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Effective June 1, 2024: New Clinical Payment Policies: Infectious Disease - Lab Screening and Testing

PA Health & Wellness, Wellcare by Allwell and Ambetter from PA Health & Wellness present new clinical payment policies to provide payment protocols for Infectious Disease Primary and Preventive Care Lab Screenings and Lab Testing related to Infectious Diseases.

To ensure accurate reimbursement, these policies will provide the clinically based rule content used to evaluate claims. This is in addition to all other reimbursement processes that PA Health & Wellness currently employs.

The new policies documents can be found below. On the effective date of 6/1/24 you will find them on our Clinical & Payment policies webpage.

Contact Us! If you have any questions, please contact our Provider Services team at: 1-844-626- 6813.

Thank you for your continued partnership and we look forward to serving our Participants in PA together,
PA Health & Wellness

Revision log

CONCERT LABORATORY PAYMENT POLICY

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

All providers billing for laboratory services must bill according to the Centers for Medicare & Medicaid Services (CMS), National Correct Coding Initiative (NCCI), and the American Medical Association (AMA)

This policy addresses laboratory services and applies to codes billed in an outpatient setting from the following sections in the AMA CPT/HCPCS Manual:

- Pathology and Laboratory Procedures (80000 Codes)
- Category III Multianalyte Assays with Algorithmic Analyses (MAAA) (M codes)
- Proprietary Lab Analysis (PLA) (U codes)
- HCPCS level I codes for lab tests (G codes and S codes)

All providers billing for laboratory services must include standard information on the claim, or services may be denied:

- Include ordering and rendering provider information on all claim transactions .
- Include appropriate and accurate diagnosis codes, related to the procedure performed, per the International Classification of Diseases (ICD) coding system created by the World Health Organization (WHO). Header codes (3 digit ICDs) may lack specificity to determine coverage in some instances and may be denied for insufficient specificity.
- Include the date and place of service on all claim transactions. Place of Service codes will be used to distinguish outpatient testing from testing provided within the Emergency Department or as a part of an inpatient hospital stay.

All providers billing for laboratory services must bill according to coding standards set by the American Medical Association (AMA), or services may be denied:

- Current Procedural Terminology (CPT) Coding must be consistent with American Medical Association (AMA) coding guidance below:
    - Codes are determined based on the attributes of the testing performed, not based on the clinical indication of the member.

    - If the laboratory has obtained an approved Proprietary Laboratory Analyses (PLA) code, the PLA code must be used.
    - If a test qualifies for a panel code(s) according to descriptions set by the AMA, the panel code(s) must be used.
    - If an appropriate panel code does not exist, either a single unit of 81479 or codes associated with individual components of the panel may be used.
    - Only one unit of the miscellaneous, non-specific code 81479 may be billed per test.
- Codes may be used when the date of service falls after the listed effective date and prior to the date of retirement.
- Proprietary codes may be used only for the specific test to which the code is assigned.
- Modifier codes should be used when appropriate. This includes but is not limited to repeat testing, testing performed on multiple specimens, and testing for multiple species.

All providers billing for laboratory services must bill according to the recommendations of Medicare, the National Correct Coding Initiative (NCCI), or services may be denied:

- If the laboratory has obtained an approved Proprietary Laboratory Analyses (PLA) code or the test has an MAAA code, the PLA/MAAA code must be used to bill for the service.
- If a test qualifies for a panel code(s), the panel code(s) must be used. For example, the NCCI Manual, Chapter 10, Section F-8 states, if one laboratory procedure evaluates multiple targets using a next generation sequencing procedure, the laboratory shall report only one unit of service representing one sequencing procedure.
- If a panel code is not appropriate (or when medical policy exclusively covers components of panels), a limited number of individual components from multi-target tests may be billed.
- Only one unit of the miscellaneous, non-specific code 81479 may be billed per test.
- If a code(s) falls under a NCCI procedure-to-procedure edit, the code must be billed in alignment with the edit. PTP edits prohibit certain codes billed in presence of other codes as they are "mutually exclusive procedures".
- If a code(s) falls under an NCCI procedure-to-procedure edit, modifiers must ONLY be used when appropriate and Modifier 59 may be used only if no other appropriate modifier describes the service.
- If a code(s) falls under a Medically Unlikely Edit (MUE), which defines the maximum units of service (UOS), the units billed must not exceed the maximum UOS. Per the NCCI Manual, the MUE is the maximum units of service (UOS) reported for a HCPCS/CPT code on the vast majority of appropriately reported claims by the same provider/supplier for the same beneficiary on the same date of service. Not all HCPCS/CPT codes have an MUEs.

References

1. American Medical Association. CPT® Code Book. Last updated 10/2023.

2. Centers Medicare NCCI Policy Manual. Chapter 10. CMS. www.cms.gov. https://www.cms.gov/medicare/coding-billing/national-correct-coding-initiative-ncci-edits/medicare-ncci-policy-manual
3. Medicare NCCI Procedure to Procedure (PTP) Edits. CMS. www.cms.gov. https://www.cms.gov/medicare/coding-billing/national-correct-coding-initiative-ncci-edits/medicare-ncci-procedure-procedure-ptp-edits
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5. Medicare NCCI FAQ Library. CMS. www.cms.gov. https://www.cms.gov/ncci-medicare/medicare-ncci-faq-library
6. World Health Organisation. ICD-11. International Classification of Diseases 11th Revision. Published 2022. https://icd.who.int/en

Revision History	
11/8/2023	Policy developed.

Important Reminder

For the purposes of this payment policy, "Health Plan" means a health plan that has adopted this payment policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any other of such health plan's affiliates, as applicable.

The purpose of this payment policy is to provide a guide to payment, which is a component of the guidelines used to assist in making coverage and payment determinations and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage and payment determinations 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 plan-level administrative policies and procedures.

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

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

Revision log

INFECTIOUS DISEASE: RESPIRATORY TESTING

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

OVERVIEW

Respiratory illnesses cause significant morbidity and mortality within the United States and around the world. Seasonal influenza, respiratory syncytial virus (RSV), and SARS-CoV-2 infect many individuals each year, and while most will recover with no complications, a significant number will be hospitalized or die. Diagnostic testing for upper respiratory tract infections can be very useful for clinicians, as clinical signs and symptoms of these infections can have significant overlap between pathogens. Accurate and rapid testing techniques may aid clinicians, via identification of a specific pathogen, in selecting the best course of treatment for patients. Optimally, treatment is started within 48-72 hours of diagnosis. Testing methods range from culture and microscopy to immunoassays and advanced molecular diagnostic techniques; technology in this space is evolving rapidly and clinical guidelines can lag as a result.

This policy is intended for use in the outpatient setting.

POLICY REFERENCE TABLE

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.

Criteria Sections	Example Tests (Labs)	Common CPT Codes	Common ICD Codes	Ref

Syndromic/Multiplex Respiratory Panels with 6 or More Targets	Respiratory Pathogen Panel, Quest Diagnostics	87632, 87633, 87486, 87581, 0115U, 0202U, 0223U, 0225U, 0373U	J42, J43, J44, J45, J47, J12, J15, J16, J17, J18	3
	ePlex Respiratory Pathogen Panel (GenMark Diagnostics, Inc)			
	Biofire FilmArray Respiratory Panel 2.1 (Biofire Diagnostics)			
	QIAstat-Dx Respiratory SARS-CoV-2 Panel (QIAGEN Sciences)			
	ePlex Respiratory Pathogen Panel 2 (GenMark Diagnostics, Inc)			
	Respiratory Pathogen with ABR (RPX) (Lab Genomics LLC, Thermofisher Scientific)			
	Respiratory Virus PCR Panel IV (Quest Diagnostics)	87632, 87633	J42, J43, J44, J45, J47, J12, J15, J16, J17, J18	
	Respiratory Viral Panel, PCR (Quest Diagnostics)			
SARS-CoV-2, RSV, or Influenza A/B, OR Multiplex Respiratory Viral Panels with 5 or Fewer Targets	Xpert Xpress SARS-CoV-2/Flu/RSV for SARS-CoV-2 and Flu targets only (Cepheid)	0240U, 0241U, 87501, 87502, 87503, 87426, 87428, 87631, 87635, 87636, 87637, 87811	J00, J01, J02, J04, J06	3, 6, 7
	Xpert Xpress SARS-CoV-2/Flu/RSV for all targets (Cepheid)			

	Infectious Agent Antigen Detection by Immunoassay			
	Infectious Agent Antigen Detection by Immunoassay, Qualitative or Semiquantitative			
	Infectious Agent Antigen Detection by Immunoassay, Qualitative or Semiquantitative, SARS-CoV-2 and Flu A/B			
	Influenza A and B and RSV RNA, Qualitative, Real-Time RT-PCR (Quest Diagnostics)			
	SARS-CoV-2 RNA (COVID-19), Qualitative NAAT (Quest Diagnostics)			
	SARS-CoV-2 RNA (COVID-19) and Influenza A and B, Qualitative NAAT (Quest Diagnostics)			
	Infectious Agent Antigen Detection by Nucleic Acid (DNA or RNA) SARS-CoV-2/Flu/RSV Multiplex Amplified Probe Technique			
	Infectious Agent Antigen Detection by Immunoassay with Direct Optical Observation			

Bacterial Respiratory Infection/Pneumonia Panels	Infectious Agent: Chlamydia pneumoniae Detection by Nucleic Acid (DNA or RNA), Direct Probe Technique	87485, 87486, 87487, 87541, 87798, 87580, 87581, 87582	R91, Z16	3
	Chlamydophila pneumoniae, DNA, Qualitative, Real-Time PCR (Quest Diagnostics)			
	Infectious Agent: Chlamydia pneumoniae Detection by Nucleic Acid (DNA or RNA), Quantification			
	Legionella DNA, Qualitative, Real-Time PCR (Quest Diagnostics)			
	Infectious Agent: Mycoplasma pneumoniae Detection by Nucleic Acid (DNA or RNA), Direct Probe Technique			
	Mycoplasma pneumoniae, DNA PCR (Labcorp)			
	Infectious Agent: Mycoplasma pneumonia Detection by Nucleic Acid (DNA or RNA), Quantification			
Influenza A and B Antibody Tests	Influenza Type A and Type B Antibody, Serum (Quest Diagnostics)	86710		1

Group A Streptococcus Pharyngitis Tests	Streptococcus Group A Antigen Detection by Immunoassay	87430, 87650, 87651, 87880	J02, J03, J35, R10, R11, R21, R23.3, R50, R51.9	2
	Streptococcus Group A Antigen Detection by Nucleic Acid Direct Probe Technique			
	Group A Streptococcus Detection, NAA (Labcorp)			
	Streptococcus Group A Antigen, Adult (Quest Diagnostics)			
Group A Streptococcus Pharyngitis Cultures	Streptococcus Group A Culture (Quest Diagnostics)	87081	J02, J03, J35, R10, R11, R21, R23.3, R50, R51.9	2, 4
Group A Streptococcus Antibody Tests	Antistreptolysin O (ASO) Antibodies (Labcorp)	86060		2

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:

RESPIRATORY PATHOGEN PANEL TESTS

Syndromic/Multiplex Respiratory Panels with 6 or More Targets

I. Syndromic Multiplex Respiratory Panels with 6 or more targets may be considered **medically necessary** when:

   A. The member presents in the outpatient setting with signs or symptoms of an acute respiratory infection, **AND**

      1. The member meets at least one of the following criteria:

         a) Immunocompromised, **OR**

         b) Has severe pneumonia, **OR**

         c) Has exacerbations of airway disease, **AND**

   B. Results of the testing will influence the member's clinical management.

II. Current evidence does not support the use of Syndromic Multiplex Respiratory Panels with 6 or more targets for all other indications.

SARS-CoV-2, RSV, or Influenza A/B, OR Multiplex Respiratory Viral Panels with 5 or Fewer Targets

I. SARS-CoV-2, RSV, or Influenza A/B, **OR** Multiplex Respiratory Viral Panels with 5 or fewer targets, may be considered **medically necessary** when:

   A. The member presents in the outpatient setting with signs or symptoms of an acute respiratory infection, **AND**

   B. Results of the testing will influence the member's clinical management.

II. Current evidence does not support the use of SARS-CoV-2, RSV, or Influenza A/B, **OR** Multiplex Respiratory Viral Panels with 5 or fewer targets, for all other indications.

Bacterial Respiratory Infection/Pneumonia Panels

I. Bacterial Respiratory Infection/Pneumonia Panels may be considered **medically necessary** when:

A. The member presents in the outpatient setting with signs or symptoms of an acute respiratory infection, **AND**

B. The member meets any of the following criteria:

1. New or worsening lung infiltrates, **OR**
2. Moderate to severe upper respiratory illness, **OR**
3. Has received empiric antibiotics before obtaining cultures, **OR**
4. Has possible multidrug-resistant bacteria or polymicrobial infection, **AND**

C. Results of the testing will influence the member's clinical management.

II. Current evidence does not support the use of Bacterial Respiratory Infection/Pneumonia Panels for all other indications.

Influenza A and B Antibody Tests

I. Current evidence does not support the use of Influenza A and B Antibody Tests for the purpose of diagnosing influenza.

Group A Streptococcus Pharyngitis Tests

I. Group A Streptococcus Pharyngitis Tests may be considered **medically necessary** when:

A. The member presents in the outpatient setting with at least one of the following:

1. Acute pharyngitis, **OR**
2. Fever, **OR**
3. Tonsillopharyngeal inflammation, **OR**
4. Patchy tonsillopharyngeal exudates, **OR**
5. Palatal petechiae, **OR**
6. Anterior cervical lymphadenitis, **OR**
7. Scarlatiniform rash, **AND**

B. The member does **NOT** have clinical and epidemiological features that strongly suggest a viral etiology (e.g., cough, rhinorrhea, hoarseness, and oral ulcers), **AND**

C. Results of the testing will influence the member's clinical management.

II. Current evidence does not support the use of Group A Streptococcus Pharyngitis Tests for all other indications.

Group A Streptococcus Pharyngitis Cultures

I. Group A Streptococcus Pharyngitis Culture may be considered **medically necessary** when:

A. The member is between the ages of 3 years and 14 years, **AND**

B. The member had a negative group A Streptococcus rapid antigen detection test (RADT), **AND**

C. The member presents in the outpatient setting with at least one of the following:

1. Acute pharyngitis, **OR**
2. Fever, **OR**
3. Tonsillopharyngeal inflammation, **OR**
4. Patchy tonsillopharyngeal exudates, **OR**
5. Palatal petechiae, **OR**
6. Anterior cervical lymphadenitis, **OR**
7. Scarlatiniform rash, **AND**

D. The member does **NOT** have clinical and epidemiological features that strongly suggest a viral etiology (e.g., cough, rhinorrhea, hoarseness, and oral ulcers), **AND**

E. Results of the testing will influence the member's clinical management.

II. Current evidence does not support the use of Group A Streptococcus Pharyngitis Culture for all other indications.

Group A Streptococcus Antibody Tests

I. Current evidence does not support the use of Group A Streptococcus Antibody Tests for the purpose of evaluating a member with acute pharyngitis for a possible group A streptococcus infection.

NOTES AND DEFINITIONS

1. **Moderate to severe upper upper respiratory illness** includes one or more clinical findings of lower respiratory illness (e.g., pneumonia, severe cough/bronchitis, shortness of breath, difficulty breathing).

2. **Severe pneumonia** is defined by the Infectious Diseases Society of America/American Thoracic Society Criteria as: the presence of one major criterion or at least three minor criteria.

   Minor criteria: respiratory rate ≥ 30 breaths/min, PaO2/FiO2 ratio ≤ 250, multilobar infiltrates, confusion/disorientation, uremia (blood urea nitrogen level ≥ 20 mg/dl), leukopenia (white blood cell count < 4,000 cells/µl), thrombocytopenia (platelet count < 100,000/µl), hypothermia (core temperature < 36°C), and hypotension requiring aggressive fluid resuscitation.

   Major criteria: septic shock with need for vasopressors and respiratory failure requiring mechanical ventilation.

3. **Airway disease** is a nonspecific clinical term for a heterogeneous group of conditions including chronic obstructive pulmonary disease (COPD), emphysema, cystic fibrosis, asthma, and bronchiectasis.

4. **Signs and symptoms of acute respiratory infection** include upper or lower respiratory tract symptoms (cough, runny nose, sore throat, bronchitis, pneumonia, bronchiolitis), with or without fever, influenza-like illness (ILI) (fever and either cough or sore throat), and respiratory distress (difficulty in breathing; often characterized by increased respiratory rate and use of accessory muscles of breathing).

BACKGROUND AND RATIONALE

Syndromic/Multiplex Respiratory Panels with 6 or More Targets

Infectious Diseases Society of America

The IDSA published clinical and diagnostic recommendations in 2020 regarding molecular testing for acute respiratory tract infections (RTIs). These recommendations state the following:

"Multiplex viral NAAT [nucleic acid amplification tests] (potentially combined with bacterial NAAT) also make clinical sense for immunocompromised and critically ill patients with pneumonia as well as for those with exacerbations of airway disease." (p. 2748).

SARS-CoV-2, RSV, or Influenza A/B, OR Multiplex Respiratory Viral Panels with 5 or Fewer Targets

Infectious Diseases Society of America

The IDSA published clinical and diagnostic recommendations in 2020 regarding molecular testing for acute respiratory tract infections (RTIs). These recommendations state the following:

"Molecular testing for multiple respiratory viruses simultaneously may also be more cost-effective than traditional antigen- or culture-based methods from a laboratory perspective, especially given certain thresholds of disease prevalence. " (p. 2744)

Centers for Disease Control and Prevention

The CDC states the following on their website discussing RSV: "Healthcare providers should consider RSV in patients with respiratory illness, particularly during the RSV season."

The CDC states the following on their website discussing COVID-19: "Key times to get tested: if you have symptoms, test immediately."

Bacterial Respiratory Infection/Pneumonia Panels

Infectious Diseases Society of America

The IDSA published clinical and diagnostic recommendations in 2020 regarding molecular testing for acute respiratory tract infections (RTIs). These recommendations state the following:

"...bacterial NAAT may prove most useful in situations where patients have new or worsening lung infiltrates, are moderately to severely ill, have received empiric antibiotics before obtaining cultures, and/or there is concern for multidrug-resistant bacteria or a polymicrobial infection." (p. 2747)

Influenza A and B Antibody Tests

Infectious Diseases Society of America

The IDSA published clinical practice guidelines in 2018 which addressed testing criteria for seasonal influenza A and B viruses. These guidelines state that serologic testing for the diagnosis

of influenza should not be used by clinicians, because the results from a single serum specimen cannot be reliably interpreted. (p. 898)

Group A Streptococcus Pharyngitis Tests

Infectious Diseases Society of America

The IDSA published clinical practice guidelines in 2012 which addressed testing criteria for group A Streptococcal pharyngitis.

"Swabbing the throat and testing for GAS [group A Streptococcus] pharyngitis by rapid antigen detection test (RADT) and/or culture should be performed because the clinical features alone do not reliably discriminate between GAS and viral pharyngitis except when overt viral features like rhinorrhea, cough, oral ulcers, and/or hoarseness are present." (p. e87)

"Patients with GAS pharyngitis commonly present with sore throat (generally of sudden onset), pain on swallowing, and fever. Headache, nausea, vomiting, and abdominal pain may also be present, especially in children. On examination, patients have tonsillopharyngeal erythema, with or without exudates, often with tender, enlarged anterior cervical lymph nodes (lymphadenitis). Other findings may include a beefy, red, swollen uvula; petechiae on the palate; excoriated nares (especially in infants); and a scarlatiniform rash." (p. e91)

Group A Streptococcus Pharyngitis Culture

Infectious Diseases Society of America

The IDSA published clinical practice guidelines in 2012 which addressed testing criteria for group A Streptococcal pharyngitis.

"In children and adolescents, negative RADT [rapid antigen detection test] tests should be backed up by a throat culture…Routine use of back-up throat cultures for those with a negative RADT is not necessary for adults in usual circumstances, because of the low incidence of GAS [group A Streptococcus] pharyngitis in adults and because the risk of subsequent acute rheumatic fever is generally exceptionally low in adults with acute pharyngitis." (p. e87)

"Swabbing the throat and testing for GAS [group A Streptococcus] pharyngitis by rapid antigen detection test (RADT) and/or culture should be performed because the clinical features alone do not reliably discriminate between GAS and viral pharyngitis except when overt viral features like rhinorrhea, cough, oral ulcers, and/or hoarseness are present." (p. e87)

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American Academy of Family Physicians

The American Academy of Family Physicians (AAFP) published guidelines for the diagnosis and treatment of streptococcal pharyngitis. This guideline defines the age range between 3 and 14 years as a suggestive criterion for the diagnosis of Streptococcal infection compared to other ages. (p. 385)

Group A Streptococcus Antibody Tests

Infectious Diseases Society of America

The IDSA published clinical practice guidelines in 2012 which addressed testing criteria for group A Streptococcal pharyngitis.

Per these guidelines, it is not recommended that individuals undergo anti-streptococcal antibody titers for the purpose of routine diagnosis of acute pharyngitis, as these results indicate a past infection and therefore do not aid in the diagnosis of the present illness. (p. e87)

"Measurement of anti-streptococcal antibody titers is often useful for diagnosis of the nonsuppurative sequelae of GAS pharyngitis, such as acute rheumatic fever and acute glomerulonephritis. However, such testing is not useful in the diagnosis of acute pharyngitis because antibody titers of the 2 most commonly used tests, antistreptolysin O (ASO) and antiDNase B, may not reach maximum levels until 3–8 weeks after acute GAS pharyngeal infection and may remain elevated for months even without active GAS infection." (p. e93-94)

Reviews, Revisions, and Approvals	Revision Date	Approval Date
Policy developed. Reviewed by external specialist.	11/23	

REFERENCES

1. Uyeki TM, Bernstein HH, Bradley JS, et al. Clinical Practice Guidelines by the Infectious Diseases Society of America: 2018 Update on Diagnosis, Treatment, Chemoprophylaxis, and Institutional Outbreak Management of Seasonal Influenzaa. *Clin Infect Dis*. 2019;68(6):895-902. doi:10.1093/cid/ciy874

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3. Hanson KE, Azar MM, Banerjee R, et al. Molecular Testing for Acute Respiratory Tract Infections: Clinical and Diagnostic Recommendations From the IDSA's Diagnostics Committee. *Clin Infect Dis*. 2020;71(10):2744-2751. doi:10.1093/cid/ciaa508
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5. CDC. Learn more about the flu season. Centers for Disease Control and Prevention. Published September 20, 2022. https://www.cdc.gov/flu/about/season/index.html. Accessed January 4, 2024.
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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.

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Revision log

INFECTIOUS DISEASE: MULTISYSTEM TESTING

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

OVERVIEW

Some pathogens cause infections with symptoms that affect a primary body system, while others cause infections that affect multiple body systems. This policy outlines the appropriate use of tests for pathogens that can cause multisystem symptoms and/or infections. Tests for pathogens that infect multiple body systems can be targeted to detect a specific pathogen(s) or non-targeted to broadly detect nucleic acid from any potential pathogen.

Cytomegalovirus (CMV) is a common infection that does not usually cause problems in healthy individuals. However, it is of particular concern in individuals with weakened immune systems (e.g., organ transplant recipients), and can lead to signs and symptoms such as fever, sore throat, swollen glands, extreme fatigue/malaise, mononucleosis, or hepatitis, and increased risk of poor outcomes (morbidity/mortality). Additionally, infections during pregnancy can lead to infection of the fetus (congenital CMV infection). One in 5 babies with congenital CMV infection will have long term health impacts, such as hearing loss, vision impairment, or small head size (microcephaly).

Metagenomic sequencing, a newer, more generalized technique, can detect multiple organisms' genomes within a single specimen. While these new tests have potential benefits, challenges remain to be explored prior to routine clinical adoption, such as whether they can reliably discern predominantly host genomic material from a small amount of pathogen genomic material or active infection from colonization, among others.

This policy is intended for use in the outpatient setting.

POLICY REFERENCE TABLE

Coding Implications

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Criteria Sections	Example Tests (Labs)	Common CPT Codes	Common ICD Codes	Ref
Cytomegalovirus (CMV) Antibody Tests	Cytomegalovirus Antibodies (IgG, IgM) (Quest Diagnostics)	86644, 86645	P07.14, P07.3, B24, L20-L30, R17, P58, P59, Q02, R16.2, F44.5, R56.9, P90, H30.9, O28.3	1, 3, 4
Cytomegalovirus (CMV) Nucleic Acid/PCR or Antigen Detection Tests	Cytomegalovirus DNA, Qualitative Real-Time PCR, Saliva (Quest Diagnostics)	87496	P07.14, P07.3, B24, L20-L30, R17, P58, P59, Q02, R16.2, F44.5, R56.9, P90, H30.9, O28.4	1, 2, 3, 5, 7
	Cytomegalovirus (CMV), Quantitative, Plasma, PCR (Labcorp)	87497	P07.14, P07.3, B24, L20-L30, R17, P58, P59, Q02, R16.2, F44.5, R56.9, P90, H30.9, O28.5	
Untargeted Metagenomic Sequencing Tests for Pathogen Detection	Karius (Karius Inc)	0152U		6
	Johns Hopkins Metagenomic Next Generation Sequencing Assay for Infectious Disease Diagnostics (Johns Hopkins Medical Microbiology Center)	0323U		

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:

CYTOMEGALOVIRUS TESTS

Cytomegalovirus (CMV) Antibody Tests

I. Cytomegalovirus (CMV) antibody tests may be considered **medically necessary** when:

A. The member is a prospective organ transplant donor or recipient undergoing pre-transplant evaluation, **OR**

B. The member has suspected mononucleosis, **AND**

1. Had negative testing for Epstein-Barr Virus (EBV), **OR**

C. The member is pregnant, **AND**

1. Has symptoms of active CMV infection, **OR**

2. Has ultrasound findings consistent with in utero CMV infection.

II. Current evidence does not support the use of cytomegalovirus (CMV) antibody tests for all other indications.

Cytomegalovirus (CMV) Nucleic Acid/PCR or Antigen Detection Tests

I. Cytomegalovirus (CMV) nucleic acid/PCR or antigen detection tests may be considered **medically necessary** when:

A. The member is immunocompromised, OR

B. The member is 12 months of age or younger, AND

1. Is a prospective organ transplant donor or recipient undergoing pre-transplant evaluation, OR

C. The member is undergoing post-transplant monitoring, **OR**

D. The member is a newborn with very low birth weight (less than 1500 grams or 3 lbs 4.9 oz), **OR**

E. The member is a premature newborn (born before 37 weeks 0 days gestation), **OR**

F. The member is an infant with suspected congenital CMV infection (signs/symptoms of congenital CMV infection such as congenital hearing loss, documented maternal CMV infection, or ultrasound findings consistent with in utero CMV infection), **OR**

G. The member is pregnant, **AND**

1. Has ultrasound findings consistent with in utero CMV infection, **OR**

H. The member has suspected mononucleosis, **AND**

1. Had negative testing for Epstein-Barr Virus (EBV).

II. Current evidence does not support the use of cytomegalovirus (CMV) nucleic acid/PCR or antigen detection tests for all other indications.

METAGENOMIC SEQUENCING TESTS

Untargeted Metagenomic Sequencing Tests for Pathogen Detection

I. Current evidence does not support untargeted metagenomic sequencing tests for pathogen detection for all indications.

NOTES AND DEFINITIONS

1. **Congenital CMV infection** in a newborn can be characterized by features including rash, jaundice (yellowing of the skin or whites of the eyes), microcephaly (small head), low birth weight, hepatosplenomegaly (enlarged liver and spleen), seizures, and retinitis (damaged eye retina).

2. **Ultrasound findings consistent with CMV infection** may include microcephaly (smaller than normal head size), calcifications of the brain and liver, echogenic bowel, hepatosplenomegaly, various abnormalities of the brain (ventriculomegaly, intra/parenchymal cysts, abnormalities of the corpus callosum, cortical malformations), and intraventricular hemorrhages.

3. **Symptoms and signs of active CMV infection** can include fever, sore throat, swollen glands, extreme fatigue/malaise, mononucleosis, or hepatitis.

4. **Symptoms and signs of mononucleosis** can include malaise/fatigue, sweats, sore throat, anorexia, nausea, headache, chills, swollen glands, fever, or splenomegaly.

BACKGROUND AND RATIONALE

Cytomegalovirus (CMV) Antibody Tests

Centers for Disease Control and Prevention

"For most people, CMV infection is not a serious health problem. However, certain groups are at a high risk for serious complications from CMV infections:

1. Infants infected in utero (congenital CMV infection)
2. Very low birth weight and premature infants
3. People with compromised immune systems, such as from organ and bone marrow transplants, and people infected with human immunodeficiency virus (HIV)"

The Third International Consensus Guidelines on the Management of Cytomegalovirus in Solid-organ Transplantation

The following pertinent recommendations are made in the consensus guidelines:

- We recommend performing donor and recipient CMV IgG serology pretransplantation for risk stratification (strong, high).*

* In children 12 months and younger with seropositivity, nucleic acid testing may be warranted to further confirm results, as false-positives may occur due to passive antibodies transferred via breastfeeding.

American Academy of Family Physicians

"The possibility of acute CMV infection should be explored if a negative heterophile antibody test rules out EBV mononucleosis. The best diagnostic test for establishing CMV mononucleosis is serology for CMV IgM antibodies, which should be positive in the majority of patients during the symptomatic phase of the illness."

Cytomegalovirus (CMV) Nucleic Acid/PCR or Antigen Detection Tests

The Third International Consensus Guidelines on the Management of Cytomegalovirus in Solid-organ Transplantation

The following pertinent recommendations are made in the consensus guidelines:

- We recommend performing donor and recipient CMV IgG serology pretransplantation for risk stratification (strong, high).*
- We recommend using QNAT calibrated to the WHO standard for diagnosis, surveillance to guide preemptive antiviral treatment, and for therapeutic monitoring due to the ability to harmonize and standardize these tests (strong, high).
- We recommend when monitoring response to antiviral therapy, that QNAT is performed weekly (strong, moderate).

* In children 12 months and younger with seropositivity, nucleic acid testing may be warranted to further confirm results, as false-positives may occur due to passive antibodies transferred via breastfeeding.

Society for Maternal-Fetal Medicine

In the 2016 Consult Series #39, the SMFM recommended the following:

- Diagnosis of suspected primary CMV infection in pregnant women should be either by IgG seroconversion or with positive CMV IgM, positive IgG, and low IgG avidity (grade 1B)
- Amniocentesis is the best option for prenatal diagnosis of fetal congenital CMV infection and should be performed at >21 weeks of gestation and >6 weeks from maternal infection (grade 1C)
- Routine screening of all pregnant women for evidence of primary CMV infection is **NOT** recommended at this time (grade 1B) (p. B5)

Centers for Disease Control and Prevention

The CDC states that the standard laboratory test for evaluation of suspected congenital CMV infection is polymerase chain reaction (PCR) on saliva, with subsequent confirmatory testing on urine.

The CDC lists the following symptoms that may be present in about 10% of infants with congenital CMV:

- Rash
- Jaundice (yellowing of the skin or whites of the eyes)
- Microcephaly (small head)
- Low birth weight
- Intrauterine growth restriction (low weight)
- Hepatosplenomegaly (enlarged liver and spleen)

- Seizures
- Retinitis (damaged eye retina)

Additionally, they list the following long-term problems that may occur in about 40 to 60% of infants born with signs of congenital CMV disease:

- Hearing loss
- Vision loss
- Intellectual disability
- Microcephaly (small head)
- Lack of coordination or weakness
- Seizures

It is important to note that some infants with hearing loss may not be detected by newborn hearing tests.

World Health Organization

The WHO defines very low birth weight as below 1.5 kg or 1500 grams, and a preterm infant as one who was born before 37 0/7 weeks of gestation. (p. vii)

UpToDate

The UpToDate article entitled "Cytomegalovirus infection in pregnancy," includes the following list of ultrasound markers as those that are suggestive, but not diagnostic, of a fetal CMV infection:

- Periventricular calcifications
- Cerebral ventriculomegaly
- Microcephaly
- Pseudocysts, periventricular or adjacent to the occipital or temporal horn
- Hyperechogenic fetal bowel
- Fetal growth restriction
- Ascites
- Pleural and/or pericardial effusion
- Hepatosplenomegaly
- Hepatic calcifications
- Polymicrogyria
- Cerebellar hypoplasia
- Large cisterna magna
- Amniotic fluid abnormalities (oligohydramnios or polyhydramnios)
- Hydrops

- Placental thickening and enlargement, heterogeneous appearance, calcifications"

Untargeted Metagenomic Sequencing Tests for Pathogen Detection

Gu, Miller, and Chiu

In their 2019 review, Gu, Miller, and Chiu state the following: "While the emergence of these new mNGS technologies is exciting, their rapid evolution often outpaces clinical test validation and the comprehensive collection of clinical evidence. Similar to other types of clinical testing, the application of these new diagnostic testing methods should be accompanied by rigorous clinical studies that (a) demonstrate clinical utility, (b) guide usage, and (c) uncover potential areas of misinterpretation. As with any new technology, the clinical adoption of mNGS testing will take time as providers become familiar with it and new guidelines are developed." (p. 16)

There are no professional guidelines or recommendations we identified to support the use of these tests.

Reviews, Revisions, and Approvals	Revision Date	Approval Date
Policy developed. Reviewed by external specialist.	11/23	

REFERENCES

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3. Kotton, CN, Kumar D, Caliendo AM, et al. The Third International Consensus Guidelines on the Management of Cytomegalovirus in Solid-organ Transplantation. *Transplantation*. 2018;102(6):900-931. Doi:10.1097/TP.0000000000021191
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Important Reminder

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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.

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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.

INFECTIOUS DISEASE: DERMATOLOGIC TESTING

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

OVERVIEW

Fungal infection of the nails (onychomycosis) is common. Toenails are more likely than fingernails to be affected. Onychomycosis is characterized by discoloration, splitting, deformation, and brittleness of the nails and can also affect the surrounding skin. Non-fungal infections and non-infectious nail conditions, such as nail dystrophy, can mimic onychomycosis. Confirmatory testing should be performed to confirm fungal infection before initiating treatment to prevent inappropriate use of antifungal medications. Available testing methods include microscopy, culture, and molecular (PCR-based) techniques.

This policy is intended for use in the outpatient setting.

POLICY REFERENCE TABLE

Coding Implications

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Criteria Sections	Example Tests (Labs)	Common CPT Codes	Common ICD Codes	Ref
Microscopy/Peroxidase Tests for Onychomycosis	Fungus Stain (LabCorp)	87206	L60.1, L60.3, L60.9	1, 2

	KOH Prep (Pacific Medical)	87220		
Fungal Culture for Onychomycosis	Culture, Fungus, Miscellaneous (Quest Diagnostics)	87102		
	Fungus (Mycology) Culture/Dermatophyte Culture (LabCorp)	87101		
	Fungal Isolate Identification (Quest Diagnostics)	87106, 87107, 87143, 87149		
Culture-Independent Molecular Tests (NAAT/PCR) for Onychomycosis	Nail-ID (Vikor Scientific)	87641, 87481, 87500, 87652, 87653, 87798		

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:

Onychomycosis (Nail Fungus) Testing

Microscopy/Peroxidase Tests for Onychomycosis

I. Microscopy/peroxidase tests for onychomycosis may be considered **medically necessary** when:

A. The member shows signs or symptoms of onychomycosis (e.g., nails that are discolored, deformed, brittle, and/or foul-smelling; subungual debris; separation of the nail from the nail bed), **AND**

B. Results of testing would influence the member's clinical management.

II. It is the policy of health plans affiliated with Centene Corporation that current evidence does not support the use of Microscopy/Peroxidase tests for any additional indications except onychomycosis.

Fungal Culture for Onychomycosis

I. Fungal culture for onychomycosis (presumptive and/or definitive) may be considered **medically necessary** when:

A. The member shows signs or symptoms of onychomycosis (e.g., nails that are discolored, deformed, brittle, and/or foul-smelling; subungual debris; separation of the nail from the nail bed), **AND**

B. Results of testing would influence the member's clinical management.

II. It is the policy of health plans affiliated with Centene Corporation that current evidence does not support the use of fungal culture for any additional indications except onychomycosis (presumptive and/or definitive).

Culture-Independent Molecular Tests (NAAT/PCR) for Onychomycosis

I. It is the policy of health plans affiliated with Centene Corporation that current evidence does not support the use of Culture-independent molecular tests (NAAT/PCR) for onychomycosis.

BACKGROUND AND RATIONALE

Microscopy/Peroxidase Tests for Onychomycosis
British Association of Dermatologists

In their 2014 onychomycosis guidelines, the British Association of Dermatologists state the following:

"Laboratory confirmation of a clinical diagnosis of tinea unguium should be obtained before starting treatment. This is important for several reasons: to eliminate nonfungal dermatological conditions from the diagnosis; to detect mixed infections; and to diagnose patients with less responsive forms of onychomycosis, such as toenail infections due to *T. rubrum*." (p. 942)

"Traditionally, laboratory detection and identification of dermatophytes consists of culture and microscopy." (p. 942)

American Academy of Family Physicians

In their 2021 rapid evidence review of onychomycosis, the AAFP listed the common signs and symptoms of onychomycosis, including: nails that are discolored, deformed, hypertrophic, or hyperkeratotic; subungual debris; separation from the nail bed; brittle nails that break easily or crumble; and nails that are foul smelling. (p. 360)

Fungal Culture for Onychomycosis

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In their 2014 onychomycosis guidelines, the British Association of Dermatologists state the following:

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Culture-Independent Molecular Tests (NAAT/PCR) for Onychomycosis

British Association of Dermatologists

In their 2014 onychomycosis guidelines, the British Association of Dermatologists state the following:

"It appears that real-time PCR significantly increased the detection rate of dermatophytes compared with culture. However, PCR may detect nonpathogenic or dead fungus, which could limit its use in identifying the true pathogen. Restriction fragment length polymorphism analysis, which identifies fungal ribosomal DNA, is very helpful for defining whether the disease is

caused by repeat infection or another fungal strain when there is a lack of response to treatment. However, this technique has not been implemented into routine clinical practice." (p. 942)

American Academy of Family Physicians

In their 2021 rapid evidence review of onychomycosis, the AAFP states the following:

"A potassium hydroxide (KOH) preparation with direct microscopy is the preferred diagnostic method [for onychomycosis] because it is highly specific, has rapid results, and is cost-effective. Diagnosis by KOH preparation alone is sufficient for treatment initiation. However, if KOH results are negative and there is high clinical suspicion for onychomycosis, other testing may be performed to confirm the diagnosis." (p. 361)

Revision log

Reviews, Revisions, and Approvals	Revision Date	Approval Date
Policy developed. Reviewed by external specialist.	11/23	

REFERENCES

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Date of Last Revision: 10/25/2023

Revision log

INFECTIOUS DISEASE: GASTROENTEROLOGIC TESTING

OVERVIEW

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

Infections of the gastrointestinal (GI) tract represent a significant cause of infectious disease worldwide. GI infections can be caused by several pathogen types, including bacteria, viruses, fungi, and parasites (e.g., protozoal illnesses such as giardiasis). Testing methods range from culture and microscopy to immunoassays and advanced molecular diagnostic techniques; technology in this space is evolving rapidly and clinical guidelines can lag as a result. This document outlines several common types of GI pathogen tests and guideline or peer-reviewed literature-supported criteria for their appropriate applications.

Gastrointestinal infections, most commonly acute diarrheal infections, lead to many outpatient visits each year. Diagnostic workups for suspected diarrheal infections historically included culture and microscopy as standard of care, but with emerging molecular platforms capable of simultaneously evaluating many viral, bacterial, and other targets, standard of care is starting to shift, requiring thoughtful approaches to weighing the clinical benefits and limitations of different diagnostic testing strategies.

This policy outlines appropriate use of multi-pathogen panels, as well as diagnostic assays targeted at Helicobacter pylori (H. pylori) given that it is one of the most common chronic infections worldwide. Testing is indicated for individuals with certain GI symptoms, such as peptic ulcer disease, to guide antibiotic treatment and eradication. H. pylori is also linked to gastric adenocarcinoma and mucosa-associated lymphoid tissue (MALT) in a small subset of infected individuals. Robust clinical guidelines exist for diagnostic testing and treatment of H. pylori infections.

This policy is intended for use in the outpatient setting.

POLICY REFERENCE TABLE

Coding Implications

Date of Last Revision: 10/25/2023

Criteria Sections	Example Tests (Labs)	Common CPT Codes	Common ICD Codes	Ref
Syndromic Multiplex Gastrointestinal Pathogen Panels with 11 or Fewer Targets	Enteric Bacterial Panel by PCR (Cleveland Clinic Laboratories)	87505, 87506	R19.5, R19.7, A09	1, 2
	Gastrointestinal Pathogen Panel, Real-Time PCR (Quest Diagnostics)			
Syndromic Multiplex Gastrointestinal Pathogen Panels with 12 or More Targets	The BioFire® FilmArray® Gastrointestinal (GI) Panel	87507, 0369U		
	GI assay (Gastrointestinal Pathogen with ABR) (Lab Genomics LLC)			
Helicobacter pylori (H. pylori) Urea Breath or Stool Antigen Tests	Helicobacter pylori Breath Test (Mayo Clinic Laboratories)	83013	K27.9, C88.4, D50.0	3, 4
	Helicobacter pylori Stool Antigen (LabCorp)	87338		
Helicobacter pylori (H. pylori) Antibody Tests	Helicobacter pylori Antibody, IgG, Serum (University of Michigan Laboratories)	86677	K27.9, C88.4, D50.0	3

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:

Date of Last Revision: 10/25/2023

GASTROINTESTINAL PATHOGEN PANEL TESTS

Syndromic Multiplex Gastrointestinal Pathogen Panels with 11 or Fewer Targets

I. Syndromic/Multiplex Gastrointestinal Pathogen Panels with 11 or Fewer Targets may be considered **medically necessary** when:

A. The member presents in the outpatient setting with suspected infectious gastroenteritis, **AND**

1. Immunocompromised status (e.g., HIV/AIDS, immunosuppression therapy, primary immunodeficiency), **OR**
2. Recent travel to/contact with travelers from an infectious diarrheal disease-endemic area, **OR**
3. Dysentery (presence of blood or mucus in stool), **OR**
4. Fever, **OR**
5. Dehydration, **OR**
6. Abdominal pain/tenderness, **OR**
7. Bacteremia, **OR**
8. Diarrhea persisting longer than 7 days, **OR**
9. The member has symptoms of enteric fever (i.e., Typhoid/paratyphoid fever), **AND**

B. Results of the testing will influence the member's clinical management.

II. The use of Syndromic/Multiplex Gastrointestinal Pathogen Panels with 11 or Fewer Targets is considered **medically necessary** once per incident of diarrheal disease, or no more than once per 14-day period.

III. Current evidence does not support Syndromic/Multiplex Gastrointestinal Pathogen Panels with 11 or Fewer Targets for all other indications.

Date of Last Revision: 10/25/2023

Syndromic Multiplex Gastrointestinal Pathogen Panels with 12 or More Targets

I. Syndromic/Multiplex Gastrointestinal Pathogen Panels with 12 or More Targets may be considered **medically necessary** when:

   A. The member presents in the outpatient setting with suspected infectious gastroenteritis, **AND**

      1. Immunocompromised status (e.g., HIV/AIDS, immunosuppression therapy, primary immunodeficiency), **OR**

      2. Recent travel to/contact with travelers from an infectious diarrheal disease-endemic area, **OR**

      3. Bacteremia, **OR**

      4. The member has symptoms of enteric fever (i.e., Typhoid/paratyphoid fever), **AND**

   B. Results of the testing will influence the member's clinical management.

II. The use of Syndromic/Multiplex Gastrointestinal Pathogen Panels with 12 or More Targets is considered **medically necessary** once per incident of diarrheal disease, or no more than once per 14-day period.

III. Current evidence does not support Syndromic/Multiplex Gastrointestinal Pathogen Panels with 12 or More Targets for all other indications.

HELICOBACTER PYLORI (H. PYLORI) TESTS

Helicobacter pylori (H. pylori) Urea Breath or Stool Antigen Tests

I. H. pylori Urea Breath or Stool Antigen Tests may be considered **medically necessary** when:

   A. The member displays at least one of the following:

      1. Active peptic ulcer disease (PUD), **OR**

      2. Low-grade gastric mucosa-associated lymphoid tissue (MALT) lymphoma, **OR**

      3. A history of endoscopic resection of early gastric cancer (EGC), **OR**

B. The member has a past history of PUD, **AND**

1. Previous cure of H. pylori infection has **NOT** been documented, **OR**

C. The member has dyspepsia, **AND**

1. Is younger than 60 years of age, **AND**

2. Does **NOT** have dyspepsia alarm features (e.g., unintended weight loss, gastrointestinal bleeding, palpable mass or lymphadenopathy), **AND**

3. Has **NOT** undergone previous investigation for dyspepsia (i.e., has uninvestigated dyspepsia), **OR**

D. The member is initiating prophylactic low-dose aspirin (e.g., following a major cardiovascular event), **OR**

E. The member is initiating chronic treatment with a non-steroidal anti-inflammatory drug (NSAID), **OR**

F. The member has unexplained iron deficiency (ID) anemia despite an appropriate evaluation, **OR**

G. The member is an adult with idiopathic thrombocytopenic purpura (ITP).

II. Current evidence does not support H. pylori Urea Breath or Stool Antigen Tests for all other indications, including, but not limited to: for the evaluation of individuals with GERD, lymphocytic gastritis, hyperplastic gastric polyps, or hyperemesis gravidarum, asymptomatic individuals with a family history of gastric cancer, and children and adolescents with functional abdominal pain or short stature.

Helicobacter pylori (H. pylori) Antibody Tests

I. Current evidence does not support H. pylori Antibody Tests for all other indications.

NOTES AND DEFINITIONS

1. **Uninvestigated dyspepsia** refers to dyspepsia that has not already been evaluated via investigations such as upper GI endoscopy and/or is not already classified as functional/organic dyspepsia.

2. **Dyspepsia alarm features/symptoms** include vomiting, bleeding or anemia, abdominal mass or unintended weight loss, and dysphagia.

3. **Symptoms of enteric fever** include high fever, abdominal pain, constipation followed by diarrhea (sometimes bloody), rash characterized by flat "rose spots" on abdomen and chest, confusion due to fever, hepatosplenomegaly, GI bleed/perforation. Travel is also a risk factor to consider in patients presenting with fever or flu-like illness after travel or contact with a traveler from endemic areas.

4. **Gastroenteritis** is characterized by vomiting and/or diarrhea.

BACKGROUND AND RATIONALE

Syndromic/Multiplex Gastrointestinal Pathogen Panels of 11 or Fewer Targets; Syndromic/Multiplex Gastrointestinal Pathogen Panels of 12 or More Targets

American College of Gastroenterology (ACG)

ACG makes the following general recommendations in their 2016 guidelines regarding diagnostic testing for suspected diarrheal infections:

- Stool diagnostic studies may be used if available in cases of dysentery, moderate-to-severe disease, and symptoms lasting >7 days to clarify the etiology of the patient's illness and enable specific directed therapy. (Strong recommendation, very low level of evidence)

The guideline acknowledges the benefit of multiplex molecular testing for diarrheal disease, but does not provide specific guidance regarding recommended panel content.

"Diarrheal disease by definition has a broad range of potential pathogens particularly well suited for multiplex molecular testing. Several well-designed studies show that molecular testing now surpasses all other approaches for the routine diagnosis of diarrhea." (p. 606)

Regarding repeat testing for persistent symptoms, the ACG guideline states:

- Serological and clinical lab testing in individuals with persistent diarrheal symptoms (between 14 and 30 days) is not recommended. (Strong recommendation, very low level of evidence) (p. 611)

Infectious Diseases Society of America (IDSA)

In their 2017 guidelines for infectious diarrhea, the IDSA stated the following: "Although the majority of diarrheal illnesses are self-limited and identification of the infectious etiology often has little value to these individual patients, for certain infections, an organism-specific diagnosis is important to guiding clinical management. However, testing all patients with acute diarrhea for these pathogens would be inefficient… Restricting testing to patients with bloody stools, fever, or abdominal tenderness can increase the likelihood of identifying a bacterial pathogen" (p. e60)

The IDSA outlines several highly specific clinical recommendations regarding diagnostic evaluation for specific pathogens and/or testing methods based on the presentation of a patient with suspected infectious diarrhea. They also summarize many exposures or conditions and the pathogens associated with each (Table 2, p. e48).

Among these pathogen associations, no exposures or situations included are associated with more than 11 pathogens, outside of "travel to a resource-challenged country". Additionally, the guideline recommends considering a "broader set of bacterial, viral, and parasitic agents" for patients with immunocompromisation/AIDS, suspected disease outbreak (for the purposes of public health coordination), and suspected enteric fever or diarrhea with bacteremia (p. e47).

Helicobacter pylori (H. pylori) Urea Breath or Stool Antigen Tests

American College of Gastroenterology (ACG)

In their 2017 guidelines, the ACG makes the following recommendations regarding the indications for testing for and treating H. pylori infection:

- All patients with active peptic ulcer disease (PUD), a past history of PUD (unless previous cure of H. pylori infection has been documented), low-grade gastric mucosa-associated lymphoid tissue (MALT) lymphoma, or a history of endoscopic resection of early gastric cancer (EGC) should be tested for H. pylori infection (strong recommendation, quality of evidence: high for active or history of PUD, low for MALT lymphoma, low for history of endoscopic resection of EGC).
- In patients with uninvestigated dyspepsia who are under the age of 60 years and without alarm features, non-endoscopic testing for H. pylori infection is a consideration (conditional recommendation, quality of evidence: high for efficacy, low for the age threshold).
- Patients with typical symptoms of gastroesophageal reflux disease (GERD) who do not have a history of PUD need not be tested for H. pylori infection.
- In patients taking long-term low-dose aspirin, testing for H. pylori infection could be considered to reduce the risk of ulcer bleeding. Those who test positive should be offered eradication therapy (conditional recommendation, moderate quality of evidence).
- Patients initiating chronic treatment with a non-steroidal anti-inflammatory drug (NSAID) should be tested for H. pylori infection (strong recommendation, moderate quality of evidence).
- Patients with unexplained iron deficiency (ID) anemia despite an appropriate evaluation should be tested for H. pylori infection (conditional recommendation, high quality of evidence).
- Adults with idiopathic thrombocytopenic purpura (ITP) should be tested for H. pylori infection (conditional recommendation, very low quality of evidence).
- There is insufficient evidence to support routine testing and treating of H. pylori in asymptomatic individuals with a family history of gastric cancer or patients with lymphocytic gastritis, hyperplastic gastric polyps and hyperemesis gravidarum (no recommendation, very low quality of evidence). (p.213-214)

Date of Last Revision: 10/25/2023

European Society for Paediatric Gastroenterology Hepatology and Nutrition/North American Society for Pediatric Gastroenterology, Hepatology and Nutrition

The following ESPGHAN/NASPGHAN recommendations made in 2016 are pertinent to the testing of children and adolescents for H. pylori infection (see publicly available guideline for full list of recommendations):

- We recommend against diagnostic testing for H pylori infection in children with functional abdominal pain.
- We recommend against diagnostic testing for H pylori infection as part of the initial investigation in children with iron deficiency anemia.
- We suggest that noninvasive diagnostic testing for H pylori infection may be considered when investigating causes of chronic immune thrombocytopenic purpura (ITP).
- We recommend against diagnostic testing for H pylori infection when investigating causes of short stature. (p. 992)

Helicobacter pylori (H. pylori) Antibody Tests

American College of Gastroenterology (ACG)

In their 2017 guidelines, the ACG acknowledges a rare appropriate indication for H. pylori antibody testing in patients with documented PUD; however, the ideal test is one that can differentiate between active/current and past infection:

"Ideally, tests which identify active infection such as a urea breath test, fecal antigen test, or when endoscopy is performed, mucosal biopsy-based testing should be utilized." (p. 216)

Reviews, Revisions, and Approvals	Revision Date	Approval Date
Policy developed. Reviewed by external specialist.	11/23	

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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.

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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.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members/enrollees and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members/enrollees and their representatives agree to be bound by such terms and conditions by providing services to members/enrollees and/or submitting claims for payment for such services.

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.

Revision log

INFECTIOUS DISEASE: PRIMARY CARE & PREVENTATIVE SCREENING

OVERVIEW

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

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

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.

Criteria Sections	Example Tests (Labs)	Common CPT Codes	Common ICD Codes	Ref
Genotyping of High Risk Human Papillomavirus (HPV) Types	Human Papillomavirus (HPV) (Aptima®) (LabCorps)	87624	Z01.419	1, 2
	Human Papillomavirus (HPV) Genotypes 16 and 18,45 (LabCorps)	87625		
Genotyping of Low Risk Human Papillomavirus (HPV) Types	HPV Low Risk (Pacific Medical Laboratories)	87623	Z01.419	3
Hepatitis C Antibody Tests	Hepatitis C Virus (HCV) Antibody Cascade to Quantitative PCR and Genotyping (LabCorps)	86803	Z11.59	4, 5, 6
Hepatitis C Nucleic Acid/PCR Tests	Hepatitis C Viral RNA, Quantitative, Real-Time PCR (Quest Diagnostics)	87522	B18.2, B19.20, Z22.52	

Group B Streptococcus Tests in Vaginal-Rectal Specimens	Group B Streptococcus Colonization Detection Culture (LabCorps)	87081, 87150, 87653, 87149	Z34.90	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 may be considered **medically necessary** when:

A. The member was 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 is was 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. 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.

Genotyping of Low Risk Human Papillomavirus (HPV) Types

I. Current evidence does not support human papillomavirus (HPV) genotyping of low risk types.

HEPATITIS C (HCV) TESTS

Hepatitis C Antibody Screening Tests

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

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

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

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

1. The member is pregnant, **OR**

2. The member is an asymptomatic adult between the ages of 18 and 79 years, **OR**

3. The member is younger than 18 or older than 79 years of age, **AND**

a) 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, individuals with a male reproductive system who have sex with those with a male reproductive system, partners of HCV-infected individuals, organ transplant donor/recipient), **OR**

4. The member requests screening (regardless of age or disclosure of potentially stigmatizing risks).

II. 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.

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 may be considered **medically necessary** when:

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

B. The member has a suspected HCV exposure within the past 6 months (regardless of antibody status), **OR**

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

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

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

II. 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

Group B Streptococcus Screening Tests of Vaginal-Rectal Specimens

I. Group B Streptococcus Screening Tests of Vaginal-Rectal Specimens may be considered **medically necessary** when:

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

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

II. 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.

III. 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.

IV. Current evidence does not support Group B Streptococcus Screening Tests of Vaginal-Rectal Specimens for all other indications.

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 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."

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 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)

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)

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)

Reviews, Revisions, and Approvals	Revision Date	Approval Date
Policy developed. Reviewed by external specialist.	11/23	

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Important Reminder

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Revision log

INFECTIOUS DISEASE: VECTOR-BORNE AND TROPICAL DISEASES TESTING

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

OVERVIEW

Vector-borne diseases are caused by bacteria, viruses, and parasites that are transmitted by other living organisms to humans. Mosquitos, fleas, and ticks are examples of vectors. Mosquitoes can transmit diseases such as malaria or Zika virus infection, and ticks can transmit Lyme disease and ehrlichiosis, among others. Risk factors for vector-borne diseases include geographical area/climate, seasonality, quality of water supply and sanitation, and social factors influencing contact with vectors, such as travel and trade. Many vector-borne illnesses are most common in tropical or subtropical environments. This policy outlines criteria for Lyme disease and Zika virus testing via serologic and molecular methods.

This policy is intended for use in the outpatient setting.

POLICY REFERENCE TABLE

Coding Implications

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Criteria Sections	Example Tests (Labs)	Common CPT Codes	Common ICD Codes	Ref

Lyme Disease Serum Antibody Tests (Borrelia burgdorferi)	Lyme Disease Ab with Reflex to Blot (IgG, IgM) (Quest Diagnostics)	86618, 86617	A69.2-A69.29, A69.23, F01-F99, G04.2, G03-G05.9, G60-G65.2, G12.21, G35, G20, I40.0-I40.9, I42, I30.0-I30.9, M79.1-M79.18, M25.40-M25.48, M79.2, M47.2, M54-M54.9, M25.40-M25.48, M25.5-M25.69, R41-R41, R21, R53.8-R53.83, W57.XXXA	1
Lyme Disease NAAT/PCR Tests (Borrelia burgdorferi)	Lyme Disease, Borrelia burgdorferi, Real-time PCR (LabCorps)	87476		
Other Non-covered Lyme Disease Tests	Lymphocyte Antigen Proliferation (ARUP Laboratories)	86353		
	Lyme Borrelia Nanotrap Urine Antigen Test (Galaxy Diagnostics)	0316U		
	Lyme ImmunoBlots IgG (IGeneX Inc.)	0042U		
	Lyme ImmunoBlot IgM (IGeneX Inc.)	0041U		
Zika Virus Nucleic Acid/PCR Tests	Zika Virus, PCR, Molecular Detection, Serum (Mayo Clinic Laboratories)	87662	Z33-Z33.3, Z34 range, Z3A.0-Z3A.49, Z36-Z36.9, O, Z20.821, O28.0-O28.9, P35.4, Q02, Q75.8-Q75.9, Q04.0-Q04.9, Q07.8-Q07.9, G96.198, G93.89,	2, 3
Zika Virus Antibody Tests	Zika Virus, IgM Antibody Capture ELISA, Serum (Mayo Clinic Laboratories)	86794		

			Q66.89, Q74.3, H35.54, H31.0-H31.9, P94.1	

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:

LYME DISEASE TESTS

Lyme Disease Serum Antibody Tests (*Borrelia burgdorferi*)

I. Lyme disease serum antibody testing (86617, 86618) may be considered **medically necessary** when:

   A. The member had a plausible exposure to *Borrelia burgdorferi*, **AND**

   B. The member has at least one of the following:

      1. Skin lesion(s) suggestive of, but atypical for erythema migrans, **OR**
      2. Suspected Lyme neuroborreliosis involving either the peripheral or central nervous system, **OR**
      3. Suspected Lyme arthritis, **OR**
      4. Acute myocarditis/pericarditis.

II. Current evidence does not support the use of Lyme disease serum antibody testing for all other indications, including, but not limited to:

   A. Asymptomatic patients following tick bite, **OR**

   B. Erythema migrans, **OR**

   C. Typical amyotrophic lateral sclerosis, **OR**

   D. Relapsing-remitting multiple sclerosis, **OR**

   E. Parkinson's disease, **OR**

F. Dementia/cognitive decline, **OR**

G. New-onset seizures, **OR**

H. Nonspecific magnetic resonance imaging (MRI) white matter abnormalities confined to the brain, **OR**

I. Psychiatric illness, **OR**

J. Children presenting with developmental or behavioral disorders, **OR**

K. Chronic cardiomyopathy of unknown cause.

Lyme Disease NAAT/PCR Tests (*Borrelia burgdorferi*)

I. Lyme disease NAAT/PCR testing may be considered **medically necessary** when:

A. The member is seropositive for Lyme disease, **AND**

B. The member has suspected Lyme arthritis, **AND**

C. This testing is necessary for making treatment decisions.

II. Current evidence does not support Lyme disease NAAT/PCR testing for all other indications, including for the purpose of diagnosing Lyme disease.

Other Non-covered Lyme Disease Tests

I. It is the policy of health plans affiliated with Centene Corporation that current evidence does not support the use of the following specific Lyme disease tests:

A. Lymphocyte transformation tests

B. Lyme Borrelia Nanotrap Urine Antigen Test

C. Lyme ImmunoBlots IgG

D. Lyme ImmunoBlot IgM

ZIKA TESTS

Zika Virus Nucleic Acid/PCR Tests

I. Zika virus nucleic acid/PCR tests may be considered **medically necessary** when:

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

1. Had a plausible exposure to Zika virus (e.g., traveled to or lives in an area with transmission or sexual relations with someone who traveled to or lives in an area with transmission), **OR**

B. +The member is 12 months of age or younger, **AND**

1. The member's mother had laboratory evidence of Zika virus infection during pregnancy, **OR**

2. Has symptoms of congenital Zika virus infection, **AND**

a) The member's mother had a plausible exposure to Zika virus (regardless of mother's Zika virus test results).

II. Current evidence does not support Zika virus nucleic acid/PCR tests for all other indications, including, but not limited to:

A. Symptomatic, non-pregnant members, **OR**

B. Routine pre-conception or prenatal screening.

Zika Virus Antibody Tests

I. Zika virus antibody tests may be considered **medically necessary** when:

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

1. Prenatal ultrasound findings are consistent with congenital Zika virus infection (e.g., microcephaly, ventriculomegaly, or abnormalities of the corpus callosum), **AND**

2. Had a plausible exposure to Zika virus (e.g., traveled to or lives in an area with transmission or had sexual relations with someone who traveled to or lives in an area with transmission), **OR**

B. The member is 12 months of age or younger, **AND**

1. The member's mother had laboratory evidence of Zika virus infection during pregnancy, **OR**
2. Has symptoms of congenital Zika virus infection, **AND**
    a) The member's mother had a plausible exposure to Zika virus.

II. Current evidence does not support Zika virus antibody tests for all other indications, including, but not limited to:

A. Symptomatic* or asymptomatic pregnant members, **OR**

B. Symptomatic*, non-pregnant members, **OR**

C. Routine pre-conception or prenatal screening.

*Personal symptoms of Zika virus infection such as fever and conjunctivitis.

NOTES AND DEFINITIONS

1. **Lyme neuroborreliosis** is characterized by cranial or peripheral nerve involvement (facial palsy, radiculoneuropathy), or central nervous system involvement (meningitis/encephalitis).
2. **Lyme arthritis** is characterized by obvious swelling of one or more joints and joint pain with movement.
3. **Congenital Zika virus infection** is a syndrome characterized by a combination of severe microcephaly, sometimes with malformation of the craniofacial bones/skull; decreased brain tissue with a specific pattern of brain damage, including subcortical calcifications; damage to the back of the eye, including macular scarring and focal retinal pigmentary mottling; congenital contractures, such as clubfoot or arthrogryposis; and hypertonia/stiff or rigid posture with restricted movement.

BACKGROUND AND RATIONALE

Lyme Disease Testing (Borrelia burgdorferi)

Infectious Diseases Society of America (IDSA), American Academy of Neurology (AAN), and American College of Rheumatology (ACR)

In the 2020 Guidelines for the Prevention, Diagnosis and Treatment of Lyme Disease, the joint societies make the following recommendations regarding diagnostic testing for Lyme disease. (p. e2-e5)

- Recommend **against** testing in:
    - Asymptomatic patients for exposure to *B. burgdorferi* following an Ixodes spp. tick bite (strong recommendation, moderate-quality evidence),
    - Patients with potential tick exposure in a Lyme disease endemic area who have 1 or more skin lesions compatible with erythema migrans; we recommend clinical diagnosis rather than laboratory testing (strong recommendation, moderate quality evidence).
    - [X.2] Patients with typical amyotrophic lateral sclerosis, relapsing-remitting multiple sclerosis, Parkinson's disease, dementia or cognitive decline, or new-onset seizures (strong recommendation, low-quality evidence).
    - Patients presenting with nonspecific magnetic resonance imaging (MRI) white matter abnormalities confined to the brain in the absence of a history of other clinical or epidemiologic support for the diagnosis of Lyme disease (weak recommendation, low-quality evidence).
    - Patients with psychiatric illness (strong recommendation, low-quality evidence)
    - Children presenting with developmental, behavioral or psychiatric disorders (weak recommendation, low-quality evidence).
    - Patients with neurological syndromes other than those listed in recommendation X.1 or X.2 , in the absence of a history of other clinical or epidemiologic support for the diagnosis of Lyme disease (strong recommendation, low-quality evidence).
    - Patients with chronic cardiomyopathy of unknown cause (weak recommendation, low-quality evidence).

- Recommend **serum antibody** testing in:
    - Patients with 1 or more skin lesions suggestive of, but atypical for erythema migrans (weak recommendation, low-quality evidence).
    - Patients with possible Lyme neuroborreliosis involving either the peripheral nervous system (PNS) or central nervous system (CNS).
        - [X.1] Patients presenting with 1 or more of the following acute disorders: meningitis, painful radiculoneuritis, mononeuropathy multiplex including confluent mononeuropathy multiplex, acute cranial neuropathies (particularly VII, VIII, less commonly III, V, VI and others), or in patients with evidence of spinal cord (or rarely brain) inflammation, the former particularly in association with painful radiculitis involving related spinal cord segments, and with epidemiologically plausible exposure to ticks infected with *B burgdorferi* (strong recommendation, moderate-quality evidence).
    - Patients with possible Lyme arthritis (strong recommendation, moderate quality of evidence).

- Patients with acute myocarditis/pericarditis of unknown cause in an appropriate epidemiologic setting, we recommend testing for Lyme disease (strong recommendation, low quality evidence).

Lyme Disease PCR Testing (*Borrelia burgdorferi*)

Infectious Diseases Society of America (IDSA), American Academy of Neurology (AAN), and American College of Rheumatology (ACR)

In the 2020 Guidelines for the Prevention, Diagnosis and Treatment of Lyme Disease, the joint societies recommend serum antibody testing over PCR or culture methods in most clinical scenarios (V.1, IX.1, p. e2-e5).

"…numerous nonserologic methods have been proposed or developed, including nucleic acid amplification tests, culture methods, and antigen detection assays, among others. At present, few nonserologic testing methods are useful or practical for clinical diagnosis, and those that are—primarily nucleic acid amplification tests—are mostly
beneficial as adjunctive tests in select clinical scenarios when 2-tiered serologic testing is positive."

The joint societies only explicitly recommend PCR testing for Lyme disease in one clinical scenario:

"In seropositive patients for whom the diagnosis of Lyme arthritis is being considered but treatment decisions require more definitive information, we recommend PCR applied to synovial fluid or tissue rather than Borrelia culture of those samples (strong recommendation, moderate-quality evidence)." (p. e5)

Other Non-covered Lyme Disease Tests

Infectious Diseases Society of America (IDSA), American Academy of Neurology (AAN), and American College of Rheumatology (ACR)

"Some commercially available laboratory testing methods, including nonstandard serology interpretation, urine antigen, DNA testing, the use of a lymphocyte transformation test, or quantitative CD57 lymphocyte assay should be avoided for clinical use due to lack of systematic, independent, reproducible validation studies." (p. e10)

Zika Virus NAAT/PCR Tests

Centers for Disease Control and Prevention (CDC)

- For asymptomatic pregnant persons living in or with recent travel to the U.S. and its territories, routine Zika virus testing is NOT currently recommended.
- For asymptomatic pregnant women with recent travel to an area with risk of Zika outside the U.S. and its territories, Zika virus testing of any kind is NOT routinely recommended; if testing is performed, it can be performed via NAAT up to 12 weeks after travel.
- Healthcare providers should test pregnant women with symptoms of Zika (e.g., fever, rash, headache, arthralgia, conjunctivitis, and muscle pain) if they may have been exposed to Zika through sex without a condom with a person who lives in or traveled to an area with risk of Zika.
- Zika virus NAAT should be performed on maternal serum and urine for pregnant women who have a fetus with prenatal ultrasound findings consistent with congenital Zika virus infection who live in or traveled to areas with a risk of Zika during pregnancy.
- Zika virus testing should NOT be performed as part of preconception screening.
- Zika testing is NOT currently recommended for symptomatic non-pregnant patients based on the current epidemiology of these viruses.

"Laboratory testing for congenital Zika virus infection is recommended for infants born to mothers with laboratory evidence of Zika virus infection during pregnancy, and for infants who have abnormal clinical findings suggestive of congenital Zika virus syndrome and a maternal epidemiologic link suggesting possible transmission, regardless of maternal Zika virus test results."

Zika Virus Antibody Tests

Centers for Disease Control and Prevention (CDC)

- Zika virus serologic testing is NOT recommended for symptomatic or asymptomatic pregnant women.
- Zika virus IgM testing should be performed on maternal serum for pregnant women who have a fetus with prenatal ultrasound findings consistent with congenital Zika virus infection who live in or traveled to areas with a risk of Zika during pregnancy or had potential sexual exposure to a partner who lives in or traveled to an area with risk of Zika.
- Zika virus testing should NOT be performed as part of preconception screening.
- Zika testing is NOT currently recommended for symptomatic non-pregnant patients based on the current epidemiology of these viruses.

"Laboratory testing for congenital Zika virus infection is recommended for infants born to mothers with laboratory evidence of Zika virus infection during pregnancy, and for infants who have abnormal clinical findings suggestive of congenital Zika virus syndrome and a maternal epidemiologic link suggesting possible transmission, regardless of maternal Zika virus test results."

Reviews, Revisions, and Approvals	Revision Date	Approval Date
Policy developed. External specialist reviewed.	11/23	

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1. Lantos PM, Rumbaugh J, Bockenstedt LK, Falck-Ytter YT, Aguero-Rosenfeld ME, Auwaerter PG, Baldwin K, Bannuru RR, Belani KK, Bowie WR, Branda JA, Clifford DB, DiMario FJ Jr, Halperin JJ, Krause PJ, Lavergne V, Liang MH, Meissner HC, Nigrovic LE, Nocton JJJ, Osani MC, Pruitt AA, Rips J, Rosenfeld LE, Savoy ML, Sood SK, Steere AC, Strle F, Sundel R, Tsao J, Vaysbrot EE, Wormser GP, Zemel LS. Clinical Practice Guidelines by the Infectious Diseases Society of America, American Academy of Neurology, and American College of Rheumatology: 2020 Guidelines for the Prevention, Diagnosis, and Treatment of Lyme Disease. Neurology. 2021 Feb 9;96(6):262-273. doi: 10.1212/WNL.0000000000011151. Epub 2020 Nov 30. Erratum in: Neurology. 2021 Feb 9;96(6):296. PMID: 33257476.
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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.

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Revision log

INFECTIOUS DISEASE: GENITOURINARY TESTING

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

OVERVIEW

Genitourinary diseases are common ailments that affect all age ranges. Urinary tract infections are caused by microorganisms that enter the urethra from the surrounding skin which can be contaminated by vaginal pathogens, fecal remnants, or mechanically introduced (e.g., during urinary catheter insertion or sexual intercourse, or less commonly, arrive to the kidney via its blood flow from infection at a different site). Pathogens can infect the lower urinary tract, causing inflammation and painful urination, or the upper urinary tract, leading to complications such as kidney infection.

Vaginitis is inflammation specifically affecting the vagina. Bacterial vaginosis (BV) is a major cause of vaginitis along with yeast infections and infection with the protozoa *Trichomonas vaginalis*. Vaginitis, particularly when observed with cervicitis, can indicate chlamydia or gonorrhea infection. The cause of vaginitis cannot be determined based on symptoms alone. Additionally, coinfection with more than one organism is not uncommon. Untreated or improperly treated infectious vaginitis can lead to poor health outcomes and increased need for follow-up visits.

Testing urine and genital secretions may enable providers to choose precise therapy and afford the patient a better outcome. Cultures, microscopic examination and molecular identification are all common testing methods for evaluating the infectious causes of various genitourinary conditions.

This policy is intended for use in the outpatient setting.

POLICY REFERENCE TABLE

Coding Implications

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Criteria Sections	Example Tests (Labs)	Common CPT Codes	Common ICD Codes	Ref
Targeted Vaginitis/Vaginosis Pathogen Testing	SureSwab Advanced Bacterial Vaginosis (BV), TMA (Kit by Hologic, Inc.; billing lab varies)	81513	L29.2, L29.3, N76.0, N76.1, N76.2, N76.3, N76.8, N76.89, N93.0, N94.1, R30.0, N89.8, Z34	1, 2, 3, 4
	Vaginosis/Vaginitis (BV, Candida, Trich) by PCR (Kit by Becton Dickinson and Company; billing lab varies)	81514		
	Bacterial Vaginosis/Vaginitis Panel (Quest Diagnostic Laboratory)	87480, 87510, 87660		
	Vaginitis (VG), NuSwab (Mayo Clinic Laboratories)	87801, 87798, 87661		
	Vaginitis Plus (VG+) With Candida (Six Species), NuSwab (LabCorp)	87491, 87591, 87661, 87798, 87801		
	SureSwab Advanced Vaginitis Plus, TMA (Quest)	81513, 87481, 87661, 87491, 87591		
	Xpert® Xpress MVP (Cepheid)	0352U		
Expanded Multiplex Vaginitis/Vaginosis Pathogen Panels	Bridge Women's Health Infectious Disease Detection Test (Bridge Diagnostics)	0330U		1, 2, 3, 4
Urine Culture for Asymptomatic Bacteriuria	Urine Culture, Routine (LabCorp)	87086, 87088	Z33-Z33.3, Z34, Z3A.0-Z3A.49, Z36-Z36.9, Z01.81, Z01.818,	5

			Z01.82, Z01.89, 52601, 52648, 52356, 52353, 50080, 50081, 52214, 52601, 52647, 52649, 53850, 53852, 53854, 55705, 55706	
Molecular/Multiplex UTI Panels	Bridge Urinary Tract Infection Detection and Resistance Test (Bridge Diagnostics)	0321U		5, 6
	Qlear UTI (Lifescan Labs of Illinois, Thermo Fisher Scientific)	0371U		
	Qlear UTI – Reflex ABR (Lifescan Labs of Illinois, Thermo Fisher Scientific)	0372U		
	Urogenital Pathogen with Rx Panel (UPX) (Lab Genomics LLC, Thermo Fisher Scientific)	0374U		
	GENETWORx UTI with ABR (RCA Laboratory Services LLC)	0416U		

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:

Targeted Vaginitis/Vaginosis Pathogen Testing

I. Targeted vaginitis/vaginosis pathogen testing via direct probe for *Gardnerella vaginalis*, *Candida albicans*, and/or *Trichomonas vaginalis*, OR nucleic acid/PCR tests for bacterial vaginosis, candidiasis, and/or trichomoniasis, OR multipathogen panel of 6 targets or fewer, with or without chlamydia and/or gonorrhea, may be considered **medically necessary** when:

   A. The member has at least one of the following:

      1. Abnormal vaginal discharge, **OR**
      2. Vulvovaginal itching, irritation, or redness (e.g., pruritus, erythema, edema), **OR**
      3. Painful sexual intercourse (dyspareunia), **OR**
      4. Painful urination (dysuria), **OR**
      5. Postcoital or contact bleeding.

II. Current evidence does not support the use of targeted vaginitis/vaginosis pathogen testing via direct probe for *Gardnerella vaginalis*, *Candida albicans*, and/or *Trichomonas vaginalis*, OR nucleic acid/PCR tests for bacterial vaginosis, candidiasis, and/or trichomoniasis, OR multipathogen panel of 6 targets or fewer, with or without chlamydia and/or gonorrhea for all other indications, including:

   A. Asymptomatic pregnant members (regardless of preterm labor risk).

Expanded Multiplex Vaginitis/Vaginosis Pathogen Panels

I. Current evidence does not support the use of expanded multiplex vaginitis/vaginosis pathogen panels with more than 6 targets.

Urinary Tract and Kidney Infections

Urine Culture for Asymptomatic Bacteriuria

I. Urine culture for asymptomatic bacteriuria may be considered **medically necessary** when:

   A. The member is pregnant, **OR**

   B. The member will undergo an endoscopic urologic procedure with mucosal trauma.

II. Current evidence does not support the use of urine culture for asymptomatic bacteriuria for all other indications.

Molecular/Multiplex UTI Panels

I. Current evidence does not support the use of molecular/multiplex UTI Panels.

NOTES AND DEFINITIONS

1. **Endoscopic urologic procedure with mucosal trauma**: examples of such procedures include, but are not limited to: transurethral surgery of the prostate or bladder, ureteroscopy including lithotripsy, and percutaneous stone surgery.

BACKGROUND AND RATIONALE

Targeted Vaginitis/Vaginosis Pathogen Testing

Up To Date

"Ideally, the abnormal vaginal discharge is tested for evidence of BV, Candida species, and trichomonas when the patient is symptomatic… The traditional gold standard tests have been culture (for candida species and trichomoniasis) and microscopy with Nugent score, followed by Amsel criteria for indeterminate tests, for BV. However, NAATs have become an established alternative to both as NAATs have similar or better test sensitivity and specificity… NAATs can be used as the initial diagnostic tool or as a follow-up to negative microscopy in patients with high clinical suspicion" (see algorithm 1 for additional details).

American College of Obstetricians and Gynecologists (ACOG)

In ACOG Practice Bulletin #215 which discusses vaginitis in nonpregnant patients, Table 1 delineates the symptoms and clinical findings associated with the various causes of vaginitis: abnormal textured/colored/malodorous vaginal discharge; pruritus, irritation, dysuria, burning, dyspareunia; vaginal or cervical-vaginal erythema with petechiae; edema, excoriations, and fissures. (p. e4) The guidelines also state that "...symptomatic patients with trichomoniasis may report…postcoital bleeding." (p. e2)

"Nucleic acid amplification testing is recommended for the diagnosis of trichomoniasis." (p. e11)

Kong et al.

"This study tracks health care spending among women diagnosed with vaginitis and finds that nucleic acid amplification tests (NAATs) are cost-effective for the diagnosis of vaginal symptoms. Women who receive a NAAT on the day of their diagnosis have significantly lower

12-month follow-up costs compared to women who receive a direct probe test or those women who are clinically evaluated without the use of a molecular test." (p. 515)

United States Preventive Services Task Force

The USPSTF published guidelines in 2020 discussing bacterial vaginosis (BV) screening in pregnant individuals. The guidelines recommend against screening for BV in pregnant patients who are not at increased risk for preterm labor. These guidelines also state that there is insufficient evidence to conclusively determine if BV screening for pregnant patients at increased risk for preterm labor is beneficial.

Expanded Multiplex Vaginitis/Vaginosis Pathogen Panels

There are no professional guidelines or recommendations we identified to support the use of these tests. The following guidelines and publications were reviewed in-depth in September 2023: United States Preventive Services Task Force, UpToDate, American College of Obstetricians and Gynecologists, Kong et al.

Urine Culture for Asymptomatic Bacteriuria

Infectious Diseases Society of America

The IDSA published an updated guideline in 2019 with clinical practice recommendations for the management of asymptomatic bacteriuria (ASB). The guidelines recommend screening for ASB in pregnant individuals (p. e85), and in individuals who are undergoing endoscopic urologic procedures associated with mucosal trauma (p. e86).

The guidelines recommend against screening for ASB, or make no recommendations for or against screening for ASB, in most other individuals, including:

- Infants and children
- Health nonpregnant people
- Functionally impaired older adults
- Older residents of long-term care facilities
- Recipients of a solid organ transplant (including kidney)
- Individuals with neutropenia
- Individuals with impaired voiding following a spinal cord injury
- Individuals with an indwelling urethral catheter
- Individuals undergoing elective nonurologic surgery
- Individuals with a urologic implant, or who are undergoing surgical implantation of a urologic device (p. e85 and e86)

Molecular/Multiplex UTI Panels

There are no professional guidelines or recommendations we identified to support the use of these tests. The following guidelines and publications were reviewed in-depth in September 2023: Infectious Disease Society of America, ACOG.

Reviews, Revisions, and Approvals	Revision Date	Approval Date
Policy developed. Reviewed by external specialist.	11/23	

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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.

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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.