

Medical Necessity Guideline:	Creation Date:	Review Date:	Effective Date:
Polymerase Chain Reaction (PCR) Respiratory Viral Panel (RVP) Testing	04/09/2024	05/24/2024	06/11/2024

PURPOSE:

This medical necessity guideline outlines the criteria to establish the medical necessity of respiratory viral panels (RVPs) for diagnosing respiratory infections in children and young adults. The guideline ensures that polymerase chain reaction (PCR) testing is used judiciously and effectively in diagnosing and managing respiratory infections, considering clinical indications, patient characteristics, and healthcare resource utilization.

DEFINITIONS: (underline and list in alphabetic order)

Analytical Validity (AV) – A term that refers to how accurately and reliably the test detects and measures a biomarker of interest.

Clinical Validity (CV) - A term that refers to the predictive value of a test for a given clinical outcome (e.g., the likelihood that disease “X” will develop in someone with a positive test).

PCR (Polymerase Chain Reaction) - A laboratory method used to make many copies of a specific piece of DNA from a sample containing very tiny amounts. Polymerase chain reaction allows these pieces of DNA to be amplified so they can be detected.

Standard-of-care (SOC) - Treatment that medical experts accept as proper for a certain type of disease and that is widely used by health care professionals. It is also called best practice, standard medical care, and standard therapy.

GUIDELINE:

- I. Driscoll Health Plan considers respiratory viral panels (RVPs) testing for five pathogens or fewer **medically necessary** when all the following are met ⁽¹⁻²⁾:
 - A. The submitted record indicates the member has one of the following clinical indications for infectious disease testing:
 1. The member is **immunocompetent**, and the clinician presumes an active infection or infection-associated complications (which may include exacerbation of underlying disease) requiring identification of a causative organism for appropriate management.

Note: Atypical clinical presentations of disease are considered appropriate indications for special populations who may not present with classic symptoms

Medical Necessity Guideline: STAR, CHIP, STAR Kids

Confidential: For use only by employees and authorized agents of Driscoll Health Plan. This document contains confidential and proprietary information NOT to be reproduced or distributed to others without the prior written consent of Driscoll Health Plan

of infection (e.g., infants < 4 months of age);

2. The member is **immunocompromised** due to an acquired disease (e.g., children and young adults with human immunodeficiency virus [HIV] or acquired immunodeficiency syndrome [AIDS]), the member is taking immunosuppressive medications (e.g., chemotherapy, biologics, transplant-related immunosuppressive drugs, high-dose systemic corticosteroids), or the member has an inherited disease that affects their immune system (e.g., congenital immunoglobulin deficiencies, Wiskott-Aldrich syndrome, DiGeorge syndrome, etc.) and identification of the offending agent is imperative.

Note: Atypical clinical presentations of disease are considered appropriate indications for testing (e.g., infants < 4 months of age). Also, in this group of patients, testing may be performed once as part of a pre-transplant evaluation, regardless of the presence of symptoms (e.g., pre-bone-marrow transplant, etc.);

- B. The test results will impact clinical management in a manner already demonstrated in the published, peer-reviewed literature to improve the clinical outcome;
- C. The test is being performed according to its intended use in the intended population for which the test was developed and validated;
- D. Targeted testing not clinically appropriate (i.e., the targeted test will not provide sufficient information for the appropriate clinical management);
- E. The panel requested includes the **minimum** number of pathogens that will yield a clinically appropriate result, which can then be used in making the correct clinical decision for management/treatment;
- F. The requested test demonstrates an equivalent or superior test performance characteristic - analytical validity (AV) and clinical validity (CV) - to the established standard-of-care (SOC) methods (e.g., culture, pathogen-specific PCR) for the majority of targets included in the panel;
- G. **And the following is clearly stated in the medical record:**
 1. Specific clinical indications for testing (e.g., clinical suspicion of a pathogen as the cause of the medical condition);
 2. Specific reason(s) for performing this exact panel testing;
 3. Provider type/specialty
 4. The place of service.

II. Driscoll Health Plan considers that RVPs testing for **six (6) pathogens, or more**, are considered **medically necessary** when the following criteria are met:

- A. The criteria in section I are met, **and** any of the following:
 1. The test is performed in a healthcare setting that cares for critically ill individuals, such as the emergency department or an inpatient facility (this includes members in an observation status);
 2. The member is immunocompromised, as defined in section I.A.2.;

Medical Necessity Guideline: STAR, CHIP, STAR Kids

Confidential: For use only by employees and authorized agents of Driscoll Health Plan. This document contains confidential and proprietary information NOT to be reproduced or distributed to others without the prior written consent of Driscoll Health Plan

3. The member is immunocompetent, and both of the following are met:
 - a. The member has a severe and established underlying respiratory pathology (e.g., severe asthma, chronic obstructive pulmonary disease [COPD], cystic fibrosis, pulmonary fibrosis, radiation therapy to the lung);
 - b. Treatment with a pharmacologic agent may be indicated according to established guidelines.

Documentation Requirements:

Please refer to Guideline, Sections I and II (above) as well as Tables 1 – 5 (e.g., CPT codes that support medical necessity [Tables 1 & 2], place of service codes supporting medical necessity [Table 3], and ICD-10 diagnosis codes that support medical necessity (Tables 4 & 5)) for details on required documentation.

BACKGROUND:

The US Food and Drug Administration (FDA) cleared the first respiratory syndromic panel in 2011.³ Since then, syndromic panel testing has expanded to multiple commercial assays for detecting infections of the respiratory system, blood, gastrointestinal (GI) system, and central nervous system. In doing this, the clinical microbiology laboratory has been revolutionized. Employing these syndromic panels, clinical microbiology laboratories have created integrated workflows that have increased time efficiencies. Beyond the laboratory, clinicians have embraced the rapid turnaround times and a broad number of potential “targets” these panels can offer, many of which had not been available to test for before the advent of these syndromic panels. However, with many advances in medicine, there are complications – the panels are costly, over-testing occurs, and sometimes the results can be confusing. Sometimes, the results have no apparent link to the actual care of the patient (e.g., multiple positive results or targets of unknown significance).⁴

Before the advent of syndromic panels, routine respiratory viral testing was limited to influenza and respiratory syncytial virus (RSV). Syndromic multiplex polymerase chain reaction (PCR) panels have allowed the rapid identification of a broad range of viruses and bacteria causing upper respiratory illness. Owing to the ease of testing, these panels have been widely adopted in clinical microbiology laboratories. While this broad testing has taught us about the prevalence and clinical significance of numerous viral illnesses (e.g., human metapneumovirus often causes severe disease, and rhinoviruses are ubiquitous), we are now faced with genuine dilemmas. Syndromic respiratory panels are costly compared with traditional methods of respiratory viral testing. The ease of testing has resulted in massive over-testing. Thus, these increased costs have been passed on to the patient and the insurance companies with little true benefit to overall

Medical Necessity Guideline: STAR, CHIP, STAR Kids

Confidential: For use only by employees and authorized agents of Driscoll Health Plan. This document contains confidential and proprietary information NOT to be reproduced or distributed to others without the prior written consent of Driscoll Health Plan

patient care/outcomes.⁵

PCR detection of nucleic acids does not rely on viable organisms. This increases sensitivity over traditional methods but does not necessarily increase the specificity of the result. Patients can shed the virus long after the illness has resolved, making repeat testing many times invalid. The other thing we have discovered in widespread syndromic panel testing is that patients will have more than one target, leaving the clinician to wonder which pathogen they are dealing with. Panels that include targets for coronaviruses HKU1, NL63, 229E, and OC43 have recently been confused, with clinicians and patients mistakenly believing they are positive for severe acute respiratory syndrome coronavirus. ² Outcome studies have been performed to quantify syndromic respiratory panels' benefits (or limitations). Only influenza, RSV, and adenovirus have an associated antiviral therapy for viral targets on respiratory syndromic panels.⁵

Theoretically, detecting other viral targets could benefit patients by decreasing the clinician's suspicion of bacterial infection and preventing initiation or promoting discontinuation of antibiotic therapy. So, how are upper respiratory syndromic panels affecting patient care? Results are mixed, with some studies showing a decrease in antibiotic therapy, decreased length of hospital stay, or decreased additional tests and imaging studies ⁶ whereas other studies showed no benefit.⁷

Multiplex molecular panels for syndromic testing are now well-established infectious disease diagnostics due to their increased sensitivity and efficiency, though their promise has only been partially fulfilled. Diagnostic stewardship is needed - selecting the right test for the right patient, generating accurate, clinically relevant results at the right time to influence clinical care optimally and to conserve health care resources - to ensure appropriate use and clinical response to results to achieve the full benefits these tests can offer.⁸

PROVIDER CLAIMS CODES:

Coding Implications

This clinical policy references Current Procedural Terminology (CPT[®]). CPT[®] is a registered trademark of the American Medical Association. All CPT codes and descriptions are copyrighted in 2022, American Medical Association. All rights reserved. CPT codes and CPT descriptions are from the current manuals, and those included herein are not intended to be all-inclusive and are included for informational purposes only. Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance before submitting claims to reimburse covered services.

Table 1: CPT codes that support medical necessity in any place of service without

Medical Necessity Guideline: STAR, CHIP, STAR Kids

Confidential: For use only by employees and authorized agents of Driscoll Health Plan. This document contains confidential and proprietary information NOT to be reproduced or distributed to others without the prior written consent of Driscoll Health Plan

diagnosis code requirements.

CPT Codes	Description
87631	Infectious agent detection by nucleic acid (DNA or RNA); respiratory virus (e.g., 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.

Table 2: CPT codes that support medical necessity when billed with the place of service codes in Table 3 and a diagnosis code in both Table 4 and Table 5

CPT Codes	Description
0115U	Respiratory infectious agent detection by nucleic acid (DNA and RNA), 18 viral types and subtypes and 2 bacterial targets, amplified probe technique, multiplex reverse transcription for RNA targets, each analyte reported as detected or undetected.
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, and 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, and 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.
87632	Infectious agent detection by nucleic acid (DNA or RNA); respiratory virus (e.g., 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 (e.g., adenovirus, influenza virus, coronavirus, metapneumovirus, parainfluenza virus, respiratory syncytial virus, rhinovirus), includes multiplex reverse transcription, when performed, and multiplex amplified probe

Medical Necessity Guideline: STAR, CHIP, STAR Kids

Confidential: For use only by employees and authorized agents of Driscoll Health Plan. This document contains confidential and proprietary information NOT to be reproduced or distributed to others without the prior written consent of Driscoll Health Plan

	technique, multiple types, or subtypes, 12-25 targets.
--	--------------------------------------------------------

Table 3: Place of service codes supporting medical necessity for codes in table 2

Place of Service Codes	Place of Service Name	Place of Service Description
19	Off-Campus-Outpatient Hospital	A portion of an off-campus hospital provider-based department that provides diagnostic, therapeutic (both surgical and nonsurgical), and rehabilitation services to sick or injured persons who do not require hospitalization or institutionalization.
21	Inpatient Hospital	A facility other than psychiatric that primarily provides diagnostic, therapeutic (both surgical and nonsurgical), and rehabilitation services by or under the supervision of physicians to patients admitted for a variety of medical conditions.
22	Outpatient Hospital (Observation)	A portion of a hospital that provides diagnostic, therapeutic (both surgical and nonsurgical), and rehabilitation services to sick or injured persons who do not require hospitalization or institutionalization.
23	Emergency Room – Hospital	A portion of a hospital where emergency diagnosis and treatment of illness or injury is provided.

Table 4: ICD-10 Diagnosis Codes that Support Medical Necessity for CPT Codes in Table 2 when Billed with a Diagnosis Code in Table 5

ICD-10-CM Code	Description
A37.00	Whooping cough due to Bordetella pertussis without pneumonia
A37.01	Whooping cough due to Bordetella pertussis with pneumonia
A37.10	Whooping cough due to Bordetella parapertussis without pneumonia
A37.11	Whooping cough due to Bordetella parapertussis with pneumonia
A37.80	Whooping cough due to other Bordetella species without pneumonia
A37.81	Whooping cough due to other Bordetella species with pneumonia
A37.90	Whooping cough, unspecified species without pneumonia
A37.91	Whooping cough, unspecified species with pneumonia
A41.81	Sepsis due to Enterococcus
A41.89	Other specified sepsis
A41.9	Sepsis, unspecified organism
A48.1	Legionnaires' disease

Medical Necessity Guideline: STAR, CHIP, STAR Kids

Confidential: For use only by employees and authorized agents of Driscoll Health Plan. This document contains confidential and proprietary information NOT to be reproduced or distributed to others without the prior written consent of Driscoll Health Plan

A48.2	Non-pneumonic Legionnaires' disease (Pontiac fever)
B25.0	Cytomegaloviral pneumonitis
B33.23	Viral pericarditis
B33.24	Viral cardiomyopathy
B59	Pneumocystosis
B97.21	SARS-associated coronavirus as the cause of diseases classified elsewhere
B97.29	Other coronavirus as the cause of diseases classified elsewhere
J05.0	Acute obstructive laryngitis (croup)
J06.9	Acute upper respiratory infection, unspecified
J09.X1	Influenza due to identified novel influenza A virus with pneumonia
J09.X2	Influenza due to identified novel influenza A virus with other respiratory manifestations
J09.X3	Influenza due to identified novel influenza A virus with gastrointestinal manifestations
J09.X9	Influenza due to identified novel influenza A virus with other manifestations
J10.01	Influenza due to other identified influenza virus with the same other identified influenza virus pneumonia
J10.08	Influenza due to other identified influenza virus with other specified pneumonia
J10.1	Influenza due to other identified influenza virus with other respiratory manifestations
J10.2	Influenza due to other identified influenza virus with gastrointestinal manifestations
J10.81	Influenza due to other identified influenza virus with encephalopathy
J10.82	Influenza due to other identified influenza virus with myocarditis
J10.83	Influenza due to other identified influenza virus with otitis media
J10.89	Influenza due to other identified influenza virus with other manifestations
J11.08	Influenza due to an unidentified influenza virus with specified pneumonia
J11.1	Influenza due to unidentified influenza virus with other respiratory manifestations
J11.2	Influenza due to unidentified influenza virus with gastrointestinal manifestations
J11.81	Influenza due to unidentified influenza virus with encephalopathy
J11.82	Influenza due to unidentified influenza virus with myocarditis
J11.83	Influenza due to unidentified influenza virus with otitis media
J11.89	Influenza due to an unidentified influenza virus with other manifestations
J12.0	Adenoviral pneumonia
J12.1	Respiratory syncytial virus pneumonia

Medical Necessity Guideline: STAR, CHIP, STAR Kids

Confidential: For use only by employees and authorized agents of Driscoll Health Plan. This document contains confidential and proprietary information NOT to be reproduced or distributed to others without the prior written consent of Driscoll Health Plan

J12.2	Parainfluenza virus pneumonia
J12.3	Human metapneumovirus pneumonia
J12.81	Pneumonia due to SARS-associated coronavirus
J12.82	Pneumonia due to coronavirus disease 2019
J12.89	Other viral pneumonia
J12.9	Viral pneumonia, unspecified
J13	Pneumonia due to Streptococcus pneumoniae
J15.0	Pneumonia due to Klebsiella pneumoniae
J15.1	Pneumonia due to Pseudomonas
J15.20	Pneumonia due to staphylococcus, unspecified
J15.211	Pneumonia due to Methicillin susceptible Staphylococcus aureus
J15.212	Pneumonia due to Methicillin resistant Staphylococcus aureus
J15.29	Pneumonia due to other staphylococcus
J15.3	Pneumonia due to streptococcus, group B
J15.4	Pneumonia due to other streptococci
J15.7	Pneumonia due to Mycoplasma pneumoniae
J15.8	Pneumonia due to other specified bacteria
J15.9	Unspecified bacterial pneumonia
J16.0	Chlamydial pneumonia
J16.8	Pneumonia due to other specified infectious organisms
J18.0	Bronchopneumonia, unspecified organism
J18.1	Lobar pneumonia, unspecified organism
J18.2	Hypostatic pneumonia, unspecified organism
J18.8	Other pneumonia, unspecified organism
J18.9	Pneumonia, unspecified organism
J20.0	Acute bronchitis due to Mycoplasma pneumoniae
J20.1	Acute bronchitis due to Hemophilus influenzae
J20.2	Acute bronchitis due to streptococcus
J20.3	Acute bronchitis due to coxsackievirus
J20.4	Acute bronchitis due to parainfluenza virus
J20.5	Acute bronchitis due to respiratory syncytial virus
J20.6	Acute bronchitis due to rhinovirus
J20.8	Acute bronchitis due to other specified organisms
J20.9	Acute bronchitis, unspecified
J21.9	Acute bronchiolitis, unspecified
J22	Unspecified acute lower respiratory infection
J44.0	Chronic obstructive pulmonary disease with (acute) lower respiratory infection
J44.1	Chronic obstructive pulmonary disease with (acute) exacerbation

Medical Necessity Guideline: STAR, CHIP, STAR Kids

Confidential: For use only by employees and authorized agents of Driscoll Health Plan. This document contains confidential and proprietary information NOT to be reproduced or distributed to others without the prior written consent of Driscoll Health Plan

J45.31	Mild persistent asthma with (acute) exacerbation
J45.32	Mild persistent asthma with status asthmaticus
J45.41	Moderate persistent asthma with (acute) exacerbation
J45.42	Moderate persistent asthma with status asthmaticus
J45.51	Severe persistent asthma with (acute) exacerbation
J45.52	Severe persistent asthma with status asthmaticus
J45.901	Unspecified asthma with (acute) exacerbation
J45.902	Unspecified asthma with status asthmaticus
J84.116	Cryptogenic organizing pneumonia
J84.117	Desquamative interstitial pneumonia
J84.2	Lymphoid interstitial pneumonia
J85.0	Gangrene and necrosis of lung
J85.1	Abscess of lung with pneumonia
J85.2	Abscess of lung without pneumonia
J85.3	Abscess of mediastinum
R05.1	Acute cough
R05.2	Subacute cough
R05.3	Chronic cough
R05.8	Other specified cough
R06.02	Shortness of breath
R06.03	Acute respiratory distress
R06.2	Wheezing
R50.9	Fever, unspecified
R65.20	Severe sepsis without septic shock
R65.21	Severe sepsis with septic shock
R78.81	Bacteremia
T86.33	Heart-lung transplant infection
T86.812	Lung transplant infection
Z03.818	Encounter for observation for suspected exposure to other biological agents ruled out
Z20.822	Contact with and (suspected) exposure to COVID-19
Z20.828	Contact with and (suspected) exposure to other viral communicable diseases
U07.1	COVID-19

Table 5: ICD-10 Diagnosis Codes that Support Medical Necessity for CPT codes in Table 2 when Billed with a Diagnosis Code in Table 4

ICD-10-CM Code	Description
----------------	-------------

Medical Necessity Guideline: STAR, CHIP, STAR Kids

Confidential: For use only by employees and authorized agents of Driscoll Health Plan. This document contains confidential and proprietary information NOT to be reproduced or distributed to others without the prior written consent of Driscoll Health Plan

B20	Human immunodeficiency virus (HIV) disease
C46.0	Kaposi's sarcoma of skin
C46.1	Kaposi's sarcoma of soft tissue
C46.2	Kaposi's sarcoma of palate
C46.3	Kaposi's sarcoma of lymph nodes
C46.4	Kaposi's sarcoma of gastrointestinal sites
C46.50	Kaposi's sarcoma of unspecified lung
C46.51	Kaposi's sarcoma of right lung
C46.52	Kaposi's sarcoma of left lung
C46.7	Kaposi's sarcoma of other sites
D57.01	Hb-SS disease with acute chest syndrome
D61.09	Other constitutional aplastic anemia
D61.1	Drug-induced aplastic anemia
D61.2	Aplastic anemia due to other external agents
D61.3	Idiopathic aplastic anemia
D61.810	Antineoplastic chemotherapy-induced pancytopenia
D61.811	Other drug-induced pancytopenia
D61.818	Other pancytopenia
D61.82	Myelophthisis
D61.89	Other specified aplastic anemias and other bone marrow failure syndromes
D61.9	Aplastic anemia, unspecified
D64.81	Anemia due to antineoplastic chemotherapy
D64.89	Other specified anemias
D70.0	Congenital agranulocytosis
D70.1	Agranulocytosis secondary to cancer chemotherapy
D70.2	Other drug-induced agranulocytosis
D70.3	Neutropenia due to infection
D70.4	Cyclic neutropenia
D70.9	Neutropenia, unspecified
D76.1	Hemophagocytic lymphohistiocytosis (HLH)
D80.0	Hereditary hypogammaglobulinemia
D80.1	Nonfamilial hypogammaglobulinemia
D80.2	Selective deficiency of immunoglobulin A (IgA)
D80.3	Selective deficiency of immunoglobulin G (IgG) subclasses
D80.4	Selective deficiency of immunoglobulin M (IgM)
D80.5	Immunodeficiency with increased immunoglobulin M (IgM)
D80.6	Antibody deficiency with near-normal immunoglobulins or with hyperimmunoglobulinemia
D80.8	Other immunodeficiencies with predominantly antibody defects

Medical Necessity Guideline: STAR, CHIP, STAR Kids

Confidential: For use only by employees and authorized agents of Driscoll Health Plan. This document contains confidential and proprietary information NOT to be reproduced or distributed to others without the prior written consent of Driscoll Health Plan

D80.9	Immunodeficiency with predominantly antibody defects, unspecified
D81.0	Severe combined immunodeficiency (SCID) with reticular dysgenesis
D81.1	Severe combined immunodeficiency (SCID) with low T- and B-cell numbers
D81.2	Severe combined immunodeficiency (SCID) with low or normal B-cell numbers
D81.30	Adenosine deaminase deficiency, unspecified
D81.31	Severe combined immunodeficiency due to adenosine deaminase deficiency
D81.32	Adenosine deaminase 2 deficiency
D81.39	Other adenosine deaminase deficiency
D81.4	Nezelof's syndrome
D81.5	Purine nucleoside phosphorylase (PNP) deficiency
D81.6	Major histocompatibility complex class I deficiency
D81.7	Major histocompatibility complex class II deficiency
D81.810	Biotinidase deficiency
D81.818	Other biotin-dependent carboxylase deficiency
D81.82	Activated Phosphoinositide 3-kinase Delta Syndrome (APDS)
D81.89	Other combined immunodeficiencies
D81.9	Combined immunodeficiency, unspecified
D82.0	Wiskott-Aldrich syndrome
D82.1	Di George's syndrome
D82.2	Immunodeficiency with short-limbed stature
D82.3	Immunodeficiency following hereditary defective response to Epstein-Barr virus
D82.4	Hyperimmunoglobulin E (IgE) syndrome
D82.8	Immunodeficiency associated with other specified major defects
D83.0	Common variable immunodeficiency with predominant abnormalities of B-cell numbers and function
D83.1	Common variable immunodeficiency with predominant immunoregulatory T-cell disorders
D83.2	Common variable immunodeficiency with autoantibodies to B- or T-cells
D83.8	Other common variable immunodeficiencies
D83.9	Common variable immunodeficiency, unspecified
D84.0	Lymphocyte function antigen-1 (LFA-1) defect
D84.1	Defects in the complement system
D84.821	Immunodeficiency due to drugs
D84.822	Immunodeficiency due to external causes
D84.89	Other immunodeficiencies
D84.9	Immunodeficiency, unspecified

Medical Necessity Guideline: STAR, CHIP, STAR Kids

Confidential: For use only by employees and authorized agents of Driscoll Health Plan. This document contains confidential and proprietary information NOT to be reproduced or distributed to others without the prior written consent of Driscoll Health Plan

D89.0	Polyclonal hypergammaglobulinemia
D89.1	Cryoglobulinemia
D89.3	Immune reconstitution syndrome
D89.41	Monoclonal mast cell activation syndrome
D89.42	Idiopathic mast cell activation syndrome
D89.43	Secondary mast cell activation
D89.44	Hereditary alpha tryptasemia
D89.49	Other mast cell activation disorder
D89.810	Acute graft-versus-host disease
D89.811	Chronic graft-versus-host disease
D89.812	Acute on chronic graft-versus-host disease
D89.813	Graft-versus-host disease, unspecified
D89.82	Autoimmune lymphoproliferative syndrome (ALPS)
D89.89	Other specified disorders involving the immune mechanism, not elsewhere classified
E08.43	Diabetes mellitus due to underlying condition with diabetic autonomic (poly)neuropathy
E10.43	Type 1 diabetes mellitus with diabetic autonomic (poly)neuropathy
E11.43	Type 2 diabetes mellitus with diabetic autonomic (poly)neuropathy
E13.43	Other specified diabetes mellitus with diabetic autonomic (poly)neuropathy
E84.0	Cystic fibrosis with pulmonary manifestations
J44.9	Chronic obstructive pulmonary disease, unspecified
J45.991	Cough variant asthma
J70.1	Chronic and other pulmonary manifestations due to radiation
J84.01	Alveolar proteinosis
J84.02	Pulmonary alveolar microlithiasis
J84.03	Idiopathic pulmonary hemosiderosis
J84.10	Pulmonary fibrosis, unspecified
J84.112	Idiopathic pulmonary fibrosis
J84.114	Acute interstitial pneumonitis
J84.170	Interstitial lung disease with progressive fibrotic phenotype in diseases classified elsewhere
J84.178	Other interstitial pulmonary diseases with fibrosis in diseases classified elsewhere
J84.81	Lymphangiomyomatosis
J84.89	Other specified interstitial pulmonary diseases
O98.711	Human immunodeficiency virus (HIV) disease complicating pregnancy, first trimester
O98.712	Human immunodeficiency virus (HIV) disease complicating pregnancy,

Medical Necessity Guideline: STAR, CHIP, STAR Kids

Confidential: For use only by employees and authorized agents of Driscoll Health Plan. This document contains confidential and proprietary information NOT to be reproduced or distributed to others without the prior written consent of Driscoll Health Plan

	second trimester
O98.713	Human immunodeficiency virus (HIV) disease complicating pregnancy, third trimester
T80.82XS	Complication of immune effector cellular therapy, sequela
Z51.11	Encounter for antineoplastic chemotherapy
Z92.850	Personal history of Chimeric Antigen Receptor T-cell therapy
Z92.858	Personal history of other cellular therapy
Z92.86	Personal history of gene therapy
Z94.0	Kidney transplant status
Z94.1	Heart transplant status
Z94.2	Lung transplant status
Z94.3	Heart and lungs transplant status
Z94.4	Liver transplant status
Z94.5	Skin transplant status
Z94.6	Bone transplant status
Z94.81	Bone marrow transplant status
Z94.82	Intestine transplant status
Z94.83	Pancreas transplant status
Z94.84	Stem cells transplant status
Z94.89	Other transplanted organ and tissue status
Z94.9	Transplanted organ and tissue status, unspecified

Medical Necessity Guideline: STAR, CHIP, STAR Kids

Confidential: For use only by employees and authorized agents of Driscoll Health Plan. This document contains confidential and proprietary information NOT to be reproduced or distributed to others without the prior written consent of Driscoll Health Plan

References:

1. Local coverage determination. Respiratory Pathogen Panel Testing (L38916). Centers for Medicare and Medicaid Services Web site.
<https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdId=38916&ver=8>. Published May 21, 2021 (currently in effect). Accessed February 8, 2024.
2. Local coverage determination. Billing and coding: Respiratory Pathogen Panel Testing (A58575). Centers for Medicare and Medicaid Services Web site.
<https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleId=58575&ver=32>. Published July 11, 2021 (revised April 1, 2023). Accessed February 8, 2024.
3. Russek-Cohen E, Feldblyum T, Whitaker KB, Hojvat S. FDA perspectives on diagnostic device clinical studies for respiratory infections. *Clin Infect Dis*. 2011;52 Suppl 4(Suppl 4):S305-S311. doi:10.1093/cid/cir056
4. Clark TW, Lindsley K, Wigmosta TB, et al. Rapid multiplex PCR for respiratory viruses reduces time to result and improves clinical care: Results of a systematic review and meta-analysis. *J Infect*. 2023;86(5):462-475. doi:10.1016/j.jinf.2023.03.005
5. Dien Bard J, McElvania E. Panels and Syndromic Testing in Clinical Microbiology. *Clin Lab Med*. 2020;40(4):393-420. doi:10.1016/j.cll.2020.08.001
6. Couturier MR, Bard JD. Direct-from-Specimen Pathogen Identification: Evolution of Syndromic Panels. *Clin Lab Med*. 2019;39(3):433-451. doi:10.1016/j.cll.2019.05.005
7. Sakata KK, Azadeh N, Brighton A, et al. Impact of Nasopharyngeal FilmArray Respiratory Panel Results on Antimicrobial Decisions in Hospitalized Patients. *Can Respir J*. 2018;2018:9821426. Published 2018 Jun 13. doi:10.1155/2018/9821426
8. Hitchcock MM, Gomez CA, Pozdol J, Banaei N. Effective Approaches to Diagnostic Stewardship of Syndromic Molecular Panels. *J Appl Lab Med*. 2024;9(1):104-115. doi:10.1093/jalm/jfad063

Medical Necessity Guideline: STAR, CHIP, STAR Kids

Confidential: For use only by employees and authorized agents of Driscoll Health Plan. This document contains confidential and proprietary information NOT to be reproduced or distributed to others without the prior written consent of Driscoll Health Plan

DOCUMENT HISTORY:

DHP Committee that Approved	<i>Review Approval Date (last 5 years)</i>				
Medical Director	04/09/2024	05/24/2024			
CMO	04/09/2024	06/11/2024			
Medical Policy Workgroup	04/12/2024	06/11/2024			
Utilization Management & Appeals Workgroup	04/16/2024	06/18/2024			
Provider Advisory Committee (PAC)	04/19/2024	07/01/2024			
Clinical Management Committee	04/22/2024	07/24/2024			
Executive Quality Committee	04/30/2024	07/30/2024			

<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>
04/09/2024	New Medical Necessity Guideline created by Fred McCurdy, MD
05/24/2024	Reviewed and revised by Dr. Fred McCurdy

Medical Necessity Guideline: STAR, CHIP, STAR Kids

Confidential: For use only by employees and authorized agents of Driscoll Health Plan. This document contains confidential and proprietary information NOT to be reproduced or distributed to others without the prior written consent of Driscoll Health Plan

Driscoll Health Plan Medical Necessity Guideline



Medical Necessity Guideline: STAR, CHIP, STAR Kids

Confidential: For use only by employees and authorized agents of Driscoll Health Plan. This document contains confidential and proprietary information NOT to be reproduced or distributed to others without the prior written consent of Driscoll Health Plan