BOSTON MEDICAL CENTER HEALTHNet PLAN

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Pharmacy Policy

Infertility Medications

Policy Number: 9.808
Version Number: 2.1
Version Effective Date: 3/1/2022

Product Applicability	☐ **All Plan[+] Products**

Well Sense Health Plan
☐ New Hampshire Medicaid

Boston Medical Center HealthNet Plan
☐ MassHealth - MCO
☐ MassHealth - ACO
☒ Qualified Health Plans/ConnectorCare/Employer Choice Direct
☐ Senior Care Options

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

Prior Authorization Policy

Products Affected:

- **Cetrotide®**
- **Chorionic Gonadotropin**
- **Ovidrel**
- **Endometrin®**
- **Gonal-f®**
- **Gonal-f® RFF**
- **leuprolide acetate**

The Plan may authorize coverage of the above products for members meeting the following criteria:

Covered Use	All FDA approved indications not otherwise excluded
Required Medical Information	**<u>Female Infertility:</u>** **Chorionic Gonadotropin, Ovidrel, Endometrin, Gonal f, Gonal f RFF and leuprolide** **Documentation of the following:** 1. A diagnosis of female infertility; **AND**

[+] *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.

	2. An active authorization for infertility services authorized by the Plan **<u>Male Factor Infertility</u>** **Gonal-f®, Gonal-f® RFF, Chorionic Gonadotropin** **Documentation of the following:** 1. A diagnosis of male infertility; AND 2. An active authorization for infertility services authorized by the Plan
Prescriber Restriction	Prescribed by or in consultation with a OBGYN or infertility specialist
Coverage Duration	<u>Female infertility</u> Duration of active authorization for infertility services approved by the plan <u>Male infertility</u> Duration of active authorization for infertility services approved by the Plan

Clinical Background Information and References

1. The Practice Committee of the American Society for Reproductive Medicine. Use of clomiphene citrate in women. American Society for Reproductive Medicine. Fertil Steril. 2006; 86(4): S187-193. Available at: http://www.asrm.org/uploadedFiles/ASRM_Content/News_and_Publications/Practice_Guidelines/Committee_Opinions/use_of_clomiphene(1).pdf
2. The Practice Committee of the American Society for Reproductive Medicine. Use of clomiphene citrate in infertile women: a committee opinion. Fertil Steril. 2013;100:341-348. Available at: http://www.asrm.org/uploadedFiles/ASRM_Content/News_and_Publications/Practice_Guidelines/Committee_Opinions/use_of_clomiphene(1).pdf.
3. The Practice Committee of the American Society for Reproductive Medicine. Gonadatropin Preparations: Past, Present, and Future. American Society for Reproductive Medicine. Fertil Steril. 2008; 90(3): S13-20. Available at: http://www.asrm.org/uploadedFiles/ASRM_Content/News_and_Publications/Practice_Guidelines/Educational_Bulletins/Use_of_exogenous.pdf
4. The Practice Committee of the American Society for Reproductive Medicine. Gonadatropin in Anovulatory Women. American Society for Reproductive Medicine. Fertil Steril. 2008; 90(3): S7-12. Available at: http://www.asrm.org/uploadedFiles/ASRM_Content/News_and_Publications/Practice_Guidelines/Technical_Bulletins/Use_of_exogenous(1).pdf
5. The Practice Committee of the American Society for Reproductive Medicine. Progesterone Supplementation during the Luteal Phase and in Early Pregnancy in the Treatment of Infertility: An Educational Bulletin. American Society for Reproductive Medicine. Fertil Steril. 2008; 90(3): S150-153. Available at: http://www.asrm.org/uploadedFiles/ASRM_Content/News_and_Publications/Practice_Guidelines/Educational_Bulletins/Progesterone_supplementation(1).pdf
6. National Collaborating Centre for Women's and Children's Health. Fertility: assessment and treatment for people with fertility problems. London: RCOG Press; 2004 Feb. 216 p. Available at: http://www.rcog.org.uk/files/rcog-corp/uploaded-files/NEBFertilityFull.pdf

7. Product information. Gonal-f®, Gonal-f® RFF (follitropin alfa).EMD Serono, Inc. Rockland, MA 02370. October 2009.
8. Product information. Cetrotide® (cetrorelix acetate). EMD Serono, Inc. Rockland, MA 02370. February 2008.
9. Product information. Ovidrel® (choriogonadotropin alfa). EMD Serono, Inc. Rockland, MA 02370. June 2010.
10. Product information. Endometrin® (progesterone). Ferring Pharmaceuticals, Inc. Parsippany, NJ 07054. August 2007.
11. Product information. Crinone® (progesterone gel). Columbia Laboratories, Inc. Livingston, NJ 07039. May 2009.
12. Kuohung W, Hornstein M. Overview of infertility. In: UptoDate, Barbieri RL (Ed), UptoDate, Waltham, MA, December 2010.
13. Seli E, Arici A. Ovulation induction with clomiphene citrate. In: UptoDate, Barbeiri RL (Ed), UptoDate, Waltham, MA. February 2011.
14. Hornstein M, Gibbons W. Unexplained infertility. In: UptoDate, Barbeiri RL (Ed), UptoDate, Waltham, MA. August 2012.
15. Fauser B.C. Overview of ovulation induction. UpToDate. Topic last updated: Nov 28,2016. Accessed August 11, 2017. https://www.uptodate.com/contents/overview-of-ovulation-induction?source=see_link&sectionName=GONADOTROPIN%20THERAPY&anchor=H14#H523299918
16. Kuohung W., Hornstein M. Treatments for female infertitily. UpToDate. Topic last updated: Oct. 10, 2016. Accessed August 11, 2017. https://www.uptodate.com/contents/treatments-for-female-infertility?source=search_result&search=infertility%20treatment&selectedTitle=1~150
17. Prevent Ovarian Hyperstimulation Syndrom, OHSS, with Lupron Trigger. Page Author: Richard Sherbahn, MD http://www.advancedfertility.com/lupron-trigger-prevent-hyperstimulation.htm

Original Approval Date	Original Effective Date	Policy Owner	Approved by
12/1/2020	1/1/2021	Pharmacy Services	Pharmacy & Therapeutics (P&T) Committee

Policy Revisions History			
Review Date	**Summary of Revisions**	**Revision Effective Date**	**Approved by**
9/10/2020	P&T Annual Review: Moved Bravelle, Cetrotide, clomiphene, Crinone, Follistim AQ, Ganirellix, Menopur, Novarel and Ovidrel to non-preferred; removed diagnosis of hypothalamic amenorrhea and the diagnosis of normogonadotropin anovulatory dysfunction from criteria; updated criteria	1/1/2021	P&T Committee

Policy Revisions History			
	language for all products to require active authorization for infertility services authorized by the plan; updated approval duration to match infertility services duration approved by the plan		
2/1/2021	Policy updated to include Crinone	2/1/2021	P&T Committee
11/11/2021	P&T Annual Review: Add Ovidrel to policy; update criteria for Male factor infertility; remove definition of male infertility from policy ; Update duration of approval for Male factor infertility; move Crinone to non formulary	3/1/2022	P&T Committee

Next Review Date

11/2022

Other Applicable Policies

OCA 3.14 Medically Necessary Policy
OCA 3.725 Infertility Services

Reference to Applicable Laws and Regulations, If Any

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.