Coding Implications
Revision Log

CONCERT INFECTIOUS DISEASE: PRIMARY CARE & PREVENTATIVE SCREENING

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

OVERVIEW

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.

This policy is intended for use in the outpatient setting.

POLICY REFERENCE TABLE

Criteria Sections	Example Tests (Labs)	Ref
Human Papillomavirus (HPV) Tests		
Genotyping of High Risk Human Papillomavirus (HPV) Types	Human Papillomavirus (HPV) (Aptima) (Labcorp)	1, 2
	Human Papillomavirus (HPV) Genotypes 16 and 18,45 (Labcorp)	
Genotyping of Low Risk Human Papillomavirus (HPV) Types	HPV Low Risk (Pacific Medical Laboratories)	3
Hepatitis C (HCV) Tests		
Hepatitis C Antibody Screening Tests	Hepatitis C Virus (HCV) Antibody Cascade to Quantitative PCR and Genotyping (Labcorp)	4, 5, 6, 8

Hepatitis C Nucleic Acid/PCR Tests	Hepatitis C Viral RNA, Quantitative, Real-Time PCR (Quest Diagnostics)	4, 5, 6
Prenatal Infectious Disease Screening Tests		
Group B Streptococcus Tests in Vaginal-Rectal Specimens	Group B Streptococcus Colonization Detection Culture (Labcorp)	7

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

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

I. Human papillomavirus (HPV) genotyping of high risk types is considered **medically necessary** when:

A. The member/enrollee is an individual born with a cervix, who is between the ages of 30 and 65 years, **AND**

1. Has **NOT** had a hysterectomy with removal of the cervix, **OR**

2. Has a history of high-grade precancerous lesion (i.e., cervical intraepithelial neoplasia [CIN] grade 2 or 3), **OR**

3. Has a history of cervical cancer, **OR**

B. The member/enrollee is an individual born with a cervix, who is younger than 30 or older than 65 years of age, **AND**

1. Is at increased risk for cervical cancer (e.g., immunocompromised, HIV infection, in-utero exposure to diethylstilbestrol, history of cervical lesion or cervical cancer).

II. 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).

III. Human papillomavirus (HPV) genotyping of high risk types is considered **investigational** for all other indications, including:

A. For evaluation of genital warts or sexually transmitted infection screening.

Genotyping of Low Risk Human Papillomavirus (HPV) Types

I. Human papillomavirus (HPV) genotyping of low risk types is considered **investigational**.

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HEPATITIS C (HCV) TESTS

Hepatitis C Antibody Screening Tests

I. Hepatitis C antibody screening tests are considered **medically necessary** when:

A. The member/enrollee does NOT have a known past positive HCV Antibody test result*, **AND**

B. The member/enrollee does not have a known history of chronic HCV infection*, **AND**

C. The member/enrollee meets at least one of the following:

1. The member/enrollee is pregnant, **OR**
2. The member/enrollee is an asymptomatic adult between the ages of 18 and 79 years, **OR**
3. The member/enrollee is a child 18 months or older, **AND**
    a) The member/enrollee was perinatally exposed to HCV, **AND**
    b) The member/enrollee has not been previously tested, **OR**
4. The member/enrollee is younger than 18 or older than 79 years of age, **AND**
    a) The member/enrollee is at increased risk of HCV infection (e.g., past or current injection drug use, liver disease, chronic hemodialysis, HIV infection, HIV PrEP use, individuals with male reproductive systems who have sexual intercourse with individuals with male reproductive systems, partners of HCV infected individuals, organ transplant donor/recipient), **OR**
5. The member/enrollee requests screening (regardless of age or disclosure of potentially stigmatizing risks).

II. Hepatitis C antibody screening tests are considered **investigational** 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/enrollees with liver disease and/or other signs and symptoms of active hepatitis C virus infection.

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Hepatitis C Nucleic Acid/PCR Tests

I. Hepatitis C nucleic acid/PCR tests for the purposes of routine screening or confirmatory testing following a positive HCV antibody screening test are considered **medically necessary** when:

   A. The member/enrollee is immunocompromised (e.g., receives chronic hemodialysis), **OR**

   B. The member/enrollee has a suspected HCV exposure within the past six months (regardless of antibody status), **OR**

   C. The member/enrollee has an initial HCV antibody positive test*, **OR**

   D. The member/enrollee 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**

   E. The member/enrollee was exposed to HCV perinatally and is between two months and 17 months of age, **OR**

   F. The member/enrollee has a history of HCV infection followed by eradication/sustained virologic response (SVR), **AND**

      1. The member/enrollee has ongoing risk factors for HCV reinfection**.

II. Hepatitis C nucleic acid/PCR tests for the purposes of routine screening or confirmatory testing following a positive HCV antibody screening test are considered **investigational** 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/enrollees with liver disease and/or other signs and symptoms of active hepatitis C virus infection.

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PRENATAL INFECTIOUS DISEASE SCREENING TESTS

Group B Streptococcus Screening Tests of Vaginal-Rectal Specimens

I. Group B Streptococcus screening tests of vaginal-rectal specimens are considered **medically necessary** when:

   A. The member/enrollee is pregnant, **AND**

   B. The pregnancy is between 36 weeks 0 days and 37 weeks and 6 days gestation.

II. Group B streptococcus screening tests of vaginal-rectal specimens is considered **investigational** for pregnant members/enrollees who have GBS bacteriuria during the current pregnancy.

III. Group B streptococcus screening tests of vaginal-rectal specimens is considered **investigational** for pregnant members/enrollees who have a history of a previous GBS-infected newborn.

IV. Group B streptococcus screening tests of vaginal-rectal specimens is considered **investigational** for all other indications.

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BACKGROUND AND RATIONALE

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 individuals with a female reproductive system aged 30 to 65 years, screen every three years with cervical cytology alone, every five years with high-risk human papillomavirus (hrHPV) testing alone, or every five years with hrHPV testing in combination with cytology (cotesting).

- Do not screen for cervical cancer in individuals with female reproductive systems 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 individuals with female reproductive systems 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." According to USPSTF, individuals with female reproductive systems 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 any of the following:

- Individuals with male reproductive systems who are partners of individuals with female reproductive systems with HPV;
- Individuals with female reproductive systems aged <25 years;
- For diagnosis of genital warts;
- 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."

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."

Hepatitis C Antibody Screening 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 individuals with female reproductive systems 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

Recommendations for Hepatitis C Testing Among Perinatally Exposed Infants and Children:

- Children aged greater than or equal to 18 months who are perinatally exposed to HCV and have not previously been tested should receive an anti-HCV test with reflex to NAT for HCV RNA

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)

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 six months, HCV-RNA or follow-up HCV-antibody testing six 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)

Centers for Disease Control and Prevention

Recommendations for Hepatitis C Testing Among Perinatally Exposed Infants and Children

- Perinatally exposed infants should receive a NAT for HCV RNA at age two to six months to identify children in whom chronic HCV infection might develop if not treated…
- Infants and children aged seven to 17 months who are perinatally exposed to HCV and have not previously been tested should receive a NAT for HCV RNA.

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 [individuals] 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:

"*Rates for GBS detection using NAAT methods have been shown to be equivalent to culture-based screening or better when the test protocol includes an 18–24-hour incubation step in enrichment broth before performing the NAAT analysis, which is similar to the process for traditional culture-based methods. Therefore,* 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)

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 2023, 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.

CPT® Codes	Description
86803	Hepatitis C antibody
86804	Hepatitis C antibody; confirmatory test (eg, immunoblot)
87520	Infectious agent detection by nucleic acid (DNA or RNA); hepatitis C, direct probe technique

CPT® Codes	Description
87521	Infectious agent detection by nucleic acid (DNA or RNA); hepatitis C, amplified probe technique, includes reverse transcription when performed
87522	Infectious agent detection by nucleic acid (DNA or RNA); hepatitis C, quantification, includes reverse transcription when performed
87623	Infectious agent detection by nucleic acid (DNA or RNA); Human Papillomavirus (HPV), low-risk types (eg, 6, 11, 42, 43, 44)
87624	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), pooled result
87625	Infectious agent detection by nucleic acid (DNA or RNA); Human Papillomavirus (HPV), types 16 and 18 only, includes type 45, if performed
87626	Infectious agent detection by nucleic acid (DNA or RNA); Human Papillomavirus (HPV), separately reported high-risk types (eg, 16, 18, 31, 45, 51, 52) and high-risk pooled result(s)
87653	Infectious agent detection by nucleic acid (DNA or RNA); Streptococcus, group B, amplified probe technique

HCPCS Codes	Description
G0476	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

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Reviews, Revisions, and Approvals	Revision Date	Approval Date
Policy developed. Reviewed by external specialist.	11/23	02/24
Added “lab” to policy title. Removed CPT and ICD-10 codes from policy reference table. Added CPT code table and moved the “coding implications” section.	02/24	
Corrected CPT code descriptions. Removed 0500T, 87081, 87149 and 87150. Corrected policy number from CG.CP.MP.105 to CG.CP.MP.05.	03/24	

Reviews, Revisions, and Approvals	Revision Date	Approval Date
Annual review. Added policy number to header. Changed policy statement verbiage from " may be considered medically necessary" to "are considered medically necessary" for the following criteria sections: Group B Streptococcus Screening Tests of Vaginal-Rectal Specimens, Genotyping of High Risk Human Papillomavirus (HPV) Types for Cervical Cancer Screening, and Hepatitis C Nucleic Acid/PCR Tests. For Hepatitis C Nucleic Acid/PCR Tests, added the following criteria option: "The member was exposed to HCV perinatally and is between 2 months and 17 months of age". Background updated. Code added to CPT Coding table: 87626. Code added to new HCPCS table: G0476. References updated.	11/24	02/25

REFERENCES

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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.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

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.