Policy Statement

Fecal analysis of the following components is considered investigative as a diagnostic test for the evaluation of intestinal dysbiosis, irritable bowel syndrome, malabsorption, or small intestinal overgrowth of bacteria:

- Triglycerides
- Chymotrypsin
- Iso-butyrate, iso-valerate, and n-valerate
- Meat and vegetable fibers
- Long-chain fatty acids
- Cholesterol
- Total short-chain fatty acids
- Levels of Lactobacilli, bifidobacteria, and Escherichia coli and other “potential pathogens,” including Aeromonas, Bacillus cereus, Campylobacter, Citrobacter, Klebsiella, Proteus, Pseudomonas, Salmonella, Shigella, Staphylococcus aureus, and Vibrio
- Identification and quantitation of fecal yeast (including Candida albicans, Candida tropicalis, Rhodotorula, and Geotrichum)
- N-butyrate
- β-glucuronidase
- pH
- Short-chain fatty acid distribution (adequate amount and proportions of the different short-chain fatty acids reflect the basic status of intestinal metabolism)
- Fecal secretory immunoglobulin A

Policy Guidelines

Coding

Effective October 1, 2019, a new CPT code describes a qualitative test for Clostridium difficile toxin testing from a stool sample:

- **0107U**: Clostridium difficile toxin(s) antigen detection by immunoassay technique, stool, qualitative, multiple-step method

The following CPT codes may be used to identify individual components of fecal analysis of intestinal dysbiosis:

- **82239**: Bile acids; total
- **82542**: Column chromatography, includes mass spectrometry, if performed (e.g., HPLC, LC, LC/MS, LC/MS-MS, GC, GC/MS-MS, GC/MS, HPLC/MS), non-drug analyte(s) not elsewhere specified, qualitative or quantitative, each specimen (used to test for short-chain fatty acids)
- **82656**: Elastase, pancreatic (EL-1), fecal, qualitative or semi-quantitative
- **82710**: Fat or lipids, feces; quantitative (used to test for fecal triglycerides)
- **82715**: Fat differential, feces, quantitative (used to test for fecal cholesterol)
- **82725**: Fatty acids, nonesterified (used to test for long-chain fatty acids)
- **83520**: Immunoassay, for analyte other than infectious agent antibody or infectious agent antigen; quantitative, not otherwise specified (used for eosinophil protein X)
- **83630**: Lactofemn, fecal; qualitative
- **83986**: pH; body fluid, not otherwise specified (used to measure fecal pH)
- **83993**: Calprotectin, fecal
- **84311**: Spectrophotometry, analyte, not elsewhere specified (used twice, once each to test for stool B-glucuronidase and chymotrypsin)
Fecal Analysis in the Diagnosis of Intestinal Dysbiosis

Fecal analysis may also include other standard components such as the following:

Stool culture
- **87045**: Culture, bacterial; stool, aerobic, with isolation and preliminary examination (e.g., KIA, LIA), Salmonella and Shigella species
- **87046**: Culture, bacterial; stool, aerobic, additional pathogens, isolation and presumptive identification of isolates, each plate
- **87075**: Culture, bacterial; any source, except blood, anaerobic with isolation and presumptive identification of isolates

Stool parasitology
- **87177**: Ova and parasites, direct smears, concentration and identification
- **87209**: Smear, primary source with interpretation; complex special stain (e.g., trichrome, iron hematoxylin) for ova and parasites

Fecal occult blood (82272-82274).
- **82272**: Blood, occult, by peroxidase activity (e.g., guaiac), qualitative, feces, 1-3 simultaneous determinations, performed for other than colorectal neoplasm screening
- **82274**: Blood, occult, by fecal hemoglobin determination by immunoassay, qualitative, feces, 1-3 simultaneous determinations

Description

Intestinal dysbiosis may be defined as a state of disordered microbial ecology that is believed to cause disease. Laboratory analysis of fecal samples is proposed as a method of identifying individuals with intestinal dysbiosis and other gastrointestinal disorders.

Related Policies
- Fecal Calprotectin Testing
- Fecal Microbiota Transplantation

Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Reproduction without authorization from Blue Shield of California is prohibited
Some state or federal mandates (e.g., Federal Employee Program [FEP]) prohibits plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

**Regulatory Status**

Clinical laboratories may develop and validate tests in-house and market them as a laboratory service; laboratory-developed tests must meet the general regulatory standards of the Clinical Laboratory Improvement Amendments. Laboratories that offer laboratory-developed tests must be licensed by the Clinical Laboratory Improvement Amendments for high-complexity testing. To date, the U.S. Food and Drug Administration has chosen not to require any regulatory review of comprehensive testing for fecal dysbiosis.

**Rationale**

**Background**

**Fecal Markers of Dysbiosis**

Laboratory analysis of both stool and urine has been investigated as markers of dysbiosis. Commercial laboratories may offer testing for comprehensive panels or individual components of various aspects of digestion, absorption, microbiology, and metabolic markers. Representative components of fecal dysbiosis testing are summarized in Table 1.

| Table 1. Components of the Fecal Dysbiosis Marker Analysis |
|-----------------|-----------------|
| **Markers**     | **Analytes**    |
| Digestion       | • Triglycerides |
|                 | • Chymotrypsin  |
|                 | • Iso-butyrate, iso-valerate, and n-valerate |
|                 | • Meat and vegetable fibers |
| Absorption      | • Long-chain fatty acids |
|                 | • Cholesterol   |
|                 | • Total fecal fat |
|                 | • Total short-chain fatty acids |
| Microbiology    | • Levels of Lactobacilli, bifidobacteria, and Escherichia coli and other “potential pathogens,” including Aeromonas, Bacillus cereus, Campylobacter, Citrobacter, Klebsiella, Proteus, Pseudomonas, Salmonella, Shigella, Staphylococcus aureus, and Vibrio |
|                 | • Identification and quantitation of fecal yeast (including Candida albicans, Candida tropicalis, Rhodotorula, and Geotrichum) (optional viral and/or parasitology components) |
| Metabolic       | • N-butyrate (considered key energy source for colonic epithelial cells) |
|                 | • β-glucuronidase |
|                 | • pH |
|                 | • Short-chain fatty acid distribution (adequate amount and proportions of the different short-chain fatty acids reflect the basic status of intestinal metabolism) |
| Immunology      | • Fecal secretory immunoglobulin A (as a measure of luminal immunologic function) |
|                 | • Calprotectin |

Fecal calprotectin as a stand-alone test is addressed in evidence review 2.04.69.

A related topic, fecal microbiota transplantation, the infusion of intestinal microorganisms to restore normal intestinal flora, is addressed in evidence review 2.01.92. Fecal microbiota transplantation has been rigorously studied for the treatment of patients with recurrent Clostridium difficile infection.
Literature Review
Evidence reviews assess whether a medical test is clinically useful. A useful test provides information to make a clinical management decision that improves the net health outcome. That is, the balance of benefits and harms is better when the test is used to manage the condition than when another test or no test is used to manage the condition.

The first step in assessing a medical test is to formulate the clinical context and purpose of the test. The test must be technically reliable, clinically valid, and clinically useful for that purpose. Evidence reviews assess the evidence on whether a test is clinically valid and clinically useful. Technical reliability is outside the scope of these reviews, and credible information on technical reliability is available from other sources. The following is a summary of the literature to date.

Fecal Testing for Intestinal Dysbiosis
The gastrointestinal tract is colonized by a large number and a variety of microorganisms including bacteria, fungi, and archaeb. The concept of intestinal dysbiosis rests on the assumption that abnormal patterns of intestinal flora, such as overgrowth of some commonly found microorganisms, have an impact on human health. Symptoms and conditions attributed to intestinal dysbiosis in addition to gastrointestinal disorders include chronic disorders (e.g., irritable bowel syndrome [IBS], inflammatory or autoimmune disorders, food allergy, atopic eczema, unexplained fatigue, arthritis, ankylosing spondylitis), malnutrition, or neuropsychiatric symptoms or neurodevelopmental conditions (e.g., autism), and breast and colon cancer.

The gastrointestinal tract symptoms attributed to intestinal dysbiosis (i.e., bloating, flatulence, diarrhea, constipation) overlap in part with either IBS or small intestinal bacterial overgrowth syndrome. The diagnosis of IBS is typically made clinically, based on a set of criteria referred to as the Rome criteria. The small intestine normally contains a limited number of bacteria, at least as compared with the large intestine. Small intestine bacterial overgrowth may occur due to altered motility (including blind loops), decreased acidity, exposure to antibiotics, or surgical resection of the small bowel. Symptoms include malabsorption, diarrhea, fatigue, and lethargy. The laboratory criterion standard for diagnosis consists of the culture of a jejunal fluid sample, but this requires invasive testing. Hydrogen breath tests, commonly used to evaluate lactose intolerance, have been adapted for use in diagnosing small intestinal bacterial overgrowth.

Clinical Context and Test Purpose
The purpose of fecal analysis in patients who have various gastrointestinal conditions is to differentiate intestinal microflora and related immunologic responses that may be related to those conditions.

The question addressed in this evidence review is: Does fecal dysbiosis testing used in individuals who have gastrointestinal conditions such as suspected intestinal dysbiosis, IBS, malabsorption, or small intestinal bacterial overgrowth improve the net health outcome?

The following PICOs were used to select literature to inform this review.

Patients
The relevant populations of interest are those with gastrointestinal conditions such as suspected intestinal dysbiosis, IBS, malabsorption, or small intestinal bacterial overgrowth.

Interventions
The intervention of interest is the use of fecal dysbiosis testing. The rationale for intestinal dysbiosis testing is that alterations in intestinal flora (e.g., overgrowth of some commonly found microorganisms) and related immunologic responses have an impact on human health and disease. The further assumption is that therapeutic (antibiotics, prebiotic, probiotic, or fecal microbiota transplantation) or lifestyle management interventions can be made to address the alterations.
The setting is ambulatory primary care or gastroenterology consultation.

Comparators
The following practices are currently being used to manage various gastrointestinal conditions: the standard approach to diagnosing specific intestinal conditions, which can include using laboratory tests, imaging, and endoscopy as indicated.

The setting is ambulatory primary care or gastroenterology consultation.

Outcomes
The general outcomes of interest are the correct diagnosis of gastrointestinal conditions potentially associated with alterations in intestinal microflora and initiation of appropriate treatment.

These tests might be used during the evaluation and treatment of acute and chronic intestinal disorders. The duration of follow-up is condition-specific and is expected to be weeks to months.

Study Selection Criteria
For the evaluation of clinical validity of fecal dysbiosis testing, methodologically credible studies were selected using the following principles:

For the evaluation of the clinical validity of the tests, studies that meet the following eligibility criteria were considered:

- Reported on the accuracy of the marketed version of the technology (including any algorithms used to calculate scores)
- Included a suitable reference standard
- Patient/sample clinical characteristics were described
- Patient/sample selection criteria were described
- Included a validation cohort separate from the development cohort.

Technical Reliability
Assessment of technical reliability focuses on specific tests and operators and requires a review of unpublished and often proprietary information. Review of specific tests, operators, and unpublished data are outside the scope of this evidence review and alternative sources exist. This evidence review focuses on the clinical validity and clinical utility.

Clinically Valid
A test must detect the presence or absence of a condition, the risk of developing a condition in the future, or treatment response (beneficial or adverse).

Establishing that fecal analysis to identify intestinal dysbiosis is beneficial would involve evidence that the fecal dysbiosis testing provides an incremental benefit to net health outcomes in patients with gastrointestinal tract symptoms as compared to current clinical pathways. No studies were identified in the initial literature review or during the literature searches for evidence review updates that compared health outcomes in individuals managed with and without fecal analysis to identify intestinal dysbiosis. There were also no studies on the accuracy of fecal analysis vs another method for diagnosing IBS, small intestine bacterial overgrowth, or other conditions. Additionally, no studies were identified establishing diagnostic criteria for intestinal dysbiosis as a disorder.

Retrospective Studies
Emmanuel et al (2016) retrospectively analyzed fecal biomarker results, dichotomized to normal or abnormal, from 3553 patients who underwent stool testing and met Rome III symptom criteria for IBS. Records were identified from samples sent to Genova Diagnostics from 2013-2014 for which patient questionnaires were completed (patient questionnaires are sent with every test kit; demographic surveys were completed for 7503 of 24258 of the fecal specimens obtained during
study period, and Rome III questionnaire results were completed for 5990 of those) and the case
definition of IBS was based on patient reporting of symptoms on the Rome III questionnaire. The
Genova Comprehensive Digestive Stool Analysis evaluates digestion/absorption markers, gut
metabolic markers, and gut microbiology markers.2 Of the 3553 patient samples included,
13.6%, 27.5%, and 58.1%, respectively, reported having constipation-predominant IBS, diarrhea-
predominant (IBS-D), and mixed subtypes of IBS. Most patients (93.5%) had at least 1 abnormal
result. There were differences by IBS subgroup, with IBS-D patients demonstrating higher rates of
abnormal fecal calprotectin, eosinophil protein X, and bacterial potential pathogens (13.4%,
12.2% and 75% of subjects, respectively) than constipation-predominant IBS patients (7.1%, 4.4%,
and 71.0%, respectively) and mixed subtypes of IBS patients (10.9%, p < 0.004 vs. IBS-D; 8.0%,
p < 0.003 vs IBS-D; 71.6%, p = 0.010 vs p IBS-D).

A retrospective analysis of data from the Genova Diagnostics database for 2256 patients who
underwent stool testing was published by Goepp et al (2014).3 Patients had symptoms
suggestive of IBS (e.g., 48% had abdominal pain, 14% had diarrhea). Eighty-three percent of
patients had at least one abnormal test result. The most common abnormal result, occurring in
73% of cases, was low growth in the beneficial bacteria lactobacillus and/or bifidobacterium.
The next most common was testing positive for eosinophil protein X and fecal calprotectin,
occurring in 14% and 12% of samples, respectively. A limitation of the study was that it did not
include a confirmation of the diagnosis of IBS (i.e., using Rome criteria) and thus the accuracy of
the Genova tests compared with clinical diagnosis could not be determined.

Nonrandomized Observational Studies
Studies using quantitative real-time polymerase chain reaction analysis have compared
microbiota in patients who had known disease with healthy controls in an attempt to identify
a microbiotic profile associated with a particular disease. None of these studies evaluated
whether the fecal analysis in patients with IBS or other conditions led to improved health
outcomes.

Andoh et al (2012) reported on fecal microbiota profiles of 161 Japanese patients with Crohn
disease (CD) and 121 healthy controls.4 Healthy individuals tended to have a different
distribution of fecal microbiota than CD patients. For example, compared with controls, CD
patients had significantly lower levels of Faecalibacterium and Eubacterium and significantly
higher levels of Streptococcus.

Sobhani et al (2011) evaluated fecal microbiota samples taken before colonoscopy from 60
patients with colorectal cancer and 119 sex-matched healthy individuals in France.5 Total
bacteria levels did not differ significantly between colorectal cancer and non-colorectal cancer
groups. There were significant elevations of the Bacteroides/Prevotella group in the colorectal
cancer population.

Joossens et al (2011) published a study comparing fecal microbiota in 68 patients with CD, 84
unaffected relatives, and 55 matched controls in Belgium.6 When samples from patients who
had CD were compared with all unaffected controls, significant differences were found in the
concentration of five bacterial species. Compared with controls, CD patients had lower levels of
Dialister invisus, an uncharacterized species of Clostridium cluster XIVa, Faecalibacterium
prausnitzii, and Bifidobacterium adolescentis as well as an increase in Ruminococcus gnavus.

Fecal markers in addition to microbiology profiles have been evaluated whether the testing can
distinguish between individuals with various gastrointestinal diseases. Langhorst et al (2008) in
Germany evaluated 139 patients (54 with IBS, 43 CD, 42 ulcerative colitis) undergoing
diagnostic ileocolonoscopy, who provided fecal samples.7 Samples were analyzed with
enzyme-linked immunosorbent assay. Patients with IBS had significantly higher levels of
lactoferrin, calprotectin, and polymorphonuclear elastase than patients who had ulcerative
colitis or CD (all p < 0.001). In the ulcerative colitis and CD groups, there were higher levels of all
three markers in patients who had inflammation compared with those who did not.
Clinically Useful
A test is clinically useful if the use of the results informs management decisions that improve the net health outcome of care. The net health outcome can be improved if patients receive correct therapy, or more effective therapy, or avoid unnecessary therapy, or avoid unnecessary testing.

Direct Evidence
Direct evidence of clinical utility is provided by studies that have compared health outcomes for patients managed with and without the test. Because these are intervention studies, the preferred evidence would be from randomized controlled trials.

Direct evidence of clinical utility is provided by studies that have compared health outcomes for patients managed with and without the test. Because these are intervention studies, the preferred evidence would be from randomized controlled trials. No randomized or comparative intervention studies supporting the clinical utility of fecal testing were identified.

Chain of Evidence
Indirect evidence on clinical utility rests on clinical validity. If the evidence is insufficient to demonstrate test performance, no inferences can be made about clinical utility.

Indirect evidence of clinical utility rests on clinical validity. It is not possible to construct a chain of evidence because there is insufficient evidence of clinical validity to draw conclusions on clinical utility.

Summary of Evidence
For individuals who have gastrointestinal conditions such as suspected intestinal dysbiosis, irritable bowel syndrome, malabsorption, or small intestinal bacterial overgrowth who receive fecal analysis testing, the evidence includes several cohort and case-control studies comparing fecal microbiota in patients who had a known disease with healthy controls.

The relevant outcomes are test validity, symptoms, and functional outcomes. The available retrospective cohort studies on fecal analysis have suggested that some components of the fecal microbiome and inflammatory markers may differ across patients with irritable bowel syndrome subtypes. No studies were identified on the diagnostic accuracy of fecal analysis vs another diagnostic approach or that compared health outcomes in patients managed with and without fecal analysis tests. No studies were identified that directly informed the use of fecal analysis in the evaluation of intestinal dysbiosis, malabsorption, or small intestinal bacterial overgrowth. The evidence is insufficient to determine the effects of the technology on health outcomes.

Supplemental Information
Practice Guidelines and Position Statements
No guidelines or statements were identified.

U.S. Preventive Services Task Force Recommendations
Not applicable.

Medicare National Coverage
There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

Ongoing and Unpublished Clinical Trials
A search of ClinicalTrials.gov in October 2019 did not identify any ongoing or unpublished trials that would likely influence this review.
References


Documentation for Clinical Review

- No records required

Coding

This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy. Inclusion or exclusion of codes does not constitute or imply member coverage or provider reimbursement.

IE

The following services may be considered investigational.

<table>
<thead>
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<th>Type</th>
<th>Code</th>
<th>Description</th>
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</thead>
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<tr>
<td>CPT®</td>
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<td>Gastrointestinal pathogen, multiplex reverse transcription and multiplex amplified probe technique, multiple types or subtypes, 22 targets (Campylobacter (C. jejuni/C. coli/C. upsaliensis), Clostridium difficile (C. difficile) toxin A/B, Plesiomonas shigelloides, Salmonella, Vibrio (V. parahaemolyticus/V. vulnificus/V. cholerae), including specific identification of Vibrio cholerae, Yersinia enterocolitica, Enteraggregative Escherichia coli (EAEC), Enteropathogenic Escherichia coli (EPEC), Enterotoxigenic Escherichia coli (ETEC) lt/st, Shiga-like toxin-producing Escherichia coli (STEC) stx1/stx2 (including specific identification of the E. coli O157 serogroup within STEC), Shigella/ Enteroinvasive Escherichia coli (EIEC), Cryptosporidium, Cyclospora cayetanensis, Entamoeba histolytica, Giardia lamblia (also known as G. intestinalis and G. duodenalis), Adenovirus F 40/41, Astrovirus, Norovirus GI/GII, Rotavirus A, Sapovirus (Genogroups I, II, IV, and V)) (Code effective 7/1/2019)</td>
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<td>82274</td>
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<td>Ova and parasites, direct smears, concentration and identification</td>
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<td>Smear, primary source with interpretation; complex special stain (e.g., trichrome, iron hematoxylin) for ova and parasites</td>
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<td>Infectious agent antigen detection by immunoassay technique, (e.g., enzyme immunoassay [EIA], enzyme-linked immunosorbent assay [ELISA], immunochromiluminometric assay [IMCA]) qualitative or semi quantitative, multiple-step method; cryptosporidium</td>
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<td>Infectious agent antigen detection by immunoassay technique, (e.g., enzyme immunoassay [EIA], enzyme-linked immunosorbent assay [ELISA], immunochromiluminometric assay [IMCA]) qualitative or semi quantitative, multiple-step method; giardia</td>
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<td>Infectious agent antigen detection by immunoassay technique, (e.g., enzyme immunoassay [EIA], enzyme-linked immunosorbent assay [ELISA], immunochromiluminometric assay [IMCA]) qualitative or semi quantitative, multiple-step method; Entamoeba histolytica dispers group</td>
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Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

<table>
<thead>
<tr>
<th>Effective Date</th>
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<tbody>
<tr>
<td>05/29/2015</td>
<td>BCBSA Medical Policy adoption</td>
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<tr>
<td>01/01/2016</td>
<td>Coding update</td>
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<tr>
<td>03/01/2016</td>
<td>Policy Revision without position change</td>
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<td>11/01/2019</td>
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<td>03/01/2020</td>
<td>Annual review. No change to policy statement. Literature review updated.</td>
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Definitions of Decision Determinations

Medically Necessary: Services that are Medically Necessary include only those which have been established as safe and effective, are furnished under generally accepted professional standards to treat illness, injury or medical condition, and which, as determined by Blue Shield, are: (a) consistent with Blue Shield medical policy; (b) consistent with the symptoms or diagnosis; (c) not furnished primarily for the convenience of the patient, the attending Physician or other provider; (d) furnished at the most appropriate level which can be provided safely and effectively to the patient; and (e) not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the Member’s illness, injury, or disease.

Investigational/Experimental: A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

Split Evaluation: Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment, procedure, or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

Prior Authorization Requirements (as applicable to your plan)

Within five days before the actual date of service, the provider must confirm with Blue Shield that the member’s health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member’s eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department at (800) 541-6652, or the Transplant Case Management Department at (800) 637-2066 ext. 3507708 or visit the provider portal at www.blueshieldca.com/provider.

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well
as contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.