POINT OF CARE TESTING ASSOCIATION

October 7, 2025

VIA Electronic Mail to: CLFS_Annual_Public_Meeting@cms.hhs.gov

Sarah Shirey-Losso
Director, Division of Ambulatory Services
Centers for Medicare and Medicaid Services
7500 Security Boulevard
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Baltimore, MD 21244

RE: CY 2026 CLFS Preliminary Determinations

Dear Ms. Shirey-Losso:

On behalf of the Point of Care Testing Association (POCTA), we are pleased to provide comments on the CY 2026 Clinical Laboratory Fee Schedule (CLFS) Preliminary Determinations.

POCTA is a collaborative effort among manufacturers of point of care (POC) diagnostic technologies that enable clinicians to monitor chronic conditions, diagnose illnesses, and provide timely information for patients in a variety of care settings, from physician offices to pharmacies to community centers to non-hospital facilities. POCTA seeks to facilitate access to safe, effective, and cost-effective patient testing at the time of treatment. POCTA works to develop reimbursement and regulatory policies that can improve health outcomes by supporting access to POC testing.

We reviewed the CY 2026 CLFS Preliminary Determinations, and offer the following comments for your consideration.

1. **POCTA supports the preliminary determinations for CPT codes 87812, 0527U, 0563U, 0564U, 0570U, and 0595U.**

In the Preliminary Determinations, CMS proposes the following crosswalks:

Code/Descriptor	Preliminary Determination
87812 *Infectious agent antigen detection by immunoassay with direct optical (ie, visual) observation; severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) and influenza virus types A and B*	**Crosswalk to 87811** *Infectious agent antigen detection by immunoassay with direct optical (ie, visual) observation; severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19])* **PLUS** **(87804 TIMES 2)** *Infectious agent antigen detection by immunoassay with direct optical (ie, visual) observation; Influenza*

Code/Descriptor	Preliminary Determination
0527U *Herpes simplex virus (HSV) types 1 and 2 and Varicella zoster virus (VZV), amplified probe technique, each pathogen reported as detected or not detected*	**Crosswalk to 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*
0563U *Infectious disease (bacterial and/or viral respiratory tract infection), pathogen-specific nucleic acid (DNA or RNA), 11 viral targets and 4 bacterial targets, qualitative RT-PCR, upper respiratory specimen, each pathogen reported as positive or negative*	**Crosswalk to 87633** *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, 12-25 targets*
0564U *Infectious disease (bacterial and/or viral respiratory tract infection), pathogen-specific nucleic acid (DNA or RNA), 10 viral targets and 4 bacterial targets, qualitative RT-PCR, upper respiratory specimen, each pathogen reported as positive or negative*	**Crosswalk to 87633**
0570U *Neurology (traumatic brain injury), analysis of glial fibrillary acidic protein (GFAP) and ubiquitin carboxyl-terminal hydrolase L1 (UCH-L1), immunoassay, whole blood or plasma, individual components reported with the overall result of elevated or non-elevated based on threshold comparison*	**Crosswalk to 0358U** *Neurology (mild cognitive impairment), analysis of B-amyloid 1-42 and 1-40, chemiluminescence enzyme immunoassay, cerebral spinal fluid, reported as positive, likely positive, or negative*
0595U *Infectious disease (tropical fever pathogens), vector-borne and zoonotic pathogens, including 2 viruses (Chikungunya virus and Dengue virus serotypes 1, 2, 3, and 4), 1 bacterium (Leptospira species), and 1 parasite with species differentiation (Plasmodium species, Plasmodium falciparum, and Plasmodium vivax/ovale), real-time RT-PCR, whole blood, each pathogen reported as detected or not detected*	**Crosswalk to 87633**

We respectfully request that CMS finalize all six crosswalks as proposed.

2. **POCTA urges CMS to crosswalk 87494 to 0402U TIMES 0.5 – not 87801 (as proposed). If CMS does not agree 0402U TIMES 0.5 is appropriate, CMS should crosswalk 87494 to 87491 PLUS 87591.**

Effective January 1, 2026, the CPT Editorial Panel approved a new code – 87494 – for multiplex amplified probe tests that detect and report individual results for chlamydia and gonorrhea. The full code descriptor reads as follows:

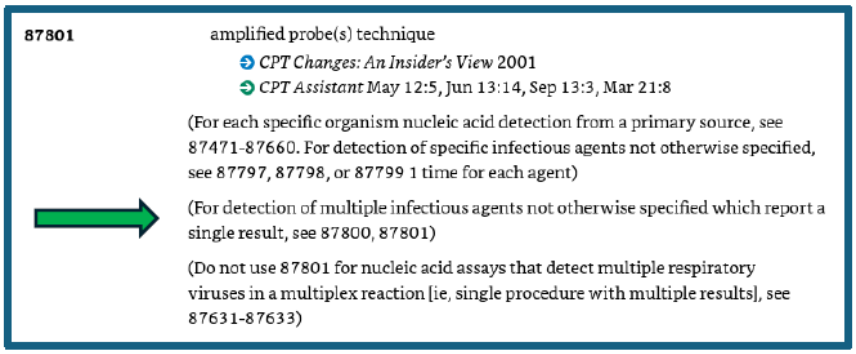
> *Infectious agent detection by nucleic acid (DNA or RNA); Chlamydia trachomatis and Neisseria gonorrhoeae, multiplex amplified probe technique*

The ability to identify and distinguish chlamydia and gonorrhea infections facilitates targeted medical follow-up and more effective patient management, as the CDC recommends different therapies for each pathogen (doxycycline, azithromycin, or levofloxacin for chlamydia,[1] ceftriaxone for gonorrhea[2]).

At the June Public Meeting, POCTA recommended that CMS crosswalk 87494 to 0402U[3] TIMES 0.5. However, in the Preliminary Determinations, CMS proposes crosswalk to 87801[4] instead. We urge CMS to reverse course and crosswalk 87494 to 0402U TIMES 0.5.

a. 87801 is not an appropriate crosswalk for 87494

Insofar as the code descriptor for 87801 references "multiple organisms" detected via amplified probe, we understand how it might *appear* an appropriate crosswalk for 87494. However, the CPT codebook explicitly instructs that 87801 does not describe a multiplex amplified probe test that reports separate results for each pathogen; rather, it reports a single, undifferentiated positive or negative result for the entire group of pathogens, without identifying which specific pathogen is positive or negative:[5]



[1] CDC, Sexually Transmitted Infections Treatment Guidelines 2021: Chlamydial Infections, https://www.cdc.gov/std/treatment-guidelines/chlamydia.htm.
[2] CDC, Gonorrhea: Clinical Treatment of Gonorrhea, https://www.cdc.gov/gonorrhea/hcp/clinical-care/index.html.
[3] Infectious agent (sexually transmitted infection), Chlamydia trachomatis, Neisseria gonorrhoeae, Trichomonas vaginalis, Mycoplasma genitalium, multiplex amplified probe technique, vaginal, endocervical, or male urine, each pathogen reported as detected or not detected.
[4] Infectious agent detection by nucleic acid (DNA or RNA), multiple organisms; amplified probe(s) technique.
[5] CPT 2025, at pg. 706.

Reporting multiple individual organism results requires the expenditure of additional resources as compared to tests that only report a single pooled result. For example, for a pooled test reported with 87801, the performing laboratory only needs one dye for all types, because the test does not differentiate between organisms. However , when reporting separate results assay described by 87494, the laboratory must use separate dyes to identify each individual organism.

b. 0402U TIMES 0.5 is the most appropriate crosswalk for 87494

Crosswalk to 0402U TIMES 0.5 is appropriate because the codes share:

- The same methodology (both are multiplex amplified probe);
- The same organisms (chlamydia and gonorrhea are included in both); and
- The same type of result (separate, qualitative result for each pathogen tested).

We understand CMS typically disfavors the use of multipliers in crosswalks unless there is a clear justification for the multiplier selected. In this case, however, a clear justification does exist – 87494 interrogates for half as many analytes and returns half as many individual analyte results as 0402U. CMS has taken a similar approach in the past, including 0387U[6] in the CY 2024 final determinations.

c. If CMS disagrees 0402U TIMES 0.5 is an appropriate crosswalk, it should select 87491 PLUS 87591 instead.

87491[7] and 87591[8] are appropriate to report individual amplified probe testing for chlamydia and gonorrhea, respectively. While CMS typically disfavors crosswalk to multiple codes, CMS agreed to this exact crosswalk – 87491 + 87591 – three years ago when it established its rate for another multiplex amplified probe test for chlamydia and gonorrhea (reported with the now-deleted 0353U[9]):

51	104	0X55U	0353U	PLA	Crosswalk to 87491 + 87591: 11 Gapfill: 0 Abstain: 1	Crosswalk to 87491 + 87591	Crosswalk to 87491 + 87591	Finalize as proposed. CMS agrees with the majority CDLT Panel recommendation to crosswalk the code. The crosswalked code(s) appear to use similar methods and resource utilization.

[6] 0387U describes an immunohistochemistry test for two biomarkers (*Oncology (melanoma), autophagy and beclin 1 regulator 1 (AMBRA1) and loricrin (AMLo) by immunohistochemistry, formalin fixed paraffin-embedded (FFPE) tissue, report for risk of progression*). CMS agreed to crosswalk to an immunohistochemistry test for four biomarkers (*Oncology (breast), immunohistochemistry, protein expression profiling of 4 biomarkers (matrix metalloproteinase-1 [MMP-1], carcinoembryonic antigen-related cell adhesion molecule 6 [CEACAM6], hyaluronoglucosaminidase [HYAL1], highly expressed in cancer protein [HEC1]), formalin-fixed paraffin-embedded precancerous breast tissue, algorithm reported as carcinoma risk score*) with a 0.5x multiplier.

[7] Infectious agent detection by nucleic acid (DNA or RNA); Chlamydia trachomatis, amplified probe technique

[8] Infectious agent detection by nucleic acid (DNA or RNA); Neisseria gonorrhoeae, amplified probe technique

[9] Infectious agent detection by nucleic acid (DNA), Chlamydia trachomatis and Neisseria gonorrhoeae, multiplex amplified probe technique, urine, vaginal, pharyngeal, or rectal, each pathogen reported as detected or not detected

As such, there is adequate precedent to support CMS taking a similar approach with 87494.

3. POCTA urges CMS to crosswalk 87627 to 0505U – not 87633 (as proposed).

Effective January 1, 2026, the CPT Editorial Panel approved a new code – 87627 – for multiplex amplified probe tests that detect and report individual results for 26 or more joint space pathogens or resistance genes. The full code descriptor reads as follows:

> *Infectious agent detection by nucleic acid (DNA or RNA); joint space pathogens and drug resistance genes, multiplex amplified probe technique, 26 or more targets*

At the June Public Meeting, POCTA recommended that CMS crosswalk 87627 to 0505U.[10] The CDLT Advisory Panel overwhelmingly (9-1 vote) supported this proposed crosswalk. In the Preliminary Determinations, however, CMS proposes crosswalk to 87633. We urge CMS to reevaluate this determination and crosswalk 87627 to 0505U.

a. 87633 is not an appropriate crosswalk for 87627.

87633 is not an appropriate crosswalk for 87627 because the assays differ with respect to the number of targets. 87633 is substantially less resource intensive than 87627, as it interrogates for substantially fewer targets (12-25) than 87627 (26+).

b. 0505U is the most appropriate crosswalk for 87627.

Crosswalk to 0505U is appropriate because the codes share:

- The same methodology (both are multiplex amplified probe tests);
- The same target material (nucleic acid);
- Similar numbers of target analytes (26 or more vs. 32); and
- The same report output (qualitative results for each target).

CMS disagreed with our recommendation for crosswalk to 0505U because its code descriptor specifically refers to "real-time PCR," while 87627 does not. However, the "multiplex amplified probe technique" referenced in 87627's descriptor includes assays run via real time PCR. Indeed, the FDA-cleared test that formed the basis of the application for this CPT code – the Joint Infection Panel – is itself a real-time PCR test.[11]

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[10] Infectious disease (vaginal infection), identification of 32 pathogenic organisms, swab, real-time PCR, reported as positive or negative for each organism.

[11] *See, e.g.,* Choe H, Kobayashi N, Hieda Y, *et al*. Automated multiplex PCR of BioFire joint infection panel enables rapid pathogen identification in periprosthetic joint infection excluding coagulase-negative Staphylococci. *J Orthopaedic Science* [epub 21 August 2025], https://doi.org/10.1016/j.jos.2025.07.008 (*"The widespread adoption of PCR technology, accelerated by the COVID-19 pandemic, has enabled many healthcare institutions to perform real-time PCR independently. Among the available PCR technologies, fully automated systems have gained attention due to their ability to perform the entire testing process with minimal human intervention. These systems enhance speed, reduce contamination risks, and minimize healthcare worker exposure. One such technology, the BIOFIRE® Joint Infection (JI) Panel (bioMérieux, Marcy*

4. POCTA urges CMS to crosswalk 0528U to 0321U – not 87633 (as proposed).

Effective January 1, 2025, the CPT Editorial Panel approved a new code for the BIOFIRE FILMARRAY Pneumonia Panel, which detects and reports results for 26 respiratory pathogens and 7 antimicrobial resistance genes. The full code descriptor reads as follows:

> *Lower respiratory tract infectious agent detection, 18 bacteria, 8 viruses, and 7 antimicrobial resistance genes, amplified probe technique, including reverse transcription for RNA targets, each analyte reported as detected or not detected with semiquantitative results for 15 bacteria*

At the June Public Meeting, POCTA recommended that CMS crosswalk 0528U to 0321U.[12] The CDLT Advisory Panel unanimously supported this proposed crosswalk. In the Preliminary Determinations, however, CMS proposes crosswalk to 87633. We urge CMS to reassess this determination and crosswalk 0528U to 0321U.

a. 87633 is not an appropriate crosswalk for 0528U.

87633 is not an appropriate crosswalk for 0528U because the assays differ with respect to the number and type of targets.

87633 is substantially less resource intensive than 0528U, as it interrogates for substantially fewer targets (12-25) than 87627 (33).

Furthermore, 87633 does not return results for antibiotic resistance genes, while 0528U does. The inclusion of drug resistance genes requires significant additional resources with respect to primers, reagents, and wells, as the same reactions do not generate resistance gene and pathogen identification results.

b. 0321U is the most appropriate crosswalk for 0528U.

Crosswalk to 0321U is appropriate because the codes share:

- The same methodology (both are multiplex amplified probe tests);
- The same target material (nucleic acid);
- Similar numbers of target analytes (36 vs. 33);
- Similar combination of organisms (both include multiple types of organisms, plus antimicrobial resistance genes); and
- The same report output (qualitative results for each target).

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l'Étoile, France), is a commercially available molecular diagnostic tool designed specifically for synovial fluid analysis in suspected PJI cases.")

[12] Infectious agent detection by nucleic acid (DNA or RNA), genitourinary pathogens, identification of 20 bacterial and fungal organisms and identification of 16 associated antibiotic-resistance genes, multiplex amplified probe technique

We understand that CMS disagreed with our recommendation for crosswalk to 0321U because the descriptor for 0321U does not specifically include reverse transcription, while 0528U does. However, the FDA-cleared labeling explicitly describes the BIOFIRE FILMARRAY Pneumonia Panel as including reverse transcription:

> *The BIOFIRE® FILMARRAY® Pneumonia Panel and BIOFIRE® FILMARRAY® Pneumonia Panel plus use nested, multiplex reverse transcription polymerase chain reaction (PCR)...*[13]

Therefore, notwithstanding the language of the code descriptor, 0528U does describe a test that includes reverse transcription. The shared characteristics demonstrate 0528U and 0321U utilize similar technology and methods, making 0321U the most appropriate crosswalk for 0528U.

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We thank you in advance for your consideration of these comments. If you have any questions about these recommendations, we would be pleased to meet to discuss them at your convenience. Please contact Mike Ryan at 202.756.8088, or via e-mail to mryan@mwe.com, if we can be helpful to CMS in any way.

Sincerely,

Mike Ryan
On behalf of the Point of Care Testing Association

[13] U.S. Food and Drug Administration, K243222, https://www.accessdata.fda.gov/cdrh_docs/pdf24/K243222.pdf, at pg. 14.