October 24, 2024

VIA Electronic Mail

Sarah Colbert-Fluchel, Senior Director, Clinical and Payment Policy
Carmin Pruitt, Staff Vice President Clinical and Payment Policy
Centene Corporation
Centene Plaza
7700 Forsyth Boulevard
St. Louis, MO 63105

RE: Payment Policy: Physician's Office Lab Testing (CC.PP.055)

Dear Ms. Colbert-Fluchel and Ms. Pruitt:

On behalf of the Point of Care Testing Association (POCTA)[i], the Urgent Care Association (UCA)[ii], and the Advanced Medical Technology Association (AdvaMed)[iii], we are writing in response to the above-captioned payment policy (hereinafter, the "POLT Policy"), which places significant restrictions on patients' ability to access timely, accurate point-of-care (POC) diagnostic tests in several states where Centene and its affiliate companies do business.

We understand and support policies that encourage the efficient use of limited payer resources. However, we believe the above-captioned policy unduly restricts access to medically necessary POC tests that can be furnished and used in patient management in real time when such use is in the best interests of patient care – including testing performed in both waived and moderately complex settings. Clinicians and patients alike need POC tests to timely diagnose disease and monitor healthcare conditions, particularly when rapid turnaround time is important to reduce the time to treat.

It is widely acknowledged that POC testing can be a valuable tool by supporting a physician's ability to rapidly, accurately diagnose disease and to prevent its spread through the community. POC testing provides "rapid actionable information for patient care at the time and site of an encounter with the health care system", "reduce[s] the need for multiple visits", and "facilitate[s] the containment of infectious disease outbreaks."[1] The National Institutes of Health has concluded that POC testing "has the potential to significantly impact health care delivery and to address the challenges of health disparities."[2]

POC testing is widely available (e.g., not requiring access to a microscope or specific expertise/training to successfully perform), and recent advances have the potential to make POC testing even simpler and more accurate. Current POC tests have been shown to deliver results with lab-equivalent sensitivity and specificity within minutes during the initial patient visit, thus enhancing providers' ability to detect and treat health risks to improve timeliness and

[1] Kozel TR, Burnham-Marusich AR. Point-of-care testing for infectious diseases: past, present, and future." *J Clin Microbiol* 2017;55(8):2313-2320. doi:10.1128/JCM.00476-17.
[2] National Institutes of Health, Research Portfolio Reporting Tools, "Point-of-Care Diagnostic Testing".

appropriateness of care and associated health outcomes. Studies have demonstrated that POC testing increases diagnostic certainty and reduces transfers from rural providers to more centralized hospitals, producing cost savings.[3] Further, POC testing may also reduce unnecessary hospital admissions and expensive follow-up tests by identifying or ruling out other illnesses.[4] POC testing also gives providers with a tool to accurately diagnose and treat patient symptoms, thus reducing the incidence of misdiagnosis and overprescribing of unnecessary/ineffective antibiotics, which can contribute to antimicrobial resistance.

The quality of testing in the POC setting is assured since the Clinical Laboratory Improvement Amendments (CLIA) require laboratories to obtain a certificate and comply with certain requirements applicable to the type of testing performed. Many POC tests have met the high accuracy bar required to obtain CLIA "waived" status and can be performed in any CLIA-certified laboratory. For those POC tests that are not waived, CLIA certification as a non-waived laboratory and requirements for proficiency testing and for inspection assure the quality of testing.

By denying access to POC testing for a number of disease conditions where such testing has been shown to be accurate and reliable, the POLT Policy will have a chilling effect on physicians' willingness to adopt – and patients' access to – POC testing.

For the reasons outlined below, we respectfully request that Centene revise its POLT Policy to add certain codes to its list of covered services when performed by a physician office laboratory.

* * * *

1. **We request that Centene expand the POLT Policy to include the following POC tests for respiratory pathogens.**

- *87420 Infectious agent antigen detection by immunoassay technique (eg, enzyme immunoassay [EIA], enzyme-linked immunosorbent assay [ELISA], fluorescence immunoassay [FIA], immunochemiluminometric assay [IMCA]), qualitative or semiquantitative; respiratory syncytial virus*
- *87449 Infectious agent antigen detection by immunoassay technique (eg, enzyme immunoassay [EIA], enzyme-linked immunosorbent assay [ELISA], fluorescence immunoassay [FIA], immunochemiluminometric assay [IMCA]), qualitative or semiquantitative; not otherwise specified, each organism*
- *87486 Infectious agent detection by nucleic acid (DNA or RNA); Chlamydia pneumoniae, amplified probe technique*
- *87502 Infectious agent detection by nucleic acid (DNA or RNA); influenza virus, for multiple types or sub-types, includes multiplex reverse transcription, when performed, and multiplex amplified probe technique, first 2 types or sub-types*
- *87503 Infectious agent detection by nucleic acid (DNA or RNA); influenza virus, for multiple types or sub-types, includes multiplex reverse transcription, when performed, and*

[3] Nichols JH, Alter D, Chen Y, *et al*. AACC guidance document on management of point-of-care testing. [Epub] J Appl Lab Med June 4, 2020, as doi:10.1093/jalm/jfaa059.
[4] St John A, Price CP. Existing and Emerging Technologies for Point-of-Care Testing. Clin Biochem Rev. 2014 Aug;35(3):155-67. PMID: 25336761; PMCID: PMC4204237.

multiplex amplified probe technique, each additional influenza virus type or sub-type beyond 2 (List separately in addition to code for primary procedure)

- *87581 Infectious agent detection by nucleic acid (DNA or RNA); Mycoplasma pneumoniae, amplified probe technique*
- *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 (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*
- *87634 Infectious agent detection by nucleic acid (DNA or RNA); respiratory syncytial virus, amplified probe technique*
- *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*
- *87637 Infectious agent detection by nucleic acid (DNA or RNA); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]), influenza virus types A and B, and respiratory syncytial virus, multiplex amplified probe technique*
- *87651 Infectious agent detection by nucleic acid (DNA or RNA); Streptococcus, group A, 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*
- *87899 Infectious agent antigen detection by immunoassay with direct optical (ie, visual) observation; not otherwise specified*
- *0115U Respiratory infectious agent detection by nucleic acid (DNA and RNA), 18 viral types and subtypes and 2 bacterial targets, amplified probe technique, including multiplex reverse transcription for RNA targets, each analyte reported as detected or not detected*
- *0240U Infectious disease (viral respiratory tract infection), pathogen-specific RNA, 3 targets (severe acute respiratory syndrome coronavirus 2 [SARS-CoV-2], influenza A, influenza B), upper respiratory specimen, each pathogen reported as detected or not detected*
- *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*

The above list includes both rapid antigen and nucleic acid amplification tests (NAATs) for respiratory illness. NAAT should be covered in all POC settings either as first line testing or to confirm (reflex) from rapid antigen testing, depending on clinical guidelines.

As set forth in the following table, well-recognized clinical guidelines generally support the availability of rapid antigen and/or NAATs for respiratory illness, including the following:

Test	Guideline statement
Influenza (87502, 87503)	IDSA (2018): *"Clinicians should use rapid molecular assays (ie, nucleic acid amplification tests)… in outpatients to improve detection of influenza virus infection (A-II)."*[5] IDSA/ASM (2024): *"Due to good diagnostic sensitivity, NAAT is considered the gold standard for detection of influenza virus in clinical samples."*[6] CDC (2022): *"Molecular influenza assays are more sensitive and specific for detecting influenza viruses than other influenza tests…."*[7]
RSV (87420, 87634)	IDSA/ASM (2024): *"NAAT testing has become the diagnostic method of choice, and the preferred specimen types include a nasopharyngeal swab or BAL fluid, if the patient has evidence of lower respiratory tract infection. Several FDA-cleared NAAT platforms exist. Although RSV can be recovered in routine viral culture, this approach is time-consuming and cytopathic effect may not be observed for up to 2 weeks."* CDC (2022): *"Nucleic acid amplification tests (NAATs), such as real-time reverse transcription-polymerase chain reaction (rRT-PCR), are highly sensitive tests for virus detection. Antigen tests are generally less sensitive than NAATs but can provide quicker results. (…) Both rRT-PCR and antigen detection tests are effective methods for diagnosing RSV."*[8]
COVID-19	IDSA (2023): *"The IDSA panel recommends a SARS-CoV-2 NAAT in symptomatic individuals suspected of having COVID-19, (strong recommendation, moderate certainty evidence)."*[9]
COVID-19 and Influenza (87636, 87637, 0240U, 0241U)	CDC (2023): For "Outpatient Clinic or Emergency Department Patients with Acute Respiratory Illness Symptoms (With or Without Fever) Not Requiring Hospital Admission": • *"Test for SARS-CoV-2 by nucleic acid detection…* • *"Test for influenza if results will change clinical management or for infection control decisions (e.g. long-term care facility resident returning to a facility, or a person of any age returning to a*

[5] Clinical Practice Guidelines by the Infectious Diseases Society of America: 2018 Update on Diagnosis, Treatment, Chemoprophylaxis, and Institutional Outbreak Management of Seasonal Influenza. *Clin Infect Dis* 2019;68(6):895-902.
[6] Miller JM, Binnicker MJ, Campbell S, Carroll KC, Chapin KC, Gonzalez MD, Harrington A, Jerris RC, Kehl SC, Leal SM Jr, Patel R, Pritt BS, Richter SS, Robinson-Dunn B, Snyder JW, Telford S 3rd, Theel ES, Thomson RB Jr, Weinstein MP, Yao JD. Guide to Utilization of the Microbiology Laboratory for Diagnosis of Infectious Diseases: 2024 Update by the Infectious Diseases Society of America (IDSA) and the American Society for Microbiology (ASM). Clin Infect Dis. 2024 Mar 5:ciae104. doi: 10.1093/cid/ciae104. Epub ahead of print. PMID: 38442248.
[7] CDC, Information on Rapid Molecular Assays, RT-PCR, and other Molecular Assays for Diagnosis of Influenza Virus Infection (Oct. 21, 2019), Information on Rapid Molecular Assays, RT-PCR, and other Molecular Assays for Diagnosis of Influenza Virus Infection | Influenza (Flu) | CDC.
[8] CDC, Diagnostic Testing for RSV (Aug. 30, 2024), Diagnostic Testing for RSV | RSV | CDC (last visited Oct. 4, 2024).
[9] IDSA Guidelines on the Diagnosis of COVID-19: Molecular Diagnostic Testing (Sept. 5, 2023), IDSA Guidelines on the Diagnosis of COVID-19: Molecular Diagnostic Testing (idsociety.org).

Test	Guideline statement
	congregate setting): order rapid influenza nucleic acid detection assay"[10]
Group A Strep (87651)	IDSA/ASM (2024): "Rapid, CLIA-waived methods for molecular group A strep testing provide improved sensitivity and may not require culture confirmation, although they have not yet been incorporated into consensus guidelines."
M. pneumoniae, C. pneumoniae (87486, 87581)	IDSA/ASM (2024): "Several FDA-approved NAAT platforms are available for the detection of a broad range of respiratory viruses and some of the "atypical bacteria" such as *Mycoplasma pneumoniae, Chlamydia pneumoniae*, and in some cases *B. pertussis* associated with respiratory syndromes (…). These have largely replaced rapid antigen detection tests and culture in most institutions."
Larger panels (87631-87633, 0115U)	American Society for Clinical Pathology (2020):[11] "Do not routinely order broad respiratory pathogen panels unless the results will affect patient management. (…) Broader testing for other respiratory pathogens may be done when the result will affect patient management; such as altering/discontinuing empiric antimicrobial therapy or changing infection control measures."
Non-specific analyte codes (87449, 87798, 87801, 87899)	IDSA/ASM (2024): "The diagnosis of adenoviral infections [is] typically made using NAAT, viral culture and/or histopathology…"

Clinician ability to accurately identify any individual respiratory pathogen alone remains poor. In one study, Hansen *et al.* reported that emergency department physician diagnoses of influenza had a sensitivity of just 36% (95% CI, 10.8-38.5%).[12] Poor clinician empiric performance may be explained, at least in part, by the fact that it is often not possible for health care providers to distinguish potential conditions based on signs and symptoms alone:

> *Both adult and pediatric patients infected with RSV often present with nonspecific, overlapping symptoms that can lead to difficulty in distinguishing it from influenza, coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), or other respiratory illnesses. Thus, empiric diagnosis*

[10] Clinical Guidance for Patients with Acute Respiratory Illness Not Being Hospitalized When SARS-CoV-2 and Influenza Viruses are Co-Circulating (Dec. 6, 2023), Clinical Guidance for Patients with Acute Respiratory Illness Not Being Hospitalized When SARS-CoV-2 and Influenza Viruses are Co-Circulating | Influenza (Flu) | CDC (last visited Oct. 4, 2024).
[11] American Society for Clinical Pathology. Thirty Five Things Physicians and Patients Should Question. 2020. ascp-35-things-list_2020_final.pdf.
[12] Hansen GT, Moore J, Herding E, *et al*. Clinical decision making in the emergency department setting using rapid PCR: Results of the CLADE study group. *J Clin Virol* 2018;102:42-49.

> *is often insufficient and should be supported by viral diagnostic testing to facilitate appropriate treatment, improved surveillance, and timely infection control.*[13]

Notwithstanding this difficulty, it remains critically important to correctly identify the underlying cause(s) of a patient's symptoms, as there are significant differences in recommended treatment options for each etiology. As summarized below, there is no overlap between the Centers for Disease Control and Prevention (CDC)-recommended treatments for COVID-19, influenza, RSV, and Group A Strep:

Test	**CDC-recommended therapy**
Influenza[14]	Tamiflu, Relenza, Rapivab, Xofluza
COVID-19[15]	Paxlovid, Veklury, Lagrevio
Group A Strep[16]	Penicillin, amoxicillin
RSV[17]	No specific treatment

Other bacterial infections presenting with similar symptoms are appropriately treated with antibiotics. If diagnosed incorrectly, patients may experience continuation/escalation of symptoms due to inappropriate treatment, and increased health care utilization (e.g., need for follow-up visits).

Fortunately, POC tests can accurately identify such condition(s) – and clinicians can use such information to inform appropriate prescribing decisions. For example, in a retrospective study, Benirschke *et al*. found that as compared to other rapid testing methods, the use of a highly sensitive and specific POC PCR test for influenza detection led to higher antiviral prescribing in positive patients (82.4% versus 69.9%, $p<0.05$) and decreased use in negative patients (2.3% versus 13.1%, $p<0.005$).[18] In a retrospective before/after study, May *et al*. found that switching from other rapid testing to molecular testing for Group A strep in outpatient primary care clinics resulted in a 44.1% reduction (10.1% molecular vs. 18.0% other, $p<0.0001$) in antibiotic prescribing for patients with a negative result. The authors concluded "implementation of POC PCR… in outpatients with acute pharyngitis symptoms reduced the volume of inappropriate antibiotic prescriptions."[19] Similarly, Rao *et al.* report that after switching to POC Group A Strep testing in a

[13] Bernstein DI, Mejias A, Rath B, *et al*. Summarizing study characteristics and diagnostic performance of commercially available tests for respiratory syncytial virus: a scoping literature review in the COVID-19 era. *J Appl Labor Med* 2022:jfac058.
[14] CDC, Treating Flu with Antiviral Drugs (Sept. 11, 2024), Treating Flu with Antiviral Drugs | Influenza (Flu) | CDC.
[15] CDC, Types of COVID-19 Treatment (July 12, 2024), Types of COVID-19 Treatment | COVID-19 | CDC.
[16] CDC, Clinical Guidance for Group A Streptococcal Pharyngitis (Mar. 1, 2024), Clinical Guidance for Group A Streptococcal Pharyngitis | Group A Strep | CDC.
[17] CDC, Symptoms and Care of RSV (Aug. 30, 2024), Symptoms and Care of RSV | RSV | CDC.
[18] Benirschke RC, McElvania E, Thomson RB, *et al*. Clinical impact of rapid point-of-care PCR influenza testing in an urgent care setting: a single-center study. *J Clin Microbiol* 2019;57(3):e01281-18.
[19] May L, Sickler J, Robbins EM, *et al*. The impact of point-of-care polymerase chain reaction testing on prescribing practices in primary care for management of Strep A: a retrospective before-after study. *Open Forum Infect Dis* 2022;9(5):ofac147.

pediatric primary care clinic, POC PCR was associated with appropriate antibiotic prescribing in 97.1% of cases, as compared to 87.5% in the previous standard of care (p=0.0065).[20]

Access to POC molecular tests may also lead to meaningful cost savings/more efficient resource utilization. In a prospective study assessing the impact of rapid RT-PCR influenza testing on physician decision-making in the emergency department, ED, Hansen *et al*. estimated that "[o]verall costs savings associated with access to RT-PCR testing in the ED resulted in $200.40/patient/ED visit. Projections over an extended influenza season (2000 ED visits) including estimated cost of providing testing resulted in net cost savings of $578,627 to $678,627."[21]

2. **We request that Centene expand the POLT Policy to include the following POC tests for sexually-transmitted illnesses (STIs).**

- *87481 Infectious agent detection by nucleic acid (DNA or RNA); Candida species, amplified probe technique*
- *87491 Infectious agent detection by nucleic acid (DNA or RNA); Chlamydia trachomatis, amplified probe technique*
- *87521 Infectious agent detection by nucleic acid (DNA or RNA); hepatitis C, amplified probe technique, includes reverse transcription when performed*
- *87529 Infectious agent detection by nucleic acid (DNA or RNA); Herpes simplex virus, amplified probe technique*
- *87563 Infectious agent detection by nucleic acid (DNA or RNA); Mycoplasma genitalium, amplified probe technique*
- *87591 Infectious agent detection by nucleic acid (DNA or RNA); Neisseria gonorrhoeae, amplified probe technique*
- *87593 Infectious agent detection by nucleic acid (DNA or RNA); Orthopoxvirus (eg, monkeypox virus, cowpox virus, vaccinia virus), amplified probe technique, each*
- *87661 Infectious agent detection by nucleic acid (DNA or RNA); Trichomonas vaginalis, amplified probe technique*
- *0352U Infectious disease (bacterial vaginosis and vaginitis), multiplex amplified probe technique, for detection of bacterial vaginosis-associated bacteria (BVAB-2, Atopobium vaginae, and Megasphera type 1), algorithm reported as detected or not detected and separate detection of Candida species (C. albicans, C. tropicalis, C. parapsilosis, C. dubliniensis), Candida glabrata/Candida krusei, and trichomonas vaginalis, vaginal-fluid specimen, each result reported as detected or not detected*
- *G0475 Hiv antigen/antibody, combination assay, screening*[22]

Access to rapid, accurate diagnostic methods are essential to help clinicians and public health officials quickly treat and prevent the spread of STIs in the community. When diagnosed at the POC, clinicians may immediately prescribe appropriate therapy, reducing the chances the patient

[20] Rao A, Berg B, Quezada T, *et al*. Diagnosis and antibiotic treatment of group a streptococcal pharyngitis in children in a primary care setting: impact of point-of-care polymerase chain reaction. *BMC Pediatr* 2019;19:24.
[21] Hansen GT, Moore J, Herding E, *et al*. Clinical decision making in the emergency department setting using rapid PCR: Results of the CLADE study group. *J Clin Virol* 2018;102:42-49.
[22] With respect to G0475 specifically, we note that the POLT Policy already includes the CPT code for HIV antigen/antibody testing (87806). If Centene and its affiliated plans recognize G-codes, we recommend that Centene add G0475 (which describes HIV antigen/antibody testing for screening purposes) to its list of POLT services.

will not receive needed treatment. Well-recognized guidelines support the availability of these tests:

Test	Guideline statement
Chlamydia/ gonorrhea (87491, 87591)	IDSA/ASM (2024): "For laboratory diagnosis of CT and GC, NAATs are the preferred assays for detection because of increased sensitivity while retaining specificity in low prevalence populations (pregnant patients) and the ability to screen with a noninvasive urine specimen." CDC (2021): "For men, C. trachomatis urethral infection can be diagnosed by testing first-void urine or a urethral swab. NAATs are the most sensitive tests for these specimens and are the recommended test for detecting C. trachomatis infection (553). NAATs that are FDA cleared for use with vaginal swab specimens can be collected by a clinician or patient in a clinical setting. Patient-collected vaginal swab specimens are equivalent in sensitivity and specificity to those collected by a clinician using NAATs, and this screening strategy is highly acceptable among women. (…) Newer NAAT-based POC tests have promising performance and are becoming commercially available."[23] USPSTF (2021): "[NAATs] for Chlamydia trachomatis and Neisseria gonorrhoeae infections are usually used for screening because their sensitivity and specificity are high for detecting these infections" [24]
Candida, trichomonas vaginalis, bacterial vaginosis (87481, 87661, 0352U)	IDSA/ASM (2024): "NAATs have been more accurate in identifying mixed and coinfections, both among vaginitis entities (BV, VVC, TV) as well as with CT and NG. Outcome data from both prospective and retrospective review of claims data and studies shows that primary testing with NAATs results in fewer repeat visits, more directed therapy, and less overall cost as the primary testing choice compared to current SOC."
M. gen (87563)	IDSA/ASM (2024): "NAATs are the best option for detection of *M. genitalium*, due to lack of culture availability secondary to specialize growth needs and cross-reactivity with serologic tests with *Mycoplasma pneumoniae*."
Hepatitis C (87521)	IDSA/ASM (2024): "Hepatitis C virus RNA can be detected by NAATs soon after infection as well as in chronic infection. NAAT for HCV can be performed qualitatively or quantitatively (by reverse- transcription PCR or transcription-mediated amplification methods)."
HSV (87529)	IDSA/ASM (2024): "For suspected cases of HSV genital lesions, NAATs are standard of care (SOC). Diagnosis with direct fluorescent antibody (DFA) or

[23] CDC, Sexually Transmitted Infections Treatment Guidelines, 2021. *MMWR* 2021;70(4) (July 23, 2021), Sexually Transmitted Infections Treatment Guidelines, 2021 (cdc.gov).
[24] US Preventive Services Task Force; Davidson KW, Barry MJ, Mangione CM, Cabana M, Caughey AB, Davis EM, Donahue KE, Doubeni CA, Krist AH, Kubik M, Li L, Ogedegbe G, Pbert L, Silverstein M, Simon MA, Stevermer J, Tseng CW, Wong JB. Screening for Chlamydia and Gonorrhea: US Preventive Services Task Force Recommendation Statement. JAMA. 2021 Sep 14;326(10):949-956. doi: 10.1001/jama.2021.14081. PMID: 34519796.

Test	Guideline statement
	cell culture are performed more commonly through reference laboratories and may require special transport conditions."
Mpox (87593)	IDSA/ASM (2024): "MPXV can be readily cultured in a variety of eukaryotic cell lines, including primary rhesus monkey kidney cells. However, cultivation in viral cell culture represents a hazard to laboratory personnel and should not be performed for diagnostic purposes. Instead, testing of dermal and/or anogenital swab specimens from suspect lesions by molecular (ie, real-time PCR) assays is the preferred approach for laboratory diagnosis."

Although symptoms overlap for many of the above-described conditions, it is critically important to accurately identify the specific pathogen(s) causing the patient's symptoms. As illustrated below, the CDC recommended regimens for many genitourinary infections do not overlap:

Test	CDC-recommended therapy
Gonorrhea[25]	Ceftriaxone
Chlamydia[26]	Doxycycline, Athizromycin, Levofloxacin
Bacterial vaginosis[27]	Metronidazole, Metronidazole gel 0.75%, Clindamycin cream 2%
Trichomonas[28]	Metronidazole, tinidazole

Ensuring patients receive the correct treatment is critically important, as evidenced by the prioritization of antimicrobial stewardship efforts by the CDC[29] and WHO.[30] Indeed, the CDC has been closely monitoring drug-resistant gonorrhea and has begun a pilot to test for drug-resistant gonorrhea in emergency departments.[31]

Traditional send-out laboratory testing leads to delays in treatment, if not loss to follow-up altogether when patients who require treatment are unreachable.[32] For example, a decision

[25] CDC. Gonococcal Infections Among Adolescents and Adults. Sexually Transmitted Infections Treatment Guidelines, 2021. Sexually Transmitted Infections Treatment Guidelines, 2021.
[26] CDC, Chlamydial Infections. Sexually Transmitted Infections Treatment Guidelines, 2021. Chlamydial Infections - STI Treatment Guidelines (cdc.gov).
[27] CDC, Bacterial Vaginosis. Sexually Transmitted Infections Treatment Guidelines, 2021. https://www.cdc.gov/std/treatment-guidelines/bv.htm.
[28] CDC, Trichomoniasis. Sexually Transmitted Infections Treatment Guidelines, 2021. Trichomoniasis - STI Treatment Guidelines (cdc.gov).
[29] CDC, Antimicrobial Resistance Solutions Initiative. Antimicrobial Resistance Solutions Initiative | Antimicrobial Resistance | CDC.
[30] Antimicrobial Resistance Diagnostic Initiative: strengthening bacteriology and mycology diagnostic capacity, laboratory systems and service delivery. Geneva: World Health Organization; 2023. Licence: CC BY-NC-SA 3.0 IGO.
[31] CDC, Pilot to Test for Drug-Resistant Gonorrhea in Emergency Departments. 2024. Pilot to Test for Drug-Resistant Gonorrhea in Emergency Departments | Antimicrobial Resistance | CDC.
[32] Widdice LE, Hsieh YH, Silver B, Barnes M, Barnes P, Gaydos CA. Performance of the Atlas Genetics Rapid Test for Chlamydia trachomatis and Women's Attitudes Toward Point-Of-Care Testing. Sex Transm Dis. 2018 Nov;45(11):723-727. doi: 10.1097/OLQ.0000000000000865. PMID: 29771869; PMCID: PMC6179923.

analysis found that compared to laboratory tests, POC testing for chlamydia allowed clinicians to treat more cases of infection by reducing loss to follow-up.[33] POC tests allow clinicians to rapidly identify the patient's diagnosis and make timely clinical decisions, reducing time to treatment and slowing the spread of antibiotic resistance.[34]

3. **We request that Centene expand the POLT Policy to include the following tests for GI related pathogens.**

- *87505 Infectious agent detection by nucleic acid (DNA or RNA); gastrointestinal pathogen (eg, Clostridium difficile, E. coli, Salmonella, Shigella, norovirus, Giardia), includes multiplex reverse transcription, when performed, and multiplex amplified probe technique, multiple types or subtypes, 3-5 targets*
- *87506 Infectious agent detection by nucleic acid (DNA or RNA); gastrointestinal pathogen (eg, Clostridium difficile, E. coli, Salmonella, Shigella, norovirus, Giardia), includes multiplex reverse transcription, when performed, and multiplex amplified probe technique, multiple types or subtypes, 6-11 targets*
- *87507 Infectious agent detection by nucleic acid (DNA or RNA); gastrointestinal pathogen (eg, Clostridium difficile, E. coli, Salmonella, Shigella, norovirus, Giardia), includes multiplex reverse transcription, when performed, and multiplex amplified probe technique, multiple types or subtypes, 12-25 targets*

Infectious gastroenteritis may be caused by a broad spectrum of pathogens resulting in the primary symptom of diarrhea. Panels for GI pathogens use multiplex amplified probe techniques and multiplex reverse transcription for the simultaneous detection of many GI pathogens such as C difficile, E coli, Salmonella, Shigella, norovirus, rotavirus, and Giardia. Multiplex PCR-based assays have shown superior sensitivity to conventional methods for detection of enteric pathogens and are increasingly used in the diagnosis of infectious gastroenteritis. These assays have significantly improved workflow and diagnostic output in the diagnosis of gastrointestinal infections.[35]

IDSA/ASM guidelines state that no laboratory testing is recommended for many gastrointestinal infections, particularly noninflammatory diarrhea and acute gastroenteritis of short duration.[36] However, for certain patients, multiplex GI panels may provide clinically useful information:

[33] Gift TL, Pate MS, Hook EW 3rd, Kassler WJ. The rapid test paradox: when fewer cases detected lead to more cases treated: a decision analysis of tests for Chlamydia trachomatis. Sex Transm Dis. 1999 Apr;26(4):232-40. doi: 10.1097/00007435-199904000-00010. PMID: 10225593.

[34] Low N, Unemo M. Molecular tests for the detection of antimicrobial resistant Neisseria gonorrhoeae: when, where, and how to use? *Curr Opin Infect Dis* 2016;29(1):45–51.

[35] Zhang, H., Morrison, S., & Tang, Y. W. (2015). Multiplex polymerase chain reaction tests for detection of pathogens associated with gastroenteritis. Clin Lab Med, 35(2), 461-486. https://doi.org/10.1016/j.cll.2015.02.006

[36] Miller JM, Binnicker MJ, Campbell S, Carroll KC, Chapin KC, Gilligan PH, Gonzalez MD, Jerris RC, Kehl SC, Patel R, Pritt BS, Richter SS, Robinson-Dunn B, Schwartzman JD, Snyder JW, Telford S 3rd, Theel ES, Thomson RB Jr, Weinstein MP, Yao JD. A Guide to Utilization of the Microbiology Laboratory for Diagnosis of Infectious Diseases: 2018 Update by the Infectious Diseases Society of America and the American Society for Microbiology. Clin Infect Dis. 2018 Aug 31;67(6):e1-e94. doi: 10.1093/cid/ciy381. PMID: 29955859; PMCID: PMC7108105.

Test	Guideline or coverage statement
Multiplex GI panels (87505-87507)	IDSA/ASM (2024): "[Multiplex panels] are recommended for immunocompromised patients and for infection control purposes." MolDX: Covers GI panels, with coverage criteria depending on size of panel and immune status of patients (among other factors)[37]

Access to a rapid method for etiologic diagnosis of GI infections may lead to more effective early treatment and infection control measures.[38] In many instances, when there is suspicion for a specific pathogen, individual tests could be ordered or a limited pathogen panel could be used. However, there may be a subset of patients – e.g., immunocompromised patients – for whom testing for a larger panel of pathogens at once may be appropriate.

4. **We request that Centene expand the POLT Policy to include the following additional POC tests.**

- *80047 Basic metabolic panel (Calcium, ionized) This panel must include the following: Calcium, ionized (82330) Carbon dioxide (bicarbonate) (82374) Chloride (82435) Creatinine (82565) Glucose (82947) Potassium (84132) Sodium (84295) Urea Nitrogen (BUN) (84520)*
- *80053 Comprehensive metabolic panel This panel must include the following: Albumin (82040) Bilirubin, total (82247) Calcium, total (82310) Carbon dioxide (bicarbonate) (82374) Chloride (82435) Creatinine (82565) Glucose (82947) Phosphatase, alkaline (84075) Potassium (84132) Protein, total (84155) Sodium (84295) Transferase, alanine amino (ALT) (SGPT) (84460) Transferase, aspartate amino (AST) (SGOT) (84450) Urea nitrogen (BUN) (84520)*
- *80061 Lipid panel This panel must include the following: Cholesterol, serum, total (82465) Lipoprotein, direct measurement, high density cholesterol (HDL cholesterol) (83718) Triglycerides (84478)*
- *82040 Albumin; serum, plasma or whole blood*
- *82310 Calcium; total*
- *82330 Calcium; ionized*
- *82374 Carbon dioxide (bicarbonate)*
- *82435 Chloride; blood*
- *83718 Lipoprotein, direct measurement; high density cholesterol (HDL cholesterol)*
- *83880 Natriuretic peptide*
- *84075 Phosphatase, alkaline;*
- *84153 Prostate specific antigen (PSA); total*
- *84154 Prostate specific antigen (PSA); free*
- *84155 Protein, total, except by refractometry; serum, plasma or whole blood*
- *84295 Sodium; serum, plasma or whole blood*
- *84450 Transferase; aspartate amino (AST) (SGOT)*

[37] MolDX: Molecular Syndromic Panels for Infectious Disease Pathogen Identification Testing (L38988), LCD - MolDX: Molecular Syndromic Panels for Infectious Disease Pathogen Identification Testing (L38988) (cms.gov).
[38] Balsalobre-Arenas L, Alarcón-Cavero T. Rapid diagnosis of gastrointestinal tract infections due to parasites, viruses, and bacteria. Enfermedades infecciosas y microbiologia clinica (English ed.). 2017 June-July;35(6):367–76. doi: 10.1016/j.eimce.2017.01.033. Epub 2017 May 19. PMCID: PMC7172322.

- *84460 Transferase; alanine amino (ALT) (SGPT)*
- *84478 Triglycerides*
- *84484 Troponin, quantitative*
- *84520 Urea nitrogen; quantitative*
- *86316 Immunoassay for tumor antigen, other antigen, quantitative (eg, CA 50, 72-4, 549), each*

Increasingly, physician offices view in-office access to general chemistry and other tests as a critical input for patient management. Physicians surveyed by the University of Washington identified several types of tests –including chemistry panels (5 or 8 test panel), lipids, and brain natriuretic peptide – for which access would be valuable in clinical practice when performed in the office.[39] A cross sectional survey found that primary care clinicians in all five countries (Australia, Belgium, the Netherlands, the UK and the USA) expressed a desire for POC tests to help them diagnose a range of both acute and chronic conditions, including troponin, BNP, and sodium. [40]

A variety of studies support the clinical utility of these types of POC tests, including the following:

- In a report focused on internal medicine practices furnishing POC access to a lipid panel and comprehensive metabolic panel, authors report a "99% reduction in letters to patients ($p<0.001$), a 75% decrease in calls to patients (not significant due to small numbers), a 50% reduction in follow-up tests per visit ($p=0.044$) and a 38% reduction in follow-up visits due to abnormal test results ($p=0.178$). Financial analysis including testing costs, revenues and efficiency gains to the practice demonstrated a net financial benefit of $11.90-14.74 per patient visit."[41]
- An observational study showed that routine lipid testing, and immediate face-to-face counselling achieved 90% compliance with medication therapy over a period. The authors concluded that by working collaboratively with patients, physicians, and other health care providers, pharmacists who have ready access to objective clinical data, and who have the necessary knowledge, skills, and resources, can provide an advanced level of care that results in successful management of dyslipidemia.[42]
- An Australian study found that certain POC tests – including triglycerides, total cholesterol, and urine albumin – have the same or better influence on therapeutic control than send-out laboratory testing.[43]

[39] Hardy, Victoria et al. "Which Point-of-Care Tests Would Be Most Beneficial to Add to Clinical Practice?: Findings From a Survey of 3 Family Medicine Clinics in the United States." Point of care vol. 16,4 (2017): 168-172. doi:10.1097/POC.0000000000000151

[40] Howick J, Cals JW, Jones C, Price CP, Plüddemann A, Heneghan C, Berger MY, Buntinx F, Hickner J, Pace W, Badrick T, Van den Bruel A, Laurence C, van Weert HC, van Severen E, Parrella A, Thompson M. Current and future use of point-of-care tests in primary care: an international survey in Australia, Belgium, The Netherlands, the UK and the USA. BMJ Open. 2014 Aug 8;4(8):e005611. doi: 10.1136/bmjopen-2014-005611. PMID: 25107438; PMCID: PMC4127935

[41] Lewandrowski EL, Yeh S, Baron J, Benjamin Crocker J, Lewandrowski K. Implementation of point-of-care testing in a general internal medicine practice: A confirmation study. Clin Chim Acta. 2017 Oct;473:71-74. doi: 10.1016/j.cca.2017.08.019. Epub 2017 Aug 19. PMID: 28830683.

[42] Bluml BM, McKenney JM, Cziraky MJ. Pharmaceutical care services and results in project ImPACT: hyperlipidemia. J Am Pharm Assoc (Wash). 2000 Mar-Apr;40(2):157-65. doi: 10.1016/s1086-5802(16)31059-2. PMID: 10730019.

[43] Bubner TK, Laurence CO, Gialamas A, Yelland LN, Ryan P, Willson KJ, Tideman P, Worley P, Beilby JJ. Effectiveness of point-of-care testing for therapeutic control of chronic conditions: results from the PoCT in General Practice Trial. Med J Aust. 2009 Jun 1;190(11):624-6. doi: 10.5694/j.1326-5377.2009.tb02590.x. PMID: 19485840.

- Testing natriuretic peptides (BNP and NT-proBNP) with POCT can help confirm a clinical diagnosis of heart failure in patients presenting in the urgent care settings, to help direct patient management. Such testing is now recommended in the latest American College of Cardiology and American Heart Association (ACC/AHA) clinical guidelines for chronic heart failure.[44]
- The National Academy of Clinical Biochemistry Laboratory Medicine Practice Guideline recommends that clinicians routinely provide POC testing in a cardiovascular diagnostic laboratory for a number of tests, including BUN; finding fair evidence that POCT in this environment improves important patient outcomes and that the benefits outweigh any potential harm.[45]
- PSA testing is widely recommended for the early detection of Prostate Cancer recurrence. In the US, the National Comprehensive Cancer Network (NCCN) recommends PSA testing every 6 to 12 months for 5 years after PCa treatment, followed by yearly monitoring.[46] PSA blood testing can help indicate if a patient needs further tests to look for prostate cancer. The earlier prostate cancer is detected, the better the chance of successful treatment and remaining disease-free. Prostate cancer deaths have decreased by about 40 percent since the advent of PSA screening, as shown in a National Cancer Institute investigation. [47]

We recognize that some of the tests referenced in this section may be of variable utility, depending on the performing office's specialty. We would be happy to help Centene identify which group(s) of physicians may most appropriately have access to each type of test in the POC.

* * * *

POC testing can increase diagnostic certainty, result in more efficient care and fewer additional office visits.[48] Such outcomes should result in a healthier patient population and lower overall treatment costs. The implementation of POCT in primary care practices has been shown to improve operational efficiency. Several studies reported reductions in follow-up communications and patient revisits, thus streamlining practice operations and reducing the administrative burden

[44] Writing Committee Members; ACC/AHA Joint Committee Members. 2022 AHA/ACC/HFSA Guideline for the Management of Heart Failure. J Card Fail. 2022 May;28(5):e1-e167. doi: 10.1016/j.cardfail.2022.02.010. Epub 2022 Apr 1. PMID: 35378257.
[45] Nichols JH, Christenson RH, Clarke W, Gronowski A, Hammett-Stabler CA, Jacobs E, Kazmierczak S, Lewandrowski K, Price C, Sacks DB, Sautter RL, Shipp G, Sokoll L, Watson ID, Winter W, Zucker ML; National Academy of Clinical Biochemistry. Executive summary. The National Academy of Clinical Biochemistry Laboratory Medicine Practice Guideline: evidence-based practice for point-of-care testing. Clin Chim Acta. 2007 Apr;379(1-2):14-28; discussion 29-30. doi: 10.1016/j.cca.2006.12.025. Epub 2007 Jan 12. PMID: 17270169.
[46] Trantham LC, Nielsen ME, Mobley LR, Wheeler SB, Carpenter WR, Biddle AK. Use of prostate-specific antigen testing as a disease surveillance tool following radical prostatectomy. Cancer. 2013 Oct 1;119(19):3523-30. doi: 10.1002/cncr.28238. Epub 2013 Jul 24. PMID: 23893821; PMCID: PMC3788002.
[47] Hans Lilja et al, "Prediction of Significant Prostate Cancer Diagnosed 20 to 30 Years Later with a Single Measure of Prostate-Specific Antigen at or Before Age 50," Cancer 117 (2011): 1210-1219, doi: 10.1002/cncr.25568.
[48] Jones, Caroline H D et al. "Primary care clinicians' attitudes towards point-of-care blood testing: a systematic review of qualitative studies." BMC family practice vol. 14 117. 14 Aug. 2013, doi:10.1186/1471-2296-14-117

on healthcare providers.[49,50] There are a variety of POC tests that can be performed in the physician's office, improving diagnosis and treatment efficiency among a wide range of conditions. Restricting access to POC tests, and covering and paying only for claims submitted from Centene's own preferred reference laboratories, will inappropriately and unnecessarily prevent patients from obtaining needed testing in a timely and clinically appropriate manner.

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Sincerely,

Mike Ryan
On behalf of Point of Care Testing Association

Lou Ellen Horwitz
Urgent Care Association

Tara Burke, PhD
AdvaMedDx

[i] POCTA seeks to facilitate access to safe, effective, and cost-effective patient testing at the time of treatment. Laboratory testing furnished at the POC benefits patients and the health care system. POC testing enables physicians to monitor chronic conditions, diagnose illnesses, and provide timely information to patients in a variety of care settings, from clinics to pharmacies to community centers to non-hospital facilities (e.g., assisted living). POCTA works to develop reimbursement policies that can improve health outcomes by supporting access to POC testing. POCTA is comprised of Abbott, Beckman Coulter, Becton, Dickinson and Company (BD), bioMérieux, Cepheid, Roche Diagnostics, and Siemens Healthineers.

[ii] The Urgent Care Association is the trade association for Urgent Care with a current membership of more than 4,000 Urgent Care centers representing clinical and business professionals from the United States and abroad.

[49] Crocker JB, Lee-Lewandrowski E, Lewandrowski N, Baron J, Gregory K, Lewandrowski K. Implementation of point-of-care testing in an ambulatory practice of an academic medical center. Am J Clin Pathol. 2014 Nov;142(5):640-6. doi: 10.1309/AJCPYK1KV2KBCDDL. PMID: 25319979.

[50] Lewandrowski EL, Yeh S, Baron J, Benjamin Crocker J, Lewandrowski K. Implementation of point-of-care testing in a general internal medicine practice: A confirmation study. Clin Chim Acta. 2017 Oct;473:71-74. doi: 10.1016/j.cca.2017.08.019. Epub 2017 Aug 19. PMID: 28830683.

[iii] A division of the Advanced Medical Technology Association (AdvaMed), AdvaMedDx is the only multi-faceted, policy organization that deals exclusively with issues facing in vitro diagnostic companies in the United States and abroad. AdvaMedDx member companies produce advanced, in vitro diagnostic tests that facilitate evidence-based medicine, improve quality of patient care, enable early detection of disease and reduce overall health care costs. Our membership includes manufacturers engaged in the development of innovative diagnostic technologies supporting the advancement of the public health, helping to deliver cutting-edge care to patients worldwide.