Clinical Policy: Gastrointestinal Pathogen Nucleic Acid Detection Panel Testing

Reference Number: CP.MP.209
Date of Last Revision: 03/24

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Multiplex molecular panels are used for the qualitative detection of nucleic acid from multiple viral, parasitic, and bacterial pathogens that cause a variety of illnesses, including infectious gastroenteritis and infectious colitis.[1] The Food and Drug Administration (FDA) have cleared several panels for diagnosis of gastrointestinal infections. This policy addresses the medical necessity criteria for Gastrointestinal Pathogen Nucleic Acid Detection Panel Testing.

Note: For criteria applicable to Medicare plans, please see MC.CP.MP.209 Gastrointestinal Pathogen Nucleic Acid Detection Panel Testing.

Policy/Criteria

I. It is the policy of non-Medicare health plans affiliated with Centene Corporation® that gastrointestinal pathogen panel testing of five or fewer targets is considered **medically necessary** when meeting all the following:

A. The member/enrollee has one of the following clinical indications for infectious disease testing:
   1. The member/enrollee is immunocompetent, and the clinical indication includes 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 (i.e., the elderly);
   2. The member/enrollee is immunocompromised (i.e., those with weakened immune systems including those with human immunodeficiency virus (HIV) or acquired immunodeficiency syndrome (AIDS), patients who are taking immunosuppressive medications (i.e., chemotherapy, biologics, transplant-related immunosuppressive drugs, high-dose systemic corticosteroids) and those with inherited diseases that affect the immune system (i.e., 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 peer-reviewed published 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 can be reasonably detected by the test;
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 (i.e., culture, pathogen-specific polymerase chain reaction [PCR]) for the majority of targets included on the panel;
G. Documentation of the following is clearly stated in the medical record:
    1. Specific clinical indications for testing (i.e., clinical suspicion of a pathogen as the cause of the patient's condition);
    2. Specific reasons for performing panel testing;
    3. Provider type/specialty and Place of Service.

II. It is the policy of non-Medicare health plans affiliated with Centene Corporation that expanded gastrointestinal pathogen panel testing of greater than five targets is considered **medically necessary** when meeting the following:
A. The criteria in section I are met, and one of the following:
    1. The member/enrollee is immunocompromised, as defined in section I.A.2.;
    2. The member/enrollee is immunocompetent and any of the following:
        a. Testing is ordered for a patient with severe and established underlying gastrointestinal (GI) pathology (i.e., 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/enrollee 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 (i.e., fever, bloody diarrhea, dysentery, dehydration, severe abdominal pain) that may warrant hospitalization;
            ii. The diarrheal illness has not resolved after seven days and the member/enrollee has not taken laxatives within 24 hours of the test.

Background

Infectious gastroenteritis is a significant global health concern characterized by diarrhea, vomiting, and other symptoms, and can lead to 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).[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 grouping of culture-independent diagnostic tests (CIDT). Multipathogen 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, and enterotoxigenic E. coli (ETEC), enteropathogenic E. coli (EPEC), and enteroaggregative E. coli (EAEC), in less time than traditional methods.

Multipathogen NAAT is associated with high clinical validity for the majority of available pathogenic targets relative to conventional testing and has a more rapid turnaround time compared with most types of conventional testing.[2] Drawbacks of molecular technologies include the need to predefine the particular microbes sought, detection of microbes at non-pathogenic levels, and increased detection of mixed infections; the relative importance of each pathogen identified may be unclear.[3]

CIDT are touted as providing a more comprehensive assessment of disease etiology by increasing the diagnostic yield compared with conventional diagnostic tests, permitting earlier initiation of appropriate therapeutic agents targeted to the detected pathogen(s), if any, rather than empirical therapy until culture results are available. The short time to results could reduce inappropriate use of antimicrobial agents to treat infections that do not require antimicrobial therapy and could shorten the time to targeted management and isolation measures for certain infections (e.g., STEC O157).[4]

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.[4]

Infectious Diseases Society of America[4]

- Culture-independent, including panel-based multiplex molecular diagnostics from stool and blood specimens, and, when indicated, culture-dependent diagnostic testing should be performed when there is a clinical suspicion of enteric fever or diarrhea with bacteremia.
- A broad differential diagnosis is recommended in immunocompromised people with diarrhea, especially those with moderate and severe primary or secondary immune deficiencies, for evaluation of stool specimens by culture, viral studies, and examination for parasites (strong, moderate). People with acquired immune deficiency syndrome (AIDS) with persistent diarrhea should undergo additional testing for other organisms including, but not limited to, Cryptosporidium, Cyclospora, Cystoisospora, microsporidia, Mycobacterium avium complex, and cytomegalovirus.
- Clinical consideration should be a part of interpreting results of multiple-pathogen nucleic acid amplification tests because these assays are DNA based and detect both viable and nonviable organisms.

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- Stool diagnostic studies may be used if available in cases of dysentery, moderate-to-severe disease, and symptoms lasting less than seven days to clarify the etiology of the patient's illness and enable specific directed therapy.
- Traditional methods of diagnosis (bacterial culture, microscopy with and without special stains and immunofluorescence, and antigen testing) fail to reveal the etiology of the majority of cases of acute diarrheal infection. If available, the use of Food and Drug Administration-approved culture-independent methods of diagnosis can be recommended at least as an adjunct to traditional methods.

Coding Implications

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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 (eg, Clostridium difficile, E. coli, Salmonella, Shigella, norovirus, Giardia), includes multiplex reverse transcription, when performed, and multiplex amplified probe technique, multiple types or subtypes, three to five targets

Table 2: CPT codes that support medical necessity when billed with place of service code in Table 3 or 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 (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 to 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 to 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 which 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 which 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 which 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
A04.3	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 nondysenteric colitis
A07.1	Giardiasis [lambliasis]
A07.2	Cryptosporidiosis
A07.4	Cyclosporiasis
A08.0	Rotaviral enteritis
A08.11	Acute gastroenteropathy 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

ICD-10-CM Code	Description
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
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

ICD-10-CM Code	Description
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

ICD-10-CM Code	Description
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

ICD-10-CM Code	Description
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 intestinal obstruction
K51.813	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 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

Reviews, Revisions, and Approvals	Revision Date	Approval Date
Policy developed.	02/21	
References reviewed and updated.	06/21	06/21
In the note below table 3, replaced "PCR" with "GI pathogen panel testing."	12/21	
Annual review. References reviewed, updated, and reformatted.	03/22	03/22
Removed deleted code 0097U	11/22	
Annual review completed. Replaced previous criteria with current in sections I. and II. and removed section III. Background updated with no impact to criteria. Reworded some extraneous language with no clinical significance. Moved code 87506 from Table 1 to Table 2. Added Place of Service Code 19 in Table 3. Added Table 4, Table 5, and Table 6 to include ICD-10 diagnosis codes which support medical necessity. References reviewed and updated.	03/23	03/23
Annual review. Specified in policy statement that this criteria applies to non-Medicare plans. Added note referring to Medicare-specific policy. Description updated with no impact on criteria. Updated Criteria II. from greater than six targets to greater than five targets. Minor rewording in Background. Table 6 codes removed, and descriptors for CPT Table 2 changed accordingly. References reviewed and updated. Reviewed by external specialist.	03/24	03/24

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Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional

organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members/enrollees. This clinical policy is not intended to recommend treatment for members/enrollees. Members/enrollees should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

 Providers, members/enrollees and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members/enrollees and their representatives agree to be bound by such terms and conditions by providing services to members/enrollees and/or submitting claims for payment for such services.

Note: For Medicaid members/enrollees, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

Note: For Medicare members/enrollees, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs, and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at http://www.cms.gov for additional information.