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August 26, 2021

Lewis G. Sandy, MD, FACP Executive Vice President, Clinical Advancement UnitedHealth Group 9900 Bren Road East Minnetonka, MN 55343

RE: Urine PCR Coverage Policy

Dr. Sandy:

The American Association of Clinical Urologists (AACU) is a leading professional organization for the specialty of urology. As such, we support the highest standards of urological clinical care through education, research, and the formulation of healthcare policy.

Urinary tract infections (UTIs) are among the most common of all bacterial infections. They account for 10.5 million office visits and 3 million emergency department visits annually in the United States. What's more, from 1998 to 2011, there was a dramatic increase in hospitalizations attributed to UTIs: cases increased by 76% and incidence increased by 52%. In 2011, that meant more than 400,000 patients were admitted with a primary diagnosis of UTI, resulting in charges of \$9.7 billion and a real total cost of \$2.8 billion.

A standard urine culture plays a significant role in managing patients with suspected UTI. However, that diagnostic test has limitations in providing optimal clinical management for patients suffering from recurrent, persistent, or complicated UTIs. A standard urine culture misses a significant number of potential uropathogens, cannot provide antibiotic susceptibility for infections with two or more organisms (polymicrobial), and does not identify pairs of organisms that change the susceptibility results of antibiotics. These inadequacies can lead to treatment failure, increased antibiotic resistance, and urosepsis, with the latter being especially dangerous. The Institute for Healthcare Improvement notes there are 750,000 sepsis cases reported each year with 210,000 fatalities and a 2013 study observes sepsis secondary to a UTI accounts for approximately 20% to 40% of all severe cases of sepsis.

We have therefore been encouraged by the benefits of multiplex polymerase chain reaction (PCR) tests in the diagnosis and management of UTIs. The PCR test is unique in that it tests for up to 40 common and documented emerging urinary tract pathogens and it is more sensitive at detecting fastidious organisms that a routine urine culture will often miss. Additionally, the results of PCR are available in as little as 5 hours, where standard cultures typically take at least 24-48 hours. The ability to test for



multiple different antibiotic resistance genes is important as it helps to guide empirical antibiotic therapy given by urologists. Knowing the resistance pattern of an organism allows a more targeted antibiotic treatment and can lead to better patient outcomes.

In the February 2020 issue of the journal Urology, Wojno et al. performed a retrospective review of 582 patients who had standard urine culture and PCR run in parallel. The study revealed that PCR was positive in 22% of cases in which the standard culture was negative. Their study also showed that PCR was far better at diagnosing patients with polymicrobial infections, 166 patients vs. only 39 for standard urine culture. In 2020, Daly et al. reported in a retrospective study that the use of PCR was associated with 13.7% decrease in hospital admissions and/or emergency department utilization vs. standard urine culture.

The notable benefits of PCR for urinary tract infections align with the Institute of Healthcare Improvement Triple Aim; improving the experience of care, improving the health of populations, and reducing per capita costs of health care. The urine PCR has a higher negative predictive value, the turnaround time is much faster, it is especially sensitive toward polymicrobial pathogens as well as more fastidious organisms, and it can provide valuable information to guide antibiotic therapy. Furthermore, better antibiotic stewardship, decreased emergency room utilization, and fewer hospital admissions will save lives and may reduce annual health care expenditures by more than a billion dollars.

We ask that you implement a positive coverage policy for Urine PCR testing to cover the following CPT codes and ICD-10 diagnosis codes:

## **CPT**

87481 3 units	87801 3 units	87556 1 unit
87500 1 unit	87651 1 unit	87563 1 unit
87640 1 unit	87532 1 unit	87150 12 units
87653 1 unit	87529 2 units	
87798 13 units	87496 1 unit	

## **ICD 10**

N39.0 Urinary tract infection	R31.0 Gross hematuria
R82.99 Other abnormal findings in urine	R31.29 Other microscopic hematuria
Z11.8 Screen for other infection/parasitic	R31.9 Hematuria, unsp
diseases	G89.29 Other chronic pain
Z87.440 Personal history of urinary (tract)	N20.0 Calculus of kidney
infections	N30.00 Acute cystitis without hematuria
N41.0 Acute prostatitis	N30.20 Other chronic cystitis without
N41.1 Chronic prostatitis	hematuria

We stand ready to address any questions and look forward to improving the diagnosis and treatment of these common, and potentially deadly, bacterial infections.

Sincerely,

Elliott R. Lieberman, MD, President

American Association of Clinical Urologists

# Loberon M.D.

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