TITLE: INTESTINAL TRANSPLANTATION

EFFECTIVE DATE: April 22, 2019

This policy was developed with input from specialists in gastroenterology and transplant surgery and endorsed by the Medical Policy Committee.

IMPORTANT INFORMATION – PLEASE READ BEFORE USING THIS POLICY

These services may or may not be covered by all Medica plans. Please refer to the member’s plan document for specific coverage information. If there is a difference between this general information and the member’s plan document, the member’s plan document will be used to determine coverage. With respect to Medicare and Minnesota Health Care Programs, this policy will apply unless those programs require different coverage. Members may contact Medica Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions about this Medica utilization management policy may call the Medica Provider Service Center toll-free at 1-800-458-5512.

Medica utilization management policies are not medical advice. Members should consult with appropriate health care providers to obtain needed medical advice, care and treatment.

PURPOSE

To promote consistency between reviewers in utilization management decision-making by providing the criteria that generally determines the medical necessity of intestinal transplantation. The Benefit Considerations box below outlines the process for addressing the needs of individuals who do not meet these criteria.

BACKGROUND

I. Definitions:

A. Intestinal Failure: The loss of absorptive capacity of the small bowel secondary to severe primary gastrointestinal disease, congenital defect, obstruction, dysmotility, trauma, vascular occlusion or surgically induced short bowel syndrome. Intestinal failure is characterized by the inability to maintain protein-energy, fluid, electrolyte, or nutrient balance and may be associated with both mortality and profound morbidity.

1. Examples of diseases or conditions which may lead to intestinal failure in adults:
   a. Mesenteric thrombosis/intestinal ischemia
   b. Crohn’s disease
   c. Trauma
   d. Volvulus
   e. Desmoid tumor
   f. Gardner’s syndrome
   g. Familial polyposis
   h. Radiation enteritis.

2. Examples of diseases or conditions which may lead to intestinal failure in children:
   a. Volvulus
   b. Gastrochisis
   c. Necrotizing enterocolitis
   d. Pseudo-obstruction
   e. Intestinal atresia
   f. Hirschsprung’s disease
   g. Trauma.

B. Short-Bowel Syndrome: Occurs as a consequence of insufficient functional small bowel to maintain protein-energy, fluid, electrolyte, nutrient balance despite administration of a normal diet. Short-bowel syndrome manifests as massive diarrhea or stomal output, electrolyte abnormalities, fat malabsorption, gastric hypersecretion, vitamin B₁₂ deficiency, hyperbilirubinemia, and hepatic steatosis.
C. **Total Parenteral Nutrition (TPN):** Administration of nutrients, usually via a central venous catheter.

D. **Small Bowel Transplantation (SBT):** Involves either the whole small bowel or a bowel segment. There are three major types:
   1. **Isolated SBT,** the recipient receives part of or the entire small bowel;
   2. **Combined small bowel-liver transplant (SBLT):** May be required if the patient with intestinal failure has irreversible liver disease;
   3. **Multivisceral transplantation (MVT):** An en bloc transplant of multiple organs such as the intestine, liver, and pancreas. These organs are dependent on the celiac and superior mesenteric arteries and maintain continuity of the portal venous system and bile duct.

E. **Substance use disorder,** as defined by the fifth edition of the Diagnostic and Statistical Manual of Mental Disorders (DSM-5), is a problematic pattern of use of an intoxicating substance leading to clinically significant impairment or distress. The symptoms associated with a substance use disorder fall into four major groupings: impaired control, social impairment, risky use, and pharmacological criteria (i.e., tolerance and withdrawal).

F. **Transplant evaluation** is a physical and psychosocial exam to determine if an individual is an acceptable candidate for transplantation. The specific exams and tests depend on the individual's diagnosis and health history and vary from hospital to hospital. Tests may include the following: cardiac evaluation; lung function tests; lab tests, including blood typing, chemistry panels, and serology testing for hepatitis, HIV and other common viruses; appropriate cancer surveillance, as indicated (e.g., colonoscopy, pap smear, mammogram, prostate cancer screening); dental evaluation with treatment of existing problems; psychosocial evaluation. Additional testing or clearance may be required to address other significant coexisting medical conditions.

**BENEFIT CONSIDERATIONS**

1. **Prior authorization** is required for:
   - Intestinal, Intestine/Liver, or Multivisceral Evaluation
   - Intestinal, Intestine/Liver, or Multivisceral Transplantation
   - Please see the prior authorization list for product specific prior authorization requirements.

2. Coverage may vary according to the terms of the member’s plan document.

3. Medica has entered into separate contracts with designated facilities to provide transplant-related health services, as described in the member’s plan document.

4. Complex cases require medical director or external review and, as necessary, discussion with the patient’s physician.

5. Underlying co-morbidity that significantly alters risk/benefit of transplant may preclude transplant eligibility.

6. If the Medical Necessity Criteria are met, Medica will authorize benefits within the limits in the member’s plan document.

7. If it appears that the Medical Necessity and Coverage Criteria are not met, the individual’s case will be reviewed by the medical director or an external reviewer. Practitioners are advised of the appeal process in their Provider Administrative Manual.

**MEDICAL NECESSITY CRITERIA**

I. **Indications for Intestinal, Intestine/Liver, or Multivisceral Transplant Evaluation**

   Documentation in the medical records indicates that **one of the following** are met:

   **A. Intestinal Transplant:** **all of the following** criteria are met:
   1. The individual has irreversible intestinal failure and a nonreconstructable GI tract
   2. The individual is dependent on Total Parenteral Nutrition (TPN)
   3. The individual has **one of the following** complications related to TPN:
      a. Loss of or impending loss of vascular access for administering TPN
      b. Recurrent sepsis (two or more episodes per year that requires hospitalization) as a result of either central line sepsis or intestinal stasis
      c. Frequent episodes of severe dehydration despite intravenous fluid supplement in addition to TPN
      d. Impending or overt liver failure due to TPN-induced liver injury.

   **B. Intestine/Liver Transplant:** **all of the following** criteria are met:
   1. The individual meets the criteria for intestinal transplant outlined in Section I.A. above
   2. The individual has **one of the following**:
      a. Biopsy proven fibrotic changes within the liver indicating that the TPN associated liver dysfunction is irreversible
b. Clinical assessment of significant portal hypertension (such as hypersplenism) where biopsy may not be available or warranted or considered safe to perform.

C. Multivisceral Transplant: all of the following criteria are met:
   1. The individual meets the criteria for intestinal transplant outlined in Section I.A. above
   2. The individual has one of the following:
      a. Technical consideration that make the anastomosis of one or more of the separate organs problematic when compared to an enbloc dissection and transplantation that requires fewer vascular and intestinal anastomoses
      b. Desmoid tumors
      c. Severe gastric or antroduodenal motility disorder (pseudoobstruction).

II. Indications for Intestinal, Intestine/Liver, or Multivisceral Transplantation
   Documentation in the medical records indicates that all of the following are met:
   A. The individual meets the institution’s suitability criteria for transplant.
   B. One of the criteria in section I are met (I. A., B. or C.).
   C. Individual or guardian is able to give informed consent. Individual/guardian and family/social support system are able to comply with the treatment regimen and the necessary follow-up. Inadequate funding to pay for immunosuppressive medications post-transplant are addressed and resolved.
   D. For individuals with a recent history (24 months) of substance use disorder, successful completion of a chemical dependency program and 6 months of documented ongoing abstinence.
   E. None of the following contraindications are present:
      1. Non-intestinal uncorrectable medical condition that would itself significantly shorten life expectancy or make transplant success unlikely
      2. Active systemic or localized infection
      3. Irreversible multisystem organ failure
      4. Active untreated or untreatable malignancy (NOTE: Patients with underlying malignancy may require oncology consult to assess prognosis and risk of recurrence)
      5. HIV infection with detectable viral load and CD4 counts less than 200/mm³, acquired Immunodeficiency Syndrome (AIDS) or AIDS-defining condition (See Appendix 1)
      6. Active substance use disorder
      7. Irreversible severe brain damage
      8. Post-transplant lymphoproliferative disease (PTLD) unless no active disease demonstrated by negative PET scan and resolved adenopathy on CT/MRI
      9. Limited irreversible rehabilitative potential
      10. Ongoing pattern of noncompliance, psychiatric illness, psychological condition or limited cognitive ability that would make compliance with a disciplined medical regimen impossible
      11. Lack of psychosocial support as indicated by either no identified caregiver or an uncommitted caregiver
      12. Inability to obtain informed consent from patient or guardian.

III. Indications for Intestinal, Intestine/Liver, or Multivisceral Retransplantation
   Documentation in the medical records indicates that all of the following criteria are met:
   A. Failed previous intestinal transplantation.
   B. All the criteria in section II are met.
   C. No history of behaviors since the previous transplant that would jeopardize a subsequent transplant.
Pre-06/2016 MPC:

06/2016 MPC:

02/2017 MPC:

02/2018 MPC:

02/2019 MPC:
• Bacterial infections, multiple or recurrent*
• Candidiasis of bronchi, trachea, or lungs
• Candidiasis of esophagus
• Cervical cancer, invasive†
• Coccidioidomycosis, disseminated or extrapulmonary
• Cryptococcosis, extrapulmonary
• Cryptosporidiosis, chronic intestinal (>1 month’s duration)
• Cytomegalovirus disease (other than liver, spleen, or nodes), onset at age >1 month
• Cytomegalovirus retinitis (with loss of vision)
• Encephalopathy attributed to HIV§
• Herpes simplex: chronic ulcers (>1 month’s duration) or bronchitis, pneumonitis, or esophagitis (onset at age >1 month)
• Histoplasmosis, disseminated or extrapulmonary
• Isosporiasis, chronic intestinal (>1 month’s duration)
• Kaposi sarcoma
• Lymphoma, Burkitt (or equivalent term)
• Lymphoma, immunoblastic (or equivalent term)
• Lymphoma, primary, of brain
• Mycobacterium avium complex or Mycobacterium kansasii, disseminated or extrapulmonary
• Mycobacterium tuberculosis of any site, pulmonary†, disseminated, or extrapulmonary
• Mycobacterium, other species or unidentified species, disseminated or extrapulmonary
• Pneumocystis jirovecii (previously known as “Pneumocystis carinii”) pneumonia
• Pneumonia, recurrent†
• Progressive multifocal leukoencephalopathy
• Salmonella septicemia, recurrent
• Toxoplasmosis of brain, onset at age >1 month
• Wasting syndrome attributed to HIV§

* Only among children aged <6 years.
† Only among adults, adolescents, and children aged ≥6 years.
§ Suggested diagnostic criteria for these illnesses, which might be particularly important for HIV encephalopathy and HIV wasting syndrome, are described in the following references:
CDC. 1994 Revised classification system for human immunodeficiency virus infection in children less than 13 years of age. MMWR 1994;43(No. RR-12).
CDC. 1993 Revised classification system for HIV infection and expanded surveillance case definition for AIDS among adolescents and adults. MMWR 1992;41(No. RR-17).