.5.1) (Part A only) MSN 15.19: "Local Coverage Determinations (LCDs) help Medicare decide what is covered. An LCD was used for your claim. You can compare your case to the LCD, and send information from your doctor if you think it could change our decision. Call 1-800-MEDICARE (1-800-633-4227) for a copy of the LCD". Spanish Version - Las Determinaciones Locales de Cobertura (LCDs en inglés) le ayudan a decidir a Medicare lo que está cubierto. Un LCD se usó para su reclamación. Usted puede comparar su caso con la determinación y enviar información de su médico si piensa que puede cambiar nuestra decisión. Para obtener una copia del LCD, llame al 1-800-MEDICARE (1-800-633-4227). MSN 15.20: "The following policies NCD 210.2.1 were used when we made this decision." Spanish Version – "Las siguientes políticas NCD 210.2.1 fueron utilizadas cuando se tomó	X	X							

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	esta decisión." NOTE: Due to system requirement, FISS has combined messages 15.19 and 15.20 so that, when used for the same line item, both messages will appear on the same MSN.									
9434 - 04.6	Effective for claims with dates of service on or after July 9, 2015, contractors shall deny line-items on claims containing HCPCS G0476, HPV screening, when the beneficiary is less than 30 years of age or older than 65 years of age.		X			X			X	
9434 - 04.6.1	When denying a line-item on claim per requirement 9434.6 contractors shall use the following messages: CARC 6: "The procedure/revenue code is inconsistent with the patient's age. Note: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present." RARC N129: "Not eligible due to the patient's age." Group Code PR (Patient Responsibility) assigning financial responsibility to the beneficiary (if a claim is received with a GA modifier indicating a signed ABN is on file).	X	X							

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	Group Code CO (Contractual Obligation) assigning financial liability to the provider (if a claim is received with a GZ modifier indicating no signed ABN is on file).									
9434 - 04.6.1.1	(Continuation of BR9434.6.1): (Part A only) MSN 15.19: "Local Coverage Determinations (LCDs) help Medicare decide what is covered. An LCD was used for your claim. You can compare your case to the LCD, and send information from your doctor if you think it could change our decision. Call 1-800-MEDICARE (1-800-633-4227) for a copy of the LCD". Spanish Version - Las Determinaciones Locales de Cobertura (LCDs en inglés) le ayudan a decidir a Medicare lo que está cubierto. Un LCD se usó para su reclamación. Usted puede comparar su caso con la determinación y enviar información de su médico si piensa que puede cambiar nuestra decisión. Para obtener una copia del LCD, llame al 1-800-MEDICARE (1-800-633-4227). MSN 15.20: "The following policies NCD 210.2.1 were used when we made this decision." Spanish Version – "Las siguientes políticas NCD 210.2.1 fueron utilizadas cuando se tomó esta decisión." NOTE: Due to system requirement, FISS has combined messages 15.19 and 15.20 so that, when used for the same line item, both messages will appear on the same MSN.	X	X							

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
9434 - 04.7	Effective for claims with dates of service on or after July 9, 2015, contractors shall deny line-items on claims containing HCPCS code G0476, HPV screening, when the claim does not contain the appropriate ICD-9 or ICD-10 diagnosis codes listed below: ICD-9: V73.81, special screening exam, HPV (primary), and V72.31, routine gynecological exam (secondary) ICD-10: Z11.51, encounter for screening for HPV(primary), and Z01.411, Encounter for gynecological exam (general) (routine) with abnormal findings (secondary), OR, Z01.419, Encounter for gynecological exam (general)(routine) without abnormal findings(secondary)	X	X							
9434 - 04.7.1	When denying a line-item on claim per requirement 9434.7, contractors shall use the following messages: CARC 167 – This (these) diagnosis(es) is (are) not covered. Note: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present. RARC N386 – "This decision was based on a National Coverage Determination (NCD). An NCD provides a coverage determination as to whether a particular item or service is covered.	X	X							

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	A copy of this policy is available at www.cms.gov/mcd/search.asp. If you do not have web access, you may contact the contractor to request a copy of the NCD." Group Code CO									
9434 - 04.7.1.1	Continuation of 9434-04.7.1): (Part A only): MSN 15.19: "Local Coverage Determinations (LCDs) help Medicare decide what is covered. An LCD was used for your claim. You can compare your case to the LCD, and send information from your doctor if you think it could change our decision. Call 1-800-MEDICARE (1-800-633-4227) for a copy of the LCD". Spanish Version - Las Determinaciones Locales de Cobertura (LCDs en inglés) le ayudan a decidir a Medicare lo que está cubierto. Un LCD se usó para su reclamación. Usted puede comparar su caso con la determinación y enviar información de su médico si piensa que puede cambiar nuestra decisión. Para obtener una copia del LCD, llame al 1-800-MEDICARE (1-800-633-4227). MSN 15.20: "The following policies NCD 210.2.1 were used when we made this decision." Spanish Version – "Las siguientes políticas NCD 210.2.1 fueron utilizadas cuando se tomó esta decisión."	X	X							

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	NOTE: Due to system requirement, FISS has combined messages 15.19 and 15.20 so that, when used for the same line item, both messages will appear on the same MSN.									
9434 - 04.8	Contractors shall apply contractor pricing for HCPCS G0476, HPV screening, on institutional claims submitted on types of bill (TOBs) 12X, 13X, 14X, 22X, and 23X for claims with dates of service on or after July 9, 2015 thru December 31, 2016.	X								
9434 - 04.8.1	Contractors shall pay for HCPCS G0476, HPV screening, on institutional claims submitted on TOB 85X based on reasonable cost.	X				X				
9434 - 04.8.2	Contractors shall pay for HCPCS G0476, HPV screening, on institutional claims submitted on TOBs 12X, 13X, 14X, 22X, and 23X based on the CLFS for claims with dates of service on or after January 1, 2017.	X				X				
9434 - 04.9	Contractors shall only pay for HCPCS G0476, HPV screening, on TOBs 12X, 13X, 14X, 22X, 23X, and 85X.	X								
9434 - 04.9.1	Contractors shall return to provider institutional claims for HCPCS G0476, HPV screening, when submitted on a TOB other than 12X, 13X, 14X, 22X, 23X, and 85X.	X								
9434 - 04.10	CWF shall calculate a next eligible date for HCPCS G0476 for a given beneficiary. The calculation shall include all applicable factors including:								X	

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	• Beneficiary Part B entitlement status • Beneficiary claims history • Utilization rules NOTE: The calculation for preventive services next eligible date shall parallel claims processing.									
9434 - 04.10.1	The next eligible dates shall be displayed on all CWF provider query screens (HUQA, HIQA, HIQH, ELGA, ELGH, and PRVN).	X				X			X	MBD, NGD
9434 - 04.10.2	When there is no next eligible date, the CWF provider query screens shall display this information in the date field to indicate why there is not a next eligible date.								X	
9434 - 04.10.3	Any change to beneficiary master data or claims data that would result in a change to any next eligible date shall result in an update to the beneficiary's next eligible date.								X	
9434 - 04.11	The Multi-Carrier System Desktop Tool (MCSDT) shall display HCPCS G0476, HPV screening, on a separate screen and in a format equivalent to the CWF HIMR screen.		X				X			
9434 - 04.12	Contractors shall not search for claims containing HCPCS G0476, HPV screening, with dates of service on or after July 92015, but contractors may adjust claims that are brought to their attention.	X	X							

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
9434 - 04.13	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): Ian Kramer, 410-786-5777 or Ian.Kramer@cms.hhs.gov (Practitioner Claims Processing) , Wanda Belle, 410-786-7491 or wanda.belle@cms.hhs.gov (Coverage) , Michelle Issa, 410-786-6656 or Michelle.Issa@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)

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 Claims Processing Manual
Chapter 18 - Preventive and Screening Services

Table of Contents
(Rev. 3460, 02-16)

Transmittals for Chapter 18

30.2.1 – Screening for Cervical Cancer with Human Papillomavirus (HPV) Testing

(Rev. 3460, Issued: 02-05-16, Effective: 07-09-16, 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)

See the Medicare National Coverage Determinations (NCD) Manual, Pub 100-03, Section 210.2.1 for complete coverage requirements for screening for cervical cancer with Human Papillomavirus testing (HPV).

The Centers for Medicare & Medicaid Services (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.

Effective for claims with dates of service on or after July 9, 2015, payment may be made for HCPCS G0476 (cervical cancer screening, all-inclusive HPV co-test with cytology (Pap smear) to detect HPV DNA or RNA sequences).

For claims with date of service from July 9, 2015 through December 31, 2016, HCPCS G0476 will be contractor priced. Beginning with date of service January 1, 2017 and after, HCPCS G0476 will be priced and paid according to the CLFS.
G0476 will be included in the January 2017 CLFS, January 1, 2016 IOCE, the January 2016 OPPS and January 1, 2016 MPFSD. HCPCS G0476 will be effective retroactive to July 9, 2015 in the IOCE & OPPS. Effective for claims with dates of service on or after July 9, 2015, payment may be made for HCPCS G0476 (cervical cancer screening, all-inclusive HPV co-test with cytology (Pap smear) to detect HPV DNA or RNA sequences) only when submitted with a Place of Service Code equal to '81', Independent Lab or '11', Office.

A. *Screening Pap Smears: A/B MAC (B)* Action for Submitting Claims to *the Common Working File* (CWF) and CWF Edit

When a *A/B MAC (B)* receives a claim for a screening Pap smear, performed on or after January 1, 1998, it must enter a deductible indicator of 1 (not subject to deductible) in field 67 of the HUBC record.

CWF will edit for screening pelvic examinations performed more frequently than allowed according to the presence of high risk factors.

30.5 – *Screening Pap Smears: Healthcare Common Procedure Coding System* (HCPCS) Codes for Billing

(Rev. 3460, Issued: 02-05-16, Effective: 07-09-16, 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)

The following HCPCS codes can be used for screening Pap smear:

A. *Screening Pap Smears:* Codes Billed to the *A/B MAC (B)* and Paid Under the *Medicare* Physician Fee Schedule *(MPFS)*

The following HCPCS codes are submitted by those providers/entities that submit claims to *A/B MACs (B)*. The deductible is waived for these services effective January 1, 1998, however, coinsurance applies.

NOTE: These codes are not billed on *A MAC* claims except for HCPCS Q0091 which may be submitted to *A/B MACs (B)*. Payment for *HCPCS* Q0091 performed in a hospital outpatient department is under *the outpatient prospective payment system (*OPPS) (see 30.5C).

- Q0091 - Screening Papanicolaou (Pap) smear, obtaining, preparing and conveyance of cervical or vaginal smear to laboratory;

- P3001 - Screening Papanicolaou smear, cervical or vaginal, up to three smears requiring interpretation by a physician;

- G0124 - Screening cytopathology, cervical or vaginal (any reporting system), collected in preservative fluid, automated thin layer preparation, requiring interpretation by physician; and

- G0141 - Screening cytopathology smears, cervical or vaginal, performed by automated system, with manual re-screening, requiring interpretation by physician.

B. *Screening Pap Smears*: Codes Paid Under the Clinical Lab Fee Schedule by *A/BMACs*

The following codes are billed to *A/B MACs (A)* by providers they serve, or billed to *A/B MACs (B)* by the physicians/suppliers they service. Deductible and coinsurance do not apply.

- P3000 - Screening Papanicolaou smear, cervical or vaginal, up to three smears, by a technician under the physician supervision;

- G0123 - Screening cytopathology, cervical or vaginal (any reporting system) collected in preservative fluid; automated thin layer preparation, screening by cytotechnologist under physician supervision;

- G0143 - Screening cytopathology, cervical or vaginal, (any reporting system), collected in preservative fluid, automated thin layer preparation, with manual screening and re-screening, by cytotechnologist under physician supervision;

- G0144 - Screening cytopathology, cervical or vaginal, (any reporting system), collected in preservative fluid, automated thin layer preparation, with screening by automated system under physician supervision;

- G0145 - Screening cytopathology, cervical or vaginal, (any reporting system), collected in preservative fluid, automated thin layer preparation, with screening by automated system and manual re-screening under physician supervision;

- G0147 - Screening cytopathology smears, cervical or vaginal, performed by automated system under physician supervision; and

- G0148 - Screening cytopathology smears, cervical or vaginal, performed by automated system with manual reevaluation.

C. *Screening Pap Smears*: Payment of Q0091 When Billed to *A/B MACs (B)*

Payment for HCPCS Q0091 in a hospital outpatient department is under OPPS. A *skilled nursing facility (*SNF) is paid using the technical component of the MPFS. For a *critical access hospital (*CAH), payment is on a reasonable cost basis. *For rural health clinics/Federally qualified health centers (*RHC/FQHCs) payment is made under the all-inclusive rate for the professional component. Deductible is not applicable, however, coinsurance applies.

The technical component of a screening Pap smear is outside the RHC/FQHC benefit. If the technical component of a screening Pap smear is furnished within a provider-based RHC/FQHC, the provider of that service bills the *A MAC* under type *of bill (TOB)* 13X, 14X, 22X, 23X, or 85X as appropriate using their base provider number (not the RHC/FQHC provider number since these services are not covered as RHC/FQHC services). For independent RHCs/FQHCs, the practitioner bills the technical component to the *A/B MACs (B)* on Form CMS-1500 or the ANSI X12N 837 P. Effective *April 1, 2006, TOB* 14X is for non-patient laboratory specimens.

D. *Screening Pap Smears*: Payment of *HCPCS* Q0091 When Billed to *A/B MACs (B)*

Payment for *HCPCS* Q0091 is paid under the *MPFS*. Deductible is not applicable, however the coinsurance applies.

Effective for *claims with dates of* service on and after July 1, 2005, on those occasions when physicians must perform a screening Pap smear (*HCPCS* Q0091) that they know will not be covered by Medicare because the low-risk patient has already received a covered Pap smear (*HCPCS* Q0091) in the past 2 years, the physician can bill *HCPCS* Q0091 and the claim will be denied appropriately. The physician shall obtain an advance beneficiary notice (ABN) in these situations as the denial will be considered a not reasonable and necessary denial. The physician indicates on the claim that an ABN has been obtained by using the GA modifier.

Effective for *claims with dates of* service on or after April 1, 1999, a covered evaluation and management (E/M) visit and *HCPCS* Q0091 may be reported by the same physician for the same date of service if the E/M visit is for a separately identifiable service. In this case, the modifier "-25" must be reported with the E/M service and the medical records must clearly document the E/M reported. Both procedure codes should be shown as separate line items on the claim. These services can also be performed separately on separate office visits.

E. *Screening Pap Smears*: CWF Editing for *HCPCS* Q0091

The CWF will edit for claims containing HCPCS Q0091 effective for dates of service on and after July 1, 2005. Previously, the editing for *HCPCS* Q0091 had been removed from the CWF. Medicare pays for a screening Pap smear every 2 years for low-risk patients based on the low-risk diagnoses, see sections 30.2 and 30.6. Medicare pays for a screening Pap smear every year for a high-risk patient based on the high-risk diagnosis, see sections 30.1 and 30.6. This criteria will be the CWF parameters for editing *HCPCS* Q0091.

In those situations where unsatisfactory screening Pap smear specimens have been collected and conveyed to clinical labs that are unable to interpret the test results, another specimen will have to be collected. When the physician bills for this reconveyance, the physician should annotate the claim with *HCPCS* Q0091 along with modifier -76, (repeat procedure by same physician).

30.6 – *Screening Pap Smears:* Diagnoses Codes

(Rev. 3460, Issued: 02-05-16, Effective: 07-09-16, 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)

Below is the current diagnoses that should be used when billing for screening Pap smear services. Effective July 1, 2005, *ICD-9* V72.31 is being added to the CWF edit as an additional low-risk diagnosis. The following chart lists the diagnosis codes that CWF must recognize for low-risk or high-risk patients for screening Pap smear services.

Low Risk Diagnosis Codes	Definitions
V76.2	Special screening for malignant neoplasms, cervix
V76.47	Special screening for malignant neoplasm, vagina

Low Risk Diagnosis Codes	Definitions
V76.49	Special screening for malignant neoplasm, other sites **NOT**E: providers use this diagnosis for women without a cervix.
V72.31	Routine gynecological examination **NOTE**: This diagnosis should only be used when the provider performs a full gynecological examination.
High Risk Diagnosis Code	
V15.89	Other

A. *Screening Pap Smears*: Applicable Diagnoses for Billing *A/B MAC (B)*

There are a number of appropriate diagnosis codes that can be used in billing for screening Pap smear services that the provider can list on the claim to give a true picture of the patient's condition. Those diagnoses can be listed in Item 21 of Form CMS-1500 or the electronic equivalent (see Chapter 26 for electronic equivalent formats). In addition, one of the following diagnoses shall appear on the claim: the low-risk diagnosis of V76.2, V76.47, V76.49 and (effective July 1, 2005, V72.31) or the high-risk diagnosis of V15.89 (for high risk patients). One of the above diagnoses must be listed in item 21of the Form CMS-1500 or the electronic equivalent to indicate either low risk or high risk depending on the patient's condition. Then either the low-risk or high-risk diagnosis must also be pointed to in Item 24E of Form CMS-1500 or the electronic equivalent. Providers must make sure that for screening Pap smears for a high-risk beneficiary, that the high-risk diagnosis code of V15.89 appears in Item 21 and V15.89 is the appropriate diagnosis code that must be pointed to in Item 24E or the electronic equivalent. If Pap smear claims do not point to one of these specific diagnoses in Item 24E or the electronic equivalent, the claim will reject in the CWF. **Periodically, *A/B MACs (B)* should do provider education on diagnosis coding of Pap smear claims.**

B. HPV Screening: Applicable Diagnoses for Billing A/B MAC (B)

Effective for claims with dates of service on or after July 9, 2015, providers shall report the following diagnosis codes when submitting claims for HCPCS G0476 - Cervical cancer screening, all-inclusive HPV co-test with cytology (Pap smear) to detect HPV DNA or RNA sequences:

ICD-9: V73.81, special screening exam, HPV (as primary), and V72.31, routine gynecological exam (as secondary)

ICD-10: Z11.51, encounter for screening for HPV, and Z01.411, encounter for gynecological exam (general)(routine) with abnormal findings, OR, Z01.419, encounter for gynecological exam (general)(routine) without abnormal findings.

C. Applicable Diagnoses for Billing *A/B MACs (A)*

Providers report one of the following diagnosis codes in Form CMS-1450 or the electronic equivalent (**NOTE:** Information regarding the form locator numbers that correspond to the diagnosis codes and a table to crosswalk its CMS-1450 form locator to the 837 transaction is found in Chapter 25.):

Low-risk diagnosis codes:

ICD-9 V76.2, special screening for malignant neoplasms, cervix, or,
ICD-9 V76.47, special screening for malignant neoplasms, vagina, or,
ICD-9 V76.49, special screening for malignant neoplasms, other sites (used for women without a cervix), or,
ICD-9 V72.31, routine gynecological exams

ICD-10 Z12.4, encounter for screening for malignant neoplasm of the cervix

ICD-10 Z12.92, encounter for screening for malignant neoplasm of the vagina
ICD-10 Z12.79, encounter for screening for malignant neoplasm of other genitourinary organs, or,
ICD-10 Z12.89, encounter for screening for malignant neoplasm of other sites
ICD-10 Z01.411, encounter for gynecological exam (general)(routine) with abnormal findings, or,
ICD-10 Z01.419, encounter for gynecological exam (general)(routine) without abnormal findings

High-risk diagnosis codes

ICD-9 V15.89, other specified personal history hazardous to health
ICD-9 V87.39, contact with and (suspected) exposure to other potentially hazardous substances
ICD-9 V69.2, high-risk sexual behavior

ICD-10 Z77.9, other contact with and (suspected) exposures hazardous to health, or,
ICD-10 Z91.89, other specified personal risk factors, not elsewhere classified, or,
ICD-10 Z92.89, personal history of other medical treatment, or,
ICD-10 Z77.29, contact with and (suspected) exposure to other hazardous substances
ICD-10 Z72.51, high-risk heterosexual behavior, or,
ICD-10 Z72.52, high-risk homosexual behavior, or,
ICD-10 Z72.53, high-risk bisexual behavior.

Periodically provider education should be done on diagnosis coding of Pap smear claims.

D. HPV Screening: Applicable Diagnoses for Billing A/B MACs (A)

Effective for claims with dates of service on or after July 9, 2015, providers shall report the following diagnosis codes when submitting claims for HCPCS G0476 - Cervical cancer screening, all-inclusive HPV co-test with cytology (Pap smear) to detect HPV DNA or RNA sequences:

ICD-9: V73.81 and V72.31
ICD-10: Z11.51 and Z01.411 or Z01.419

30.7 – TOB and Revenue Codes for Form CMS-1450

(Rev. 3460, Issued: 02-05-16, Effective: 07-09-16, 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)

The applicable TOBs for screening Pap smears are 12X, 13X, 14X, 22X, 23X, and 85X. Use revenue code 0311 (laboratory, pathology, cytology). Report the screening Pap smear as a diagnostic clinical laboratory service using one of the HCPCS codes shown in §30.5.B.

In addition, CAHs electing method II report professional services under revenue codes 096X, 097X, or 098X.

Effective April 1, 2006, TOB 14X is for non-patient laboratory specimens.

HPV Screening: Effective for claims with dates of service on and after July 9, 2015, HCPCS G0476, Cervical cancer screening, all-inclusive HPV co-test with cytology (Pap smear) to detect HPV DNA or RNA sequences, shall be paid only on TOBs 12X, 13X, 14X, 22X, 23X, and 85X.

30.8 - MSN Messages

(Rev. 3460, Issued: 02-05-16, Effective: 07-09-16, 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)

If there are no high risk factors, and the screening Pap smear and/or screening pelvic examination is being denied because the procedure/examination is performed more frequently than allowed use MSN 18.17:

> Medicare pays for a screening Pap smear and/or screening pelvic examination only once every (2, 3) years unless high risk factors are present.

HPV Screening: Effective for claims with dates of service on and after July 9, 2015:

A. If denying line-items on claims containing HCPCS G0476, HPV screening, when reported more than once in a 5-year period [at least 4 years and 11 full months (59 months total) must elapse from the date of the last screening], use the following messages:

(Part A Only) MSN 15.19: "Local Coverage Determinations (LCDs) help Medicare decide what is covered. An LCD was used for your claim. You can compare your case to the LCD, and send information from your doctor if you think it could change our decision. Call 1-800-MEDICARE (1-800-633-4227) for a copy of the LCD".

Spanish Version - Las Determinaciones Locales de Cobertura (LCDs en inglés) le ayudan a decidir a Medicare lo que está cubierto. Un LCD se usó para su reclamación. Usted puede comparar su caso con la determinación y enviar información de su médico si piensa que puede cambiar nuestra decisión. Para obtener una copia del LCD, llame al 1-800-MEDICARE (1-800-633-4227).

MSN 15.20: "The following policies NCD 210.2.1 were used when we made this decision."

Spanish Version – "Las siguientes políticas NCD 210.2.1 fueron utilizadas cuando se tomó esta decisión."

B. If denying line-items on claims containing HCPCS G0476, HPV screening, when the beneficiary is not between the ages of 30-65, use the following messages:

(Part A Only) MSN 15.19: "Local Coverage Determinations (LCDs) help Medicare decide what is covered. An LCD was used for your claim. You can compare your case to the LCD, and send information from your doctor if you think it could change our decision. Call 1-800-MEDICARE (1-800-633-4227) for a copy of the LCD".

Spanish Version - Las Determinaciones Locales de Cobertura (LCDs en inglés) le ayudan a decidir a Medicare lo que está cubierto. Un LCD se usó para su reclamación. Usted puede comparar su caso con la determinación y enviar información de su médico si piensa que puede cambiar nuestra decisión. Para obtener una copia del LCD, llame al 1-800-MEDICARE (1-800-633-4227).

MSN 15.20: "The following policies NCD 210.2.1 were used when we made this decision."

Spanish Version – "Las siguientes políticas NCD 210.2.1 fueron utilizadas cuando se tomó esta decisión."

C. If denying line-items on claims containing HCPCS G0476, HPV screening, when the claim does not contain the appropriate ICD-9 or ICD-10 diagnosis codes listed below:

ICD-9: V73.81 and V72.31

ICD-10: Z11.51 and Z01.411 or, Z01.419

Use the following messages:

(Part A Only)MSN 15.19: "Local Coverage Determinations (LCDs) help Medicare decide what is covered. An LCD was used for your claim. You can compare your case to the LCD, and send information from your doctor if you think it could change our decision. Call 1-800-MEDICARE (1-800-633-4227) for a copy of the LCD".

Spanish Version - Las Determinaciones Locales de Cobertura (LCDs en inglés) le ayudan a decidir a Medicare lo que está cubierto. Un LCD se usó para su reclamación. Usted puede comparar su caso con la determinación y enviar información de su médico si piensa que puede cambiar nuestra decisión. Para obtener una copia del LCD, llame al 1-800-MEDICARE (1-800-633-4227).

MSN 15.20: "The following policies NCD 210.2.1 were used when we made this decision."

Spanish Version – "Las siguientes políticas NCD 210.2.1 fueron utilizadas cuando se tomó esta decisión."

D. If denying line-items on institutional claims for HCPCS G0476, HPV screening, when submitted on a TOB other than 12X, 13X, 14X, 22X, 23X, and 85X, use the following message:

MSN 21.25: "This service was denied because Medicare only covers this service in certain settings."
Spanish Version: "El servicio fue denegado porque Medicare solamente lo cubre en ciertas situaciones."

30.9 - Remittance Advice Codes

(Rev. 3460, Issued: 02-05-16, Effective: 07-09-16, 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)

Pap Smear Screening: If high risk factors are not present, and the screening Pap smear and/or screening pelvic examination is being denied because the procedure/examination is performed more frequently than allowed, use existing ANSI X12N 835:

- Claim adjustment reason code 119 - "Benefit maximum for this time period has been reached" at the line level, and

- Remark code M83 - "Service is not covered unless the patient is classified as at high risk: at the line item level.

HPV Screening: Effective for claims with dates of service on and after July 9, 2015:

A. If denying line-items on claims containing HCPCS G0476, HPV screening, when reported more than once in a 5-year period [at least 4 years and 11 months (59 months total) must elapse from the date of the last screening], use the following messages:

CARC 119: "Benefit maximum for this time period or occurrence has been reached."

RARC N386: "This decision was based on a National Coverage Determination (NCD). An NCD provides a coverage determination as to whether a particular item
or service is covered. A copy of this policy is available at www.cms.gov/mcd/search.asp. If you do not have web access, you may contact the contractor to request a copy of the NCD."

Group Code PR (Patient Responsibility) assigning financial responsibility to the beneficiary (if a claim is received with a GA modifier indicating a signed ABN is on file).

Group Code CO (Contractual Obligation) assigning financial liability to the provider (if a claim is received with a GZ modifier indicating no signed ABN is on file).

B. If denying line-items on claims containing HCPCS G0476, HPV screening, when the beneficiary is not between the ages of 30-65, use the following messages:

CARC 6: "The procedure/revenue code is inconsistent with the patient's age. Note: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present."

RARC N129: "Not eligible due to the patient's age."

Group Code PR (Patient Responsibility) assigning financial responsibility to the beneficiary (if a claim is received with a GA modifier indicating a signed ABN is on file).

Group Code CO (Contractual Obligation) assigning financial liability to the provider (if a claim is received with a GZ modifier indicating no signed ABN is on file).

C. If denying line-items on claims containing HCPCS G0476, HPV screening, when the claim does not contain the appropriate ICD-9 or ICD-10 diagnosis codes listed below:

ICD-9: V73.81 and V72.31

ICD-10: Z11.51 and Z01.411, or, Z01.419

Use the following messages:

CARC 167 – This (these) diagnosis(es) is (are) not covered. Note: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present.

RARC N386 – "This decision was based on a National Coverage Determination (NCD). An NCD provides a coverage determination as to whether a particular item or service is covered. A copy of this policy is available at www.cms.gov/mcd/search.asp. If you do not have web access, you may contact the contractor to request a copy of the NCD."

Group Code CO assigning financial liability to the provider

D. If denying line-items on institutional claims for HCPCS G0476, HPV screening, when submitted on a TOB other than 12X, 13X, 14X, 22X, 23x, and 85X, use the following messages:

CARC 170: "Payment is denied when performed/billed by this type of provider. Note: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present."

RARC N95 – "This provider type/provider specialty may not bill this service."

Group Code CO assigning financial liability to the provider