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Medical Policy

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

Policy Number: OCA 3.26
Version Number: 21
Version Effective Date: 12/01/21

Product Applicability	☒ **All Plan+ Products**
WellSense Health Plan ☒ NH Medicaid ☒ NH Medicare Advantage	**Boston Medical Center HealthNet Plan** ☒ MassHealth ☒ Qualified Health Plans/ConnectorCare/Employer Choice Direct ☒ Senior Care Options

+ Note: Disclaimer and audit information is located at the end of this document.

Policy Summary

The Plan considers small bowel transplantation, small bowel-liver transplantation, or multivisceral transplantation for the treatment of irreversible intestinal failure for adults and children (including infants) to be medically necessary when applicable Plan medical criteria are met. 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 clinical appropriateness) and according to the guidelines specified in the Plan's *Transplant Administration* policy, policy number OCA 3.10.

Prior authorization is required for ALL transplantation services provided to a Plan member (even when a separate Plan authorization has already been obtained for an inpatient admission but the authorization does NOT include transplantation services), with final approval required by a Plan Medical Director. Prior authorization requests for transplantation services are evaluated with medical necessity criteria in the applicable Plan medical policy. If there is no Plan medical policy for the requested type of transplantation, the Plan uses InterQual® criteria to determine the medical

+ *Plan* refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name WellSense Health Plan.

necessity. 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. 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 transplant is performed must be a member of the Organ Procurement and Transplantation Network (OPTN) and comply with applicable OPTN organ allocation and procurement guidelines.

Clinical Criteria

The Plan considers small bowel transplantation or multivisceral transplantation to be medically necessary when ALL applicable criteria are met in items A through C:

A. **Initial Transplantation and Retransplantation Criteria for Adult and Pediatric Members** – Criteria are met either in item 1 or item 2:

1. **Initial Transplantation Criteria:**

   ALL of the following criteria are met in items a through d:

   a. Total irreversible intestinal failure with loss of absorption and inability to maintain protein-energy, fluid, electrolyte, or micronutrient balance; AND

   b. Transplantation is for any of the indications listed 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; OR

      (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; OR

      (3) Failure of TPN and ANY of the following criteria are met in items (a) through (d):

         (a) Sepsis with ANY of the following conditions listed 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 despite intravenous fluid supplementation in addition to TPN; OR

(c) Impending or overt liver failure due to TPN-induced liver injury with ANY of the clinical manifestations listed 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) Loss of vascular access including but not limited to thrombosis of TWO (2) or more of the major central veins and failure of TPN therapy; AND

c. All individual eligibility criteria of the transplanting institution are met and the member does NOT have a contraindication specified in the Limitations section; AND

d. The donor meets ONE (1) of the guidelines 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 member is a suitable candidate for a living donor transplant and ONE (1) of the criteria is met 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** - Member has met criteria for the initial transplant with ANY of the following indications documented in items a through c:

    a. Graft failure of an initial small bowel, small bowel-liver, or multivisceral transplant due to technical reason (excluding serious reportable event and/or provider-preventable condition) or hyperacute rejection; OR

    b. Chronic rejection; OR

    c. Recurrent disease; AND

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

2. **Small Bowel-Liver Transplantation** - ANY of the following criteria is met 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 criteria 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, colon) to be transplanted from ANY of the conditions listed 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. See the Plan's *Transplantation of Pancreas or Pancreas-Kidney* medical policy, policy number OCA 3.25; AND

C. **Age-Specific Criteria -** Criteria are met for EITHER item 1 or item 2:

1. **Age-Specific Criteria for Adult Members (Age 18 or Older on the Date of Service) -** Adult member is diagnosed with ANY of the following conditions listed in items a through e:

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

b. Intestinal vascular insufficiency, includes but NOT limited to 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 a condition 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 gunshot wound or motor vehicle accident; OR

e. Other conditions including ANY of the conditions in items (1) through (4):

(1) Massive resection secondary to tumor; OR

(2) Pseudo-obstruction; OR

(3) Radiation enteritis; OR

(4) Volvulus; OR

2. **Age-Specific Criteria for Pediatric Members (Under Age 18 on the Date of Service) -** Pediatric member is diagnosed with ANY of the conditions listed in items a through c:

   a. Congenital condition, including ANY of the conditions listed in items (1) through (4):

      (1) Atresia or stenosis; OR

      (2) Gastroschisis; OR

      (3) Dysmotility disorder, including ANY of the conditions listed 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 of the conditions listed in item (a) or (b):

         (a) Microvillus inclusion disease; OR

         (b) Tufting enteropathy; OR

   b. Perinatal complication, including ANY of the complications listed in item (1) or (2):

      (1) Necrotizing enterocolitis (NEC); OR

      (2) Volvulus; OR

   c. Other condition, including ANY of the conditions listed in items (1) through (4):

      (1) Short gut syndrome; OR

      (2) Status post intestinal transplant; OR

      (3) Trauma; OR

      (4) Chronic intestinal pseudo-obstruction.

Limitations and Exclusions

1. **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 TPN unless the intestinal transplant is considered medically necessary to treat a malignancy or for another indication.

2. **Genetic testing:** Plan prior authorization is required for genetic testing according to the guidelines in the Plan's *Genetic/Genomic Testing and Pharmacogenetics* medical policy, policy number OCA 3.727, including genetic testing to estimate the probability of active rejection with AlloMap, AlloSure, or myTAIHEART. Plan-adopted InterQual® criteria must be met.

3. **Small bowel, small bowel-liver or multivisceral xenotransplantation** (e.g., porcine xenografts) is considered experimental and investigational or NOT medically necessary due to limited evidence demonstrating the clinical utility or clinical validity of treatment for any indication.

4. **Contraindications** include but are not limited to ANY of the conditions in items a though o:

    a. Acute or chronic infection that is not adequately treated; OR

    b. Active substance abuse/alcohol use within the last 6 months UNLESS the member has decompensated alcohol-associated cirrhosis with a documented Child-Pugh score of class C or a Model of End-Stage Liver Disease score including serum Na (MELDNa score) of at least 21. Abstinence is an intervention likely to improve the likelihood of long-term success post-transplant, although adherence to the 6-month rule is NOT the sole predictor of alcohol use post-transplant. Submitted for following for Plan Medical Director Review:

        (1) Member's pre-transplant assessment includes documentation of the member's diagnosis, prognosis, MELD/MELDNa score or Child-Pugh score to classify the severity of liver disease, current and previous medical and mental health illnesses, results of prior treatment, and detailed history of substance/alcohol consumption; AND

        (2) Member assessment that includes predictors for post-transplant abstinence compliance from alcohol and drug use; AND

        (3) Documentation that the transplant facility does NOT require adherence to the 6–month abstinence rule and the member has an acceptable transplant prognosis; OR

    c. Active systemic illness/disease that is likely to negatively affect the outcome of the transplant and/or could be exacerbated by immunosuppression; 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 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, Kaposi's sarcoma, or 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; OR

h. Known, current malignancy 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, when the malignancy is NOT an indication for transplant; AND

j. Multisystem organ failure including cardiac, pulmonary, and/or neurologic (but since kidney transplant can be part of multivisceral transplant, renal failure is NOT contraindication); OR

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.

Variations

The Plan uses guidance from the Centers for Medicare & Medicaid Services (CMS) for medical necessity and coverage determinations for Senior Care Options (SCO) members and WellSense Medicare Advantage HMO members, including but not limited to national coverage determinations (NCDs), local coverage determinations (LCDs), local coverage articles (LCAs), and documentation included in Medicare manuals. At the time of the Plan's most recent policy review, CMS NCD 260.5 includes

nationally covered indications for intestinal and multivisceral transplants. Verify CMS guidelines in effect on the date of the prior authorization request. When there is no guidance from CMS for the requested service, Plan-adopted clinical review criteria will be used to determine the medical necessity of the service.

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 Stated 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). Since 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 Clinical Criteria section and Limitation and Exclusions 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 this Applicable Coding section. Review the Plan's reimbursement policies for Plan billing guidelines. Coverage for services is subject to benefit eligibility under the member's benefit plan in effect at the time of the service. Member benefit documents are available at the following websites: www.bmchp.org for BMC HealthNet Plan members, www.SeniorsGetMore.org for Senior Care Options members, www.wellsense.org for WellSense New Hampshire Medicaid members, and www.WellSense.org/Medicare for WellSense Medicare Advantage HMO members.

CPT Codes	**Description: Codes Covered When Medically Necessary**
44133	Donor enterectomy (including cold preservation), open; partial, from living donor
44135	Intestinal allotransplantation; from cadaver donor
44136	Intestinal allotransplantation; from living donor
HCPCS Codes	**Description: Codes Covered When Medically Necessary**
S2053	Transplantation of small intestine and liver allografts Plan Note: Code is NOT payable for the Senior Care Options and WellSense Medicare Advantage HMO products.

S2054	Transplantation of multivisceral organs Plan note: Code is NOT payable for the Senior Care Options and WellSense Medicare Advantage HMO products.

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Policy History

Original Approval Date	Original Effective Date* and Version Number	Policy Owner	Original Policy Approved by
Regulatory Approval: N/A Internal Approval: 08/02/05	10/02/05 Version 1	Medical Policy Manager as Chair of Medical Policy, Criteria, and Technology Assessment Committee (MPCTAC)	Quality and Clinical Management Committee (Q&CMC)

*Effective Date for the BMC HealthNet Plan Commercial Product: 01/01/12
*Effective Date of the WellSense New Hampshire Medicaid Product: 01/01/13
*Effective Date for Senior Care Options Product: 01/01/16
*Effective Date for the WellSense Medicare Advantage HMO Product: 01/01/22

Policy Revisions History			
Review Date	**Summary of Revisions**	**Revision Effective Date and Version Number**	**Approved by**
02/06/07	Updated template and references.	Version 2	02/06/07: Q&CMC
02/19/08	Revised clinical criteria.	Version 3	02/19/08: MPCTAC 02/26/08: Utilization Management Committee (UMC) 03/12/08: QIC
02/24/09	Updated clinical criteria for HIV, updated coding and references.	Version 4	02/24/09: MPCTAC 02/24/09: UMC 03/25/09: QIC
02/01/10	Updated references.	Version 5	02/22/10: MPCTAC 03/24/10: QIC
02/01/11	Updated adult and pediatric clinical indications, updated references.	Version 6	03/16/11: MPCTAC 04/27/11: QIC
03/13/12	Updated references, clarified two contraindications.	Version 7	03/21/12: MPCTAC 04/25/12: QIC
08/01/12	Off cycle review for Well Sense Health Plan, revised Summary statement, reformatted and revised Medical Policy Statement, revised Applicable Coding introductory paragraph, revised Limitations.	Version 8	08/13/12: MPCTAC 09/06/12: QIC
03/01/13	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 section, 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	07/01/13 Version 9	03/20/13: MPCTAC 04/18/13: QIC

Policy Revisions History			
	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 Reportable Event/Provider Preventable Condition* policy, and *Experimental and Investigational Treatment* policy.		
08/14/13 and 08/15/13	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.	Version 10	08/14/13: MPCTAC (electronic vote) 08/15/13: QIC
03/01/14	Review for effective date 07/0/1/14. Revised and reformatted criteria in the Medical Policy Statement section and Limitations section. Updated references.	07/01/14 Version 11	03/19/14: MPCTAC 04/16/14: QIC
12/01/14	Review for effective date 03/01/15. Removed CPT code 44132 from the list of codes requiring prior authorization.	03/01/15 Version 12	12/02/14: MPCTC (electronic vote) 12/10/14: QIC
03/01/15	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.	07/01/15 Version 13	03/18/15: MPCTAC 04/08/15: QIC
11/25/15	Review for effective date 01/01/16. Updated template with list of	01/01/16 Version 14	11/18/15: MPCTAC 11/25/15: MPCTAC

Policy Revisions History			
	applicable products and notes. Revised language in the Applicable Coding section.		(electronic vote) 12/09/15: QIC
03/01/16	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.	07/01/16 Version 15	03/16/16: MPCTAC 04/13/16: QIC
03/01/17	Review for effective date 06/07/17. Administrative change made to the Summary, Limitations, Definitions, Clinical Background Information, and References sections. Updated criteria in the Medical Policy Statement section. Plan note added to the Applicable Coding section.	06/07/17 Version 16	03/15/17: MPCTAC
03/01/18	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.	04/01/18 Version 17	03/21/18: MPCTAC
03/01/19	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.	06/01/19 Version 18	03/20/19: MPCTAC
03/01/20	Review for effective date 04/01/20. Administrative changes made to the Policy Summary, Limitations, Definitions, References, Other Applicable Policies, and Reference to Applicable Laws and Regulations sections.	04/01/20 Version 19	03/12/20: MPCTAC (electronic vote)
04/01/21	Review for effective date 07/01/21. Administrative changes made to the Policy Summary, Medical Policy Statement, and References sections.	07/01/21 Version 21	04/21/21: MPCTAC

Policy Revisions History			
	Criteria revised in the Limitations section.		
11/01/21	Review for effective date 12/01/21. Adopted new medical policy template; removed administrative sections, the Medical Policy Statement section renamed the Clinical Criteria section, and the Limitations section renamed the Limitations and Exclusions section. Added WellSense Medicare Advantage HMO as an applicable product effective 01/01/22. Administrative changes made to the Policy Summary, Clinical Criteria, Limitations and Exclusions, Applicable Coding, and References sections.	12/01/21 Version 22	11/17/21: MPCTAC

Next Review Date

03/01/22

Authorizing Entity

MPCTAC

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.