Medical Policy

Experimental and Investigational Treatment

**Policy Number:** OCA 3.12  
**Version Number:** 18  
**Version Effective Date:** 07/01/20

<table>
<thead>
<tr>
<th>Product Applicability</th>
<th>All Plan Products</th>
</tr>
</thead>
<tbody>
<tr>
<td>Well Sense Health Plan</td>
<td>MassHealth ACO</td>
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<tr>
<td>Boston Medical Center HealthNet Plan</td>
<td>MassHealth MCO</td>
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<tr>
<td></td>
<td>Qualified Health Plans/ConnectorCare/Employer Choice Direct</td>
</tr>
<tr>
<td></td>
<td>Senior Care Options ◊</td>
</tr>
</tbody>
</table>

**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**

Experimental and investigational treatment, as described in this policy, is not covered by the Plan. The Plan complies with coverage guidelines for all applicable state-mandated benefits and federally-mandated benefits that are medically necessary for the member’s condition. All Plan policies are developed in accordance with state, federal and accrediting organization guidelines and requirements including National Committee for Quality Assurance (NCQA).
The Plan’s Prior Authorization/Notification Requirements Matrix includes a list of services that require prior authorization or Plan notification. Review the Plan’s Prior Authorization CPT Code Look-up Tool and Prior Authorization HCPCS Code Look-up Tool for the prior authorization requirement for each of the service’s applicable, industry-standard billing code(s). The Plan’s prior authorization matrix, code look-up tools, medical policies, reimbursement policies, and the member’s applicable benefit documents are available at www.bmchp.org for BMC HealthNet Plan members (with benefit documents for Senior Care Options members available at www.SeniorsGetMore.org) and posted at www.wellsense.org for Well Sense Health Plan members.

It will be determined during the Plan’s prior authorization process if a service is considered experimental and investigational for the requested indication. The Plan’s Medically Necessary medical policy, policy number OCA 3.14, specifies the product-specific definitions of medically necessary treatment. See the product-specific definitions of cosmetic services and reconstructive surgery and procedures in the Plan’s Cosmetic, Reconstructive, and Restorative Services medical policy, policy number OCA 3.69. 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. The Plan’s Clinical Technology Evaluation administrative policy, policy number OCA 3.13, includes definitions for evidence-based medicine and medical technology assessment, and the policy outlines the process for evaluating new technology and the new application of existing technology. Review the Plan’s applicable Clinical Trials reimbursement policy if the requested service is related to a clinical trial: reimbursement policy number 4.134 for BMC HealthNet Plan members, reimbursement policy number SCO 4.134 for Senior Care Options members, or reimbursement policy number WS 4.12 for Well Sense Health Plan members.

**Description of Item or Service**

Not applicable.

**Medical Policy Statement**

See Definitions section of this policy for applicable criteria by Plan product.

**Limitations**

Experimental and investigational treatment, as described in this policy, is NOT covered for Plan members.
Definitions

1. **Qualified Health Plans, ConnectorCare, and Employer Choice Direct Definitions:**

   The fact that a treatment is offered as a last resort does not mean that it is not an experimental or investigational treatment.

   a. **Experimental or Investigational/Experimental or Investigational Treatment:**

      A treatment, service, procedure, supply, device, biological product, or drug (collectively “treatment”) is considered to be experimental or investigational for use in the diagnosis or treatment of a medical condition if ANY of the following is true, as specified below in items (1) through (5):

      (1) In the case of a drug, device, or biological product, it cannot be marketed lawfully without the approval of the U.S. Food and Drug Administration (FDA) and final approval has not been given by the FDA; OR

      (2) The treatment is described as experimental (or investigational, unproven, or under study) in the written informed consent document provided, or to be provided, to the member by the health care professional or facility providing the treatment; OR

      (3) Authoritative evidence (as defined below in this product-specific section) does not permit conclusions concerning the effect of the treatment on health outcomes; OR

      (4) There is insufficient authoritative evidence that the treatment improves the net health outcome. (Net health outcome means that the treatment’s beneficial effects on health outcomes outweigh any harmful effects of the treatment on health outcomes. See definition of Authoritative Evidence specified below.) There is insufficient authoritative evidence that the treatment is as beneficial as any established alternative. This means that the treatment does not improve net outcome as much as or more than established alternatives; OR

      (5) There is insufficient authoritative evidence that the treatment’s improvement in health outcomes is attainable outside the investigational setting. (See the definition of Authoritative Evidence specified below.)

   b. **Authoritative Evidence:**

      Authoritative evidence, as used in this product-specific definition of experimental or investigational treatment, shall mean only the following:

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*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 Well Sense Health Plan.*
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1. Reports and articles, of well-designed and well-conducted studies, published in authoritative English-language medical and scientific publications. The publications must be subject to peer review by qualified medical or scientific experts prior to publication. In evaluating this evidence, the Plan takes into consideration both the quality of the published studies and the consistency of results;

2. Opinions and evaluations by national medical associations, other reputable technology assessment bodies, and health care professionals with recognized clinical expertise in treating the medical condition or providing the treatment. In evaluating this evidence, the Plan takes into consideration the scientific quality of the evidence upon which the opinions and evaluations are based.

c. Net Health Outcome:

Net health outcome means that the treatment’s beneficial effects on health outcomes outweigh any harmful effects of the treatment on health outcomes.

2. **MassHealth ACO and MassHealth MCO Contract Definition:**

Experimental Treatment: Services for which there is insufficient authoritative evidence that the service is reasonably calculated to prevent, diagnose, prevent the worsening of, alleviate, correct, or cure conditions in the enrollee that endanger life, cause suffering or pain, cause physical deformity or malfunction, threaten to cause or aggravate a disability or result in illness or infirmity.

3. **Definitions for Well Sense Health Plan Products:**

The fact that a treatment is offered as a last resort does not mean that it is not an experimental or investigational treatment. If a treatment is experimental or investigational, Well Sense Health Plan will not cover (or pay for) that treatment or any related services or drugs that are provided to the member for the purpose of furnishing the experimental or investigational treatment (except as specified in the Plan’s *Clinical Trials* medical policy, policy number OCA 3.192.

a. **Experimental or Investigational:**

The Plan considers a procedure, service, test, supply, device, biological product, or drug (collectively “treatment”) to be experimental or investigational for use in the diagnosis or treatment of a medical condition if ANY of the following is true, as specified below in items (1) through (7):

(1) The treatment is described as experimental or investigational in the member’s benefit documents; OR
(2) The treatment is described as experimental or investigational in any current Centers for Medicare and Medicaid Services National or Local Coverage Determination; OR

(3) In the case of a drug, device, or biological product, it cannot be marketed lawfully without the approval of the U.S. Food and Drug Administration (FDA) and final approval has not been given by the FDA; OR

(4) The treatment is described as experimental (or investigational, unproven, or under study) in the written informed consent document provided, or to be provided, to the member by the health care professional or facility providing the treatment; OR

(5) Authoritative evidence (as defined in this product-specific section) does not permit conclusions concerning the effect of the treatment on health outcomes; OR

(6) There is insufficient authoritative evidence that the treatment improves the net health outcome (as defined in this product-specific section). There is insufficient authoritative evidence that the treatment is as beneficial as any established alternative. This means that the treatment does not improve net outcome as much as or more than established alternatives; OR

(7) There is insufficient authoritative evidence that the treatment’s improvement in health outcomes is attainable outside the investigational setting.

b. Authoritative Evidence:

Authoritative evidence, as used in this product-specific definition of experimental or investigational treatment, shall mean only the following:

(1) Reports and articles, of well-designed and well-conducted studies, published in authoritative English-language medical and scientific publications. The publications must be subject to peer review by qualified medical or scientific experts prior to publication. In evaluating this evidence, the Plan takes into consideration both the quality of the published studies and the consistency of results.

(2) Opinions and evaluations by national medical associations, other reputable technology assessment bodies, and health care professionals with recognized clinical expertise in treating the medical condition or providing the treatment. In evaluating this evidence, the Plan takes into consideration the scientific quality of the evidence upon which the opinions and evaluations are based.
c. **Net Health Outcome:**

Net health outcome means that the treatment’s beneficial effects on health outcomes outweigh any harmful effects of the treatment on health outcomes.

**References**


Contract between the Commonwealth Health Insurance Connector Authority and Plan.

Contract between the Massachusetts Executive Office of Health and Human Services (EOHHS) and Plan.

Contract between the Executive Office of Health and Human Services (EOHHS) and the Plan to Serve as an Accountable Care Partnership Plan for the Accountable Care Organization (ACO) Program.

Contract between the New Hampshire Department of Health and Human Services and Plan.


Senior Care Options Contract between the Massachusetts Executive Office of Health and Human Services (EOHHS) and Plan and Medicare Advantage Special Needs Plan Contract between the Centers for Medicare & Medicaid Services (CMS) and the Plan.

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: 08/01/08</td>
<td>12/06/05 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: 12/06/05</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 Product(s): 01/01/13
*Effective Date for the Senior Care Options Product(s): 01/01/16

Experimental and Investigational Treatment

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<table>
<thead>
<tr>
<th>Review Date</th>
<th>Summary of Revisions</th>
<th>Revision Effective Date and Version Number</th>
<th>Approved by</th>
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<tbody>
<tr>
<td>02/21/07</td>
<td>Updated policy and procedure sections, added Commonwealth Care language and references.</td>
<td>Version 2</td>
<td>02/21/07: Utilization Management Committee (UMC)</td>
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<td>03/06/07: Q&amp;CMC</td>
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<tr>
<td>05/20/08</td>
<td>Changed procedure and responsibility section to indicate that the Plan’s licensed pharmacists can determine if service requests are considered experimental treatment.</td>
<td>Version 3</td>
<td>05/20/08: UMC</td>
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<tr>
<td>06/19/08</td>
<td>Changed title and all references consistently to “Investigational and Experimental”. Changed statement from “For Commonwealth Care Members, the Plan does not cover patient care services provided pursuit to a qualified clinical trial” to “For Commonwealth Care Members, the Plan may cover patient care services provided pursuit to a qualified clinical trial” to allow the Plan to approve member appeals for these services.</td>
<td>Version 4</td>
<td>06/19/08: Quality Improvement Committee (QIC)</td>
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<tr>
<td>08/25/09</td>
<td>Removed the information about clinical trials in the Policy Statement section and updated references.</td>
<td>Version 5</td>
<td>09/22/09: MPCTAC</td>
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<td>09/23/09: QIC</td>
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<tr>
<td>07/01/10</td>
<td>Formatted into criteria template and updated references.</td>
<td>Version 6</td>
<td>07/21/10: MPCTAC</td>
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<td>08/25/10: QIC</td>
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<tr>
<td>07/01/11</td>
<td>Added Commercial Plan language and definition for experimental and investigational treatment and updated references.</td>
<td>Version 7</td>
<td>07/22/11: MPCTAC</td>
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<td>08/24/11: QIC</td>
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<tr>
<td>08/01/12</td>
<td>Updated references. Revised the following sections: Summary, Description of Item of Service, Medical Policy Statement, and Definitions.</td>
<td>Version 8</td>
<td>07/18/12: MPCTAC</td>
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<td>08/22/12: QIC</td>
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<td>08/30/12: MPCTAC</td>
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<td>09/06/12: QIC</td>
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<td>08/01/13 Version 9</td>
<td>06/19/13: MPCTAC</td>
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<td>07/18/13: QIC</td>
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<td>06/01/14</td>
<td>Review for effective date 08/01/14. Revised Summary and Definitions section. Replaced reference to Commercial product with Qualified</td>
<td>08/01/14 Version 10</td>
<td>06/18/14: MPCTAC</td>
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<td>07/09/14: QIC</td>
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<thead>
<tr>
<th>Date</th>
<th>Revision Details</th>
<th>Version Date</th>
<th>Reviewer</th>
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<tbody>
<tr>
<td>08/01/15</td>
<td>Review for effective date 08/01/15. Removed Commonwealth Care, Commonwealth Choice, and Employer Choice from the list of applicable products because the products are no longer available. Administrative changes made to the Definitions and References sections.</td>
<td>08/01/15</td>
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<td>07/08/15</td>
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<tr>
<td>11/01/15</td>
<td>Review for effective date 01/01/16. Updated template with list of applicable products and notes. Updated Summary and References sections.</td>
<td>01/01/16</td>
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<tr>
<td>08/31/17</td>
<td>Updated the Product Applicability, Definitions, and References sections to incorporate the Accountable Care Organization (ACO).</td>
<td>08/31/17</td>
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<td>08/31/17</td>
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<td>(electronic vote)</td>
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<td>02/01/18</td>
<td>Review for effective date 03/01/18. Administrative changes made to the Policy Summary and Definitions sections.</td>
<td>03/01/18</td>
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<td>06/01/18</td>
<td>Review for effective date 07/01/18. Administrative changes made to the Policy Summary, References, Other Applicable Policies, and Reference to Applicable Laws and Regulations sections.</td>
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### Policy Revisions History

| Laws and Regulations sections. |

**Last Review Date**

06/01/20

**Next Review Date**

06/01/21

**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
- Medical Policy - *Clinical Trials*, policy number OCA 3.192
- Medical Policy - *Cosmetic, Reconstructive, and Restorative Services*, policy number OCA 3.69
- Medical Policy - *Medically Necessary*, policy number OCA 3.14
- 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 SCO 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
- Reimbursement Policy - *Non-Reimbursed Codes*, policy number WS 4.38
- Reimbursement Policy - *Outpatient Hospital*, policy number 4.17
- Reimbursement Policy - *Outpatient Hospital*, policy number SCO 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 - *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

**Reference to Applicable Laws and Regulations**


130 CMR 410.00. Code of Massachusetts Regulations. Division of Medical Assistance. Outpatient Hospital Services.

130 CMR 415.000. Code of Massachusetts Regulations. Division of Medical Assistance. Acute Inpatient Hospital Services.


130 CMR 450.000. Code of Massachusetts Regulations. Division of Medical Assistance. Administrative and Billing Regulations.


211 CMR 52.00. Code of Massachusetts Regulations. Division of Insurance. Managed Care Consumer Protections and Accreditation of Carriers.

211 CMR 52.03. Code of Massachusetts Regulations. Definitions. Medical Necessity or Medically Necessary.


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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

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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.