CLINICAL PAYMENT AND CODING POLICY

If a conflict arises between a Clinical Payment and Coding Policy (CPCP) and any plan document under which a member is entitled to Covered Services, the plan document will govern. If a conflict arises between a CPCP and any provider contract pursuant to which a provider participates in and/or provides Covered Services to eligible member(s) and/or plans, the provider contract will govern. "Plan documents" include, but are not limited to, Certificates of Health Care Benefits, benefit booklets, Summary Plan Descriptions, and other coverage documents. BCBSTX may use reasonable discretion interpreting and applying this policy to services being delivered in a particular case. BCBSTX has full and final discretionary authority for their interpretation and application to the extent provided under any applicable plan documents.

Providers are responsible for submission of accurate documentation of services performed. Providers are expected to submit claims for services rendered using valid code combinations from Health Insurance Portability and Accountability Act (HIPAA) approved code sets. Claims should be coded appropriately according to industry standard coding guidelines including, but not limited to: Uniform Billing (UB) Editor, American Medical Association (AMA), Current Procedural Terminology (CPT®), CPT® Assistant, Healthcare Common Procedure Coding System (HCPCS), ICD-10 CM and PCS, National Drug Codes (NDC), Diagnosis Related Group (DRG) guidelines, Centers for Medicare and Medicaid Services (CMS) National Correct Coding Initiative (NCCI) Policy Manual, CCI table edits and other CMS guidelines.

Claims are subject to the code edit protocols for services/procedures billed. Claim submissions are subject to claim review including but not limited to, any terms of benefit coverage, provider contract language, medical policies, clinical payment and coding policies as well as coding software logic. Upon request, the provider is urged to submit any additional documentation.

Pathogen Panel Testing

Policy Number: CPCPLAB045

Version 1.0

Enterprise Medical Policy Committee Approval Date: 1/25/2022

Plan Effective Date: May 1, 2022

Description

BCBSTX has implemented certain lab management reimbursement criteria. Not all requirements apply to each product. Providers are urged to review Plan documents for eligible coverage for services rendered.

Reimbursement Information:

1. Multiplex PCR-based panel testing of up to **5** respiratory pathogens **may be reimbursable** for patients displaying signs and symptoms of a respiratory tract infection, as evidenced by a compatible clinical syndrome including at least one of the following: temperature of 102 or greater, pronounced dyspnea, tachypnea, or tachycardia.

2. In the outpatient setting, multiplex PCR-based panel testing of **6 or MORE** respiratory pathogens **is not reimbursable**.

3. In the outpatient setting, multiplex PCR-based panel testing of pathogens in CSF **is not reimbursable**

4. In the outpatient setting, molecular detection-based panel testing of bloodstream pathogens **is not reimbursable.**

5. Using molecular-based panel testing for general screening of microorganisms **is not reimbursable.** These tests include, but are not limited to the following:
    a. Molecular-based panel testing of vaginal swabs, such as SmartJane™
    b. Molecular-based panel testing on urine samples, such as UroSwab®

6. Molecular detection-based panel testing of urine pathogens for the diagnosis of urinary tract infections **is not reimbursable**.

7. In the outpatient setting, using molecular-based panel testing to screen for or diagnose wound infections (i.e., skin/soft tissue infections), including diagnostic testing to confirm biofilm presence, **is not reimbursable.**

Procedure Codes

Codes
87483, 87631, 87632, 87633, 87636, 87637, 0068U, 0086U, 0112U, 0115U, 0140U, 0141U, 0142U, 0151U, 0152U, 0240U, 0241U

References:

Armstrong, D., Meyr, Andrew. (2021, January 12). Basic principles of wound management. Retrieved from https://www.uptodate.com/contents/basic-principles-of-wound-management

ASCP. (2019a). Do not routinely order broad respiratory pathogen panels unless the result will affect patient management. Retrieved from https://www.choosingwisely.org/clinician-lists/ascp-broad-respiratory-pathogen-panels/

Babady, N. E., England, M. R., Jurcic Smith, K. L., He, T., Wijetunge, D. S., Tang, Y. W., . . . Greene, W. (2018). Multicenter Evaluation of the ePlex Respiratory Pathogen Panel for the Detection of Viral and Bacterial Respiratory Tract Pathogens in Nasopharyngeal Swabs. *J Clin Microbiol, 56*(2). doi:10.1128/jcm.01658-17

Banerjee, R., Teng, C. B., Cunningham, S. A., Ihde, S. M., Steckelberg, J. M., Moriarty, J. P., . . . Patel, R. (2015). Randomized Trial of Rapid Multiplex Polymerase Chain Reaction-Based Blood Culture Identification and Susceptibility Testing. *Clin Infect Dis, 61*(7), 1071-1080. doi:10.1093/cid/civ447

BioCode. (2020b). FDA-Cleared Respiratory Pathogen Panel (RPP). Retrieved from https://apbiocode.com/rpp_panel.htm

BioFire. (2020a). The BioFire® FilmArray® Blood Culture Identification (BCID) Panel. Retrieved from https://www.biofiredx.com/products/the-filmarray-panels/filmarraybcid/

BioFire. (2020b). The BioFire® FilmArray® Meningitis/Encephalitis (ME) Panel. Retrieved from https://www.biofiredx.com/products/the-filmarray-panels/filmarrayme/

BioFire. (2021). The BioFire® FilmArray® Respiratory 2.1 (RP2.1) Panel. Retrieved from https://www.biofiredx.com/products/the-filmarray-panels/filmarrayrp/

Bonkat, G., Bartoletti, R., Bruyere, F., Cai, T., Geerlings, S. E., Koves, B., . . . Veeratterapillay, R. (2021, March). European Association of Urology (EAU) Guidelines on Urological Infections. Retrieved from http://uroweb.org/guideline/urological-infections/#3

Bonnin, P., Miszczak, F., Kin, N., Resa, C., Dina, J., Gouarin, S., . . . Vabret, A. J. B. I. D. (2016). Study and interest of cellular load in respiratory samples for the optimization of molecular virological diagnosis in clinical practice. *16*(1), 384. doi:10.1186/s12879-016-1730-9

Caliendo, A. M. (2011). Multiplex PCR and Emerging Technologies for the Detection of Respiratory Pathogens. *Clinical Infectious Diseases, 52*(suppl_4), S326-S330. doi:10.1093/cid/cir047

Caliendo, A. M., Gilbert, D. N., Ginocchio, C. C., Hanson, K. E., May, L., Quinn, T. C., . . . for the Infectious Diseases Society of, A. (2013). Better Tests, Better Care: Improved Diagnostics for Infectious Diseases. *Clinical Infectious Diseases, 57*(suppl_3), S139-S170. doi:10.1093/cid/cit578

Cardwell, S. M., Crandon, J. L., Nicolau, D. P., McClure, M. H., & Nailor, M. D. (2016). Epidemiology and economics of adult patients hospitalized with urinary tract infections. *Hosp Pract (1995), 44*(1), 33-40. doi:10.1080/21548331.2016.1133214

CDC. (2019a). Respiratory Infections. Retrieved from https://wwwnc.cdc.gov/travel/yellowbook/2020/posttravel-evaluation/respiratory-infections

CDC. (2019b). What is sepsis? Retrieved from https://www.cdc.gov/sepsis/what-is-sepsis.html

Chang, S.-S., Hsieh, W.-H., Liu, T.-S., Lee, S.-H., Wang, C.-H., Chou, H.-C., . . . Lee, C.-C. (2013). Multiplex PCR System for Rapid Detection of Pathogens in Patients with Presumed Sepsis – A Systemic Review and Meta-Analysis. *PLOS ONE, 8*(5), e62323. doi:10.1371/journal.pone.0062323

Dando, S. J., Mackay-Sim, A., Norton, R., Currie, B. J., St John, J. A., Ekberg, J. A., . . . Beacham, I. R. (2014). Pathogens penetrating the central nervous system: infection pathways and the cellular and molecular mechanisms of invasion. *Clin Microbiol Rev, 27*(4), 691-726. doi:10.1128/cmr.00118-13

Diagnostics, M. (2015a). OneSwab. Retrieved from https://www.mdlab.com/forms/Brochures/OSUS.pdf

Diagnostics, M. (2015b). UroSwab. Retrieved from https://www.mdlab.com/forms/Flyers/Female_STD_flyer.pdf

Fernandez-Soto, P., Sanchez-Hernandez, A., Gandasegui, J., Bajo Santos, C., Lopez-Aban, J., Saugar, J. M., . . . Muro, A. (2016). Strong-LAMP: A LAMP Assay for Strongyloides spp. Detection in Stool and Urine Samples. Towards the Diagnosis of Human Strongyloidiasis Starting from a Rodent Model. *PLoS Negl Trop Dis, 10*(7), e0004836. doi:10.1371/journal.pntd.0004836

GenetWorx. (2019). Wounds Pathogen Panel. Retrieved from https://www.genetworx.com/services/wound-pathogen-panel

GenMark. (2020a). Blood Culture Identification (BCID) Panels. Retrieved from https://www.genmarkdx.com/solutions/panels/eplex-panels/blood-culture-identification-panels/

GenMark. (2020b). Respiratory Pathogen (RP) Panel and NEW Respiratory Pathogen Panel 2 (RP2). Retrieved from https://www.genmarkdx.com/solutions/panels/eplex-panels/respiratory-pathogen-panel/

Ginocchio, C. C. (2007). Detection of respiratory viruses using non-molecular based methods. *J Clin Virol, 40 Suppl 1*, S11-14. doi:10.1016/s1386-6532(07)70004-5

Ginocchio, C. C., Zhang, F., Manji, R., Arora, S., Bornfreund, M., Falk, L., . . . Crawford, J. M. (2009). Evaluation of multiple test methods for the detection of the novel 2009 influenza A (H1N1) during the New York City outbreak. *J Clin Virol, 45*(3), 191-195. doi:10.1016/j.jcv.2009.06.005

Gyawali, B., Ramakrishna, K., & Dhamoon, A. S. (2019). Sepsis: The evolution in definition, pathophysiology, and management. *SAGE Open Med, 7*, 2050312119835043. doi:10.1177/2050312119835043

Hansen, L. S., Lykkegaard, J., Thomsen, J. L., & Hansen, M. P. (2020). Acute lower respiratory tract infections: Symptoms, findings and management in Danish general practice. *Eur J Gen Pract, 26*(1), 14-20. doi:10.1080/13814788.2019.1674279

Hill, A. T., Gold, P. M., El Solh, A. A., Metlay, J. P., Ireland, B., & Irwin, R. S. (2019). Adult Outpatients With Acute Cough Due to Suspected Pneumonia or Influenza: CHEST Guideline and Expert Panel Report. *Chest, 155*(1), 155-167. doi:10.1016/j.chest.2018.09.016

Hooton, T. M., & Gupta, K. (2019). Acute complicated urinary tract infection (including pyelonephritis) in adults. *UpToDate.* Retrieved from https://www.uptodate.com/contents/acute-complicated-urinary-tract-infection-including-pyelonephritis-in-adults

Humphries, R. M., & Linscott, A. J. (2015). Laboratory diagnosis of bacterial gastroenteritis. *Clin Microbiol Rev, 28*(1), 3-31. doi:10.1128/cmr.00073-14

Liesenfeld, O., Lehman, L., Hunfeld, K. P., & Kost, G. (2014). Molecular diagnosis of sepsis: New aspects and recent developments. *European journal of microbiology & immunology, 4*(1), 1-25. doi:10.1556/EuJMI.4.2014.1.1

Liesman, R. M., Strasburg, A. P., Heitman, A. K., Theel, E. S., Patel, R., & Binnicker, M. J. (2018). Evaluation of a Commercial Multiplex Molecular Panel for Diagnosis of Infectious Meningitis and Encephalitis. *J Clin Microbiol, 56*(4). doi:10.1128/jcm.01927-17

Luminex. (2020a). NxTAG® Respiratory Pathogen Panel. Retrieved from https://www.luminexcorp.com/nxtag-respiratory-pathogen-panel/

Mahony, J. B., Blackhouse, G., Babwah, J., Smieja, M., Buracond, S., Chong, S., . . . Goeree, R. (2009). Cost Analysis of Multiplex PCR Testing for Diagnosing Respiratory Virus Infections. *J Clin Microbiol, 47*(9), 2812. Retrieved from http://jcm.asm.org/content/47/9/2812.abstract

McDonald, D., Gagliardo, C., Chiu, S., & Di Pentima, M. C. (2020). Impact of a Rapid Diagnostic Meningitis/Encephalitis Panel on Antimicrobial Use and Clinical Outcomes in Children. Antibiotics (Basel, Switzerland), 9(11). doi:10.3390/antibiotics9110822

Medina, M., & Castillo-Pino, E. (2019). An introduction to the epidemiology and burden of urinary tract infections. *Ther Adv Urol, 11*, 1756287219832172. doi:10.1177/1756287219832172

Meyrier, A. (2019). Sampling and evaluation of voided urine in the diagnosis of urinary tract infection in adults. *UpToDate.* Retrieved from https://www.uptodate.com/contents/sampling-and-evaluation-of-voided-urine-in-the-diagnosis-of-urinary-tract-infection-in-adults

Microbiology, A. S. f. (2017). MolDX: Multiplex Nucleic Acid Amplified Tests for RespiratoryViral Panels (DL37301). Retrieved from https://www.amp.org/AMP/assets/File/position-statements/2017/JointCommentLettertoNoridioanJEforMultiplexViralPanelTests-Respiratory-DL37301.pdf

MicroGenDX. (2019a). Urology. Retrieved from https://microgendx.com/urology/

MicroGenDX. (2019b). Wound Care Retrieved from https://microgendx.com/wound-care/

Miller, J. M., Pritt, B. S., Theel, E. S., Yao, J. D., Binnicker, M. J., Patel, R., . . . Weinstein, M. P. (2018). 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 Microbiologya. *Clinical Infectious Diseases, 67*(6), e1-e94. doi:10.1093/cid/ciy381

Nijhuis, R. H. T., Guerendiain, D., Claas, E. C. J., & Templeton, K. E. (2017). Comparison of ePlex Respiratory Pathogen Panel with Laboratory-Developed Real-Time PCR Assays for Detection of Respiratory Pathogens. J Clin Microbiol, 55(6), 1938-1945. doi:10.1128/jcm.00221-17

NovaDX. (2019). NOVADX ABX DIAGNOSIS. Retrieved from https://www.novadx.com/abx-uti-testing-menu

Palavecino, E. (2015). One Sample, Multiple Results The Use of Multiplex PCR for Diagnosis of Infectious Syndromes. *Clinical Laboratory News.* Retrieved from https://www.aacc.org/publications/cln/articles/2015/april/one-sample-multiple-results

Pammi, M. (2019, April 4). Clinical features and diagnosis of bacterial sepsis in the preterm infant (<34 weeks gestation). Retrieved from https://www.uptodate.com/contents/clinical-features-and-diagnosis-of-bacterial-sepsis-in-the-preterm-infant-less-than34-weeks-gestation

Petti, C. A., Polage, Christopher R. (2019, June 21). Molecular diagnosis of central nervous system infections. Retrieved from https://www.uptodate.com/contents/molecular-diagnosis-of-central-nervous-system-infections

QIAGEN. (2020). QIAstat-Dx Respiratory SARS-CoV-2 Panel. Retrieved from https://www.qiagen.com/us/products/diagnostics-and-clinical-research/infectious-disease/qiastat-dx-syndromic-testing/qiastat-dx-eua-us/

Ramers, C., Billman, G., Hartin, M., Ho, S., & Sawyer, M. H. (2000). Impact of a diagnostic cerebrospinal fluid enterovirus polymerase chain reaction test on patient management. *Jama, 283*(20), 2680-2685.

Ray, G. T., Suaya, J. A., & Baxter, R. (2013). Incidence, microbiology, and patient characteristics of skin and soft-tissue infections in a U.S. population: a retrospective population-based study. *BMC Infect Dis, 13*, 252. doi:10.1186/1471-2334-13-252

Rhodes, A., Evans, L. E., Alhazzani, W., Levy, M. M., Antonelli, M., Ferrer, R., . . . Dellinger, R. P. (2017). Surviving Sepsis Campaign: International Guidelines for Management of Sepsis and Septic Shock: 2016. *Crit Care Med, 45*(3), 486-552. doi:10.1097/ccm.0000000000002255

Robinson, C. C., Willis, M., Meagher, A., Gieseker, K. E., Rotbart, H., & Glode, M. P. (2002). Impact of rapid polymerase chain reaction results on management of pediatric patients with enteroviral meningitis. *Pediatr Infect Dis J, 21*(4), 283-286.

Scallan, E., Griffin, P. M., Angulo, F. J., Tauxe, R. V., & Hoekstra, R. M. (2011). Foodborne illness acquired in the United States--unspecified agents. *Emerg Infect Dis, 17*(1), 16-22. doi:10.3201/eid1701.091101p2

Schultz, G., Bjarnsholt, T., James, G. A., Leaper, D. J., McBain, A. J., Malone, M., . . . Wolcott, R. D. (2017). Consensus guidelines for the identification and treatment of biofilms in chronic nonhealing wounds. *Wound Repair Regen, 25*(5), 744-757. doi:10.1111/wrr.12590
Seegene. (2020). Sepsis. Retrieved from http://www.arrowdiagnostics.it/download/microbiologia/sepsi/Magicplex-Sepsis-Real-time-Test.pdf

Stellrecht, K. A., Harding, I., Woron, A. M., Lepow, M. L., & Venezia, R. A. (2002). The impact of an enteroviral RT-PCR assay on the diagnosis of aseptic meningitis and patient management. *J Clin Virol, 25 Suppl 1*, S19-26.

Subramony, A., Zachariah, P., Krones, A., Whittier, S., & Saiman, L. (2016). Impact of Multiplex Polymerase Chain Reaction Testing for Respiratory Pathogens on Healthcare Resource Utilization for Pediatric Inpatients. *J Pediatr, 173*, 196-201.e192. doi:10.1016/j.jpeds.2016.02.050

T2Biosystems. (2019). T2Bacteria Panel. Retrieved from https://www.t2biosystems.com/products-technology/t2bacteria-panel/

Thomas, M., & Bomar, P. A. (2020). Upper Respiratory Tract Infection. In *StatPearls*. Treasure Island (FL): StatPearls Publishing StatPearls Publishing LLC.

Tunkel, A. R., Glaser, C. A., Bloch, K. C., Sejvar, J. J., Marra, C. M., Roos, K. L., . . . Whitley, R. J. (2008). The Management of Encephalitis: Clinical Practice Guidelines by the Infectious Diseases Society of America. *Clinical Infectious Diseases, 47*(3), 303-327. doi:10.1086/589747

Tzanakaki, G., Tsopanomichalou, M., Kesanopoulos, K., Matzourani, R., Sioumala, M., Tabaki, A., & Kremastinou, J. (2005). Simultaneous single-tube PCR assay for the detection of Neisseria meningitidis, Haemophilus influenzae type b and Streptococcus pneumoniae. *Clin Microbiol Infect, 11*(5), 386-390. doi:10.1111/j.1469-0691.2005.01109.x

Ubiome. (2018c). SmartJane Sample Report. Retrieved from https://s3-us-west-1.amazonaws.com/ubiome-assets/wp-content/uploads/2018/10/16141949/SmartJane-Sample-Report_2.1.2.pdf

Uyeki, T. M., Bernstein, H. H., Bradley, J. S., Englund, J. A., File, T. M., Jr., Fry, A. M., . . . Pavia, A. T. (2018). Clinical Practice Guidelines by the Infectious Diseases Society of America: 2018 Update on Diagnosis, Treatment, Chemoprophylaxis, and Institutional Outbreak Management of Seasonal Influenzaa. doi:10.1093/cid/ciy866

V. Wintzingerode, F., Göbel, U. B., & Stackebrandt, E. (1997). Determination of microbial diversity in environmental samples: pitfalls of PCR-based rRNA analysis. *21*(3), 213-229. doi:doi:10.1111/j.1574-6976.1997.tb00351.x

van Rijn, A. L., Nijhuis, R. H. T., Bekker, V., Groeneveld, G. H., Wessels, E., Feltkamp, M. C. W., & Claas, E. C. J. (2018). Clinical implications of rapid ePlex(R) Respiratory Pathogen Panel testing compared to laboratory-developed real-time PCR. *Eur J Clin Microbiol Infect Dis, 37*(3), 571-577. doi:10.1007/s10096-017-3151-0

Viracor. (2019). Skin and Soft Tissue Infection Panel TEM-PCR™. Retrieved from https://www.viracor-eurofins.com/test-menu/220798p-skin-and-soft-tissue-infection-panel-tem-pcr/

Visseaux, B., Le Hingrat, Q., Collin, G., Bouzid, D., Lebourgeois, S., Le Pluart, D., . . . Houhou-Fidouh, N. (2020). Evaluation of the QIAstat-Dx Respiratory SARS-CoV-2 Panel, the First Rapid Multiplex PCR Commercial Assay for SARS-CoV-2 Detection. Journal of Clinical Microbiology, 58(8), e00630-00620. doi:10.1128/JCM.00630-20

Ward, C., Stocker, K., Begum, J., Wade, P., Ebrahimsa, U., & Goldenberg, S. D. (2015). Performance evaluation of the Verigene(R) (Nanosphere) and FilmArray(R) (BioFire(R)) molecular assays for identification of causative organisms in bacterial bloodstream infections. *Eur J Clin Microbiol Infect Dis, 34*(3), 487-496. doi:10.1007/s10096-014-2252-2

Watts, G. S., Youens-Clark, K., Slepian, M. J., Wolk, D. M., Oshiro, M. M., Metzger, G. S., . . . Hurwitz, B. L. (2017). 16S rRNA gene sequencing on a benchtop sequencer: accuracy for identification of clinically important bacteria. *Journal of applied microbiology, 123*(6), 1584-1596. doi:10.1111/jam.13590

Weiss, S. L., Peters, M. J., Alhazzani, W., Agus, M. S. D., Flori, H. R., Inwald, D. P., . . . Tissieres, P. (2020). Surviving Sepsis Campaign International Guidelines for the Management of Septic Shock and Sepsis-Associated Organ Dysfunction in Children. *Pediatr Crit Care Med, 21*(2), e52-e106. doi:10.1097/pcc.0000000000002198

Yan, Y., Zhang, S., & Tang, Y. W. (2011). Molecular assays for the detection and characterization of respiratory viruses. *Semin Respir Crit Care Med, 32*(4), 512-526. doi:10.1055/s-0031-1283288

Policy Update History:

5/1/2022	New policy