Priority Health

MEDICAL POLICY
No. 91643-R1

INFECTIOUS DISEASE MOLECULAR PANELS

Effective Date: December 1, 2025 | **Review Dates: 08/24, 8/25, 11/25**
Date Of Origin: 8/14/2024 | **Status: Current**

Summary of Changes

- Addition:
  - Gastrointestinal pathogen panel (GIPP) are medically necessary when criteria are met.

I. POLICY/CRITERIA

Scope:

- This policy does not address nucleic acid testing for SARS-CoV-2 (COVID-19).
- This policy does not address standard and established laboratory methods such as microscopy, gram stain, culture, histology, or antibody or antigen tests.
- This policy does not address testing performed in an inpatient level of care setting or emergency room.
- This policy does not address benefit level determinations (e.g., whether tests are covered as a preventative benefits), please see plan documents.

A. General criteria: Infectious disease pathogen molecular panels are medically necessary when the following criteria are met:

1. Testing is performed according to the intended use of the test in the intended patient population for which the test was developed and validated.
2. Tests must demonstrate equivalent or superior test performance characteristics (i.e., analytical validity and clinical validity) to established standard-of-care methods (i.e., culture, pathogen-specific polymerase chain reaction) for the targets included on the panel.
3. The results of testing will impact clinical management as already demonstrated in the peer-reviewed published literature to improve patient outcomes.
4. An evaluation for more than 1 pathogen by molecular testing is necessary for the member's management (testing for a single pathogen is not reasonable and necessary for the specific infection, patient, or indication). The test panel includes at least the minimum pathogens required for clinical decision making for its intended use.

5. Expanded panel testing is only indicated when targeted panel testing is not appropriate (i.e., will not provide sufficient information for the appropriate clinical management).
6. The member to be tested has a clinical indication for infectious disease testing.
7. Documentation of the following is clearly stated in the medical record:
    a. Specific clinical indications for testing (i.e., clinical suspicion of a pathogen as the cause of the member's condition)
    b. Why the evaluation for more than one pathogen by molecular testing is necessary for clinical management of the member or why testing for a single pathogen is not reasonable and necessary for the specific infection, individual or indication.
8. Testing must be performed according to Clinical Laboratory Improvement Amendments (CLIA) and/or Food and Drug Administration (FDA) regulations and consistent with the intended-use labeling directions.

B. Gastrointestinal pathogen panel (GIPP)

1. GIPP testing is medically necessary for the following clinical indications:
    a. Acute diarrhea with moderate-to-severe symptoms (such as fever, dysentery, severe dehydration).
    b. Gastrointestinal infection with moderate-to-severe symptoms (such as fever, dysentery, severe dehydration).
    c. Community-acquired diarrhea that persists for more than seven days, or individuals with travel-associated diarrhea of uncertain etiology.
    d. Immunocompromised individuals with acute diarrhea or moderate to severe gastrointestinal infection. Immunocompromise may support the use of panels with 12 or more pathogens.
2. Molecular GIPP testing, with any number of targets, is not medically necessary for the following indications:
    a. Immunocompetent individuals with mild diarrhea, particularly of ≤ 7 days' duration.
    b. Members in whom the clinical presentation of acute diarrhea suggests a specific infectious etiology, unless first-line laboratory testing should fail to detect the suspected organism, and there is still a high clinical suspicion of infectious etiology.
3. More than one type of test for the same organism is not medically necessary for the same date of service or within 7 days.

C. Respiratory (RP) and Pneumonia (PNP) Panels

1. Targeted RP or PNP panels (up to and including 5 pathogens) are medically necessary when all of the following criteria are met:
    a. The general criteria for infectious disease pathogen molecular panels in I.A are met; and
    b. Member is immune-competent; and

c. Has severe and established underlying respiratory pathology (i.e., severe asthma, chronic obstructive pulmonary disease, cystic fibrosis, pulmonary fibrosis, radiation therapy to the lung); And
d. Treatment with antibiotics may be indicated according to established guidelines.

2. Panel testing for asthma exacerbations is not medically necessary without the additional presence of either fever and purulent sputum or radiographic evidence of pneumonia.
3. Panel testing for uncomplicated community acquired pneumonia (CAP) is not medically necessary.
4. Only one panel will be covered for a given member for the same clinical indication.
5. Expanded panels (6 or more targets) are not medically necessary, including but not be limited to:
    a. BioFire FilmArray Respiratory Panel (RP)
    b. BioFire Respiratory Panel 2.1
    c. BioFire SpotFire Respiratory (R) Panel
    d. ePlex Respiratory Pathogen (RP) Panel
    e. ePlex Respiratory Pathogen Panel 2 (RP2)
    f. NxTAG Respiratory Pathogen Panel
    g. NxTAG Respiratory Pathogen Panel + SARS-CoV-2
    h. QIAstat-Dx Respiratory SARS-CoV-2 Panel

D. Urogenital/Anogenital (UG/AG) Panels:

1. Sexually transmitted infections (STIs): Panel testing is medically necessary when all the following are met:
    a. The general criteria for infectious disease pathogen molecular panels in I.A are met.
    b. Member has epidemiologic indication or potential exposure to sexually transmitted pathogens, even in the absence of clinical symptoms (documentation of the high-risk reason for panel testing is clearly stated in the medical record); or
    c. In the absence of a high-risk experience, if the primary clinical concern is for a few specific pathogens due to specific signs and symptoms targeted panels (less than 5 pathogen) may be medically necessary. Expanded panels (6 or more targets) are considered not medically necessary.
2. Vaginitis/vaginosis: Testing is medically necessary when all the following are met:
    a. The general criteria for infectious disease pathogen molecular panels in I.A are met.
    b. Targeted panels for the diagnosis of symptomatic member are medically necessary.

c. Expanded panels (6 or more targets) are considered not medically necessary.

E. The following are not medically necessary:
1. Panels intended for home use (including those that have been FDA-approved/cleared).
2. A panel performed as a test of cure.
3. A panel to confirm a diagnosis or known information.
4. A panel to determine risk for developing a disease or condition.
5. Using a panel without diagnosis specific indications.
6. Performing more than 1 panel on the same date of service for the same clinical indication.
7. Using a panel that does not have the minimum pathogens required for clinical decision making.
8. Using expanded panels if the primary clinical concern is for specific pathogens due to specific signs and symptoms.

F. Tests determined to be experimental, investigational, or unproven are not medically necessary due to insufficient evidence in peer-reviewed literature of analytic validity, clinical validity and/or clinical utility. Please see medical policy *Experimental/Investigational/Unproven Care/Benefit Exceptions (#91117).* Panels considered investigational and experimental include but are not limited to:

1. MicroGenDx qPCR & NGS for Infection

II. BACKGROUND/DESCRIPTION

Infectious diseases are caused by microscopic organisms (bacteria, viruses, fungi, and parasites) that penetrate the body's protective barriers (e.g., skin, mucous membranes) and can result in symptoms ranging from mild to severe. Although symptoms can indicate a disease, a laboratory test may be necessary to identify the specific microorganism causing the infection so that appropriate treatment can be prescribed.

Traditional methods for diagnosing infectious diseases include microbiological approaches, such as culture and gram staining. Newer approaches have been developed using DNA sequencing technology to identify microbial agents. Nucleic acid amplification test (NAAT or NAT) is a type of genetic test used for infectious disease. This technique makes numerous copies of genetic material from the microbes present in a sample so that it can be more easily detected. Today, in most clinical settings, NAATs have replaced virus cultures as the gold standard, due to their high specificity, faster turnaround times, and absence of limitations posed by the need for susceptible cell lines (Fox, 2007). One type of NAAT is polymerase chain reaction (PCR). These tests provide faster results than traditional methods and are more sensitive and specific. PCR-based tests have been developed further into multiplex assays which allow for simultaneous detection of several biological agents. First-generation methods for determining the nucleotide sequence of DNA (e.g. Sanger sequencing) is a low-throughput method used

to determine a portion of the nucleotide sequence of an individual's genome. This technique uses PCR amplification of genetic regions of interest followed by sequencing of PCR products. Next-generation sequencing is a high-throughput, massively parallel, culture-free sequencing method that tests for an array of potential pathogens within a microbial sample simultaneously in a single sequencing run in order to determine a cause of disease. Metagenomic NGS is an evolving, novel molecular technology proposed to detect pathogens for infectious disease and can potentially provide direct, unbiased analysis of microbial composition of specimens without reliance on traditional culture or targeted molecular tests.

The majority FDA-approved molecular panels for a given platform consist of a predetermined test menu of pathogens. Smaller panels or targeted panels, typically detect about 3-5 pathogens. The commonly used commercially available larger or expanded panels can detect approximately 20 targets or pathogens or more. Some include pathogens that typically cause different clinical presentations, such that simultaneously testing for these pathogens should not be a common event. They deviate from being syndromic in their approach to diagnosis. Finally, the targets and organisms on a panel can vary between manufacturers, with some panels differentiating among numerous subtypes and strains of species, many of which are not clinically meaningful for most patients. For example, differentiating among the different types and subtypes of parainfluenza virus may be good for epidemiologic tracking, but is not likely to result in any meaningful impact to patient care. Further, large panels do not appropriately regard patient risk factors, or a pre-test probability of a particular pathogen causing infection. The patient's medical history and exposures are important to assess prior to testing (MoIDX). Viral infections in immune-competent patients are often self-limiting and resolve without complication. Further, with few exceptions, there is often no specific treatment for viral infections, other than supportive care, and testing may not change patient management. All of this may result in an excess of unnecessary testing in immune-competent individuals. On the other hand, in immune-compromised patients, common and rare pathogens can cause severe illness, and concurrent infection with multiple respiratory viruses have been identified as predictors of in-hospital mortality.

Gastrointestinal pathogen panel (GIPP)

Gastrointestinal infections include a wide variety of disease presentations as well as infectious agents. For many of these infections, particularly noninflammatory diarrhea and acute gastroenteritis of short duration, no laboratory testing is recommended. Gastrointestinal infections encompass a wide variety of symptoms and recognized infectious agents. The appropriate diagnostic approach to diarrheal illness is determined by the patient's age, severity of disease, duration and type of illness, time of year, and geographic location. For most patients with acute diarrhea, diagnostic testing is not indicated. However, fecal testing, using culture or culture independent methods, is indicated for patients with moderate to severe, bloody, febrile, dysenteric, nosocomial, or persistent diarrheal illnesses or for immunocompromised patients (ISDA, 2024). Culture independent methods are often routinely available for Clostridioides difficile (C

difficle) and may be available for other bacterial, viral, and protozoic causes of gastrointestinal infections. C. difficile testing should be limited to patients with new onset diarrhea who are not taking laxatives with typical clinical presentation and risk factors. Although often included in multiplex molecular panels, singleplex testing is adequate.

Stool culture has longer time to result and often fails to detect the causative agent. Thus, when available, culture-independent methods are recommended for detection of bacterial pathogens (ACG, 2016). Viral gastroenteritis is often self-resolving; thus multiplex panels targeting viruses often have little clinical impact (ISDA, 2024). Highly multiplexed assays allow for the detection of mixed infections where the importance of each pathogen is unclear. They may also allow for the detection of pathogens, such as enteroaggregative or enteropathogenic E. coli or viruses where clinical significance and the indication for therapy is unclear. Culture independent methods should not be used as test of cure because they will detect both viable and non-viable organisms. Multiplex molecular panels allow for the qualitative detection of nucleic acid from multiple viral, parasitic, and bacterial pathogens in stool samples collected from patients with symptoms of gastroenteritis or infectious colitis (Binnicker, 2015; Freeman et al., 2017). Several panels have been cleared by the Food and Drug Administration (FDA) for diagnosis of gastrointestinal infections, including FilmArray, xTAG, and Verigene. Benefits of multiplex panels over conventional testing include the ability to test for an array of pathogen types using minimal sample volume, high-throughput platforms, rapid turnaround time, and an improved capacity to detect coinfections. The xTAG gastrointestinal pathogen panel (GPP) assay made by Luminex Corporation was the first multiplex molecular panel to receive FDA clearance in 2013 for diagnosis of infectious gastroenteritis. The test has up to 15 pathogenic targets. The FilmArray GI panel from BioFire Diagnostics received FDA clearance in 2014. FilmArray tests have 22 targets, and testing is performed within a closed reaction pouch using a FilmArray analyzer. For both xTAG and FilmArray, the majority of studies consistently reported >90% sensitivity and specificity across target pathogens. Overall diagnostic yield rates were markedly higher with xTAG and FilmArray panels (22%-54%) compared with conventional testing (6%-12%).

The ISDA recommends against performing repeat testing (within 7 days) during the same episode of diarrhea and against testing stool from asymptomatic patients, except for epidemiological studies (ISDA, 2017). Th most sensitive method of diagnosis of clostridioides difficile in stool specimens from patients likely to have CDI based on clinical symptoms is nucleic acid amplification test (NAAT) alone or a multistep algorithm for testing (ie, GDH plus toxin; GDH plus toxin, arbitrated by NAAT; or NAAT plus toxin) rather than a toxin test alone when there are preagreed institutional criteria for patient stool submission (ISDA, 2017).

Respiratory Panels

The number of pathogens that cause pneumonia is lengthy, establishing the microbiologic etiology of pneumonia is inherently difficult. Current tools to assist in pneumonia diagnosis include respiratory tract cultures (sputum, BAL, tracheal aspirate, mini-BAL), urine antigens (pneumococcal, Legionella), serology, and PCR for viral and certain

bacterial pathogens. A large study (Jain, 2015) found that despite current diagnostic tests, no pathogen was detected in most patients. Among 2259 patients who had radiographic evidence of pneumonia and specimens available for both bacterial and viral testing, a pathogen was detected in 853 (38%): one or more viruses in 530 (23%), bacteria in 247 (11%), bacterial and viral pathogens in 59 (3%), and a fungal or mycobacterial pathogen in 17 (1%). The most common pathogens were human rhinovirus (in 9% of patients), influenza virus (in 6%), and Streptococcus pneumoniae (in 5%). In their 2019 clinical practice guideline, the Infectious Diseases Society of America and the American Thoracic Society suggest that clinicians should not use diagnostic testing in patients with non-severe community-acquired pneumonia (CAP) being treated with typical therapy (Metlay, 2019).

The availability of pathogen-specific treatment options for respiratory tract infections (RTIs) increased the need for rapid diagnostic tests. Besides, retrospective studies, improved lab-based detection methods and the intensified search for new viruses since the beginning of the twenty-first century led to the discovery of several novel respiratory viruses such as SARS coronavirus (SARS-CoV), MERS coronavirus (MERS-CoV), novel strains of influenza virus A and B, and SARS coronavirus 2 (SARS-CoV-2). Although clinical presentation may be similar among different viruses, associated symptoms may range from a mild cold to a severe respiratory illness, and thus require a fast and reliable diagnosis. Multitarget respiratory pathogen panels are intended to simultaneously detect nucleic acids from multiple respiratory viral and bacterial pathogens in a single sample, typically a nasopharyngeal swab, from a patient with suspected respiratory infection. Even if a test is deemed safe and effective in terms of analytical validity (the accuracy and reliability of a test in measuring what it is designed to measure) and clinical validity (the ability of a test to accurately identify or predict the presence or absence of a specific condition), the test must also have clinical utility or demonstrate that it is reasonable and necessary. Clinical utility refers to the usefulness of a test in improving clinical outcomes or guiding clinical decision-making.

The increasing number of commercially available rapid point-of-care tests (POCTs) for respiratory viruses illustrates both the need for faster and reliable diagnostic tests but also significant limitations (Nelson, 2020). In contrast to lab-based tests, point-of-care tests (POCTs) are performed at the site of sample collection (e.g., bedside, physician's office, or emergency department) and provide results usually in <2 hours (Basile et al., 2018; Vos et al., 2019). Furthermore, they require only little hands-on time and no specific laboratory training as most critical steps are automated in a single device. The latter may range from handheld to benchtop size and is not designed for high-throughput sample processing. POCTs and other fast diagnostic tests performed in laboratories but provide results within 1–2 hours may be called near-POCTs. Prompt identification of the causative pathogen may help the responsible healthcare professional choosing the appropriate treatment or take the right decisions in outbreak situations, regarding hospitalization and quarantine (Brendish et al., 2015).

The cobas® eplex Respiratory Pathogen Panel identifies common viral and bacterial organisms associated with upper respiratory infection (Roche, 2024). In a study by

Babady and colleagues (2018), the performance of the ePlex Respiratory Pathogen (RP) panel for the simultaneous detection of 19 viruses and 2 bacteria was evaluated. Prospectively and retrospectively collected nasopharyngeal swab (NPS) specimens (n = 2,908) were evaluated by using the ePlex RP panel, with the BioFire FilmArray Respiratory Panel (BioFire RP) as the comparator method. Discordance analysis was performed by using target-specific PCRs and bidirectional sequencing. The reproducibility of the assay was evaluated by using reproducibility panels comprised of 6 pathogens. The overall agreement between the ePlex RP and BioFire RP results was >95% for all targets. Positive percent agreement with the BioFire RP result for viruses ranged from 85.1% (95% confidence interval [CI], 80.2% to 88.9%) to 95.1% (95% CI, 89.0% to 97.9%), while negative percent agreement values ranged from 99.5% (95% CI, 99.1% to 99.7%) to 99.8% (95% CI, 99.5% to 99.9%). Additional testing of discordant targets (12%) confirmed the results of ePlex RP for 38% of samples tested. Reproducibility was 100% for all targets tested, with the exception of adenovirus, for which reproducibility were 91.6% at low virus concentrations and 100% at moderate virus concentrations. In another comparator study by Nijhuis et al (2017), the performance of the respiratory pathogen (RP) panel was compared with those of laboratory developed real-time PCR assays, using a variety of previously collected clinical respiratory specimens. A total of 343 clinical specimens as well as 29 external quality assessment (EQA) specimens and 2 different Middle East respiratory syndrome coronavirus isolates have been assessed in this study. The RP panel showed an agreement of 97.4% with the real-time PCR assay regarding 464 pathogens found in the clinical specimens. All pathogens present in clinical samples and EQA samples with a threshold cycle (CT) value of <30 were detected correctly using the RP panel. The RP panel detected 17 additional pathogens, 7 of which could be confirmed by discrepant testing. There is a lack of high-quality, prospective, randomized controlled trials evaluating the performance of the ePlex respiratory pathogen panel.

The BioFire Respiratory Panel 2.1 (RP2.1) is a PCR-based multiplexed nucleic acid test intended for use with the BioFire FilmArray 2.0 or BioFire FilmArray Torch systems for the simultaneous qualitative detection and identification of multiple respiratory viral and bacterial nucleic acids in nasopharyngeal swabs (NPS) obtained from individuals suspected of respiratory tract infections, including COVID-19. The BioFire RP2.1 Panel offers a run time of about 45 minutes, includes 22 targets and reports an overall 97.1% sensitivity and 99.3% specificity. There is insufficient evidence supporting the use of the BioFire Respiratory Panel 2.1 (RP2.1) to aid in the diagnosis of respiratory infection if used in conjunction with other clinical and epidemiological information.

Urogenital/Anogenital (UG/AG) Panels

Vaginitis is a general term for disorders of the vagina and vulva caused by infection, inflammation or changes in the normal vaginal flora. Bacterial vaginosis, Candida vulvovaginitis, and trichomoniasis are the most common infections. Vaginitis and balanitis are diagnosed with a series of standardized clinical tests, such as bacterial culture, physical examination, microscopy and/or vaginal pH, or molecular diagnostic testing such as DNA probe assays or NAATs.

Bacterial Vaginosis (BV) is a condition caused by an imbalance in the normal bacteria vaginal flora. BV can be diagnosed by using clinical criteria (i.e., Amsel's diagnostic criteria) or by determining the Nugent score from a vaginal Gram stain. Vaginal Gram stain, considered the reference standard laboratory method for diagnosing BV, is used to determine the relative concentration of lactobacilli (i.e., long gram-positive rods), small gram-negative and gram-variable rods (i.e., G. vaginalis or Bacteroides), and curved gram-negative rods (i.e., Mobiluncus) characteristic of BV. A Nugent score of 0–3 is consistent with a Lactobacillus-predominant vaginal microbiota, 4–6 with intermediate microbiota (emergence of G. vaginalis), and 7–10 with BV (CDC, 2021).

Multiple BV NAATs are now available as an alternative method of diagnosis of BV among symptomatic women. These tests are based on detection of specific bacterial nucleic acids and have high sensitivity and specificity for BV (i.e., G. vaginalis, A. vaginae, BVAB2, or Megasphaera type 1) (1006) and certain lactobacilli (i.e., Lactobacillus crispatus, Lactobacillus jensenii, and Lactobacillus gasseri). They can be performed on either clinician- or self-collected vaginal specimens with results available in <24 hours, depending on the availability of the molecular diagnostic platform. Five quantitative multiplex PCR assays are available: Max Vaginal Panel, Aptima BV, NuSwab VG, OneSwab BV Panel PCR with Lactobacillus Profiling by qPCR, and SureSwab BV (CDC, 2021). BD Max and Aptima BV are FDA cleared, and NuSwab VG, OneSwab BV Panel PCR with Lactobacillus Profiling by qPCR, and SureSwab BV are laboratory-developed tests.

Cervical cancer screening detects precancerous changes of the cervix (e.g., cervical dysplasia), often making treatment possible before cervical cancer develops. Screening uses human papillomavirus (HPV) testing, cervical cytology (Pap test), or a combination of the two tests (eg, "co-testing"). HPV testing identifies oncogenic (ie, high-risk) HPV subtypes that are associated with cervical cancer. The subtypes that are tested have slight variation across the various testing systems, but all test for at least the 13 most common types. HPV genotyping refers to testing for individual HPV types, usually HPV 16 or 18, but some tests may also include HPV 45. Cell samples for cervical cytology and HPV testing are traditionally obtained during a speculum examination, however self-collection of an HPV sample by the patient can also be performed. In the United States, the FDA has approved several devices for self-collection. For self-collection, patients collect samples from the vagina using the specimen collection kit provided by the manufacturer. Collection occurs by the patient, but in a health care setting (UpToDate, 2024). However, American College of Obstetrics and Gynecology (2021) states that "although HPV self-sampling has the potential to greatly improve access to cervical cancer screening, and there is an increasing body of evidence to support its efficacy and utility, it is still investigational in the United States."

III. CENTERS FOR MEDICARE & MEDICAID SERVICES (CMS) COVERAGE DETERMINATION

Any applicable federal or state mandates will take precedence over this medical coverage policy.

Medicare: Refer to the CMS Online Manual System (IOMs) and Transmittals.

For the most current applicable CMS National Coverage Determination (NCD)/Local Coverage Determination (LCD)/Local Coverage Article (LCA) refer to CMS Medicare Coverage Database.

The information below is current as of the review date for this policy. However, the coverage issues and policies maintained by CMS are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. MAC jurisdiction for purposes of local coverage determinations is governed by the geographic service area where the Medicare Advantage plan is contracted to provide the service. Please refer to the Medicare Coverage Database website for the most current applicable NCD, LCD, LCA, and CMS Online Manual System/Transmittals.

National Coverage Determinations (NCDs)	
National Coverage Determinations (NCDs)	N/A
Local Coverage Determinations (LCDs)	
Moldx	Molecular Syndromic Panels For Infectious Disease Pathogen Identification Testing (L39044)

IV. GUIDELINES/POSITION STATEMENTS

Medical/Professional Society	Guideline
American College of Gastroenterology (ACG)	Clinical Guideline: Diagnosis, Treatment, and Prevention of Acute Diarrheal Infections in Adults (2016)
American Urological Association/Canadian Urological Association/Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction	Recurrent uncomplicated urinary tract infections in women (2025)
The Infectious Diseases Society of America (IDSA)	Clinical Practice Guidelines for the Diagnosis and Management of Infectious Diarrhea (2017)
The Infectious Diseases Society of America (IDSA) and the American Society for Microbiology (ASM)	Guide to Utilization of the Microbiology Laboratory for Diagnosis of Infectious Diseases (2024)
The U.S. Preventive Services Task Force	Asymptomatic Bacteriuria in Adults: Screening (2019)
	Chlamydia and Gonorrhea: Screening (2021)

	Genital Herpes Infection: Serologic Screening (2023)

V. MEDICAL NECESSITY REVIEW

Prior authorization for certain drug, services, and procedures may or may not be required. In cases where prior authorization is required, providers will submit a request demonstrating that a drug, service, or procedure is medically necessary. For more information, please refer to the Priority Health Provider Manual.

VI. APPLICATION TO PRODUCTS

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

- **HMO/EPO:** ***This policy applies to insured HMO/EPO plans.***
- **POS:** ***This policy applies to insured POS plans.***
- **PPO:** ***This policy applies to insured PPO plans. Consult individual plan documents as state mandated benefits may apply. If there is a conflict between this policy and a plan document, the provisions of the plan document will govern.***
- **ASO:** ***For self-funded plans, consult individual plan documents. If there is a conflict between this policy and a self-funded plan document, the provisions of the plan document will govern.***
- **INDIVIDUAL:** ***For individual policies, consult the individual insurance policy. If there is a conflict between this medical policy and the individual insurance policy document, the provisions of the individual insurance policy will govern.***
- **MEDICARE:** ***Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, this policy applies.***
- **MEDICAID/HEALTHY MICHIGAN PLAN:** ***For Medicaid/Healthy Michigan Plan members, this policy will apply. Coverage is based on medical necessity criteria being met and the appropriate code(s) from the coding section of this policy being included on the Michigan Medicaid Fee Schedule located at: http://www.michigan.gov/mdch/0,1607,7-132-2945_42542_42543_42546_42551-159815--,00.html. If there is a discrepancy between this policy and the Michigan Medicaid Provider Manual located at: http://www.michigan.gov/mdch/0,1607,7-132-2945_5100-87572--,00.html, the Michigan Medicaid Provider Manual will govern. If there is a discrepancy or lack of guidance in the Michigan Medicaid Provider Manual, the Priority Health contract with Michigan Medicaid will govern. For Medical Supplies/DME/Prosthetics and Orthotics, please refer to the Michigan Medicaid Fee Schedule to verify coverage.***

VII. CODING INFORMATION

CPT/HCPCS Codes

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

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

87636 Infectious agent detection by nucleic acid (DNA or RNA); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID19]) 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 [COVID19]), influenza virus types A and B, and respiratory syncytial virus, multiplex amplified probe technique

0402U 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

0483U Infectious disease (Neisseria gonorrhoeae), sensitivity, ciprofloxacin resistance (gyrA S91F point mutation), oral, rectal, or vaginal swab, algorithm reported as probability of fluoroquinolone resistance

0484U Infectious disease (Mycoplasma genitalium), macrolide sensitivity (23S rRNA point mutation), oral, rectal, or vaginal swab, algorithm reported as probability of macrolide resistance

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

87800 Infectious agent detection by nucleic acid (DNA or RNA), multiple organisms; direct probe(s) technique

87801 Infectious agent detection by nucleic acid (DNA or RNA), multiple organisms; amplified probe(s) technique

87999 Unlisted microbiology procedure (Explanatory notes must accompany claim)

Non-Covered Procedures

86581 Streptococcus pneumoniae antibody (IgG), serotypes, multiplex immunoassay, quantitative

0202U Infectious disease (bacterial or viral respiratory tract infection), pathogen-specific nucleic acid (DNA or RNA), 22 targets including severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), qualitative RT-PCR, nasopharyngeal swab, each pathogen reported as detected or not detected

0223U Infectious disease (bacterial or viral respiratory tract infection), pathogen specific nucleic acid (DNA or RNA), 22 targets including severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), qualitative RT-PCR, nasopharyngeal swab, each pathogen reported as detected or not detected

0225U Infectious disease (bacterial or viral respiratory tract infection) pathogen-specific DNA and RNA, 21 targets, including severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), amplified probe technique, including multiplex reverse transcription for RNA targets, each analyte reported as detected or not detected

0311U Infectious disease (bacterial), quantitative antimicrobial susceptibility reported as phenotypic minimum inhibitory concentration (MIC)–based antimicrobial susceptibility for each organisms identified [Accelerate PhenoTest BC Kit AST]

0321U 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

0330U Infectious agent detection by nucleic acid (DNA or RNA), vaginal pathogen panel, identification of 27 organisms, amplified probe technique, vaginal swab

0323U Infectious agent detection by nucleic acid (DNA and RNA), central nervous system pathogen, metagenomic next-generation sequencing, cerebrospinal fluid (CSF), identification of pathogenic bacteria, viruses, parasites, or fungi

0351U Infectious disease (bacterial or viral), biochemical assays, tumor necrosis factor-related apoptosis-inducing ligand (TRAIL), interferon gamma-induced protein-hyphen10 (IP- 10), and C-reactive protein, serum, algorithm reported as likelihood of bacterial infection

0371U Infectious agent detection by nucleic acid (DNA or RNA), genitourinary pathogen, semiquantitative identification, DNA from 16 bacterial organisms and 1 fungal organism, multiplex amplified probe technique via quantitative polymerase chain reaction (qPCR), urine

0372U Infectious disease (genitourinary pathogens), antibiotic-resistance gene detection, multiplex amplified probe technique, urine, reported as an antimicrobial stewardship risk score

0427U Monocyte distribution width, whole blood (List separately in addition to code for primary procedure)

0441U Infectious disease (bacterial, fungal, or viral infection), semiquantitative biomechanical assessment (via deformability cytometry), whole blood, with algorithmic analysis and result reported as an index [IntelliSep]

0442U Infectious disease (respiratory infection), Myxovirus resistance protein A (MxA) and C-hyphenreactive protein (CRP), fingerstick whole blood specimen, each biomarker reported as present or absent [Configuration and FebriDx Bacterial/Non-Bacterial Point of Care- Assay]
0010U Infectious disease (bacterial), strain typing by whole genome sequencing, phylogenetic-based report of strain relatedness, per submitted isolate
0086U Infectious disease (bacterial and fungal), organism identification, blood culture, using rRNA FISH, 6 or more organism targets, reported as positive or negative with phenotypic minimum inhibitory concentration (MIC)- based antimicrobial susceptibility [Accelerate PhenoTest BC Kit]
0112U Infectious agent detection and identification, targeted sequence analysis (16S and 18S rRNA genes) with drug-esistance gene
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
0152U Infectious disease (bacteria, fungi, parasites, and DNA viruses), DNA, PCR and next-generation sequencing, plasma, detection of >1,000 potential microbial organisms for significant positive pathogens
0480U Infectious disease (bacteria, viruses, fungi, and parasites), cerebrospinal fluid (CSF), metagenomic next generation sequencing (DNA and RNA), bioinformatic analysis, with positive pathogen identification
0504U Infectious disease (urinary tract infection), identification of 17 pathologic organisms, urine, realtime PCR, reported as positive or negative for each organism
0505U Infectious disease (vaginal infection), identification of 32 pathogenic organisms, swab, real-time PCR, reported as positive or negative for each organism
0528U 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
0531U Infectious disease (acid-fast bacteria and invasive fungi), DNA (673 organisms), next-generation sequencing, plasma
0556U Infectious disease (bacterial or viral respiratory tract infection), pathogen-specific DNA and RNA by real-time PCR, 12 targets, nasopharyngeal or oropharyngeal swab, including multiplex reverse transcription for RNA targets, each analyte reported as detected or not detected
0557U Infectious disease (bacterial vaginosis and vaginitis), real-time amplification of DNA markers for Atopobium vaginae, Gardnerella vaginalis, Megasphaera types 1 and 2, bacterial vaginosis associated bacteria-2 and -3 (BVAB-2, BVAB-3), Mobiluncus species, Trichomonas vaginalis, Neisseria gonorrhoeae, Candida species (C. albicans, C. tropicalis, C. parapsilosis, C. glabrata, C. krusei), Herpes simplex viruses 1 and 2, vaginal fluid, reported as detected or not detected for each organism
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

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

0574U Mycobacterium tuberculosis, culture filtrate protein-10-kDa (CFP-10), serum or plasma, liquid chromatography mass spectrometry (LC-MS)

0588U Infectious disease (bacterial or viral), 32 genes (29 informative and 3 housekeeping), immune response mRNA, gene expression profiling by split-well multiplex reverse transcription loop-mediated isothermal amplification (RT-LAMP), whole blood, reported as continuous risk scores for likelihood of bacterial and viral infection and likelihood of severe illness within the next 7 days

0590U Infectious disease (bacterial and fungal), DNA of 44 organisms (34 bacteria, 10 fungi), urine, next-generation sequencing, reported as positive or negative for each organism

0593U Infectious disease (genitourinary pathogens), DNA, 46 targets (28 pathogens, 18 resistance genes), RT-PCR amplified probe technique, urine, each analyte reported as detected or not detected

0594U Infectious disease (sepsis), semiquantitative measurement of pancreatic stone protein concentration, whole blood, reported as risk of sepsis

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

The below CPT codes are covered only with one of the following ICD-10 diagnosis codes

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

81514 Infectious disease, bacterial vaginosis and vaginitis, quantitative real-time amplification of DNA markers for Gardnerella vaginalis, Atopobium vaginae, Megasphaera type 1, Bacterial Vaginosis Associated Bacteria-2 (BVAB-2), and Lactobacillus species (L. crispatus and L. jensenii), utilizing vaginal-fluid specimens, algorithm reported as a positive or negative for high likelihood of bacterial vaginosis, includes separate detection of Trichomonas vaginalis and/or Candida species (C. albicans, C. tropicalis, C. parapsilosis, C. dubliniensis), Candida glabrata, Candida krusei, when reported

81515 Infectious disease, bacterial vaginosis and vaginitis, real-time PCR amplification of DNA markers for Atopobium vaginae, Atopobium species, Megasphaera type 1, and Bacterial Vaginosis Associated Bacteria-2 (BVAB-2), utilizing vaginal-fluid specimens, algorithm reported as positive or negative for high likelihood of

bacterial vaginosis, includes separate detection of Trichomonas vaginalis and Candida species (C. albicans, C. tropicalis, C. parapsilosis, C. dubliniensis), Candida glabrata/Candida krusei, when reported

ICD-10 Codes

A51.0	Primary genital syphilis
A51.1	Primary anal syphilis
A51.31	Condyloma latum
A52.76	Other genitourinary symptomatic late syphilis
A54.00 -A54.03	Gonococcal infections
A54.09	Other gonococcal infection of lower genitourinary tract
A54.1	Gonococcal infection of lower genitourinary tract with periurethral and accessory gland abscess
A54.21-A54.24	Gonococcal infections
A54.29	Other gonococcal genitourinary infections
A54.6	Gonococcal infection of anus and rectum
A56.00-A56.02	Chlamydial infection
A56.09	Other chlamydial infection of lower genitourinary track
A56.11	Chlamydial female pelvic inflammatory disease
A56.19	Other chlamydial genitourinary infection
A56.2 -A56.3	Chlamydial infection
A59.00-A59.03	Trichomoniasis
A59.09	Other urogenital trichomoniasis
A60.00-A60.04	Herpesviral infection
A60.09	Herpesviral infection of other urogenital tract
A60.1	Herpesviral infection of perianal skin and rectum
A60.9	Anogenital herpesviral infection, unspecified
A63.0	Anogenital (venereal) warts
B20	Human immunodeficiency virus [HIV] disease
B37.31-B37.32	Acute or chronic candidiasis of vulva and vagina
B37.41	Candidal cystitis and urethritis
B37.42	Candidal balanitis
B37.49	Other urogenital candidiasis
B37.89	Other sites of candidiasis
D26.0	Other benign neoplasm of cervix uteri
L29.2	Pruritus vulvae
L29.3	Anogenital pruritus, unspecified
N34.1-N34.2	Urethritis
N41.0	Acute prostatitis
N41.3	Prostatocystitis
N48.5	Ulcer of penis
N76.0-N76.3	Vaginitis
N76.5-N76.6	Ulceration of vagina or vulva
N76.82	Fournier disease of vagina and vulva
N76.89	Other specified inflammation of vagina and vulva

N77.1	Vaginitis, vulvitis and vulvovaginitis in diseases classified elsewhere
N89.8	Other specified noninflammatory disorders of vagina
N93.0	Postcoital and contact bleeding
N93.8	Other specified abnormal uterine and vaginal bleeding
O98.711-O98.713	Human immunodeficiency virus [HIV] disease complicating pregnancy
R10.2	Pelvic and perineal pain
R30.0	Dysuria
T74.21XA	Adult sexual abuse, confirmed, initial encounter
T74.21XD	Adult sexual abuse, confirmed, subsequent encounter
T74.21XS	Adult sexual abuse, confirmed, sequela
T74.51XA	Adult forced sexual exploitation, confirmed, initial encounter
T74.51XD	Adult forced sexual exploitation, confirmed, subsequent encounter
T74.51XS	Adult forced sexual exploitation, confirmed, sequela
T76.21XA	Adult sexual abuse, suspected, initial encounter
T76.21XD	Adult sexual abuse, suspected, subsequent encounter
T76.21XS	Adult sexual abuse, suspected, sequela
T76.51XA	Adult forced sexual exploitation, suspected, initial encounter
T76.51XD	Adult forced sexual exploitation, suspected, subsequent encounter
T76.51XS	Adult forced sexual exploitation, suspected, sequela
Z04.41	Encounter for examination and observation following alleged adult rape
Z04.71	Encounter for examination and observation following alleged adult physical abuse
Z04.81	Encounter for examination and observation of victim following forced sexual exploitation
Z11.3	Encounter for screening for infections with a predominantly sexual mode of transmission
Z20.2	Contact with and (suspected) exposure to infections with a predominantly sexual mode of transmission
Z20.6	Contact with and (suspected) exposure to human immunodeficiency virus [HIV]
Z21	Asymptomatic human immunodeficiency virus [HIV] infection status
Z33.1	Pregnant state, incidental
Z33.3	Pregnant state, gestational carrier
Z72.51-Z72.53	High risk sexual behavior
Z72.89	Other problems related to lifestyle

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of medical professionals and are based upon a review of published and unpublished information including, but not limited to, current medical literature, guidelines published by public health and health research agencies, and community medical practices in the treatment and diagnosis of disease. Because medical practice, information, and technology are constantly changing, Priority Health reserves the right to review and update its medical policies at its discretion.

Priority Health's medical policies are intended to serve as a resource to the plan. They are not intended to limit the plan's ability to interpret plan language as deemed appropriate. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment they choose to provide.

The name "Priority Health" and the term "plan" mean Priority Health, Priority Health Managed Benefits, Inc., Priority Health Insurance Company and Priority Health Government Programs, Inc.