Clinical Policy: Primary Care and Preventive Lab Screening

Reference Number: TX.CP.MP.305
Effective Date: 03/24

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

I. Description

In some instances, testing of healthy/asymptomatic individuals for infectious diseases is recommended as part of public health prevention and minimization of harm efforts. This policy outlines criteria for human papillomavirus (HPV), hepatitis C virus (HCV), and group B streptococcus (GBS).

HPV is the most common sexually transmitted infection in the United States, per the CDC. There are several types of HPV. Some types of HPV can cause genital warts (low-risk/non-oncogenic) and some types can lead to cancers (high-risk/oncogenic), including cervical cancer. Routine cervical cancer screening is recommended for individuals with a cervix via cytology (pap smear), high-risk HPV testing, or co-testing.

Per the US Preventive Services Task Force, HCV infections are the most common chronic blood-borne pathogen infections in the United States, and a leading cause of morbidity and mortality, primarily via chronic liver disease complications. Universal HCV infection screening is recommended for adults and robust diagnosis and treatment algorithms are available.

It is common for the vaginal tract to be colonized with a bacteria called group B streptococcus. This is usually not a problem for the health of the individual but can lead to illness in a newborn baby if the bacteria is transferred during vaginal delivery. Screening for GBS is recommended during pregnancy.

Note: This policy is applicable to laboratory services delivered in an outpatient setting.

II. Policy/Criteria

It is the policy of health plans affiliated with Centene Corporation® that the specific tests noted below are **medically necessary** when meeting the related criteria:

HUMAN PAPILLOMAVIRUS (HPV) TESTS

i. Genotyping of High Risk Human Papillomavirus (HPV) Types for Cervical Cancer Screening

A. Human papillomavirus (HPV) genotyping of high-risk types may be considered medically necessary when:

1. A member who is between the ages of 30 and 65 years and born with a cervix, has not had a hysterectomy with removal of the cervix, has a history of high-grade precancerous lesion (i.e., cervical intraepithelial neoplasia [CIN] grade 2 or 3), or has a history of cervical cancer; or

2. A member who is younger than 30 or older than 65 years of age, was born with a cervix, and is at increased risk for cervical cancer (e.g., immunocompromised, HIV infection, in-utero exposure to diethylstilbestrol, history of cervical lesion or cervical cancer).
3. Human papillomavirus (HPV) genotyping of high-risk types is considered medically necessary once every 5 years, in absence of increased risk factors for cervical cancer (e.g., immunocompromised, HIV infection, in-utero exposure to diethylstilbestrol, history of cervical lesion or cervical cancer).
4. Current evidence does not support human papillomavirus (HPV) genotyping of high-risk types for all other indications, including for evaluation of genital warts or sexually transmitted infection screening.

B. Genotyping of Low Risk Human Papillomavirus (HPV) Types
Current evidence does not support human papillomavirus (HPV) genotyping of low risk types.

HEPATITIS C (HCV) TESTS

ii. Hepatitis C Antibody Screening Tests

A. Hepatitis C Antibody Screening Tests may be considered medically necessary when:

1. The member does not have a known past positive HCV Antibody test result* or a known history of chronic HCV infection*, and
2. The member is pregnant, is an asymptomatic adult between the ages of 18 and 79 years, or younger than 18 or older than 79 years of age; and
3. The member is at increased risk of HCV infection (e.g., past or current injection drug use, liver disease, chronic hemodialysis, HIV infection, HIV PrEP use, is an individual with a male reproductive system who have sex with those with a male reproductive system, has partners of HCV-infected individuals, is an organ transplant donor/recipient), or
4. The member requests screening (regardless of age or disclosure of potentially stigmatizing risks).

B. Current evidence does not support Hepatitis C Antibody Screening Tests for all other indications**.

**A quantitative HCV-RNA test rather than an HCV-antibody test is recommended to assess for HCV recurrence.*

***This criteria does not apply to members with liver disease and/or other signs and symptoms of active hepatitis C virus infection.*

iii. Hepatitis C Nucleic Acid/PCR Tests

A. Hepatitis C Nucleic Acid/PCR Tests for the purposes of routine screening or confirmatory testing following a positive HCV antibody screening test may be considered medically necessary when:

1. The member is immunocompromised (e.g., receives chronic hemodialysis), has a suspected HCV exposure within the past 6 months (regardless of antibody status), has an initial HCV antibody positive test*, is undergoing monitoring for chronic HCV infection (i.e., prior to starting direct-acting antiviral (DAA) treatment, while receiving treatment or having completed therapy, **or h**as a history of HCV infection followed by eradication/sustained virologic response (SVR); and
2. The member has ongoing risk factors for HCV reinfection**.

B. Current evidence does not support Hepatitis C Nucleic Acid/PCR Tests for the purposes of routine screening or confirmatory testing following a positive HCV antibody screening test for all other indications***.

**This includes PCR testing as an automatic reflex from initial antibody tests; this approach is considered the most appropriate option for initial HCV screening.*
***A quantitative HCV-RNA test rather than an HCV-antibody test is recommended to assess for HCV recurrence.*
****This criteria does not apply to members with liver disease and/or other signs and symptoms of active hepatitis C virus infection.*

PRENATAL INFECTIOUS DISEASE SCREENING TESTS

iv. Group B Streptococcus Screening Tests of Vaginal-Rectal Specimens

A. **Group B Streptococcus Screening Tests of Vaginal-Rectal Specimens may be considered medically necessary when** the member is pregnant, and the pregnancy is between 36 weeks 0 days and 37 weeks and 6 days gestation.
B. Current evidence does not support Group B Streptococcus Screening Tests of Vaginal-Rectal Specimens for pregnant members who have GBS bacteriuria during the current pregnancy.
C. Current evidence does not support Group B Streptococcus Screening Tests of Vaginal-Rectal Specimens for pregnant members who have a history of a previous GBS-infected newborn.
D. Current evidence does not support Group B Streptococcus Screening Tests of Vaginal-Rectal Specimens for all other indications.

III. Background and Rationale

A. Genotyping of High Risk Human Papillomavirus (HPV) Types for Cervical Cancer Screening

United States Preventive Services Task Force
In their 2018 recommendations, the USPSTF states the following:

- For women aged 30 to 65 years, screen every 3 years with cervical cytology alone, every 5 years with high-risk human papillomavirus (hrHPV) testing alone, or every 5 years with hrHPV testing in combination with cytology (cotesting).
- Do not screen for cervical cancer in women who have had a hysterectomy with removal of the cervix and do not have a history of a high-grade precancerous lesion (ie, cervical intraepithelial neoplasia [CIN] grade 2 or 3) or cervical cancer.
- Do not screen for cervical cancer in women older than 65 years who have had adequate prior screening and are not otherwise at high risk for cervical cancer.

"Certain risk factors further increase risk for cervical cancer, including HIV infection, a compromised immune system, in utero exposure to diethylstilbestrol, and previous treatment of a high-grade precancerous lesion or cervical cancer. Women with these risk factors should receive individualized follow-up."

Centers for Disease Control and Prevention
In their 2021 guidelines regarding HPV testing, the CDC states the following:
"These tests should not be used for male partners of women with HPV or women aged <25 years, for diagnosis of genital warts, or as a general STI test. HPV testing is not recommended for anogenital wart diagnosis because test results are not confirmatory and do not guide genital wart management."

B. Genotyping of Low Risk Human Papillomavirus (HPV) Types

American Academy of Family Physicians
In their 2021 Choosing Wisely recommendations, the AAFP states the following:
"There is no medical indication for low-risk HPV testing because the infection is not associated with disease progression and there is no treatment of therapy change indicated with low-risk HPV is identified."

C. Hepatitis C Antibody Tests

United States Preventive Services Task Force

- Screen adults aged 18 to 79 years with anti–HCV antibody testing followed by confirmatory polymerase chain reaction testing.
- Consider screening persons younger than 18 years and older than 79 years who are at high risk for infection (eg, those with past or current injection drug use).

Centers for Disease Control and Prevention
Universal hepatitis C screening:
- Hepatitis C screening for all pregnant women during each pregnancy, except in settings where the prevalence of HCV infection (HCV RNA-positivity) is less than 0.1%*

One-time hepatitis C testing regardless of age or setting prevalence among people with recognized conditions or exposures:
- People with HIV
- People who ever injected drugs and shared needles, syringes, or other drug preparation equipment, including those who injected once or a few times many years ago.
- People with selected medical conditions, including:
  - people who ever received maintenance hemodialysis
  - people with persistently abnormal ALT levels
- Prior recipients of transfusions or organ transplants, including:
  - people who received clotting factor concentrates produced before 1987
  - people who received a transfusion of blood or blood components before July 1992
  - people who received an organ transplant before July 1992
  - people who were notified that they received blood from a donor who later tested positive for HCV infection.

Routine periodic testing for people with ongoing risk factors, while risk factors persist:
- People who currently inject drugs and share needles, syringes, or other drug preparation equipment
- People with selected medical conditions, including:
  - people who ever received maintenance hemodialysis.

Any person who requests hepatitis C testing should receive it, regardless of disclosure of risk, because many persons may be reluctant to disclose stigmatizing risks.

Infectious Diseases Society of America and American Association for the Study of Liver Diseases
Initial HCV Testing and Follow-Up Recommendations from ISDA and AASLD:
- HCV-antibody testing with reflex HCV RNA polymerase chain reaction (PCR) testing is recommended for initial HCV testing.
- Among persons at risk of reinfection after previous spontaneous or treatment-related viral clearance, HCV-RNA testing is recommended because a positive HCV-antibody test is expected. (p. 4)

D. Hepatitis C Nucleic Acid/PCR Tests

Infectious Diseases Society of America and American Association for the Study of Liver Diseases

Initial HCV Testing and Follow-Up Recommendations:

- HCV-antibody testing with reflex HCV RNA polymerase chain reaction (PCR) testing is recommended for initial HCV testing.
- Among persons with a negative HCV-antibody test who were exposed to HCV within the prior 6 months, HCV-RNA or follow-up HCV-antibody testing 6 months or longer after exposure is recommended. HCV-RNA testing can also be considered for immunocompromised persons.
- Among persons at risk of reinfection after previous spontaneous or treatment-related viral clearance, HCV-RNA testing is recommended because a positive HCV-antibody test is expected.
- Quantitative HCV-RNA testing is recommended prior to initiation of antiviral therapy to document the baseline level of viremia (ie, baseline viral load). (p. 4)

Monitoring Patients Who Are Starting HCV Treatment, Are on Treatment, or Have Completed Therapy

- Quantitative HCV RNA (HCV viral load) testing is recommended any time prior to starting DAA therapy. (p. 1)

Recommended Monitoring During Antiviral Therapy

- Quantitative HCV viral load testing is recommended 12 or more weeks after completion of therapy to document sustained virologic response (SVR), which is consistent with cure of chronic HCV infection. (p. 2)

Recommended Follow-Up for Patients Who Achieved a Sustained Virologic Response (SVR)

- For noncirrhotic patients, recommended follow-up screening indications are the same as for any individual (universal screening recommendations)
- Assessment for HCV recurrence is recommended annually if the patient has ongoing risk factors for HCV infection. In such cases, a quantitative HCV-RNA test rather than an HCV-antibody test is recommended to assess for HCV recurrence. (p. 9)

E. Group B Streptococcus Tests in Vaginal-Rectal Specimens

American College of Obstetrics and Gynecology

In 2019 (reaffirmed 2022), the American College of Obstetrics and Gynecology (ACOG) published Committee Opinion Number 797 which addresses prevention of group B Streptococcal (GBS) disease in newborns via screening of pregnant individuals. These guidelines state the following: "...all pregnant women should undergo antepartum screening for GBS at 36 0/7 - 37 6/7 weeks of gestation, unless intrapartum antibiotic prophylaxis for GBS is indicated because of GBS bacteriuria during the pregnancy or because of a history of a previous GBS-infected newborn." (p. e52)

Regarding the methodology of screening: "...NAAT [nucleic acid amplification testing]-based testing offers a reasonable and potentially more sensitive alternative to

a culture for antepartum screening and some laboratories, albeit a minority, report the use of these newer tests for routine antepartum screening." (p. e55)

IV. Coding Implications

This clinical policy references Current Procedural Terminology (CPT®). CPT® is a registered trademark of the American Medical Association. All CPT codes and descriptions are copyrighted 2022, American Medical Association. All rights reserved. CPT codes and CPT descriptions are from the current manuals and those included herein are not intended to be all-inclusive and are included for informational purposes only. Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

Table 1

Criteria Sections	Lab Tests	References
Genotyping of High Risk Human Papillomavirus (HPV) Types	Human Papillomavirus (HPV)	1, 2
	Human Papillomavirus (HPV) Genotypes 16 and 18, 45	
Genotyping of Low Risk Human Papillomavirus (HPV) Types	HPV Low Risk	3
Hepatitis C Antibody Tests	Hepatitis C Virus (HCV) Antibody Cascade to Quantitative PCR and Genotyping	4, 5, 6
Hepatitis C Nucleic Acid/PCR Tests	Hepatitis C Viral RNA, Quantitative, Real-Time PCR	
Group B Streptococcus Tests in Vaginal-Rectal Specimens	Group B Streptococcus Colonization Detection Culture	7

Table 2

CPT® Codes	Description
0500T	Infectious agent detection by nucleic acid (DNA or RNA), Human Papillomavirus (HPV) for five or more separately reported high-risk HPV types (eg, 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 68) (ie, genotyping)
86803	Antibody; Zika virus, IgM
86804	Hepatitis C antibody

CPT® Codes	Description
87081	Culture, bacterial; aerobic isolate, additional methods required for definitive identification, each isolate
87149	Culture, typing; immunologic method, other than immunofluorescence (eg, agglutination grouping), per antiserum
87150	Culture, typing; identification by nucleic acid (DNA or RNA) probe, direct probe technique, per culture or isolate, each organism probed
87520	Infectious agent detection by nucleic acid (DNA or RNA); hepatitis B virus, quantification
87521	Infectious agent detection by nucleic acid (DNA or RNA); hepatitis C, direct probe technique
87522	Infectious agent detection by nucleic acid (DNA or RNA); hepatitis C, amplified probe technique, includes reverse transcription when performed
87623	Infectious agent detection by nucleic acid (DNA or RNA); Orthopoxvirus (eg, monkeypox virus, cowpox virus, vaccinia virus), amplified probe technique, each
87624	Infectious agent detection by nucleic acid (DNA or RNA); Human Papillomavirus (HPV), low-risk types (eg, 6, 11, 42, 43, 44)
87625	Infectious agent detection by nucleic acid (DNA or RNA); Human Papillomavirus (HPV), high-risk types (eg, 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 68)
87653	Infectious agent detection by nucleic acid (DNA or RNA); Streptococcus, group A, quantification

Reviews, Revisions, and Approvals	Revision Date	Approval Date
Policy developed	02/24	02/24

References

1. Cervical Cancer: Screening. United States Preventive Services Task Force. Updated August 21, 2018. Accessed September 20, 2023. https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/cervical-cancer-screening
2. Sexually Transmitted Infections Treatment Guidelines, 2021: Human Papillomavirus (HPV) Infection. Centers for Disease Control and Prevention. Updated July 22, 2021. Accessed January 2, 2024. https://www.cdc.gov/std/treatment-guidelines/hpv.htm
3. Quinlan JD. Human Papillomavirus: Screening, Testing, and Prevention. *Am Fam Physician*. 2021 Aug 1;104(2):152-159. PMID: 34383440.

4. HCV guidance: Recommendations for testing, managing, and treating hepatitis C. Recommendations for Testing, Managing, and Treating Hepatitis C | HCV Guidance. Accessed January 2, 2024. https://www.hcvguidelines.org/.
5. Testing recommendations for hepatitis C virus infection. Centers for Disease Control and Prevention. July 13, 2023. Accessed January 2, 2024. https://www.cdc.gov/hepatitis/hcv/guidelinesc.htm.
6. Bhattacharya D, Aronsohn A, Price J, Lo Re V; AASLD-IDSA HCV Guidance Panel. Hepatitis C Guidance 2023 Update: AASLD-IDSA Recommendations for Testing, Managing, and Treating Hepatitis C Virus Infection. Clin Infect Dis. 2023 May 25:ciad319. doi: 10.1093/cid/ciad319. Epub ahead of print. PMID: 37229695.
7. Prevention of Group B Streptococcal Early-Onset Disease in Newborns: ACOG Committee Opinion, Number 797. Obstet Gynecol. 2020;135(2):e51-e72.

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise

professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members/enrollees. This clinical policy is not intended to recommend treatment for members/enrollees. Members/enrollees should consult with their treating physician in connection with diagnosis and treatment decisions.

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Note: For Medicaid members/enrollees, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

Note: For Medicare members/enrollees, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs, and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at http://www.cms.gov for additional information.