

Medical Necessity Guideline: Multiplex Respiratory and GI PCR Testing	Creation Date: 06/17/2020	Review Date: 05/23/2023	Effective Date: 06/26/2020
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PURPOSE:

To define the indications for performing respiratory and gastrointestinal (GI) viral panels by polymerase chain reaction (PCR) testing done outside the recommended places of service (POS).

DEFINITIONS:

Multiplex PCR - the simultaneous detection of multiple targets in a single reaction well, with a different pair of primers for each target. This technique requires two or more probes that can be distinguished from each other and detected simultaneously. ⁽¹⁾

GUIDELINE:

Driscoll Health Plan follows the policy guideline that respiratory viral panels (R-PCRs) and GI viral panels (GI-PCR) are covered for an immunocompromised, immunosuppressed, or an otherwise high-risk members when testing is performed in an inpatient hospital admission, emergency rooms where test results will influence admission decisions or admission for observation. Examples of conditions that could put members at high-risk for complications include members on cancer treatments, transplant patients, members on monoclonal antibody treatments, cystic fibrosis, or other chronic lung diseases.

The routine use of R-PCRs and GI-PCRs is not medically indicated in the usual outpatient setting to diagnose and manage acute respiratory or GI illnesses. The routine use of R-PCR, instead of COVID – 19 specific testing, is inappropriate and not medically indicated. The inclusion of Chlamydia DNA Amp Probe, and Mycoplasma Pneumonia DNA Amp Probe alone or with R-PCRs is also considered not medically necessary for routine diagnosis and management of acute respiratory illnesses. Requests for these tests require prior authorization and medical director review on a case-by-case basis.

Additional criteria for medical necessity for performing either R-PCR or GI-PCR in the outpatient setting include

- The patient has failed reasonable and appropriate management AND/OR
- Diagnostic testing will substantially aid or change clinical management

Required Documentation:

1. Member is immunocompromised, immunosuppressed, or otherwise at high risk for respiratory or GI complications.
2. Clinic notes or specialty notes listing the diagnosis, comorbidities, duration of the symptoms, vital signs, current treatments, current, and past testing,
3. Explanation of how results of these broad tests will alter decision-making and management, such as avoidance of hospitalization.

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Background

Polymerase chain reaction (PCR), respiratory viral panels (RVP), and GIVP may detect the RNA or DNA of multiple respiratory viruses as a single test, often through a nasal, nasopharyngeal, or oropharyngeal swab. Viral pathogens are the most common cause of respiratory tract infections. PCR testing effectively confirms respiratory viral infections with very high sensitivity and specificity. Rhinovirus, parainfluenza virus, coronavirus, adenovirus, respiratory syncytial virus, Coxsackie virus, human metapneumovirus, and influenza virus account for most cases of viral respiratory infections. ⁽¹⁾

Multiplex PCR testing can detect numerous respiratory viruses; that number varies with the type and brand of testing being performed. However, the diagnostic role and importance of these multipathogen panels in identifying specific viruses in the setting of a respiratory infection is quite limited because the care and management of the patient is not altered based on the pathogen identified if any. For example, the child with a URI, cough, and wheezing who might be positive for RSV would not be managed any differently than the child with parainfluenza virus, adenovirus, rhinovirus, human metapneumovirus, enterovirus, Coxsackie virus, or coronavirus. ⁽²⁾

The Infectious Disease Society of America recommends that “clinicians should use multiplex RT-PCR assays targeting a panel of respiratory pathogens, including influenza viruses, in hospitalized immunocompromised patients” and that “clinicians can consider using multiplex RT-PCR assays targeting a panel of respiratory pathogens, including influenza viruses, in hospitalized patients who are not immunocompromised if it might influence care (e.g., aid in cohorting decisions, reduce testing, or decrease antibiotic use).” ⁽³⁾

Multiplex PCR testing for GI illnesses can detect a host of viruses and bacteria with the panel varying with labs. These panels can include Adenovirus F 40/41; Campylobacter; Clostridium difficile toxin A/B; Cryptosporidium; Cyclospora cayetanensis; E coli O157; Entamoeba histolytica; enteroaggregative E coli (EAEC); enteropathogenic E coli (EPAC); enterotoxigenic E coli (ETEC) lt/st; Giardia lamblia; norovirus GI/GII; Plesiomonas shigelloides; rotavirus A; Salmonella; Sapovirus; Shiga-like toxin-producing E coli (STEC) stx1/stx2; Shigella/enteroinvasive E coli (EIEC); Vibrio; Vibrio cholerae; Yersinia enterocolitica. The use of this panel in the evaluation of the member with an acute GI illness is not indicated.

Mayo Clinic Laboratories list the following indications for the use of GIVP:

“Briefly, the gastrointestinal pathogen panel should be considered for patients with community-acquired diarrhea of <7 days duration, travel-related diarrhea, or diarrhea with warning signs or risk factors for severe disease, since it tests for all of the common bacterial, viral, and parasitic cases of diarrhea.” ⁽⁶⁾

Hayes Precision Medicine Briefs find no utility in Respiratory Panels. ^(4, 5)

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PROVIDER CLAIMS CODES:

CPT		
87633	87581	87634

RVPs and GIVPs are payable in the following place of service without Prior Authorization		
POS 21	POS 22	POS 23

REFERENCES:

1. Biorad (2020), Multiplex PCR – Principles and use of Multiplex PCR, found at <https://www.bio-rad.com/featured/en/multiplex-pcr.html>; accessed 5/21/2021.
2. Weintraub, Benjamin; Upper Respiratory Tract Infections, *Pediatrics in Review*. December 2015, 36(12):554-556; DOI: <https://doi.org/10.1542/pir.36-12-554>; Accessed 05/21/2022.
3. Clinical Practice Guidelines by the Infectious Diseases Society of America: 2018 Update on Diagnosis, Treatment, Chemoprophylaxis, and Institutional Outbreak Management of Seasonal Influenza. *Clin Inf Dis* 2019; Volume 68, Issue 6, Pages e1–e47, <https://doi.org/10.1093/cid/ciy866>; Accessed 05/21/2022.
4. Hayes Precision Medicine Research Brief, “FilmArray Respiratory Panel and FilmArray Respiratory Panel 2 (BioFire Diagnostics LLC),” September 2019; Accessed 05/21/2021.
5. Hayes Precision Medicine Research Brief, “FilmArray Respiratory Panel 2 (BioFire Diagnostics LLC),” May 2020. Accessed 05/21/2022.
6. GIP – Overview: Gastrointestinal Pathogen Panel, PCR, Feces, found at URL: <https://www.mayocliniclabs.com/test-catalog/Overview/6319>. Accessed May 24, 2022, Corpus Christi Texas.

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DOCUMENT HISTORY:

DHP Committee that Approved	<i>Review Approval Date (last 5 years)</i>				
Medical Director	06/22/2020	06/10/2021	05/24/2022	05/23/2023	
CMO	06/22/2020	06/10/2021	06/07/2022	06/06/2023	
Medical Policy Workgroup <i>Effective 2022</i>			06/07/2022	06/06/2023	
Medical Management <i>Retired December 2020</i>	06/22/2020				
Utilization Management & Appeals <i>Effective January 2021</i>		06/10/2021	06/21/2022	06/20/2023	
Utilization Management Behavioral Health <i>Retired December 2020</i>	06/22/2020				
Provider Advisory Committee (PAC) <i>Effective 2022</i>			06/17/2022	06/09/2023	
Clinical Management Committee <i>Effective March 2021</i>		06/17/2021	06/24/2022 & 08/23/2022	07/20/2023	
Quality Management <i>Retired 2020</i>	06/26/2020				

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Executive Quality Committee <i>Effective 2021</i>		08/04/2021	06/28/2022	07/25/2023	
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<i>Document Owner</i>	<i>Organization</i>	<i>Department</i>
Dr. Fred McCurdy, Medical Director	Driscoll Health Plan	Utilization Management

<i>Review/Revision Date</i>	<i>Review/Revision Information, etc.</i>
03/0/2018	Introduction of Guideline and FAX BLAST
11/28/2019	No change
05/18/2020	Rewrite of Guideline with conversion to new format, new language, added and updated references
06/16/2020	Minor punctuation and formatting in accord with Dr. Serrao edit request
05/21/2021	Reviewed references for currency including Hayes – Included COVID 19 as part of a panel, verified codes
05/09/2022	Reviewed references and Hayes for currency – Dr. Thomas Morris
05/24/2022	Final editing and review by Dr. Fred McCurdy
05/23/2023	Reviewed by Drs Thomas Morris and Fred McCurdy

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