Driscoll Health Plan
Medical Necessity Guideline

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Gastrointestinal Pathogen Nucleic Acid Detection Panel Testing	04/09/2024	05/24/2024	06/11/2024

PURPOSE:

This medical necessity guideline outlines the criteria for the medical necessity of Gastrointestinal Pathogen Nucleic Acid Detection Panel Testing (GIP-NADP) for diagnosing gastrointestinal infections. The guideline aims to ensure that GIP-NADP testing is used judiciously and effectively in diagnosing and managing gastrointestinal infections, considering clinical indications, patient characteristics, and healthcare resource utilization.

LINE OF BUSINESS: STAR, STAR Kids, and CHIP

DEFINITIONS:

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.

GIP-NADP - Gastrointestinal Pathogen Nucleic Acid Detection Panel Testing

NAAT - Nucleic acid amplification testing (NAAT) uses a microorganism's DNA or RNA to directly identify specific bacteria, viruses, and/or protozoa rather than standard microorganism detection techniques (e.g., bacterial culture, individual real-time PCR, immunoassays, and/or microscopy).

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 gastrointestinal pathogen panel testing of five or fewer targets is considered **medically necessary** when meeting **ALL** the following:
   A. The member has one of the following clinical indications for infectious disease testing:

4525 Ayers St.
Corpus Christi, Texas 78415
Telephone (877) 455-1053 Fax (866) 741-5650

1. The member is **immunocompetent**, and the clinical record documents a presumption of active infection or infection-associated complications (which may include exacerbation of underlying disease) that require the 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 of infection (e.g., infants <4 months of age)*;
2. The member is **immunocompromised** (e.g., children and young adults with human immunodeficiency virus [HIV] or acquired immunodeficiency syndrome [AIDS], those taking immunosuppressive medications [e.g., chemotherapy, biologics, transplant-related immunosuppressive drugs, high-dose systemic corticosteroids], and members with inherited diseases that affect the immune system [e.g., congenital immunoglobulin deficiencies].
   ***Note**: atypical clinical presentations of disease are considered appropriate indications for testing. In this population, testing may be performed once as part of a pre-transplant evaluation, regardless of the presence of symptoms*;

B. The results of testing will impact clinical management in a manner already demonstrated in the published, peer-reviewed literature to improve patient outcomes;
C. Testing is performed according to the intended use of the test in the intended population for which the test was developed and validated;
D. Targeted testing is not appropriate (i.e., will not provide sufficient information for appropriate clinical management);
E. The panel performed includes at least the minimum pathogens required for clinical decision-making for its intended use that the test can reasonably detect.
F. The registered test demonstrates equivalent or superior test performance characteristics - analytical validity (AV) and clinical validity (CV) - to established standard-of-care (SOC) methods (e.g., culture, pathogen-specific polymerase chain reaction [PCR]) for the majority of targets included on the panel;
G. <u>Documentation of the following is clearly stated in the medical record:</u>
   1. Specific clinical indications for testing (e.g., clinical suspicion of a pathogen as the cause of the patient's condition);
   2. Specific reasons for performing panel testing including why targeted testing is not appropriate;
   3. Previous stool studies/targeted testing, if performed, and results;
   4. Provider type/specialty and Place of Service.

II. Driscoll Health Plan considers expanded gastrointestinal pathogen panel testing of greater than six targets is considered **medically necessary** when meeting the

following:

A. The criteria in section I are met, **and** one of the following:
    1. The test is performed in a healthcare setting that cares for critically ill individuals, such as the emergency department or inpatient facility (this includes members in an observation status);
    2. The member is **immunocompromised**, as defined in section I.A.2.;
    3. The member is **immunocompetent** and any of the following:
        a. Testing is ordered for a patient with severe and established underlying gastrointestinal (GI) pathology (e.g., inflammatory bowel disease [IBD], paralytic ileus, radiation therapy to the intestine), and identification of an infectious cause is necessary to determine next steps in clinical management;
        b. The member is seriously or critically ill or at imminent risk of becoming seriously or critically ill as a result of a presumed GI infection, and the patient is being treated in an appropriate critical care facility;
        c. The clinical indication for GI panel testing is diarrhea and any of the following:
            i. The diarrheal illness is acute or persistent with signs or risk factors for severe disease (e.g., fever, bloody diarrhea, dysentery, dehydration, severe abdominal pain) that may warrant hospitalization;
            ii. The diarrheal illness has persisted >7 days, and the member/enrollee had not taken laxatives within 24 hours of the test.

Documentation Requirements:

Please refer to Guideline, Sections I and II (above) as well as Tables 1 – 6 (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, & 6]) for details on required documentation.

BACKGROUND:

Infectious gastroenteritis is a very common condition that accounts for approximately 10% of pediatric deaths and is the second most frequent cause of death worldwide [1] via diarrhea, vomiting, and other symptoms, and life-threatening dehydration in severe cases. Causes include infections with bacteria (e.g., Clostridium difficile, Escherichia coli, Shigella), viruses (e.g., norovirus, rotavirus), or parasites (e.g., Cryptosporidium, Giardia). [1, 2]

Nucleic acid amplification testing (NAAT) uses a microorganism's DNA or RNA to directly identify specific bacteria, viruses, and/or protozoa rather than standard

microorganism detection techniques (e.g., bacterial culture, individual real-time PCR, immunoassays, and/or microscopy). Multiplex NAAT tests are included in the larger culture-independent diagnostic tests (CIDT) grouping. Mult pathogen NAATs can simultaneously detect viral, parasitic, and bacterial agents, including some pathogens that previously could not be easily detected in the clinical setting, such as norovirus, enterotoxigenic E. coli (ETEC), enteropathogenic E. coli (EPEC), and enteroaggregative E. coli (EAEC), in less time than traditional methods. [3, 4]

Multi-pathogen NAAT is associated with high clinical validity for most available pathogenic targets relative to conventional testing. It has a more rapid turnaround time than most traditional testing types. Drawbacks of molecular technologies include the need to predefine the microbes sought, detection of microbes at nonpathogenic levels, and increased detection of mixed infections; the relative importance of each pathogen identified may be unclear. [1]

Cotter et al. published a multicenter, cross-sectional study of children with diarrhea that raises concerns about the widespread use of gastrointestinal pathogen (GIP) testing. The study compared outcomes between children who underwent GIP testing and historical controls before such testing became readily available. Here are the key findings and conclusions drawn by the authors:

1. **Study Design**: The study analyzed data from multiple centers and employed a cross-sectional design to assess the impact of GIP testing on various outcomes in children with diarrhea.
2. **Comparison with Historical Controls**: The study compared outcomes in children who received GIP testing to those in historical controls before GIP testing was widely available to evaluate the effect of GIP testing on patient management.
3. **Key Outcomes**:
    - **Stool Testing**: After implementing GIP testing, the proportion of children undergoing stool testing increased by 21%. The post-GIP testing group also had a statistically higher percentage of positive results.
    - **Time to Result and Treatment**: The study found a decreased time to both test results and treatment in the post-GIP testing period.
    - **Benefit Subset**: Only a small subset (3%) of the total study population received treatment for bacterial or parasitic infections.
    - **Length of Stay (LOS), Ancillary Testing, and Hospital Charges**: Overall, no statistical difference was observed between the before- and after-GIP testing groups regarding LOS, ancillary testing, or hospital charges.
4. **Author's Conclusions**:
    - The authors concluded that while GIP testing improved the time to result and treatment, only a small subset of patients truly benefited from it.
    - They suggested that the widespread use of GIP testing could result in low-value care, as it did not significantly impact other key outcomes such as LOS, ancillary testing,

or hospital charges.

In summary, while GIP testing resulted in faster diagnosis and treatment for a subset of children with diarrhea, its widespread use may not significantly impact overall patient outcomes or healthcare resource utilization. This study raises questions about the appropriateness of routine GIP testing and highlights the importance of considering its potential benefits and limitations in clinical practice.[2] Conversely, individuals who are immunocompromised are more likely to experience severe or prolonged illness. Diarrhea in immunocompromised patients may involve a broad spectrum of potential causes, including bacterial, viral, parasitic, and fungal pathogens, depending on underlying immune status. Rapid identification and institution of treatment is paramount in these patients.[5, 6]

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 and with any diagnosis.

CPT®* Codes	Description
87505	Infectious agent detection by nucleic acid (DNA or RNA); gastrointestinal pathogen (e.g., 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

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

CPT®* Codes	Description

87506	Infectious agent detection by nucleic acid (DNA or RNA); gastrointestinal pathogen (e.g., 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 (e.g., 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

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

Place of Service Code	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 a CPT code in Table 2 when also billed with an ICD-10 diagnosis code in Table 5

ICD-10-CM Code	Description
A00.0	Cholera due to Vibrio cholerae 01, biovar cholerae
A00.1	Cholera due to Vibrio cholerae 01, biovar eltor
A00.9	Cholera, unspecified
A01.00	Typhoid fever, unspecified
A01.09	Typhoid fever with other complications

A01.1	Paratyphoid fever A
A01.2	Paratyphoid fever B
A01.3	Paratyphoid fever C
A02.0	Salmonella enteritis
A02.8	Other specified salmonella infections
A03.0	Shigellosis due to Shigella dysenteriae
A03.1	Shigellosis due to Shigella flexneri
A03.2	Shigellosis due to Shigella boydii
A03.3	Shigellosis due to Shigella sonnei
A03.8	Other shigellosis
A04.0	Enteropathogenic Escherichia coli infection
A04.1	Enterotoxigenic Escherichia coli infection
A04.2	Enteroinvasive Escherichia coli infection
A03.3	Enterohemorrhagic Escherichia coli infection
A04.5	Campylobacter enteritis
A04.6	Enteritis due to Yersinia enterocolitica
A04.71	Enterocolitis due to Clostridium difficile, recurrent
A04.72	Enterocolitis due to Clostridium difficile, not specified as recurrent
A04.8	Other specified bacterial intestinal infections
A04.9	Bacterial intestinal infection, unspecified
A05.0	Foodborne staphylococcal intoxication
A05.1	Botulism food poisoning
A05.2	Foodborne Clostridium perfringens [Clostridium welchii] intoxication
A05.3	Foodborne Vibrio parahaemolyticus intoxication
A05.4	Foodborne Bacillus cereus intoxication
A05.5	Foodborne Vibrio vulnificus intoxication
A06.0	Acute amebic dysentery
A06.1	Chronic intestinal amebiasis
A06.2	Amebic non-dysenteric colitis
A07.1	Giardiasis [lambliasis]
A07.2	Cryptosporidiosis
A07.4	Cyclosporiasis
A08.0	Rotaviral enteritis
A08.11	Acute gastro enteropathy due to Norwalk agent
A08.2	Adenoviral enteritis
A08.32	Astrovirus enteritis
A09	Infectious gastroenteritis and colitis, unspecified

A32.11	Listerial meningitis
A32.12	Listerial meningoencephalitis
A32.7	Listerial sepsis
K56.0	Paralytic ileus
M31.19	Other thrombotic microangiopathy
R10.0	Acute abdomen
R19.7	Diarrhea, unspecified

Table 5: ICD-10 diagnosis codes that support medical necessity for a CPT code in Table 2 when also billed with an ICD-10 diagnosis code in Table 4

ICD-10-CM Code	Description
B20	Human Immunodeficiency virus (HIV) disease
B25.1	Cytomegaloviral hepatitis
B25.2	Cytomegaloviral pancreatitis
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
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
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
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
K50.011	Crohn's disease of small intestine with rectal bleeding
K50.012	Crohn's disease of small intestine with intestinal obstruction
K50.013	Crohn's disease of small intestine with fistula
K50.018	Crohn's disease of small intestine with other complication
K50.111	Crohn's disease of large intestine with rectal bleeding
K50.112	Crohn's disease of large intestine with intestinal obstruction
K50.113	Crohn's disease of large intestine with fistula
K50.118	Crohn's disease of large intestine with other complication
K50.812	Crohn's disease of both small and large intestine with intestinal obstruction
K50.813	Crohn's disease of both small and large intestine with fistula
K50.818	Crohn's disease of both small and large intestine with other complication
K50.911	Crohn's disease, unspecified, with rectal bleeding
K50.912	Crohn's disease, unspecified, with intestinal obstruction
K50.913	Crohn's disease, unspecified, with fistula
K50.918	Crohn's disease, unspecified, with other complication
K51.011	Ulcerative (chronic) pancolitis with rectal bleeding
K51.012	Ulcerative (chronic) pancolitis with intestinal obstruction
K51.013	Ulcerative (chronic) pancolitis with fistula
K51.018	Ulcerative (chronic) pancolitis with other complication
K51.019	Ulcerative (chronic) pancolitis with unspecified complications
K51.211	Ulcerative (chronic) proctitis with rectal bleeding
K51.212	Ulcerative (chronic) proctitis with intestinal obstruction
K51.213	Ulcerative (chronic) proctitis with fistula
K51.218	Ulcerative (chronic) proctitis with other complication
K51.219	Ulcerative (chronic) proctitis with unspecified complications
K51.311	Ulcerative (chronic) rectosigmoiditis with rectal bleeding
K51.312	Ulcerative (chronic) rectosigmoiditis with intestinal obstruction
K51.313	Ulcerative (chronic) rectosigmoiditis with fistula
K51.318	Ulcerative (chronic) rectosigmoiditis with other complication
K51.319	Ulcerative (chronic) rectosigmoiditis with unspecified complications
K51.411	Inflammatory polyps of colon with rectal bleeding
K51.412	Inflammatory polyps of colon with intestinal obstruction
K51.413	Inflammatory polyps of colon with fistula
K51.418	Inflammatory polyps of colon with other complication

K51.419	Inflammatory polyps of colon with unspecified complications
K51.511	Left sided colitis with rectal bleeding
K51.512	Left sided colitis with intestinal obstruction
K51.513	Left sided colitis with fistula
K51.518	Left sided colitis with other complication
K51.519	Left sided colitis with unspecified complications
K51.811	Other ulcerative colitis with rectal bleeding
K51.812	Other ulcerative colitis with rectal bleeding
K51.812	Other ulcerative colitis with fistula
K51.818	Other ulcerative colitis with other complication
K51.911	Ulcerative colitis, unspecified with rectal bleeding
K51.912	Ulcerative colitis, unspecified with intestinal obstruction
K51.913	Ulcerative colitis, unspecified with fistula
K51.918	Ulcerative colitis, unspecified with other complication
K52.0	Gastroenteritis and colitis due to radiation
K56.3	Gallstone ileus
K62.7	Radiation proctitis
O98.711	Human immunodeficiency virus (HIV) disease complicating pregnancy, first trimester
O98.712	Human immunodeficiency virus (HIV) disease complicating pregnancy, 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 lung 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 cell transplant status
Z94.89	Other transplanted organ and tissue status

Table 6: ICD-10 diagnosis codes that support medical necessity when billed with a CPT code in Table 2

ICD-10-CM Code	Description
Z94.0	Kidney transplant status
Z94.1	Heart transplant status
Z94.2	Lung transplant status
Z94.3	Heart and lung 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 cell transplant status
Z94.89	Other transplanted organ and tissue status

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