BOSTON MEDICAL CENTER HEALTHNet PLAN

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WELL SENSE HEALTH PLAN

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Administrative Policy

Transplant Administration

Policy Number: OCA 3.10
Version Number: 19
Version Effective Date: 12/01/21

Product Applicability	☒ **All Plan+ Products**
WellSense Health Plan	**Boston Medical Center HealthNet Plan**
☒ NH Medicaid	☒ MassHealth ACO
☒ NH Medicare Advantage	☒ MassHealth MCO
	☒ 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 transplantation services to be **medically necessary** when applicable Plan medical criteria are met and the member meets the eligibility criteria from the transplanting institution. 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 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.** 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 specifies applicable medical necessity criteria in the following transplantation medical policies: *Transplantation of Lung or Lobar Lung* medical policy, policy number OCA 3.24; *Transplantation of Pancreas or Pancreas-Kidney* medical policy, policy number OCA 3.25; and *Transplantation of Small Bowel, Small Bowel-Liver, or Multivisceral Organs* medical policy, policy number OCA 3.26.

+ *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.

The Plan-adopted written clinical review criteria are used to determine the medical necessity of services that require utilization review. In addition, clinical review criteria are used to determine the most clinically appropriate level of care and intensity of services to ensure the provision of medically necessary 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 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. When a member is deemed to be an appropriate candidate for transplant 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, indicates the product-specific definitions of medically necessary treatment, and the Plan's *Experimental and Investigational Treatment* medical policy, policy number OCA 3.12, specifies the product-specific definitions of experimental or investigational treatment.

Plan prior authorization is required for genetic testing according to the guidelines specified in the Plan's *Genetic/Genomic Testing and Pharmacogenetics* medical policy, policy number OCA 3.727, and are based on the type of genetic test requested, indication(s) for testing, and if the test is ordered, administered, and processed by participating providers and participating laboratories (or non-participating providers and non-participating laboratories); this includes all genetic testing associated with pre-and/or post-transplantation services. Genetic/genomic testing is considered medically necessary when the Plan's applicable medical policy criteria are met or Plan-adopted InterQual® criteria are met for the requested genetic test when criteria are not included in a Plan medical policy. Plan Medical Director Review is required for individual consideration when clinical review criteria are not established for the requested genetic test and/or specified indication(s) for testing.

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 and WellSense Medicare Advantage HMO 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. If a transplant is requested for a WellSense New Hampshire Medicaid 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).

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.

Policy Statement

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 administrative guidelines specified in this policy. Clinical review criteria are used to determine the most clinically appropriate level of care and intensity of services to ensure the provision of medically necessary services. **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. The Plan follows the procedure outlined below when evaluating requests for transplantation services and managing care related to transplantation services, as specified in items 1 through 5:

1. The Plan receives a request for **evaluation** of a member for transplantation services from the member's primary care provider, the physician treating the condition potentially necessitating a transplant, or the transplant specialist. An **evaluation** for transplantation services 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. Requests for evaluation will be processed according to Plan guidelines specified below in item a or item b:

    a. Requests for evaluation of a member for transplant services received from **participating providers** may be approved without Medical Director review (but Plan Medical Director review may be required for some requests for evaluation of transplant services from participating providers); OR

b. Requests for evaluation of a member for transplant services received from **non-participating providers** require Medical Director approval; AND

2. If a member is deemed an appropriate candidate for transplantation services, requests for approval of the transplant are evaluated with clinical review criteria utilizing the applicable Plan medical policy or, in the absence of such, InterQual® criteria, with **final approval by a Plan Medical Director**; AND

3. If the transplant is approved by a Plan Medical Director, the Office of Clinical Affairs (OCA) Prior Authorization staff completes the following tasks, as specified below in items a through d:

   a. Determines if a request to upgrade to rate category 2 (RC2) status is appropriate (for MassHealth members only) and, if so, submits the request through designated Plan channels; AND

   b. Notifies OCA Inpatient Utilization Management (UM) Department so Plan staff in that department will monitor for an admission; AND

   c. Notifies OCA Complex Care Management Department so Plan staff in that department will evaluate ongoing care management needs; AND

   d. Notifies the Plan's financial departments, as applicable, including but not limited to Claims, Finance, and Contracting; AND

4. Upon admission for a transplant, the Inpatient UM staff notifies the following departments, as specified below in items a through c:

   a. Complex Care Management Department; AND

   b. Finance Department; AND

   c. Claims Department; AND

5. Post-transplant, Inpatient UM staff coordinates the member's hospital discharge with the facility's transplant coordinator and the Plan's primary Complex Care Manager. If the member agrees to participate in and utilize the Plan's care management services, the Complex Care Manager continues to follow the member through discharge and post-transplant care for a minimum of one (1) year or as appropriate.

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 has released numerous guidelines for transplantation services. Verify CMS guidelines in effect on the date of the prior authorization request that are appropriate for the service and indication for treatment. 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.

Definitions:

Clinical Review Criteria (for BMC HealthNet Plan Products): Criteria used to determine the most clinically appropriate and necessary level of care and intensity of services to ensure the provision of medically necessary services. Review the Plan's *Medically Necessary* medical policy, policy number OCA 3.14, for the product-specific definition of medically necessary treatment. For the MassHealth ACO product, medical necessity guidelines established by the Plan will be no more restrictive than the applicable contractual MassHealth ACO and MCO definition of Medically Necessary or Medical Necessity, as specified in the Plan's *Medically Necessary* medical policy, policy number OCA 3.14. Additionally, if there is a change in the Plan's medical necessity review process, the Plan will notify the Executive Office of Health and Human Services (EOHHS) no less than 60 calendar days prior to any change (or another timeframe as specified by EOHHS). The Plan's *Clinical Review Criteria* administrative policy, policy number OCA 3.201, includes product-specific definitions of clinical review criteria, a summary of the Plan's procedure for applying clinical review criteria to services that require prior authorization, and specifies which entities are responsible for the development, implementation, and monitoring of the Plan's clinical review criteria.

Clinical Review Criteria (for WellSense New Hampshire Medicaid Product): A set of medical decision standards employed in the utilization review process in order to ensure members receive appropriate care, at an appropriate time, in an appropriate setting by an appropriate provider and at an appropriate level of care. Criteria are consistent with an efficient and effective utilization of resources available to recipients. The Plan's *Clinical Review Criteria* administrative policy, policy number OCA 3.201, includes product-specific definitions of clinical review criteria, a summary of the Plan's procedure for applying clinical review criteria to services that require prior authorization, and specifies which entities are responsible for the development, implementation, and monitoring of the Plan's clinical review criteria.

Office of Clinical Affairs Staff (OCA): Plan staff members within the OCA that include but are not limited to OCA UM staff, Plan licensed pharmacists, Plan Medical Directors, Physician Reviewers, and the Chief Medical Officer. The Directors of OCA, including the Director of Utilization Management and the Director of Pharmacy, or their designees are responsible for ensuring OCA UM staff training, evaluating, and monitoring. The Plan's OCA UM staff, Plan licensed pharmacists, and Plan Medical Directors/Physician Reviewers consistently use applicable Plan clinical review criteria when determining the medical necessity of health care services. The Chief Medical Officer or designee is responsible for ensuring Medical Director/Physician Reviewer training, evaluation, and monitoring to ensure consistent application of clinical review criteria and medical necessity determinations.

Office of Clinical Affairs Utilization Management Staff: The Plan's Office of Clinical Affairs (OCA) Utilization Management (UM) staff includes both the Pharmacy UM staff and UM staff. Reporting to the Director of Pharmacy, the Pharmacy UM staff reviews requests for pharmacotherapy or directs requests to a partner clinical vendor for delegated utilization management. Reporting to the Director of Utilization Management, appropriately qualified UM staff reviews medical, surgical, behavioral health, and/or dental requests for service or directs requests to a partner clinical vendor for delegated utilization management.

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U.S. Food and Drug Administration. Vaccines, Blood & Biologics. Xenotransplantation. 2018 Feb 5.

Policy History

Original Approval Date	Original Effective Date* and Version Number	Policy Owner	Original Policy Approved by
Regulatory Approval: N/A Internal Approval: 09/01/04	09/01/04 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 for 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**
08/02/05	Updated Definitions and Procedure	Version 2	08/02/05: Q&CMC

Policy Revisions History			
	sections.		
03/13/07	Updated Policy Statement and Procedure sections.	Version 3	03/13/07: Utilization Management Committee (UMC) 04/04/07: QIC
04/22/08	No changes.	Version 4	04/22/08: UMC 06/19/08: QIC
07/01/10	Updated clinician titles and Procedure section.	Version 5	07/09/10: UMC 07/28/10: QIC
10/26/11	Updated policy to reflect the application to the commercial product.	Version 6	10/17/11: UMC 10/26/11: QIC
08/01/12	Updated Policy Statement and Procedure sections. Updated policy to reflect the application to the WellSense New Hampshire Medicaid product.	Version 7	08/09/12: UMC
08/20/12	Off cycle review, updated Procedure section.	Version 8	08/30/12: MPCTAC 09/06/12: QIC
05/01/13	Review for effective date 06/20/13. Updated Summary section and referenced applicable Plan policies. Deleted the Responsibilities and Accountability section since it is not included in other medical and administrative policies reviewed by MPCTAC and approved by QIC. Renamed "Procedure" section the "Policy Statement" section and revised text. Deleted references to Centers of Excellence.	06/20/13 Version 9	05/15/13: MPCTAC 06/20/13: QIC
04/01/14	Review for effective date 08/01/14. Revised Summary section. Revised Policy Statement section, including adding a definition for "evaluation for transplantation services."	08/01/14 Version 10	04/16/14: MPCTAC 05/14/14: QIC
03/01/15	Review for effective date 04/08/15. Removed Commonwealth Care, Commonwealth Choice, and Employer Choice from the list of applicable products because the products are no longer available. Updated Summary section. Clarified language in the Medical Policy Statement section without changing criteria.	04/08/15 Version 11	03/18/15: MPCTAC 04/08/15: QIC
11/01/15	Review for effective date 01/01/16.	01/01/16	11/18/15: MPCTAC

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Policy Revisions History			
	Updated template with list of applicable products and notes.	Version 12	12/09/15: QIC
03/01/16	Review for effective date 04/13/16. Updated Summary, Clinical Background Information, References, and Reference to Applicable Laws and Regulations sections. Administrative changes made to the Policy Statement section.	04/13/16 Version 13	03/16/16: MPCTAC 04/13/16: QIC
03/01/17	Review for effective date 03/15/17. Updated Summary and References sections.	03/15/17 Version 14	03/15/17: MPCTAC
03/01/18	Review for effective date 04/01/18. Updated Policy Summary, References, and Other Applicable Policies sections. Administrative changes made to the Policy Statement section.	04/01/18 Version 15	03/21/18: MPCTAC
03/01/19	Review for effective date 04/01/19. Administrative changes made to the Policy Summary, Policy Statement, Definitions, References, Other Applicable Policies, and Reference to Applicable Laws and Regulations sections.	04/01/19 Version 16	03/20/19: MPCTAC
03/01/20	Review for effective date 04/01/20. Administrative changes made to the Policy Summary, Policy Statement, References, and Reference to Applicable Laws and Regulations sections.	04/01/20 Version 17	03/12/20: MPCTAC (electronic vote)
03/01/21	Review for effective date 04/01/21. Administrative changes made to the Policy Statement and References sections.	04/01/21 Version 18	03/17/21: MPCTAC
11/01/21	Review for effective date 12/01/21. Added WellSense Medicare Advantage HMO as an applicable product effective 01/01/22. Removed the Clinical Background Information, Other Applicable Policies, and Reference to Applicable Laws and Regulations sections. Administrative changes made to the Policy Summary section. Added the Variations section.	12/01/21 Version 19	11/17/21: MPCTAC

Next Review Date

03/01/22

Authorizing Entity

MPCTAC

Reference to Applicable Laws and Regulations

42 CFR 405, 482, 488, and 498. Code of Federal Regulations. Centers for Medicare & Medicaid Services (CMS). Medicare Program. Hospital Conditions of Participation: Requirements for Approval and Re-Approval of Transplant Centers to Perform Organ Transplants. Final Rule. 2007 Mar 30.

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He-W 531. New Hampshire Code of Administrative Rules. Medical Assistance. Physician Services.

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RSA Chapter 420-E. New Hampshire Revised Statutes. Insurance. Licensure of Medical Utilization Review Entitles.

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.

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