



UM-CDG-066 Molecular Syndromic Panels for
Infectious Disease Pathogen Identification Testing

Approved By:
Director, Health Services

Effective Date:
10/20/2025

This Policy applies to all SECUR affiliates, associates, and subsidiaries.

Approved by Courtney Gonzales, Director of Health Services on behalf of the Utilization Management Committee.

PURPOSE

This coverage determination guideline serves to address outpatient testing with panels using molecular syndromic panels for infectious disease pathogen identification testing. This coverage determination guideline defines a panel as a test that detects greater than one (1) pathogen. This coverage determination guideline also differentiates (where appropriate) between small, targeted panels (up to five (5) pathogens) and larger, expanded panels (six (6) or greater pathogens). This distinction is primarily applied to the Respiratory and Gastrointestinal Panels. A “syndromic panel” is further defined as one that simultaneously detects multiple different pathogens associated with similar and overlapping clinical symptomatology.

This is not a coverage determination guideline for metagenomic next-generation sequencing, mass spectrometry, or fluorescence in situ hybridization (FISH).

For SECUR Health Plan members, National Coverage Determinations (NCD) and Local Coverage Determinations (LCD) will be applied to requests when applicable. SECUR Health Plan Coverage Determination Guidelines (CDG) will be utilized in the absence of an appropriate NCD and/or LCD.

DEFINITIONS

None

POLICY

SECUR Health Plan will consider molecular syndromic infectious disease pathogen identification panel tests as medically necessary when the following criteria are met:

1. Member has a clinical indication for infectious disease testing:
 - For immunocompromised members, the clinical indication includes a presumption of active infection or infection-associated complications that require the identification of a causative organism for appropriate management. Atypical clinical presentations of disease are considered appropriate indications for special populations that may not present with classic symptoms of infection, such as the elderly.
 - For immunocompromised members or acquired immunodeficiency syndrome (AIDS), members who are taking immunosuppressive medications, and those with inherited diseases that affect the immune system, atypical clinical presentations of disease are considered appropriate indications for testing. In this patient population *testing may be performed once* as a part of a pre-transplant evaluation, regardless of presence of symptoms.

- For certain panels, such as the Urogenital/Anogenital Panel, epidemiologic indication or potential exposure to pathogens because of a high-risk experience is considered an appropriate indication, even in the absence of clinical symptoms.
2. The results of testing will impact clinical management in a manner already demonstrated in the peer-reviewed literature to improve member outcomes.
3. Testing is performed according to the intended use of the test in the intended patient population for which the test was developed and validated.
 - This includes performing the test using the intended sample types along with parallel testing that must accompany the test.
 - This also includes the provision, by the lab to ordering providers, of major limitations of a given panel test.
4. An evaluation for more than one (1) pathogen by molecular testing is necessary for member management. The panel performed includes at least the minimum pathogens required for clinical decision making for its intended use that cannot be reasonably detected by the test.
5. Expanded panel testing is only indicated when targeted panel testing is not appropriate.
6. Services that do not have a US Food and Drug Administration (FDA) cleared/approved indication, as well as FDA-approved tests performed in ways inconsistent with their intended use labeling directions will require registration with Molecular Diagnostic Services Program (MoIDX®) and a Technical Assessment (TA) to demonstrate compliance of the service with this coverage determination guideline.
7. Registered tests must demonstrate equivalent or superior test performance characteristics including analytical validity (AV) and clinical validity (CV) to established standard of care (SOC) methods.
 - CV of any new organisms and analytes that are not already established as SOC or that do not have a predicate test that is covered by SECUR Health Plan must be established through a study published in the peer-reviewed literature for the intended use of the test in the intended population.
8. Documentation of the following must be clearly stated in the supporting documentation provided with the request:
 - Specific clinical indications for testing
 - Specific reasons for performing panel testing
 - Provider type/specialty and place of service
9. Testing must be performed according to Clinical Laboratory Improvement Amendments (CLIA) and/or FDA regulations. CLIA waived tests may be performed in healthcare settings that operate under a CLIA Certificate of Waiver or Certificate of Compliance/Certificate of Accreditation. *Panels intended for home use do not meet the coverage criteria of this coverage determination guideline regardless of FDA approval or clearance.*

SECUR Health Plan will consider molecular syndromic panel tests as not medically necessary for the below:

1. Test is performed as a test of cure.
2. Member has previously tested by molecular diagnostic methods for the same pathogens within fourteen (14) days for the same clinical indication.
 - If a previous panel test was performed with a similar/duplicative intended use, a subsequent test is only medically necessary if the non-duplicative content of the second test is deemed medically necessary.
 - *Exception: Repeat panel testing for the same clinical indication will only be considered medically necessary if the first panel yielded a negative result and there is a high index of suspicion for a pathogen as the cause of the symptoms and the member's clinical condition is not improving or is deteriorating after a clinically appropriate length of time. In these cases, one (1) additional panel test may be covered between one (1) and fourteen (14) days after the initial panel test, if the test fulfills the criteria for coverage set forth in this coverage determination guideline.*

For the specific panel types listed below, the following additional criteria must be met:

Respiratory (RP) and Pneumonia (PNP) Panels will only be considered medically necessary when targeted testing is not appropriate and according to the following criteria:

1. For immune-competent members, at least one (1) of the following must apply:
 - Testing is ordered by a clinician specialist in infectious disease or pulmonary for a member with severe and established underlying respiratory pathology and treatment with antibiotics may be indicated according to established guidelines.
 - Specific examples that do not meet coverage criteria according to the established guidelines include asthma exacerbations without the additional presence of either fever or purulent sputum or radiographic evidence of pneumonia and uncomplicated community acquired pneumonia (CAP).
2. For immune-suppressed members, testing is ordered by a clinician specialist in either infectious disease, pulmonology, oncology, transplant, or the member is being managed by an appropriate critical care facility.
3. For all members, only one (1) of the following panels, RP or PNP, will be considered medically necessary for a given member for the same clinical indication. The PNP should be prioritized in the evaluation of pneumonia from lower respiratory tract specimens. For the purposes of repeat panel testing for the same clinical indication, RP and PNP will be considered as equivalent tests, such that if criteria for repeat testing are met, as defined above, a clinical may choose to perform the repeat test using the PNP, even if the original test was performed using the RP.

Gastrointestinal (GI) panels will only be considered medically necessary when targeted testing is not appropriate and according to the following additional criteria:

1. For immune-competent members, at least one (1) of the following must apply:
 - Testing is ordered by a clinical specialist in infectious disease or gastroenterology for a member with severe and established underlying GI pathology and identification of an infectious cause is necessary to determine next steps in member management.
 - The member is seriously or critically ill or at imminent risk of becoming seriously or critically ill because of a resumed GI infection and the member is being treated in an appropriate critical care facility.
 - The member's clinical indication for GI panel testing is diarrhea and the diarrheal illness must be acute or persistent with signs and risk factors for severe disease that may warrant hospitalization and/or the diarrheal illness is not resolving after seven (7) days and the member has not taken laxatives within 24 hours of the test.
2. For immune-suppressed members, testing must be ordered by a clinical specialist in infectious disease, gastroenterology, oncology, transplant, or the member is being managed in an appropriate critical care facility.

Urogenital/Anogenital (UG/AG) panels will be considered medically necessary when epidemiologic indication or potential exposure to sexually transmitted pathogens is present, even in the absence of clinical symptoms. Documentation of the high-risk reason for the panel testing must be indicated in the provided supporting documentation with the request.

In the absence of a high-risk experience, if the primary clinical concern is for a few specific pathogens due to specific signs or symptoms, it is expected that only a small, targeted panel will be performed. In these instances, expanded panels will not be considered medically necessary.

For the diagnosis of infectious vaginosis/vaginitis, it is considered medically necessary to perform a panel that

includes a combination of at least two (2) of the following:

- Gardnerella vaginalis
- Other bacterial vaginosis (BV) associated bacteria (BAVD)
- Trichomonas vaginalis
- Candida species

Meningoencephalitis (ME) Panels will be considered medically necessary according to the following additional criteria:

1. For immune-competent members, the member has at least two (2) of the following indicators of central nervous system (CNS) infection: cerebrospinal fluid (CSF) markers, radiology, clinical signs and symptoms consistent with meningitis or encephalitis, epidemiologic indication or exposure. For immune-compromised members, at least one (1) of the previous must be present.
2. For all members, testing is from a sample collected via lumbar puncture and not an indwelling medical device.

Bloodstream Infection (BSI) Panels will be considered medically necessary if there exists a clinical concern for bacteremia or sepsis and microbe(s) were seen on a Gram stain from the member's blood and the member is being managed in an appropriate critical care facility (this includes the emergency department) and personnel are equipped for rapid (within 24 hours) tailoring of antimicrobial therapy because of rapid testing.

Urinary Tract Infection (UTI) Panels will be considered medically necessary if the member is symptomatic and at a higher risk for UTI complications and/or is seen in urogynecology or urology specialty care settings.

Additional tests that demonstrate similar indicated uses and equivalent or superior performance to SOC or other covered tests, as demonstrated in a TA, may similarly be considered medically necessary under this coverage determination guideline. Additional syndromic panel types and indications may also be covered according to the established criteria within this coverage determination guideline.

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