BOSTON MEDICAL CENTER HEALTHNet PLAN

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WELL SENSE HEALTH PLAN

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Medical Policy

Preimplantation Genetic Testing

Policy Number: OCA 3.726
Version Number: 15
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 ACO ☐ 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 **preimplantation genetic testing (PGT)** to be **medically necessary** when applicable Plan criteria are met, as specified in the Medical Policy Statement and Limitations sections of this policy. PGT is a group of genetic assays used to analyze the DNA from oocytes or embryos to identify genetic abnormalities (translocations) soon after fertilization following in vitro fertilization (IVF) and prior to implantation. The Plan considers preimplantation genetic testing for aneuploidy (PGT-A), formerly called preimplantation genetic screening to NOT be medically necessary. Prior authorization is required.

It will be determined during the Plan's prior authorization process if the service is considered medically necessary for the requested indication. The Plan's *Medically Necessary* medical policy, policy number OCA 3.14, includes the product-specific definitions of medically necessary treatment. 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. Review the following Plan medical policies available at www.bmchp.org for clinical review criteria, applicable definitions, and prior

authorization requirements for BMC HealthNet Plan members and at www.wellsense.org for WellSense Medicare Advantage HMO members *Experimental and Investigational Treatment* medical policy, policy number OCA 3.12; *Infertility Services* medical policy, policy number OCA 3.725; and *Genetic/Genomic Testing and Pharmacogenetics* medical policy, policy number OCA 3.726.

There are three (3) types of PGT: PGT for monogenic/single gene defects (PGT-M), PGT for chromosomal structural rearrangements (PGT-SR), and PGT for aneuploidies (PGT-A).

1. **Preimplantation Genetic Testing for Monogenic (Single-Gene) Disorders (PGT-M)**: PGT-M is targeted to single gene disorders and is used to establish a pregnancy unaffected by specific genetic characteristics, such as a known heritable genetic mutation carried by one or both biological parents. PGT-M is also used to select embryos for transfer with specific characteristics, such as gender or compatible human leukocyte antigen complex type. PGT-M uses only a few cells from the early embryo, usually at the blastocyst stage. The Plan considers PGT-M **medically necessary** when medical necessity criteria are met.

2. **Preimplantation Genetic Testing for Structural Rearrangements (PGT-SR)**: PGT-SR is used to establish a pregnancy unaffected by a structural chromosomal abnormality in a couple with a balanced translocation, deletions, or additions/duplications. The Plan considers PGT-SR **medically necessary** when Plan criteria are met.

3. **Preimplantation Genetic Testing for Aneuploidy (PGT-A)**: Formerly known as preimplantation genetic screening (PGS), PGT-A is a broader test that screens for aneuploidy (structural and numerical aberrations of chromosomes) in all chromosomes, including the 22 pairs of autosomes and the sex chromosomes X and Y. PGT-A is used to identify embryos with de novo aneuploidy, including subchromosomal deletions and additions/duplications, in embryo(s) of couples presumed to be chromosomally normal. The Plan considers PGT-A **NOT medically necessary** due to limited evidences supporting the clinical utility of testing.

Clinical Criteria

The Plan considers PGT-M and/or PGT-SR, including in vitro fertilization (IVF) with or without intracytoplasmic sperm injection (ICSI), medically necessary when applicable Plan criteria are met in items 1 through 4:

1. **Member Criteria:**

   ALL of the following member criteria are met, as specified below in items a through e:

   a. Member meets the Plan's definition of infertility, general eligibility and evaluation requirements, and service-specific criteria for coverage of infertility services, as specified in Plan's *Infertility Services* medical policy, policy number OCA 3.725; AND

b. Member is undergoing IVF for the evaluation of embryos that have been identified at an increased risk of a genetic disorder, and infertility services, including IVF, are covered for the member; AND

c. The member has a > 5% chance of live birth per cycle of IVF with or without ICSI; AND

d. The results of PGT will impact clinical decision making and/or the clinical outcome; AND

e. The member has benefit coverage for PGT and infertility services; AND

2. **Medical Record Documentation Criteria:**

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

a. The member has received genetic counseling that includes a discussion of alternatives to the procedure such as prenatal diagnosis by ultrasound, chorionic villus sampling, or amniocentesis; AND

b. The member discussed with the provider other reproductive options, including gamete donation, remaining childless, accepting genetic risk without testing, and/or adoption; AND

c. The services are provided in a center where appropriate expertise (i.e., genetic counseling, molecular genetics, maternal-fetal medicine, embryology) is available; AND

3. **Test-Specific Criteria:**

PGT-M and/or PGT-SR are considered medically necessary when applicable Plan criteria are met (i.e., item a for PGT-M and item b for PGT-SR):

a. PGT-M is considered medically necessary when ANY of the criteria in items (1) through (5) are met:

(1) Both partners are known carriers of a single gene autosomal recessive disorder; OR

(2) One (1) partner is a known carrier of a single gene autosomal recessive disorder and the partners have one (1) offspring that has been diagnosed with that recessive disorder; OR

(3) One (1) partner is a known carrier of a single gene autosomal dominant disorder; OR

(4) One (1) partner is at risk (50%) of carrying a mutation of a single-gene dominant disorder (by virtue of having an affected biological parent or biological sibling) but does not wish to know his/her carrier status (which would be revealed if standard

prenatal diagnosis were performed and the fetus revealed to be affected); IVF/PGT allows for unaffected embryos to be selected and implanted without revealing to the parents whether or not any affected embryos were also detected; OR

(5) One (1) partner is a known carrier of a single X-linked disorder; AND/OR

b. PGT-SR is considered medically necessary to evaluate an embryo with an elevated risk of being affected by a genetic disorder involving the rearrangement or size of a chromosome; e.g., one parent with a known balanced (reciprocal or non-Robertsonian) chromosomal translocation or an unbalanced (Robertsonian) chromosomal translocation; AND

4. **Testing Frequency Criteria**:

ONE (1) of the criteria must be met in item a or item b:

a. The Plan considers **up to two (2) PGT procedures** medically necessary in conjunction with IVF with or without ICSI for members who meet the above criteria (with each PGT procedure including PGT-M, PGT-SR, and/or PGT-M in combination with PGT-SR); OR

b. Beyond testing frequency specified above in item 4a, the member is eligible for **up to two (2) additional PGT procedures** with IVF with or without ICSI (with each PGT procedure including PGT-M, PGT-SR, and/or PGT-M in combination with PGT-SR) when ALL of the following criteria are met in items (1) through (3):

(1) The member had previously undergone two (2) cycles of PGT with IVF with or without ICSI (with each PGT procedure including PGT-M, PGT-SR, and/or PGT-M in combination with PGT-SR); AND

(2) The member continues to meet the applicable PGT criteria specified above in this Medical Policy Statement section for PGT-M, PGT-SR, and/or PGT-M in combination with PGT-SR; AND

(3) There has been an intervening birth.

Limitations and Exclusions

1. The Plan considers preimplantation genetic testing for aneuploidy (PGT-A), formerly called preimplantation genetic screening, to NOT be medically necessary, including but NOT limited to SMART PGT-A (Pre-implantation Genetic Testing - Aneuploidy) by Igenomix®.

2. The Plan considers preimplantation genetic testing (PGT) for non-medical gender selection and/or testing for non-medical traits to NOT be medically necessary, this includes PGT for

monogenic gene diseases (PGT-M), PGT for a chromosomal rearrangements or abnormalities in the size of chromosomes (PGT-SR), and PGT for aneuploidy (PGT-A).

3. The Plan considers ANY the following services or indications for PGT listed in items a though j to NOT be medically necessary due to limited evidence demonstrating the clinical utility of testing (including PGT-M, PGT-SR, and PGT-A unless stated otherwise):

   a. Carrier testing to determine the embryo's carrier status; OR

   b. Human leukocyte antigen (HLA) typing of an embryo to identify a future suitable stem cell, tissue, or organ transplantation donor when applicable medical necessity criteria for PGT in are NOT met; OR

   c. Preimplantation genetic testing for aneuploidy (PGT-A), formerly known as preimplantation genetic screening (PGS), used to screen embryos for chromosomal abnormalities in the absence of specific inherited genetic conditions identified in either biological parent; OR

   d. Screening for autosomal recessive disorders when the embryos are created using donor egg or donor sperm, except in cases when one of the parents is a carrier of a recessive condition, and the donor's status is unknown; OR

   e. Detecting genetic or chromosomal abnormalities contributed by donor egg or donor sperm; OR

   f. Screening for adult-onset/late-onset disorders or predisposition to disease (e.g., Alzheimer's disease, cancer predisposition) unless Plan criteria are met; OR

   g. An individual or couple who are using illicit substances or abusing substances known to negatively interfere with fertility or fetal development (e.g., marijuana, opiates, cocaine, or alcohol); OR

   h. Preimplantation genetic testing for aneuploidy (PGT-A), formerly known as preimplantation genetic screening (PGS) for purposes of optimizing IVF outcomes in a female member/member with female reproductive organs with advanced maternal age, history of failed IVF cycles, and/or recurrent miscarriages, in the absence of inherited genetic abnormalities; OR

   i. PGT for chromosomal microarray or whole-genome sequencing; OR

   j. PGT for multifactorial inheritance disorders and/or variants of unknown significance.

Variations

The Plan uses guidance from the Centers for Medicare & Medicaid Services (CMS) for medical necessity and coverage determinations for 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, no applicable clinical guidelines were found from CMS. Verify CMS criteria in effect for the requested service on the date of the prior authorization request for a WellSense Medicare Advantage HMO member. When there is no guidance from CMS for the requested service for the specified indication on the date of the prior authorization request, 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 Limitations 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 www.bmchp.org for BMC HealthNet Plan members and posted at www.WellSense.org/Medicare for WellSense Medicare Advantage HMO members.

CPT Codes	Description: Codes Covered When Medically Necessary
89290	Biopsy, oocyte polar body or embryo blastomere, microtechnique (for preimplantation genetic diagnosis); less than or equal to 5 embryos
89291	Biopsy, oocyte polar body or embryo blastomere, microtechnique (for preimplantation genetic diagnosis); greater than 5 embryos

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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: 07/11/11: Medical Policy, Criteria, and Technology Assessment Committee (MPCTAC) 07/27/11: Quality Improvement Committee (QIC)	01/01/12 Version 1	Medical Policy Manager as Chair of MPCTAC	MPCTAC and QIC

*Effective Date for the BMC HealthNet Plan Commercial Product: 01/01/12

*Effective Date for the WellSense Medicare Advantage HMO Product: 01/01/22

Note: Policy title was *Preimplantation Genetic Testing (Preimplantation Genetic Diagnosis and Preimplantation Genetic Screening* until 06/30/19. Policy title changed to *Preimplantation Genetic Testing* as of 07/01/19.

Policy Revisions History			
Review Date	**Summary of Revisions**	**Revision Effective Date and Version Number**	**Approved by**
06/01/12	Review for effective date 08/01/12. Referenced Plan policy, *Genetic Testing Guidelines*, policy number (OCA: 3.726). Revised the introductory paragraph in Applicable Coding section and updated references.	08/01/12 Version 2	06/20/12: MPCTAC 07/25/12: QIC
06/01/13	Review for effective date 08/01/13. Revised title. Referenced applicable Plan policies. Revised Summary section. Reformatted Medical Policy Statement section and Limitations without changing criteria. Removed redundant text from Clinical Background Information section and added relevant documentation.	08/01/13 Version 3	06/19/13: MPCTAC 07/18/13: QIC
06/01/14	Review for effective date 08/01/14. Revised Policy Summary, Description of Item or Service, Definitions, and Clinical Background Information sections. Moved criteria from the Summary section to the Medical Policy Statement section without changing Plan criteria. Revised introductory paragraph in the Applicable Coding section without changing the applicable code list. Updated references.	08/01/14 Version 4	06/18/14: MPCTAC 07/09/14: QIC

Policy Revisions History			
06/01/15	Review for effective date 10/01/15. Updated References and Description of Item or Service section. Revised title and the Limitations section.	10/01/15 Version 5	06/17/15: MPCTAC 07/08/15: QIC
11/25/15	Review for effective date 01/01/16. Updated template with list of applicable products. Revised language in the Applicable Coding section.	01/01/16 Version 6	11/18/15: MPCTAC 11/25/15: MPCTAC (electronic vote) 12/09/15: QIC
06/01/16	Review for effective date 10/01/16. Revised criteria in the Limitations section. Updated Definitions, Clinical Background Information, References, and References to Applicable Laws and Regulations sections.	10/01/16 Version 7	06/15/16: MPCTAC 07/13/16: QIC
09/28/16	Review for effective date 11/01/16. Administrative changes made to clarify language related to gender.	11/01/16 Version 8	09/30/16: MPCTAC (electronic vote) 10/12/16: QIC
06/01/17	Review for effective date 09/01/17. Revised criteria in the Medical Policy Statement section. Updated Summary, Definitions, and References sections. Administrative changes made to the Limitations section.	09/01/17 Version 9	06/21/17: MPCTAC
06/01/18	Review for effective date 09/01/18. Administrative changes made to the Policy Summary, Description of Item or Service, References, and Other Applicable Policies sections. Criteria updated in the Limitations section.	09/01/18 Version 10	06/20/18: MPCTAC
06/01/19	Review for effective date 09/01/19. Revised the policy title. Administrative change made to the Policy Summary, Description of Item or Service, Definitions, Clinical Background Information, References, and Reference to Applicable Laws and Regulations sections. Criteria revised in the Medical Policy Statement and Limitations sections.	09/01/19 Version 11	06/19/19: MPCTAC
06/01/20	Review for effective date 07/01/20. Administrative changes made to the Description of Item or Service, Applicable Coding, References, and Reference to Applicable Laws and Regulations sections.	07/01/20 Version 12	06/17/20: MPCTAC
11/01/20	Review for effective date 12/01/20. Administrative changes made to the Limitations section.	11/18/20 Version 13	11/18/20: MPCTAC
06/01/21	Review for effective date 07/01/21. Administrative changes made to the Policy Summary, Limitations, and References sections.	07/01/21 Version 14	06/16/21: MPCTAC
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	12/01/21 Version 15	11/17/21: MPCTAC

Policy Revisions History			
	Policy Summary, Clinical Criteria, Limitations and Exclusions, Applicable Coding, and References sections.		

Next Review Date

06/01/22

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

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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.

[+] *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.