Provider Partners Health Plans

**Medical Coverage Policy**

Effective Date 01/30/2024
Next Review Date 01/30/2025
Policy Number: 26C.003

# Urine PCR Testing

## Overview

This Coverage Policy addresses Urine PCR Testing in the diagnosis of infectious conditions for Provider Partners Health Plans' members. This test detects the genetic material of pathogens (e.g., bacteria, viruses) in urine samples using polymerase chain reaction (PCR) technology.

## Instructions for Use

Medical Coverage Policies are reviewed by the Provider Partners Utilization Management Committee (UMC) and provide assistance in interpreting Provider Partners benefit plans. Our medical policies are intended to be used in connection with the independent professional medical judgement of a qualified health care provider. Provider Partners may also use various National and Local Coverage guidelines, Local Coverage Articles as well as the tools developed by third parties, such as the InterQual® criteria, as well as the PPHP specific policies, to assist us in administering health benefits.

## Description

Polymerase Chain Reaction (PCR) is a molecular diagnostic technique that amplifies specific DNA or RNA sequences to detect the presence of pathogens in a urine sample. Urine PCR testing is particularly useful in detecting infections caused by pathogens that are difficult to identify through culture or standard urinalysis when bacteria that may not be able to be grown on typical agar.

## Application

This Medical Policy applies to all Provider Partners Health Plans.

## Criteria/Coverage Rationale

The following four criteria are necessary for urine PCR testing to occur:

1. PCR testing is approved based on the presence of appropriate clinical orders from providers (PCP, NP, specialist) AND
2. The request must specify PCR or molecular testing AND
3. The patient is symptomatic AND
4. There must be documented medical necessity that supports the testing.

***Medical Necessity Criteria:***

- Refractory UTI – failed standard therapy
- Immunocompromised patient

- Questionable result from standard testing
- Complicated UTI, such as male, fever, foreign body, stone, obstruction
- Need for more prompt treatment due to risk.
- Interstitial cystitis or pelvic (gyn) disease
- Consideration for divergence from standard treatment course

**PCR Panel Testing IS NOT medically necessary in the following circumstances**:

- f/u testing for cure
- prior PCR testing within 14 days for the same pathogens
- used across the board i.e. standing orders.

## Clinical Evidence/Background

Urine PCR is a laboratory test promoted to healthcare professionals working in long-term care facilities (LTCFs) as a rapid diagnostic platform for urinary tract infection (UTI). Interactions with personnel implementing antimicrobial stewardship (AS) in LTCF prompted inquiries regarding the place of urine PCR testing within the context of AS. Rapid diagnostics can facilitate stewardship through timely identification of an infective organism, but this typically occurs when antimicrobial stewards optimize their utilization.

**Polymerase Chain Reaction (PCR) testing can detect bacteria that may not be able to be grown on typical agar. These tests are potentially available within 24 hours compared to several days with traditional culture results**.

PCR tests have been shown to detect bacteria in 1/3 of symptomatic patients in which standard cultures have been negative. However, **it has not been demonstrated that treating organisms detected in this manner yields superior results or symptom resolution**. Outcome studies with the use of PCR panels is very limited with most data only available from vendors and suppliers, not independent entities.

Because PCR testing detects microbial nucleic acid and not live organisms, **positive results do not necessarily infer current active infection.** This can be a big deal in the NH population in which even colonizing live organisms routinely lead to excess treatment. This tool has the potential to further expand this problem.

**Culture-based methods of diagnosis remain the standard of care.**

For respiratory infections, PCR testing has become standard of care. Not so for urinary tract settings. For the evaluation of UTI, multiplex PCR panels have shown agreement of 90% with standard urine cultures for the ID of pathologic organisms.

## Definitions

- **PCR testing-** Polymerase Chain Reaction (PCR) testing can detect bacteria that may not be able to be grown on typical agar. These tests are potentially available within 24 hours compared to several days with traditional culture results.
- **Urinary Tract Infection (UTI)**: An infection that affects any part of the urinary system, including the kidneys, bladder, ureters, and urethra.
- **Resistance Testing**: Testing used to identify the presence of pathogens resistant to standard treatments, which may guide therapy.

## Medicare Coverage Determinations

CMS has defined PCR coverage directives (NCDs) for many types of infections i.e. respiratory, bone & joint, meningeal, gyn, & others. **CMS has NOT developed NCDs for UTIs.**
LCDs for UTI were developed in June 2022 but **only about half of the Medicare administrative contractors (MACs) have adopted associated LCDs for UTIs**. Thus, the rules are different in those states with and those without LCDs.
In the absence of a NCD or applicable LCD, the MACs shall consider an item or service to be reasonable and necessary if the service meets a list of key criteria. For our purposes, the key parameters of those criteria are:
**Covered**:

- Ordered by a qualified health care profession (MD/DO, NP, PA)
- When there is a clear indication for PCR testing based on the criteria outlined above.
- In cases where molecular testing can provide more accurate, timely, or clinically relevant information for diagnosis and treatment.

**Not Covered**:

- Routine screening without symptoms or risk factors.
- Testing where alternative, less invasive or lower-cost diagnostic methods are available and clinically appropriate.
- When PCR is performed without clinical indication or based solely on patient request without a diagnostic rationale.

| Coverage Type | Jurisdiction Medicare Administrative Contractors (MACs) | Determination Name/Number | Revision Effective Date | Applicable States/Territories |
|---|---|---|---|---|

| | | | | |
|---|---|---|---|---|
| NCD | N/A | Not Developed | N/A | N/A |
| LCD | Noridian Healthcare Solutions, LLC | MolDX: Molecular Syndromic Panels for Infectious Disease Pathogen Identification Testing (L39001) | 06/02/2022 | CA, HI, NE |
| | Wisconsin Physicians Service Insurance Corporation | MolDX: Molecular Syndromic Panels for Infectious Disease Pathogen Identification Testing (L39044) | 06/09/2022 | AL, AK, AR, AK, CA, CO, CT, DE, FL, GA, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MO, MS, NE, ND, NH, NJ, NM, NC, NV, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VT, VA, WAS, WV,WI, WY |

Note: Please review the current Medicare Policy for the most up-to-date information.
(NCD= National Coverage Determinations; LCD = Local Coverage Determination

## Coding

| Codes | Number | Description |
|---|---|---|
| **CPT** | **81513** | Infectious disease, bacterial vaginosis, quantitative real-time amplification of RNA markers for Atopobium vaginae, Gardnerella vaginalis, and Lactobacillus species, utilizing vaginal-fluid specimens, algorithm reported as a positive or negative result for bacterial vaginosis |
| | **87077** | Culture, bacterial; aerobic isolate, additional methods required for definitive identification, each isolate |
| | **87140** | Culture, typing; immunofluorescent method, each antiserum |
| | **87143** | Culture, typing; gas liquid chromatography (GLC) or high-pressure liquid chromatography (HPLC) method |
| | **87147** | Culture, typing; immunologic method, other than immunofluorescence (e.g., agglutination grouping), per antiserum |
| | **87149** | Culture, typing; identification by nucleic acid (DNA or RNA) probe, direct probe technique, per culture or isolate, each organism probed |
| | **87506** | Infectious agent detection by nucleic acid (DNA or RNA); gastrointestinal pathogen (eg, Clostridium difficile, E. coli, Salmonella, Shigella, |

| Codes | Number | Description |
|---|---|---|
| | | norovirus, Giardia), includes multiplex reverse transcription, when performed, and multiplex amplified probe technique, multiple types, or subtypes, 6-11 targets |
| | **87631** | Infectious agent detection by nucleic acid (DNA or RNA); respiratory virus (eg, adenovirus, influenza virus, coronavirus, metapneumovirus, parainfluenza virus, respiratory syncytial virus, rhinovirus), includes multiplex reverse transcription, when performed, and multiplex amplified probe technique, multiple types, or subtypes, 3-5 targets |
| | **87632** | Infectious agent detection by nucleic acid (DNA or RNA); respiratory virus (eg, adenovirus, influenza virus, coronavirus, metapneumovirus, parainfluenza virus, respiratory syncytial virus, rhinovirus), includes multiplex reverse transcription, when performed, and multiplex amplified probe technique, multiple types, or subtypes, 6-11 targets |
| | **87633** | Infectious agent detection by nucleic acid (DNA or RNA); respiratory virus (e.g., adenovirus, influenza virus, coronavirus, metapneumovirus, parainfluenza virus, respiratory syncytial virus, rhinovirus), includes multiplex reverse transcription, when performed, and multiplex amplified probe technique, multiple types, or subtypes, 12-25 targets |
| | **87636** | Infectious agent detection by nucleic acid (DNA or RNA); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) and influenza virus types A and B, multiplex amplified probe technique |
| | **87798** | Infectious agent detection by nucleic acid (DNA or RNA), not otherwise specified; amplified probe technique, each organism |
| | **87801** | Infectious agent detection by nucleic acid (DNA or RNA), multiple organisms; amplified probe(s) technique |
| | | |
| **HCPCs** | **0241U** | Infectious disease (viral respiratory tract infection), pathogen-specific RNA, 4 targets (severe acute respiratory syndrome coronavirus 2 [SARS-CoV-2], influenza A, influenza B, respiratory syncytial virus [RSV]), upper respiratory specimen, each pathogen reported as detected or not detected |

## References

1. Daly A, Baunoch D, Rehling K, et al. Utilization of M-PCR and P-AST for diagnosis and management of urinary tract infections in home-based primary care. JOJ Urol Nephrol. 2020;7(2).

2. National Institute for Health and Care Excellence's guideline on "Urinary tract infections in adults" 2015; Accessed 6/24/24 at https://www.nice.org.uk/guidance/qs90/resources/urinary-tract-infections-in-adults-pdf-2098962322117
3. Vollstedt A, Baunoch D, Wolfe A, et al. Bacterial interactions as detected by pooled antibiotic susceptibility testing (P-AST) in polymicrobial urine specimens. J Surg Urol. 2020:1(1):1-10.
4. Werneburg GT. Editorial comment. Urology. 2020; 136:125-126.
5. Wojno KJ, Baunoch D, Luke N, et al. Multiplex PCR based urinary tract infection (UTI) analysis compared to traditional urine culture in identifying significant pathogens in symptomatic patients. Urology. 2020; 136:119-126.
6. Zering J, Stohs E. Urine polymerase chain reaction tests: stewardship helper or hinderance? Antimicrobial Stewardship & Healthcare Epidemiology (2024), 4, e77, 1–3. Accessed 6/24/24 doi:10.1017/ash.2024.71

## Policy History/Revision Information

| Date | Summary of Changes |
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