Medical Policy

Transplantation of Small Bowel, Small Bowel-Liver or Multivisceral Organs

Policy Number: OCA 3.26
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Product Applicability

<table>
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<tr>
<th>Well Sense Health Plan</th>
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Notes:
+ Disclaimer and audit information is located at the end of this document.
◊ The guidelines included in this Plan policy are applicable to members enrolled in Senior Care Options only if there are no criteria established for the specified service in a Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) on the date of the prior authorization request. Review the member’s product-specific benefit documents at www.SeniorsGetMore.org to determine coverage guidelines for Senior Care Options.

Policy Summary

The Plan considers small bowel transplantation, small bowel-liver transplantation, or transplantation of multivisceral organs for the treatment of irreversible intestinal failure for adults and children (including infants) to be medically necessary when Plan medical criteria are met. All transplant-related consults, evaluations, procedures, and post-transplant follow-up services should be managed within the Plan’s provider network or at the most appropriate preferred transplant facility, depending upon the type of transplant. Prior authorization is required for ALL transplantation services. It will be determined...
during the Plan’s prior authorization process if the specific transplant service is considered medically necessary for the requested indication within the Plan’s provider network, as appropriate.

Prior authorization requests for transplantation services for Plan members are evaluated utilizing medical necessity criteria in the applicable Plan medical policy. If there is no Plan medical policy for the requested type of transplantation (e.g., transplantation of the liver without small bowel transplant), the Plan uses InterQual® criteria to determine the medical necessity of the requested transplantation services. The Plan conducts an individual evaluation of the member’s medical condition based on the guidelines outlined in the Plan’s Clinical Review Criteria administrative policy, policy number OCA 3.201, when there is no applicable Plan medical policy and InterQual® criteria are not established for the requested type of transplantation. Review the Plan’s Transplantation of Pancreas or Pancreas-Kidney medical policy, policy number OCA 3.25, rather than this policy for medical necessity criteria for pancreas transplants that do NOT include transplantation of multivisceral organs or for combined kidney-pancreas transplants. When a member is deemed to be an appropriate candidate for transplantation services based on the Plan’s applicable medical necessity criteria and the evaluation conducted by the treating provider, final approval is required by a Plan Medical Director for the member’s transplantation. In addition, Plan Medical Director review is required when the Plan’s applicable medical necessity criteria are not met for requested transplantation services.

The Plan’s Clinical Technology Evaluation administrative policy, policy number OCA 3.13, outlines the Plan’s process for evaluating new technology and the new application of existing technology. The Plan’s Medically Necessary medical policy, policy number OCA 3.14, specifies the product-specific definitions of medically necessary treatment, and the Plan’s Experimental and Investigational Treatment medical policy, policy number OCA 3.12, indicates the product-specific definitions of experimental or investigational treatment.

The Plan member must meet the eligibility criteria from the transplanting institution. The eligibility criteria of the transplanting institution must follow the applicable United Network for Organ Sharing (UNOS) guidelines. The hospital in which the organ transplants are performed must be a member of the Organ Procurement and Transplantation Network (OPTN) in accordance with the Public Health Service Act, comply with applicable OPTN organ allocation and procurement guidelines, and follow the Centers for Medicare & Medicaid Services (CMS) applicable conditions of participation for the specified organ to be transplanted (including but not limited to the following Code of Federal Regulations: 42 CFR Parts 405, 482, 488, and 498). The transplant program (including affiliated transplant facility, transplant surgeons, transplant physicians, and staff) must follow the designated UNOS/OPTN transplant program criteria for the applicable transplant service and comply with all applicable UNOS/OPTN professional standards. Senior Care Options members will have access to transplant services according all applicable CMS guidelines, including but not limited to the provisions specified in the Medicare Managed Care Manual, Chapter 4 – Benefits and Beneficiary Protections, 10.11 Transplant Services.
Review the member’s applicable benefit documents available at www.bmchp.org for benefit coverage and associated transplant guidelines for a BMC HealthNet Plan member, at www.SeniorsGetMore.org for a Senior Care Options member, and at www.wellsense.org for a Well Sense Health Plan member. If a transplant is requested for a Well Sense Health Plan member and authorized by the Plan as medically necessary, a Plan-approved transplant center will review the case to determine the member’s status as a candidate for a transplant at that facility (based on the clinical guidelines utilized by the transplant program).

**Description of Item or Service**

**Small Bowel Transplant:** A small bowel transplant usually involves the removal of the small intestine from a deceased donor, removal of the recipient’s small intestine, and replacement with the donor’s intestine. A cadaveric small bowel transplant is always considered before transplantation from a living donor. Living donor small bowel transplantation is an alternative to cadaveric small bowel transplantation for the treatment of patients with irreversible intestinal failure who cannot tolerate total parenteral nutrition (TPN) and is considered when a cadaver donor is unavailable in a timely manner. If a living donor is used, a segment of the donor's small intestine is transplanted. A small bowel transplant is typically performed on individuals with short bowel syndrome, but the procedure is appropriate for certain other conditions.

**Small Bowel-Liver Transplant:** A small bowel-liver transplant involves the removal of the small intestine and liver from a deceased donor, removal of the recipient’s small intestine and liver, and replacement with the donor’s intestine and liver. A small bowel-liver transplant is indicated for individuals with intestinal failure and liver failure.

**Multivisceral Transplant:** Transplantation of the small bowel and liver with one (1) or more of the following organs from the digestive system: stomach, duodenum, pancreas, and/or colon. A multivisceral transplant is indicated when anatomic or other medical problems preclude a small bowel transplant. Multivisceral transplantation is considered when individuals have irreversible failure of three (3) or more abdominal organs including the small bowel. The most common indications for multivisceral transplantation are total occlusion of the splanchnic circulation, extensive gastrointestinal polyposis, hollow visceral myopathy or neuropathy, and/or some abdominal malignancies.

**Medical Policy Statement**

When a member is deemed an appropriate candidate for transplantation services based on the Plan’s applicable medical necessity criteria and the evaluation conducted by the treating provider, final approval is required by a Plan Medical Director for the member’s transplantation. In addition, Plan Medical Director review is required when the Plan’s applicable medical necessity criteria are not met for requested transplantation services. An evaluation for transplantation services conducted by the treating provider is defined as a consultation and diagnostic testing or other testing required to assess a member’s appropriateness and readiness for transplantation; an evaluation does not include care required as part of the course of treatment for the underlying medical condition. See the Policy

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Statement section of the Plan’s Transplant Administration policy, administrative policy number OCA 3.10, for guidelines on how the Plan processes requests for evaluations by participating providers and non-participating providers.

The Plan member must meet eligibility criteria from the transplanting institution for the requested transplantation services. The eligibility criteria of the transplanting institution must follow applicable United Network for Organ Sharing (UNOS) guidelines. The hospital in which the organ transplants are performed must be a member of the Organ Procurement and Transplantation Network (OPTN) and comply with applicable OPTN organ allocation and procurement guidelines. Review the Plan’s Transplantation of Pancreas or Pancreas-Kidney medical policy, policy number OCA 3.25, rather than this policy for medical necessity criteria for pancreas transplants that do NOT include transplantation of multivisceral organs or for combined kidney-pancreas transplants. The Plan considers small bowel transplantation or multivisceral transplantation to be medically necessary when medical record documentation supports that ALL of the following applicable Plan criteria have been met, as specified below in item A (Initial Transplantation and Retransplantation Criteria for Adult and Pediatric Members), item B (Procedure-Specific Criteria for Adult and Pediatric Members), and item C (Age-Specific Criteria):

A. Initial Transplantation and Retransplantation Criteria for Adult and Pediatric Members: **

See applicable criteria below, EITHER item 1 for criteria for an initial transplantation or item 2 for criteria for retransplantation.

1. Initial Transplantation Criteria:

   ALL of the following criteria must be met for each adult member or pediatric member who is a candidate for an initial transplantation, as specified below in items a through d:

   a. Member has total irreversible intestinal failure characterized by BOTH of the following conditions, as specified below in items (1) and (2):

      (1) Loss of absorption; AND

      (2) The inability to maintain protein-energy, fluid, electrolyte, or micronutrient balance; AND

   b. Transplantation is for any ONE (1) of the following indications, as specified below in items (1) through (3):

      (1) Treatment of malignancy* when the transplant surgeon has determined that transplantation is the most appropriate treatment for the member’s condition (and treatment is consistent with the guidelines specified in the Limitations section of this policy; OR

   Transplantation of Small Bowel, Small Bowel-Liver, or Multivisceral Organs

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* Note: Deliberate patient selection of small bowel, small bowel-liver, or multivisceral transplantation is essential for a member diagnosed with a malignancy, even when complete tumor removal is technically feasible. Treatment must be consistent with current and applicable clinical guidelines from both the United Network for Organ Sharing (UNOS) and the National Comprehensive Cancer Network (NCCN) when transplantation is used to treat a malignancy. Transplant patients are subject to intensive immunosuppression, and the biological behavior of a neoplasm may be unpredictable.

(2) Intra-abdominal non-metastasizing tumor(s) that is growing locally and is progressively obstructing the bowel where removal of the tumor(s) requires resecting the entire intestine and replacing it with a transplanted intestine (when the transplant surgeon has determined that transplantation is the most appropriate treatment for the member’s medical condition and treatment is consistent with the guidelines specified in the Limitations section of this policy); OR

(3) Failure of total parenteral nutrition (TPN), including home parenteral nutrition, resulting from any ONE (1) of the following criteria, as specified below as items (a) through (e):

(a) Sepsis with at least ONE (1) of the following, as specified below in item (i) or item (ii):

(i) Severe sepsis as evidenced by the development of two (2) or more episodes of systemic sepsis per year secondary to line sepsis, requiring hospitalization; OR

(ii) A single episode of line-related fungemia, septic shock, and/or acute respiratory distress syndrome (ARDS); OR

(b) Frequent episodes of severe dehydration (as defined by the treating provider) despite intravenous fluid supplementation in addition to TPN (since frequent episodes of dehydration are detrimental to all body organs, especially the kidney and the central nervous system, with the development of multiple kidney stones, renal failure, and permanent brain damage); OR

(c) Impending or overt liver failure due to TPN-induced liver injury with at least ONE (1) of the following clinical manifestations, as specified below in items (i) through (vii):

(i) Coagulopathy; OR
(ii) Elevated serum bilirubin and/or liver enzymes; OR

(iii) Gastroesophageal varices; OR

(iv) Hepatic fibrosis or cirrhosis; OR

(v) Splenomegaly; OR

(vi) Stomal bleeding; OR

(vii) Thrombocytopenia; OR

(d) Thrombosis of TWO (2) or more of the major central veins including jugular, subclavian, or femoral veins, as a life-threatening complication and failure of TPN therapy; OR

(e) Loss of vascular access; AND

c. All individual eligibility criteria of the transplanting institution are met; AND

d. The donor meets ONE (1) of the following guidelines, as specified below in item (1) or item (2):

(1) A cadaver donor will be used for the small bowel, small bowel-liver, or multivisceral transplant; OR

(2) A living donor will be used rather than a cadaver donor for a small bowel transplant or small bowel-liver transplant when the transplant team has determined that the member is a suitable candidate for a living donor transplant and ONE (1) of the following criteria are met, as specified below in item (a) or item (b):

(a) A cadaver donor is unavailable; OR

(b) Member is deteriorating clinically to the point of transplant ineligibility while waiting for cadaveric organ donation; OR

2. **Retransplantation Criteria:**

Retransplantation is covered when BOTH of the following criteria are met for an adult or pediatric member who is a candidate for retransplantation, as specified below in item a. and item b:
a. Criteria are met for the initial transplant (as specified in item A1 above, Initial Transplantation Criteria); AND

b. The member has at least ONE (1) of the following indications, as specified below in items (1) through (3):

(1) Graft failure of an initial small bowel, small bowel-liver, or multivisceral transplant due to ONE (1) of the following, as specified below in item (a) or item (b):

(a) Technical reason, excluding serious reportable event and/or provider-preventable condition; † OR

† Note: See the Plan’s Provider Preventable Conditions and Serious Reportable Events reimbursement policy (policy number 4.610 for BMC HealthNet Plan members, policy number SCO 4.610 for Senior Care Options members, and policy number WS 4.29 for Well Sense Health Plan members) for definitions of serious reportable events and provider-preventable conditions.

(b) Hyperacute rejection (see Definitions section); OR

(2) Chronic rejection (see Definitions section); OR

(3) Recurrent disease; AND

B. Procedure-Specific Criteria for Adult and Pediatric Members: **

The transplant surgeon has determined that transplantation is the most appropriate treatment for the member’s medical condition and ONE (1) of the following categories of applicable, procedure-specific criteria is met, as specified below in items 1 through 3:

1. **Isolated Small Bowel Transplantation:**

   Small bowel transplantation will be performed with a cadaveric intestine UNLESS a cadaveric intestine is NOT available and a living donor must be used as an alternative (since cadaveric small bowel transplant is always considered before transplantation from a living donor); OR

2. **Small Bowel-Liver Transplantation:**

   Member meets at least ONE (1) of the following criteria, as specified below in items a through d:

a. Member has intestinal failure with end-stage hepatic disease; OR
b. Member has intestinal failure from a hypercoagulable state associated with enzyme deficiencies that can be corrected by a liver graft; OR

c. Member has mesenteric venous thrombosis; OR

d. The member has documented, unreconstructable portomesenteric venous systems; OR

3. **Multivisceral Transplantation:**

Member meets ALL of the following criteria, as specified below in items a through c:

a. The member requires transplantation of the small bowel; AND

b. The member has concurrent liver failure requiring a liver transplant; AND

c. The member meets at least ONE (1) of the following criteria, as specified below item (1) or item (2):

   (1) The member has documented, unreconstructable portomesenteric venous systems; OR

   (2) The member requires ONE (1) or more abdominal visceral organs (i.e., stomach, duodenum, jejunum, ileum, pancreas,∞ and/or colon) to be transplanted (as determined by the treating transplant surgeon) due at least ONE (1) of the following conditions, as specified below in items (a) through (c):

   (a) Concomitant organ failure; OR

   (b) Anatomical abnormalities; OR

   (c) Pancreas∞ transplant for a member with a history of diabetes and pancreatic exocrine insufficiency (as determined by the transplant surgeon); AND

∞ Note: See the Plan’s *Transplantation of Pancreas or Pancreas-Kidney* medical policy, policy number OCA 3.25, rather than this policy for medical necessity criteria for pancreas transplants that do NOT include transplantation of multivisceral organs or for combined kidney-pancreas transplants.

C. **Age-Specific Criteria: **

See applicable, age-specific criteria listed below, EITHER item 1 for an adult member (age 18 or older on the date of service) or item 2 for a pediatric member (age less than 18 years old on the date of service).
1. **Age-Specific Criteria for Adult Members (Age 18 or Older on the Date of Service):**

   The adult member is diagnosed with at least ONE (1) of the following conditions, as specified below in items a through e:

   a. Granulomatous disease, including but not limited to Crohn’s disease; OR

   b. Intestinal vascular insufficiency, including but not limited to ONE (1) of the following conditions, as specified below in items (1) through (3):

      (1) Budd-Chiari syndrome; OR

      (2) Mesenteric artery insufficiency; OR

      (3) Mesenteric venous thrombosis (due to hypercoagulable state, protein S or C deficiency and antithrombin III deficiency); OR

   c. Neoplasm, including but not limited to ONE (1) of the following conditions, as specified below in items (1) through (3):

      (1) Familial adenomatous polyposis (FAP); OR

      (2) Gardner’s syndrome; OR

      (3) Diffuse mesenteric fibroadenomatosis; OR

   d. Trauma, including but not limited to ONE (1) of the following events, as specified below in items (1) and (2):

      (1) Gunshot wound; OR

      (2) Motor vehicle accident; OR

   e. Other conditions including ONE (1) of the following conditions, as specified below in items (1) through (4):

      (1) Massive resection secondary to tumor; OR

      (2) Pseudo-obstruction; OR

      (3) Radiation enteritis; OR
2. **Age-Specific Criteria for Pediatric Members (Under Age 18 on the Date of Service):**

   The pediatric member is diagnosed with at least ONE (1) of the following conditions, as specified below in items a through c:

   a. Congenital condition, including any ONE (1) of the following conditions specified below in items (1) through (4):

      (1) Atresia or stenosis; OR
      (2) Gastroschisis; OR
      (3) Dysmotility disorder, including any ONE (1) of the following conditions, as specified below in items (a) through (c):
         (a) Hirschsprung’s disease; OR
         (b) Megacystis microcolon; OR
         (c) Intestinal pseudo-obstruction; OR
      (4) Mucosal cell disease, including any ONE (1) of the following conditions, as specified below in item (a) or item (b):
         (a) Microvillus inclusion disease; OR
         (b) Tufting enteropathy; OR
   
   b. Perinatal complication, including any ONE (1) of the following complications, as specified below in item (1) or item (2):

      (1) Necrotizing enterocolitis (NEC); OR
      (2) Volvulus; OR
   
   c. Other condition, including any ONE (1) of the following conditions specified below in items (1) through (4):

      (1) Short gut syndrome; OR
      (2) Status post intestinal transplant; OR

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Transplantation of Small Bowel, Small Bowel-Liver, or Multivisceral Organs

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(3) Trauma; OR

(4) Chronic intestinal pseudo-obstruction

** Note: ALL applicable criteria must be met for an initial transplantation or retransplantation (as specified above in item A), ALL applicable procedure-specific criteria must be met (as specified above in item B), and ALL applicable age-specific criteria must be met (as specified above item C) for the Plan to consider the transplant service medically necessary.

Limitations

All transplant-related consultations, evaluations, procedures, and post-transplant follow-up services should be managed within the Plan’s provider network or at the most appropriate preferred transplant facility (depending upon the type of transplant) and according to the administrative guidelines specified in the Plan’s Transplant Administration policy, administrative policy number OCA 3.10. Prior authorization is required for ALL transplantation services.

Prior authorization requests for transplantation services for Plan members are evaluated utilizing medical necessity criteria in the applicable Plan medical policy. If there is no Plan medical policy for the requested type of transplantation (e.g., simultaneous pancreas and lung transplantation), the Plan uses InterQual® criteria to determine the medical necessity of the requested transplantation services. The Plan conducts an individual evaluation of the member’s medical condition based on the guidelines outlined in the Plan’s Clinical Review Criteria administrative policy, policy number OCA 3.201, when there is no applicable Plan medical policy and InterQual® criteria are not established for the requested type of transplantation. **When a member is deemed to be an appropriate candidate for transplantation** services based on the Plan’s applicable medical necessity criteria and the evaluation conducted by the treating provider, **final approval is required by a Plan Medical Director** for the member’s transplantation. In addition, Plan Medical Director review is required when the Plan’s applicable medical necessity criteria are not met for requested transplantation services.

1. **Individual Consideration by Plan Medical Director:**

   a. Plan Medical Director review is required for a member older than age 65 on the date of service; OR

   b. Any request for a small bowel transplantation, small bowel-liver transplantation, or transplantation of multivisceral organs that does NOT meet applicable medical necessity criteria specified in the Medical Policy Statement section of this policy requires individual consideration by a Plan Medical Director. The Plan Medical Director will evaluate the individual member’s clinical needs and circumstances based on the guidelines included in the Plan’s Clinical Review Criteria administrative policy, policy number OCA 3.201.
2. **Absence of TPN Failure:** A small bowel transplant, small bowel-liver transplant, or multivisceral transplant in an adult or pediatric member is considered NOT medically necessary for those who have NOT failed total parenteral nutrition unless the intestinal transplant is considered medically necessary to treat a malignancy or for another indication, as determined by the transplantation surgeon (e.g., dysmotility disorder, genetic intestinal disorder of the mucosal cells, disease with a high potential for malignant degeneration, neoplastic tumors of the gastrointestinal tract and pancreas that are limited to the abdominal cavity, radiation-induced bowel injury, and/or unreconstructable portomesenteric thrombosis with associated liver failure).

2. **Xenotransplantation:** Small bowel, small bowel-liver or multivisceral xenotransplantation (e.g., porcine xenografts) is considered experimental and investigational for any indication. See the Plan’s Experimental and Investigational Treatment medical policy, policy number OCA 3.12, for the product-specific definitions of experimental or investigational treatment.

3. **Contraindications:**

   Many factors can affect the outcome of organ transplantation. Fairly rigid selection criteria are required to obtain optimal results for each patient. The treating provider must submit clinical documentation to the Plan Medical Director explaining why the member with any of these contraindications is an appropriate candidate for the requested transplant. Contraindications include but are not limited to at least ONE (1) of the following, as specified below in items a through o:

   a. Acute or chronic infection that is not adequately treated; OR
   b. Active substance abuse within the last six (6) months; OR
   c. Active systemic illness that is likely to negatively affect the outcome of the transplant; OR
   d. AIDS (diagnosis based on CDC definition of CD4 count, 200cells/ mm3) unless ALL of the following are noted in the member’s medical record, as specified below in items (1) through (4):

      (1) CD4 count greater than 200cells/ mm3 for more than 6 months; AND
      (2) HIV-1 RNA undetectable; AND
      (3) On stable anti-retroviral therapy for more than three (3) months; AND
      (4) No other complications from AIDS (e.g., opportunistic infection, including aspergillus, tuberculosis, coccidioidomycosis, resistant fungal infections, Kaposi’s sarcoma or Transplantation of Small Bowel, Small Bowel-Liver, or Multivisceral Organs

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other neoplasm); OR

e. Cerebral edema; OR

f. Congenital immune deficiency syndrome(s); OR

g. Demonstrated patient noncompliance which would place the organ at risk by not adhering to medical recommendations; OR

h. Malignancy known and active (including metastatic cancer, other than non-melanomatous skin cancer) when the malignancy is NOT an indication for small bowel, small bowel-liver, or multivisceral transplantation; OR

i. Aggressive malignancy recently treated with a high or moderate risk of recurrence as assessed by the transplant team, when the malignancy is NOT an indication for small bowel, small bowel-liver, or multivisceral transplantation; OR

j. Multisystem organ failure including cardiac, pulmonary, and/or neurologic;◊ OR

◊ Note: Since kidney transplant can be included as part of a multivisceral transplant, renal failure itself is NOT a contraindication.

k. Tissue incompatibility between donor and recipient as determined by a positive preoperative crossmatch; OR

l. Severe physical debilitation not responsive to previous intensive nutritional support; OR

m. Severe irresolvable cardiac, respiratory, and/or neurologic complications that would affect the outcome of the transplant; OR

n. Uncontrollable sepsis; OR

o. Morbid obesity with a BMI > 40; these types of transplants require intra-abdominal surgery, and post-transplantation wound healing is affected by an elevated BMI (i.e., relative contraindication).

Review the Plan’s Transplantation of Pancreas or Pancreas-Kidney medical policy, policy number OCA 3.25, rather than this policy for medical necessity criteria for pancreas transplants that do NOT include transplantation of multivisceral organs or for combined kidney-pancreas transplants.
Definition: The loss of absorptive capacity of the small bowel secondary to severe primary gastrointestinal disease or surgically induced short bowel syndrome. Intestinal failure results from obstruction, dysmotility, surgical resection, congenital defect, or disease-associated loss of absorption and is characterized by the inability to maintain protein-energy, fluid, electrolyte, or micronutrient balance.

Mesenteric Venous Thrombosis: Thrombus or a blood clot that blocks blood flow in the mesenteric venous system. There are two (2) main mesenteric veins that drain the small and large intestines. The inferior mesenteric vein drains the left colon into the splenic vein, which later joins the superior mesenteric vein to form the portal vein to the liver. The superior mesenteric vein drains the remaining to the colon and the small bowel. This condition stops the venous blood return of the intestines and if acute, can result in damage to the intestine. There are several diseases that can lead to mesenteric venous thrombosis. Many of the diseases cause swelling (inflammation) of the tissues surrounding the veins, and include appendicitis, cancer, diverticulitis, and/or pancreatitis. Liver disease with cirrhosis can cause venous stasis with resulting thrombosis.

Short Bowel Syndrome (Short Gut Syndrome): A condition in which the absorbing surface of the small intestine is inadequate due to extensive disease or surgical removal of a large portion of small intestine. Short-bowel syndrome results from surgical resection, congenital defect, or disease-associated loss of absorption and is characterized by the inability to maintain protein-energy, fluid, electrolyte, or micronutrient balances when on a conventionally accepted, normal diet. Etiologies of short bowel syndrome include volvulus, atresias, necrotizing enterocolitis, Crohn’s disease, gastroschisis, thrombosis of the superior mesenteric artery, desmoid tumors, and/or trauma. Patients with short bowel syndrome are typically unable to obtain adequate nutrition from enteral feeding and become dependent upon total parenteral nutrition (TPN).

Transplant Rejection: A process in which a transplant recipient’s immune system attacks the transplanted organ or tissue. There are three (3) clinicopathologic stages of rejection:

1. Hyperacute Rejection: A recipient’s immune reaction that occurs within a few minutes after the transplant when the antigens are completely unmatched, resulting in organ failure within the first hours after transplantation. The tissue must be removed right away so the recipient does not die.

2. Acute Rejection: A recipient’s immune reaction that occurs any time from the first week after the transplant (during which the immune response increases in intensity) and generally up to 60 to 90 days after organ transplantation. It may be Grade I (mild), Grade II (moderate) or Grade III (severe). All recipients have some amount of acute rejection.
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3. Chronic Rejection: A recipient’s immune reaction that occurs more than 60 days after transplantation and can take place over many years. This is the body’s constant immune response against the new organ that slowly damages the transplanted tissues or organ.

Xenotransplantation: According to the U.S. Public Health Service, xenotransplantation is defined as any procedure that involves the transplantation, implantation, or infusion into a human recipient of either of the following, as specified below in item 1 or item 2:

1. Live cells, tissues, or organs from a non-human animal source; or

2. Human body fluids, cells, tissues or organs that have had ex vivo contact with live non-human animal cells, tissues, or organs. (See this policy’s Limitations section.)

Applicable Coding

The Plan uses and adopts up-to-date Current Procedural Terminology (CPT) codes from the American Medical Association (AMA), International Statistical Classification of Diseases and Related Health Problems, 10th revision (ICD-10) diagnosis codes developed by the World Health Organization and adapted in the United States by the National Center for Health Statistics (NCHS) of the Centers for Disease Control under the U.S. Department of Health and Human Services, and the Health Care Common Procedure Coding System (HCPCS) established and maintained by the Centers for Medicare & Medicaid Services (CMS). Because the AMA, NCHS, and CMS may update codes more frequently or at different intervals than Plan policy updates, the list of applicable codes included in this Plan policy is for informational purposes only, may not be all inclusive, and is subject to change without prior notification. Whether a code is listed in the Applicable Coding section of this Plan policy does not constitute or imply member coverage or provider reimbursement. Providers are responsible for reporting all services using the most up-to-date industry-standard procedure and diagnosis codes as published by the AMA, NCHS, and CMS at the time of the service.

Providers are responsible for obtaining prior authorization for the services specified in the Medical Policy Statement section and Limitation section of this Plan policy, even if an applicable code appropriately describing the service that is the subject of this Plan policy is not included in the Applicable Coding section of this Plan policy. Coverage for services is subject to benefit eligibility under the member’s benefit plan. Please refer to the member’s benefits document in effect at the time of the service to determine coverage or non-coverage as it applies to an individual member. See Plan reimbursement policies for Plan billing guidelines.

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<th>CPT Codes</th>
<th>Description: Codes Covered When Medically Necessary</th>
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<tr>
<td>44133</td>
<td>Donor enterectomy (including cold preservation), open; partial, from living donor</td>
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<tr>
<td>44135</td>
<td>Intestinal allotransplantation; from cadaver donor</td>
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<tr>
<td>44136</td>
<td>Intestinal allotransplantation; from living donor</td>
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## Clinical Background Information

A small bowel transplant is typically performed in individuals with short bowel syndrome (SBS). Parenteral nutrition is the mainstay of therapy for adults and children with SBS and other causes of intestinal failure. In infants, SBS is generally due to congenital anomalies. In adults, severe SBS usually occurs following a massive small bowel resection, which results in rapid intestinal transit and loss of absorptive function.

Small bowel, small bowel-liver and multivisceral transplantation can be a lifesaving procedure and has become the treatment of choice for patients with irreversible intestinal and/or multivisceral organ failure who can no longer be sustained on total parenteral nutrition (TPN). Combined small bowel-liver transplant is indicated when there is documented end-stage hepatic disease. Patients can survive total intestinal failure with TPN therapy. However, frequently patients lose the ability to tolerate long term TPN therapy secondary to liver failure, thrombosis of central veins, infections from central lines, and/or dehydration. Many factors can affect the outcomes of small bowel, small bowel-liver, and multivisceral transplantations; patient selection criteria are based on obtaining optimal results for each recipient.

At the time of the Plan’s most recent policy review, the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) #260.5 for intestinal and multi-visceral transplantation states that intestinal and multi-visceral transplantations are covered by Medicare when performed for the purpose of restoring intestinal function in patients with irreversible intestinal failure who have failed total parenteral nutrition (TPN) and meet applicable CMS criteria. CMS defines intestinal failure as the loss of absorptive capacity of the small bowel secondary to severe primary gastrointestinal disease or surgically induced short bowel syndrome. Multi-visceral transplantation includes organs in the digestive system (stomach, duodenum, pancreas, liver and intestine). CMS requires that services be provided at a Medicare-approved liver transplant centers that perform intestine transplants, combined liver-intestine transplants, and multivisceral transplants (as specified in 42 CFR Parts 405, 482, 488, and 498 Medicare Program, Hospital Conditions of Participation: Requirements for Approval and Re-Approval of Transplant Centers to Perform Organ Transplants, Final Rule, March 30, 2007). CMS NCD 190.1 states histocompatibility testing is safe and effective when it is performed on patients in preparation for a kidney transplant. CMS evaluates detailed criteria for facility participation that include but are not limited to the following: clinical experience, patient selection of suitable candidates, patient management, maintenance of data, organ procurement, laboratory services, and billing guidelines. Senior Care Options members will have access to transplant services according all

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applicable CMS guidelines, including but not limited to the provisions specified in the Medicare Managed Care Manual, Chapter 4 – Benefits and Beneficiary Protections, 10.11 Transplant Services. Determine what applicable CMS criteria are in effect for pancreas or pancreas-kidney transplant services in an NCD or LCD on the date of the prior authorization request for a Senior Care Options member.

The U.S. Department of Health and Human Services (DHHS) has oversight responsibility for the organ allocation system in the United States. Congress established the Organ Procurement and Transplantation Network (OPTN) when it enacted the National Organ Transplant Act (NOTA) of 1984. The Act called for a unified transplant network to be operated by a private, nonprofit organization under federal contract. United Network for Organ Sharing (UNOS) was awarded the initial OPTN contract in 1986 and continues to administer the OPTN.

References


Transplantation of Small Bowel, Small Bowel-Liver, or Multivisceral Organs

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Policy History

<table>
<thead>
<tr>
<th>Original Approval Date</th>
<th>Original Effective Date* and Version Number</th>
<th>Policy Owner</th>
<th>Original Policy Approved by</th>
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<tbody>
<tr>
<td>Regulatory Approval: N/A</td>
<td>10/02/05 Version 1</td>
<td>Medical Policy Manager as Chair of Medical Policy, Criteria, and Technology Assessment Committee (MPCTAC)</td>
<td>Quality and Clinical Management Committee (Q&amp;CMC)</td>
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<td>Internal Approval: 08/02/05</td>
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*Effective Date for the BMC HealthNet Plan Commercial Product(s): 01/01/12
*Effective Date for the Well Sense Heath Plan New Hampshire Medicaid Product(s): 01/01/13
*Effective Date for Senior Care Options Product(s): 01/01/16

Policy Revisions History

<table>
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<th>Review Date</th>
<th>Summary of Revisions</th>
<th>Revision Effective Date and Version Number</th>
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<tr>
<td>02/06/07</td>
<td>Updated template and references.</td>
<td>Version 2</td>
<td>02/06/07: Q&amp;CMC</td>
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<tr>
<td>02/19/08</td>
<td>Revised clinical criteria.</td>
<td>Version 3</td>
<td>02/19/08: MPCTAC 02/26/08: Utilization Management Committee (UMC)</td>
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Transplantation of Small Bowel, Small Bowel-Liver, or Multivisceral Organs

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<tr>
<td>02/24/09</td>
<td>Updated clinical criteria for HIV, updated coding and references.</td>
<td>Version 4</td>
<td>02/24/09: QIC</td>
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<td>Version 5</td>
<td>02/22/10: MPCTAC</td>
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<td>03/24/10: QIC</td>
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<tr>
<td>02/01/11</td>
<td>Updated adult and pediatric clinical indications, updated references.</td>
<td>Version 6</td>
<td>03/16/11: MPCTAC</td>
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<td>04/27/11: QIC</td>
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<td>03/13/12</td>
<td>Updated references, clarified two contraindications.</td>
<td>Version 7</td>
<td>03/21/12: MPCTAC</td>
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<td>04/25/12: QIC</td>
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<td>08/01/12</td>
<td>Off cycle review for Well Sense Health Plan, revised Summary statement, reformatted and revised Medical Policy Statement, revised Applicable Coding introductory paragraph, revised Limitations.</td>
<td>Version 8</td>
<td>08/13/12: MPCTAC</td>
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<td>09/06/12: QIC</td>
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<td>03/01/13</td>
<td>Review for effective date 07/01/13. Revised title, updated and added references, revised Summary section, moved description of multivisceral transplant from Definition section to Description of Item or Service, and added small bowel-liver transplant to Description of Item or Service. Reformatted, revised, and added medical criteria in Medical Policy Statement section (formerly titled the Clinical Guidelines Statement section). Added limitations and moved contraindications from Medical Policy Statement section to Limitations section. Moved criteria for failed TPN therapy from Clinical Background Information section to the Medical Policy Statement section. Deleted HCPCS code S2055 from applicable code list and revised language in Applicable Coding section. Revised text in Clinical Background Information section and changed name of policy category from “Clinical Coverage Guidelines” to “Medical Policy.” Referenced Medically Necessary policy, Reimbursement Guidelines: Serious</td>
<td>07/01/13</td>
<td>03/20/13: MPCTAC</td>
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<td>08/14/13</td>
<td>Reportable Event/Provider Preventable Condition policy, and Experimental and Investigational Treatment policy.</td>
<td>Version 10</td>
<td>08/14/13: MPCTAC (electronic vote) 08/15/13: QIC</td>
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<tr>
<td>03/01/14</td>
<td>Off cycle review for Well Sense Health Plan and merged policy format. Incorporate policy revisions dated 03/01/13 (as specified above) for the Well Sense Health Plan product; these policy revisions were approved by MPCTAC on 03/20/13 and QIC on 04/18/13 for applicable Plan products.</td>
<td>07/01/14</td>
<td>03/19/14: MPCTAC 04/16/14: QIC</td>
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<td>12/01/14</td>
<td>Review for effective date 07/01/14. Revised and reformatted criteria in the Medical Policy Statement section and Limitations section. Updated references.</td>
<td>03/01/15</td>
<td>12/02/14: MPCTC (electronic vote) 12/10/14: QIC</td>
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<td>03/01/15</td>
<td>Review for effective date 07/01/15. Updated Summary, Definitions, and References sections. Revised criteria in the Medical Policy Statement section. Removed Commonwealth Care, Commonwealth Choice, and Employer Choice from the list of applicable products because the products are no longer available.</td>
<td>07/01/15</td>
<td>03/18/15: MPCTAC 04/08/15: QIC</td>
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<td>11/25/15</td>
<td>Review for effective date 01/01/16. Updated template with list of applicable products and notes. Revised language in the Applicable Coding section.</td>
<td>01/01/16</td>
<td>11/18/15: MPCTAC 11/25/15: MPCTAC (electronic vote) 12/09/15: QIC</td>
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<td>03/01/16</td>
<td>Review for effective date 07/01/16. Updated Summary, Description of Item or Service, Clinical Background Information, References, and Reference to Applicable Laws and Regulations sections. Revised criteria in the Limitations section.</td>
<td>07/01/16</td>
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<td>03/01/17</td>
<td>Review for effective date 06/07/17. Administrative change made to the Summary, Limitations, Definitions, Clinical Background Information, and</td>
<td>06/07/17</td>
<td>03/15/17: MPCTAC</td>
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Policy Revisions History

<table>
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<tr>
<td>03/01/18</td>
<td>Review for effective date 04/01/18. Administrative changes made to the Medical Policy Statement, Limitations, and Applicable Coding sections. Updated the Policy Summary, Clinical Background Information, References, and Other Applicable Policies sections.</td>
<td>04/01/18 Version 17</td>
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<td>03/01/19</td>
<td>Review for effective date 06/01/19. Criteria revised in the Medical Policy Statement and Limitations sections. Administrative changes made to the Description of Item or Service, References, Other Applicable Policies, and Reference to Applicable Laws and Regulations sections.</td>
<td>06/01/19 Version 18</td>
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Last Review Date

03/01/19

Next Review Date

03/01/20

Authorizing Entity

MPCTAC

Other Applicable Policies

Administrative Policy - Clinical Review Criteria, policy number OCA 3.201
Administrative Policy - Clinical Technology Evaluation, policy number OCA 3.13
Administrative Policy - Transplantation Administration, policy number OCA 3.10
Medical Policy - Experimental and Investigational Treatment, policy number OCA 3.12
Medical Policy - Medically Necessary, policy number OCA 3.14
Medical Policy - Transplantation of Lung or Lobar Lung, policy number OCA 3.24
Medical Policy - Transplantation of Pancreas or Pancreas-Kidney, policy number OCA 3.25
Reimbursement Policy - Anesthesia, policy number 4.103
Reimbursement Policy - Anesthesia, policy number SCO 4.103

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Reimbursement Policy - Anesthesia, policy number WS 4.11
Reimbursement Policy - Bilateral and Multiple Procedure Reductions, policy number 4.607
Reimbursement Policy - Bilateral and Multiple Procedure Reductions, policy number SCO 4.607
Reimbursement Policy - Diabetes Self-Management Training (DSMT)/Medical Nutrition Therapy (MNT), policy number 4.32
Reimbursement Policy - Diabetes Self-Management Training (DSMT)/Medical Nutrition Therapy (MNT), policy number WS 4.32
Reimbursement Policy - General Billing and Coding Guidelines, policy number 4.31
Reimbursement Policy - General Billing and Coding Guidelines, policy number SCO 4.31
Reimbursement Policy - General Billing and Coding Guidelines, policy number WS 4.17
Reimbursement Policy - General Clinical Editing and Payment Accuracy Review Guidelines, policy number 4.108
Reimbursement Policy - General Clinical Editing and Payment Accuracy Review Guidelines, policy number WS 4.18
Reimbursement Policy - Hospital, policy number WS 4.21
Reimbursement Policy - Inpatient Hospital, policy number 4.110
Reimbursement Policy - Inpatient Hospital, policy number SCO 4.110
Reimbursement Policy - Non-Participating Provider, policy number WS 4.5
Reimbursement Policy - Non-Reimbursed Codes, policy number 4.38
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Reimbursement Policy - Outpatient Hospital, policy number SCO 4.17
Reimbursement Policy - Outpatient Hospital, policy number WS 4.17
Reimbursement Policy - Physician and Non Physician Practitioner Services, policy number 4.608
Reimbursement Policy - Physician and Non Physician Practitioner Services, policy number SCO 4.608
Reimbursement Policy - Physician and Non Physician Practitioner Services, policy number WS 4.28
Reimbursement Policy - Professional Bilateral and Multiple Procedure Reductions, policy number WS 4.24
Reimbursement Policy - Provider Preventable Conditions and Serious Reportable Events, policy number 4.610
Reimbursement Policy - Provider Preventable Conditions and Serious Reportable Events, policy number SCO 4.610
Reimbursement Policy - Provider Preventable Conditions and Serious Reportable Events, policy number WS 4.29

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Reference to Applicable Laws and Regulations


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Disclaimer Information: +

Medical Policies are the Plan’s guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other Plan Policies, as well as the Member’s benefit document, and when appropriate, coordinates with the Member’s health care Providers to consider the individual Member’s health care needs.

Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan’s service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as the Member’s benefit document, take precedence over these guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.