



wellsense.org | 877-957-1300

Pharmacy Policy

Hydroxyprogesterone Caproate

Policy Number: 9.800

Revision Number: R0

Version Effective Date: 1/1/2021

| | |
|---|---|
| Product Applicability <input type="checkbox"/> All Plan+ Products | |
| Well Sense Health Plan <input checked="" type="checkbox"/> New Hampshire Medicaid <input type="checkbox"/> _____ | Boston Medical Center HealthNet Plan <input type="checkbox"/> MassHealth - MCO <input type="checkbox"/> MassHealth - ACO <input type="checkbox"/> Qualified Health Plans/ConnectorCare/Employer Choice Direct <input type="checkbox"/> Senior Care Options <input type="checkbox"/> _____ |

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

Prior Authorization Policy

Products Affected:

- Hydroxyprogesterone caproate (Makena)
- Makena (hydroxyprogesterone caproate)

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

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|-------------------------------------|--|
| Covered Use | All FDA approved indications unless otherwise excluded |
| Exclusion Criteria | None |
| Required Medical Information | Documentation of the following: 1. The member is pregnant with a single child and will begin treatment between 16 weeks 0 days and 20 weeks 6 days gestation (<i>must document current gestation and expected date of delivery</i>); AND |

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| | <ol style="list-style-type: none"> 2. The member has a history of a spontaneous preterm birth of a single child at < 37 weeks gestation and treatable risk factors for preterm birth such as smoking or substance abuse have been discussed; AND 3. The member does NOT have any contraindications to hydroxyprogesterone caproate such as: current diagnosis or history of thrombosis, thromboembolic disorders, breast cancer, other hormone-sensitive cancers, undiagnosed abnormal vaginal bleeding unrelated to pregnancy, cholestatic jaundice of pregnancy, benign or malignant liver tumors or active liver disease, and uncontrolled hypertension; |
| Age Restrictions | None |
| Prescriber Restriction | None |
| Coverage Duration | 21 weeks |
| Other criteria | None |

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. International Academy of Compounding Pharmacists (IACP) News Alert. FDA Issues Statement Regarding Makena and Pharmacists Ability to Compound 17P. iacpinfo@iacprx.org. Missouri City, TX 77459. March 2011. Accessed June 30, 2011.
5. Makena (hydroxyprogesterone caproate) [prescribing information]. Waltham, MA: Lumara Health; December 2015.
6. Meis PJ, Klebanoff M, Thom E, et al. Prevention of recurrent preterm delivery by 17 hydroxyprogesterone caproate. Obstet & Gynecol.2007;110:865-872.
7. Robinson JN, Norwitz ER. Risk factors for preterm labor and delivery. UpToDate. Updated April 2016. Accessed April 2016.
8. 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.
9. Su LL, Samuel M, Chong YS. Progestational agents for treating threatened or established preterm labour. Cochrane Database Syst Rev. 2010 Jan 20;(1):CD006770
10. 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>
11. 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

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12. 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, NH DHHS |

| 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, NH DHHS |

Next Review Date

2021

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.

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

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applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.

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