Primary HPV Screening for Cervical Cancer Screening: Technical Guide for Coding and Billing

~As of May 2023~

This resource was developed by the Insurance Coverage and Payors Workgroup as a part of the American Cancer Society National Roundtable on Cervical Cancer's Primary HPV Screening Initiative which aims to support the transition and implementation of primary HPV screening across the United States. To learn more about the transition to primary HPV screening and this initiative, please visit our webpage here.

Primary HPV Screening for Cervical Cancer Screening and Genotyping

Primary HPV screening for cervical cancer screening is when the first cervical screening test used is a high-risk HPV test. If the test is negative, the patient has a very low risk of screening abnormalities for the next 5 years and would subsequently have another high-risk HPV screening test done again in 5 years. If the primary HPV test is positive for a high-risk HPV genotype, then further management is based on the results of cytology or colposcopy.

Primary HPV screening is an FDA-approved and guideline-recommended strategy for the early detection of cervical precancer. Primary HPV screening every 5 years is the preferred screening strategy for women and people with a cervix aged 25-64, according to the American Cancer Society Guidelines for the Prevention and Early Detection of Cervical Cancer.[1] The United States Preventive Services Task Force's (USPSTF) detailed review of these data resulted in an August 2018 recommendation of primary high-risk HPV screening, with a grade of "A", to screen for cervical cancer.[2]

FDA-Approved Primary HPV Test	Individual Genotypes Reported	Pooled Genotypes Reported
cobas® HPV (approved 2014)	16 and 18	(31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, 68)
Onclarity™ HPV (approved 2018)	16, 18, 31, 45, 51, 52	(33+58), (35+39+68), (56+59+66)

There are currently two FDA-approved tests for primary HPV screening for cervical cancer screening with genotyping: the Roche cobas® HPV test and the BD Onclarity™ HPV Assay, which test for oncogenic (high-risk) types of HPV DNA in cervical specimens. They both test for the presence of oncogenic (high-risk) types of HPV DNA in patient specimens taken from the cervix. Extensive clinical evidence supports the reasonableness, necessity, and appropriateness of the primary HPV test for cervical cancer screening.

Though primary HPV screening is now considered the preferred option, cotesting (cytology + HPV test) every 5 years and cytology-based screening every three years are currently the most commonly utilized screening methods. These alternative screening approaches are acceptable to utilize when primary HPV screening is not available and while practices and laboratories transition to primary HPV-based screening.

Benefits of Primary HPV Screening

HPV screening predicts future risk of cervical precancer and cancer better than cytology alone.[3] Cotesting (HPV test + cytology) offers little benefit over primary HPV screening. The contribution cytology makes to cotesting is minimal compared to the utility of the HPV test.[4] Furthermore, in a study evaluating the cost-effectiveness of different cervical cancer screening methods in the U.S., cotesting detected 14 additional cases of CIN3+ than primary HPV screening alone but would require 100,277 more cytology tests and 566 more colposcopies at an additional cost of $2.38 million.[5]

Transitioning to primary HPV screening is also a key step for preparing for the future of self-sampling because self-collected samples are analyzed on an HPV-based platform. Self-sampling will enable improved access to cervical cancer screening by reducing barriers and thus, will contribute to reducing health disparities. In addition to greater uptake of screening, the reported advantages of self-sampling include convenience, privacy, less embarrassment and anxiety, ease of use, and less discomfort and pain compared with in-office specimen collection.[6, 7, 8] These advantages make self-sampling a viable approach to screening in never- and under-screened populations.[9, 10]

Insurance Coverage Analysis

Most payors have extended coverage to include screening with the primary HPV test every five years, to align with the USPSTF's "A" grade recommendation. Always check with the individual payor and plan policy for specific guidance.

Commercial

Among the top 25 commercial payors in the United States (by number of lives), 100% are now covering primary HPV screening.

Primary HPV Screening Coverage for Cervical Cancer Screening	
Top 25 commercial payors	Represent nearly 80% of the commercially insured US population
Coverage as of Oct 2021	100% of the top 25 commercial payors are now covering primary HPV screening

Public (Medicare and Medicaid)

In 2015, the Centers for Medicare and Medicaid Services (CMS) determined that the evidence is sufficient to add HPV screening once every five years as an additional preventive service benefit under the Medicare program for asymptomatic beneficiaries aged 30-65 years in conjunction with cytology screening (i.e. cotesting) under a national coverage determination (NCD). The ACS Primary HPV Screening Initiative is advocating with CMS to expand national coverage of cervical cancer screening to include primary HPV screening with FDA-approved and cleared laboratory tests, used in accordance with FDA-approved labeling and in compliance with the Clinical Laboratory Improvement Act (CLIA) regulations, based on the USPSTF recommendations.

State Medicaid plans provide coverage for some form of HPV screening in all states. The majority of Medicaid plans follow the 2018 USPSTF recommendations and therefore cover primary HPV screening. Check with your state's Medicaid office to learn if primary HPV screening is covered for cervical cancer screening.

Coding and Billing Guidance

Only one CPT code is needed for primary HPV screening with an FDA-approved test. Decisions about the specific code(s) to report are the responsibility of the performing laboratory.

CPT code 87624: *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)*

Under CPT code 87624, the Roche cobas® HPV test reports three results – a high-risk pool and individual results for the presence of high-risk genotypes 16 and 18. The BD Onclarity™ test reports individual results for the presence of six high-risk genotypes: 16, 18, 45, 31, 51, and 52 and grouped results for the remaining eight high-risk genotypes.

If only types 16, 18, and 45 are performed by a subsequent reflex test, the CPT code to be reported should be 87625. Please note that CPT code 87625 is not used for the current FDA-approved primary HPV screening tests.

Category I CPT codes (e.g. 87624) are considered the “gold standard” for Healthcare Common Procedure Coding System (HCPCS) coding and are recognized by virtually all payors. Other categories of codes (e.g., Category III) may not be recognized by all payors and could create coverage and reimbursement challenges.

The 2023 Medicare Payment Rate for CPT code 87624 is $35.09. Medicaid and private payor rates may vary.

Additional primary HPV screening resources for laboratories and IT systems can be found here.

Other resources

1. AMA: CPT Assistant
2. ACOG: Payment Advocacy & Policy Portal
3. CMS NCD: Screening for Cervical Cancer with Human Papillomavirus (HPV)
4. KFF: Medicaid Coverage of Family Planning Benefits: Results from a State Survey

References

1. Fontham ETH, Wolf AMD, Church TR, Etzioni R, Flowers CR, Herzig A, Guerra CE, Oeffinger KC, Shih YT, Walter LC, Kim JJ, Andrews KS, DeSantis CE, Fedewa SA, Manassaram-Baptiste D, Saslow D, Wender RC, Smith RA. Cervical cancer screening for individuals at average risk: 2020 guideline update from the American Cancer Society. *CA Cancer J Clin*. 2020;70(5):321-346.
2. Curry SJ, Krist AH, Owens DK, et al. Screening for cervical cancer: US Preventive Services Task Force recommendation statement. *JAMA.* 2018;320: 674- 686.
3. Katki HA, Kinney WK, Fetterman B, Lorey T, Poitras NE, Cheung L, Demuth F, Schiffman M, Wacholder S, Castle PE. Cervical cancer risk for women undergoing concurrent testing for human papillomavirus and cervical cytology: a population-based study in routine clinical practice. *Lancet Oncol*. 2011;12(7):663-72.
4. Gage JC, Schiffman M, Katki HA, Castle PE, Fetterman B, Wentzensen N, Poitras NE, Lorey T, Cheung LC, Kinney WK. Reassurance against future risk of precancer and cancer conferred by a negative human papillomavirus test. *J Natl Cancer Inst*. 2014;106(8):dju153.
5. Jin XW, Lipold L, Foucher J, Sikon A, Brainard J, Belinson J, Schramm S, Nottingham K, Hu B, Rothberg MB. Cost-effectiveness of primary HPV testing, cytology and co-testing as cervical cancer screening for women above age 30 years. *J Gen Intern Med*. 2016;31(11):1338-1344.
6. Madzima TR, Vahabi M, Lofters A. Emerging role of HPV self-sampling in cervical cancer screening for hard-to-reach women: Focused literature review. *Can Fam Physician*. 2017 Aug;63(8):597-601.
7. Bais AG, van Kemenade FJ, Berkhof J, Verheijen RH, Snijders PJ, Voorhorst F, Babović M, van Ballegooijen M, Helmerhorst TJ, Meijer CJ. Human papillomavirus testing on self-sampled cervicovaginal brushes: an effective alternative to protect nonresponders in cervical screening programs. *Int J Cancer*. 2007 Apr 1;120(7):1505-10.
8. Sankaranarayanan R, Nene BM, Shastri SS, Jayant K, Muwonge R, Budukh AM, Hingmire S, Malvi SG, Thorat R, Kothari A, Chinoy R, Kelkar R, Kane S, Desai S, Keskar VR, Rajeshwarkar R, Panse N, Dinshaw KA. HPV screening for cervical cancer in rural India. *N Engl J Med*. 2009 Apr 2;360(14):1385-94.
9. Yeh PT, Kennedy CE, de Vuyst H, Narasimhan M. Self-sampling for human papillomavirus (HPV) testing: a systematic review and meta-analysis. *BMJ Glob Health*. 2019 May 14;4(3):e001351.
10. Nelson EJ, Maynard BR, Loux T, Fatla J, Gordon R, Arnold LD. The acceptability of self-sampled screening for HPV DNA: a systematic review and meta-analysis. *Sex Transm Infect*. 2017 Feb;93(1):56-61.