DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

MLN Matters® Number: MM9434 Revised

Related Change Request (CR) #: CR 9434

Related CR Release Date: February 5, 2016

Effective Date: July 9, 2015

Related CR Transmittal #: R189NCD and R3460CP

Implementation Date: July 5, 2016 (CWF analysis and design), October 3, 2016 (CWF Coding, Testing and Implementation, MCS and FISS implementation; January 3, 2017 (requirement 9434-04.8.2), March 7, 2016 (non-shared MAC edits)

Screening for Cervical Cancer with Human Papillomavirus (HPV) Testing—National Coverage Determination (NCD) 210.2.1

Note: this article was revised on April 22, 2016, to correct the G code in two places on pages 2 and 3. The correct code is G0476. All other information remains the same.

Provider Types Affected

This MLN Matters® Article is intended for physicians and other providers submitting claims to Medicare Administrative Contractors (MACs) for services provided to Medicare beneficiaries.

Provider Action Needed

Change Request (CR) 9434 announces that the Centers for Medicare & Medicaid Services (CMS) has determined that, effective for dates of service on or after July 9, 2015, evidence is sufficient to add Human Papillomavirus (HPV) testing under specified conditions. Make sure that your billing staffs are aware of this change.

Background

Medicare covers a screening pelvic examination and Pap test for all female beneficiaries at 12- or 24-month intervals, based on specific risk factors; however, current Medicare coverage does not include the HPV testing.

Section 1861(ddd) of the Social Security Act (the Act) (see **http://www.ssa.gov/OP_Home/ssact/title18/1861.htm**) states that 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); and,
3. Appropriate for individuals entitled to benefits under Part A or enrolled under Part B.

CMS has reviewed the USPSTF recommendations and supporting evidence for screening for cervical cancer with HPV co-testing, and has determined that the criteria were met. Therefore, effective for claims with dates of service on or after July 9, 2015, CMS will cover screening for cervical cancer with HPV co-testing under the following conditions:

> CMS has determined that the evidence is sufficient to add HPV testing once every 5 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.

A new Healthcare Common Procedure Coding System (HCPCS) code, G0476 (HPV combo assay, CA screen), Type of Service (TOS) 5 (diagnostic lab), has been created for this benefit. This code will:

- Be effective retroactive back to the effective date of July 9, 2015;
- Be included in the January 2016, Integrated Outpatient Code Editor, Outpatient Prospective Payment System, and Medicare Physician Fee Schedule Database;
- Be MAC-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**; and,
- Beginning January 1, 2017, this will be priced and paid according to the Clinical Laboratory Fee Schedule (CLFS).

In addition, you should be aware of the following:

1. Your MACs will not apply beneficiary coinsurance and deductibles to claim lines containing HCPCS G0476, HPV screening;
2. Part B MACs shall only accept claims with a Place of Service Code equal to '81', Independent Lab or '11', Office; and
3. Effective for claims with dates of service on or after July 9, 2015, your MACs will 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]. The next eligible dates for this service are shown on all Common Working File (CWF) provider query screens (HUQA, HIQA, HIQH, ELGA, ELGH, and PRVN).

   When denying a line-item on a claim for this requirement they will use the following messages:

   - Claim Adjustment Reason Code (CARC) 119 – "Benefit maximum for this time period or occurrence has been reached;"
   - Remittance Advice Remark Code (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" if the claim contains a GZ modifier to denote a signed Advance Beneficiary Notice (ABN) is not on file or with Group Code "PR" (Patient Responsibility) if the claim has a GA modifier to show a signed ABN is on file.

4. HCPCS Code G0476 will be paid only for institutional claims submitted on Type of Bill codes (TOB) 12X, 13X, 14X, 22X, 23X, and 85X. Institutional claims on other TOBs will be returned to the provider.
5. Effective for claims with dates of service on or after July 9, 2015, your MACs will 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.

   When denying a line-item on claims for this requirement, they will 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 "CO" if the claim contains a GZ modifier to denote a signed Advance Beneficiary Notice (ABN) is not on file or with Group Code "PR" (Patient Responsibility) if the claim has a GA modifier to show a signed ABN is on file.

6. Effective for claims with dates of service on or after July 9, 2015, you must report the following diagnosis codes when submitting claims for HCPCS G0476:
    - ICD-9 (for dates of service prior to October 1, 2015): 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.

    Effective on this date, your MACs will deny line-items on claims containing HCPCS Code G0476, HPV screening, when the claim does not contain these codes.

    When denying a line-item on claim for this requirement, they will 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;" and
    - Group Code CO.
7. This NCD does not change current policy as it relates to screening for pap smears and pelvic exams as described in the Medicare NCD Manual, section 210.2, or in the Medicare Claims Processing Manual, chapter 18, section 30, which you can find at **https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/ncd103c1_Part4.pdf** on the CMS website.

Additional Information

The official instruction, CR 9434, was issued to your MAC via two transmittals. The first updates the NCD Manual and is available at **https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R189NCD.pdf** and the second transmittal updates the "Medicare Claims Processing Manual" and it is available at **https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R3460CP.pdf** on the CMS website.

If you have any questions, please contact your MAC at their toll-free number. That number is available at **http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/index.html** under - How Does It Work.

Document History

- This article was revised on April 22, 2016, to correct the reference to G0476 in two places on pages 2 and 3. The original article mentioned G4076, which is incorrect. All references should have shown G0476.