BOSTON MEDICAL CENTER HEALTHNet PLAN

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Pharmacy Policy

Hydroxyprogesterone Caproate

Policy Number: 9.800
Version Number: 2.0
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:

- **Hydroxyprogesterone caproate (Makena) vial**
- **Makena (hydroxyprogesterone caproate) autoinjector**

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

Covered Use	All FDA approved indications unless otherwise excluded
Exclusion Criteria	None
Required Medical Information	1. The member is pregnant with a single child; AND 2. Treatment to beginbetween 16 weeks 0 days and 20 weeks 6 days gestation *(must document current gestation and expected date of delivery);* ***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.

	3. The member has a history of a spontaneous preterm birth of a single child at < 37 weeks gestation
Age Restrictions	16 years and older
Prescriber Restriction	None
Coverage Duration	21 weeks
Other criteria	None

Applicable Jcode

Hydoxyprogesterone caproate/Makena	J1726

Clinical Background Information and References

1. Bernstein P, Berck D, Burgess T, et al. Prevention of preterm birth: the role of 17a-hydroxyprogesterone caproate. American College of Obstetricians and Gynecologists, District II in conjunction with the March of Dimes New York State Chapter. Compiled Jan 2009. Accessed June 30, 2011.
2. Dodd JM, Flenady V, Cincotta R, Crowther CA. Prenatal administration of progesterone for preventing preterm birth. Cochrane Database Syst Rev. 2006 Jan 25;(1):CD004947.
3. Farine D, Mundle WR, Dodd J, et al. The use of progesterone for prevention of preterm birth. J Obstet Gynaecol Can 2008;30(1):67-71.
4. Makena (hydroxyprogesterone caproate) [prescribing information]. Waltham, MA: Lumara Health; December 2015.
5. Meis PJ, Klebanoff M, Thom E, et al. Prevention of recurrent preterm delivery by 17 hydroxyprogesterone caproate. Obstet & Gynecol.2007;110:865-872.
6. Robinson JN, Norwitz ER. Risk factors for preterm labor and delivery. UpToDate. Updated April 2016. Accessed April 2016.
7. Society for the Maternal Fetal Medicine Publications Committee. Progesterone and preterm birth prevention: translating clinical trials data into clinical practice. Am J Obstet Gynecol. 2012 May;206(5):376-385.
8. Su LL, Samuel M, Chong YS. Progestational agents for treating threatened or established preterm labour. Cochrane Database Syst Rev. 2010 Jan 20;(1):CD006770
9. Updated FDA Statement on Compounded Versions of hydroxyprogesterone caproate (the active ingredient in Makena). June 15, 2012. Available at http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm308546.htm
10. Committee on Practice Bulletins—Obstetrics. American College of Obstetricians and Gynecologists. Practice bulletin no. 130: prediction and prevention of preterm birth. Obstet Gynecol. 2012;120(4):964-973
11. Norwitz ER. Progesterone supplementation to reduce the risk of spontaneous preterm birth. UpToDate. Updated April 2016. Accessed April 2016.

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**
12/1/2020	9.031 Hydroxyprogesterone Policy retired, new policy created	1/1/2021	P&T Committee
11/11/2021	P&T Annual review: Removed contraindication section; added age restriction and Jcode; Added PA to hydroxyprogesterone 1250mg/5ml vial; minor language updates	3/1/2022	P&T Committee

Next Review Date

11/2022

Other Applicable Policies

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.

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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.