GUIDELINES
This policy does not certify benefits or authorization of benefits, which is designated by each individual policyholder contract. Paramount applies coding edits to all medical claims through coding logic software to evaluate the accuracy and adherence to accepted national standards. This guideline is solely for explaining correct procedure reporting and does not imply coverage and reimbursement.

SCOPE
X Professional
X Facility

DESCRIPTION
Human papillomavirus (HPV) is a virus that infects epithelial cells and can induce a variety of benign and malignant tumors in humans. Most of these infections resolve spontaneously but some progress to a high-grade preinvasive cervical lesion (cervical intraepithelial neoplasia) or cervical cancer.

Human papillomavirus (HPV) is a small, double-stranded DNA virus that infects epithelial cells and can induce a variety of benign and malignant tumors in humans. Most HPV infections resolve spontaneously, but if an oncogenic (high-risk) HPV persists, there may be progression to a high-grade preinvasive cervical lesion (cervical intraepithelial neoplasia) or cervical cancer. Testing cervical specimens for DNA of oncogenic types of HPV is useful in the evaluation of certain abnormal PAP smears.

The goal of HPV testing is to improve accuracy in identifying those women at increased risk for cervical cancer and to decrease unnecessary referrals for colposcopic evaluation.

POLICY

**HMO, PPO, Individual Marketplace, & Advantage**
HPV screening (87623, 87624, and 87625) for women aged 30-65 years does not require prior authorization.

HPV Reflex testing (87623, 87624, 87625) for women aged 21-29 and over age 65 years with cervical cytology screening test results reported as ASC-US or LSIL, does not require a prior authorization.

**Elite/ProMedica Medicare Plan**
HPV screening (G0476) for women aged 30-65 years does not require prior authorization.

**HMO, PPO, Individual Marketplace, Advantage, Elite/ProMedica Medicare Plan**
Prior authorization is required for ages under 30 and over the age of 65 for all product lines. With the exception of HPV Reflex testing as documented above.

COVERAGE CRITERIA
**HMO, PPO, Individual Marketplace, Advantage**
Testing in asymptomatic individuals is not medically necessary before age 30.
Routine cervical cancer screening and HPV testing with FDA approved techniques (e.g., conventional Pap smear, liquid based cytology, cobas® HPV test) is considered medically appropriate, for women of age 30-65.

HPV high-risk testing, in conjunction with Pap smears, meets the definition of medical necessity for the purpose of
screening women aged 30 - 65 years for cervical abnormalities.

- high risk HPV testing alone may be performed every 5 years, or
- high risk HPV testing may be performed every 5 years in combination with Pap smear (co-testing) for routine screening.

The use of HPV tests as a primary screening test for cervical cancer in women younger than 30 years of age is considered experimental and investigational.

The U.S. Preventive Services Task Force (USPSTF), August 21, 2018, guidelines indicate that for average-risk women aged 30-65 years, high-risk human papillomavirus testing alone every 5 years as an alternative to screening with cervical cytology alone every 3 years or screening with a combination of cytology and high-risk HPV testing every 5 years. The Society of Gynecologic Oncology, the American Society of Cytopathology and the College of American Pathologist also recommend for these women, co-testing with cervical cytology and high-risk HPV testing every 5 years is preferred, screening with cervical cytology alone every 3 years is acceptable and high-risk HPV testing alone can be considered as an alternative screening strategy.

HPV testing meets the definition of medical necessity for the purpose of following-up with prior cytology-negative co-testing result and positive HPV tests in women aged 30 years and older.

- Test again by co-testing in one year, or
  - If the 1-year repeat co-test result is HPV-negative and cytology negative, repeat co-testing in 3 years is recommended.
- Be tested by HPV high risk oncogenic subtype genotyping
  - If the HPV 16 and HPV 18 test results are negative, repeat co-testing in 1 year is recommended.

HPV testing has not been proven to be effective and is therefore, is considered not medically necessary in the routine triage of women with low-grade squamous intraepithelial lesions (LSIL) found through screening examinations (e.g., cervical cytology)

**Testing in symptomatic individuals under age 30 and over age 65**

Human papillomavirus (HPV) testing of high-risk sub-types has been medically proven to be effective and therefore, is considered medically appropriate for women of any age meeting the following criteria:

- Are high-risk, or
  - Risk factors may include organ transplant recipients, HIV infection, a compromised immune system, in utero exposure to diethylstilbestrol (DES), and previous treatment of a high-grade precancerous lesion or cervical cancer.
- Symptomatic, or
- Have a prior abnormal Pap smear of interpretation of atypical cells of undetermined significance (ASCUS)
  - dysplasia of cervix,
  - atypical squamous cells of undetermined significance (ASCUS),
  - atypical squamous cells high-grads SIL (ASC-H),
  - low-grade squamous intra-epithelial lesions (LSIL),
  - atypical glandular cells not otherwise specified (AGC NOS), or
  - following up from AGC NOS with a negative colposcopy results with in the past 2 years.

**Elite/ProMedica Medicare Plan**

Human Papillomavirus (HPV) testing (G0476) is considered medically necessary once every five years for asymptomatic members aged 30 to 65 years in conjunction with the Pap smear test.

HPV testing of a cervical specimen is indicated when the PAP smear result is reported as atypical squamous cells of indeterminate significance (ASC-US), atypical glandular cells (AGC), or atypical squamous cells cannot rule out high-grade lesion (ASC-H). Use either of the following:

- Encounter for screening for HPV – Z11.51 and Encounter for gynecological exam (general) (routine) with abnormal findings – Z01.411
- Encounter for gynecological exam (general) (routine) without abnormal findings – Z01.419
HPV Reflex testing:
The purpose of reflex HPV testing is to detect the Human Papillomavirus (HPV) in a Pap test sample and to help decide what follow up is needed for women in specific age groups with a low-grade Pap test result (ASC-US or LSIL). The clinical utility of HPV reflex testing depends on the patient’s age and Pap findings.

- HPV Co-Testing* (recommended in women 30-65yrs.) If Pap is negative reflex to HPV high risk and if positive then HPV Genotyping 16/18.
- Reflex* HPV High Risk (ASCUS or LSIL Pap results)
- Reflex* HPV High Risk in younger women (21-29 yrs.) with abnormal Pap/biopsy results.

*Co-Testing: Cervical cytology plus the HPV co-test are performed on the same date of service. The result of the HPV test is reported regardless if the Pap has a positive or negative result.

** Reflex: Cervical cytology with reflex HPV testing means if the result of the Pap is ASC-US, then the HPV sample is ran by the laboratory. Therefore, the HPV test is dependent on the result of the Pap.

CODING/BILLING INFORMATION
The appearance of a code in this section does not necessarily indicate coverage. Codes that are covered may have selection criteria that must be met. Payment for supplies may be included in payment for other services rendered.

<table>
<thead>
<tr>
<th>CPT CODES</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>87623</td>
<td>Infectious agent detection by nucleic acid (DNA or RNA); Human Papillomavirus (HPV), low-risk types (e.g., 6, 11, 42, 43, 44)</td>
</tr>
<tr>
<td>87624</td>
<td>Infectious agent detection by nucleic acid (DNA or RNA); Human Papillomavirus (HPV), high-risk types (e.g.,16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 68)</td>
</tr>
<tr>
<td>87625</td>
<td>Infectious agent detection by nucleic acid (DNA or RNA); Human Papillomavirus (HPV), types 16 and 18 only, includes type 45, if performed</td>
</tr>
<tr>
<td>0096U</td>
<td>Human papillomavirus (HPV), high-risk types (ie, 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, 68) male urine</td>
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</tbody>
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<table>
<thead>
<tr>
<th>HCPCS CODE</th>
<th>Description</th>
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<tbody>
<tr>
<td>G0476</td>
<td>Infectious agent detection by nucleic acid (DNA or RNA); Human Papillomavirus (HPV), high-risk types (e.g.,16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 68) for cervical cancer screening, must be performed in addition to pap test</td>
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</tbody>
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<table>
<thead>
<tr>
<th>ICD-10 CODES</th>
<th>Description</th>
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<tbody>
<tr>
<td>Z11.51</td>
<td>Encounter for screening for human papillomavirus (HPV)</td>
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<tr>
<td>Z01.411</td>
<td>Encounter for gynecological examination (general) (routine) with abnormal findings</td>
</tr>
<tr>
<td>Z01.419</td>
<td>Encounter for gynecological examination (general) (routine) without abnormal findings</td>
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<tr>
<td>N87.0-N87.9</td>
<td>Dysplasia of cervix uteri (code range)</td>
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<table>
<thead>
<tr>
<th>Abnormal Cytological Findings</th>
<th>Description</th>
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<tbody>
<tr>
<td>R87.610-R87.619</td>
<td>Abnormal cytological findings in specimens from cervix uteri (code range)</td>
</tr>
<tr>
<td>R87.620-R87.629</td>
<td>Abnormal cytological findings on specimens from vagina (code range)</td>
</tr>
<tr>
<td>R87.810-R87.811</td>
<td>High risk human papillomavirus [HPV] DNA test positive from female genital organs (code range)</td>
</tr>
<tr>
<td>R87.820-R87.821</td>
<td>Low risk human papillomavirus (HPV) DNA test positive from female genital organs (code range)</td>
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</tbody>
</table>

REVISION HISTORY EXPLANATION
ORIGINAL EFFECTIVE DATE: 05/27/2016
05/27/16: TAWG evaluated HPV testing for primary cervical cancer screening for women under age 30 using the Cobas lab test. Policy created to reflect most current clinical evidence per TAWG.
05/09/17: Added HCPCS code G0476 & ICD-10 codes Z11.51, Z01.411, Z01.419 per CMS guidelines. Policy created to reflect most current clinical evidence per the Medical Policy Steering Committee.
05/25/20: Updated Medical Policy. Clarification that a Prior Authorization is required for coverage under the age of 30 and over the age of 65.
07/29/20: Updated Medical Policy. To allow the HPV Reflex testing (87623, 87624, 87625) for women aged 21-29 and over age 65 years with cervical cytology screening test results reported as ASC-US or LSIL, to not require a prior authorization.
10/15/20: Corrected documentation, HPV Reflex to HPV Reflex.
12/22/2020: Medical policy placed on the new Paramount Medical Policy Format

REFERENCES/RESOURCES
Centers for Medicare and Medicaid Services, CMS Manual System and other CMS publications and services
Ohio Department of Medicaid
American Medical Association, Current Procedural Terminology (CPT®) and associated publications and services
Centers for Medicare and Medicaid Services, Healthcare Common Procedure Coding System, HCPCS Release and Code Sets
Industry Standard Review
Hayes, Inc.
The U.S. Preventive Services Task Force (USPSTF),
American college of Obstetricians and Gynecologists (ACOG)