



MEDICATION POLICY

Generic Name: Hydroxyprogesterone Caproate Injection

Therapeutic Class or Brand Name: Hydroxyprogesterone Caproate Injection

Applicable Drugs (if Therapeutic Class):

Makena®, Compounded 17P

Date of Origin: 5/12/16

Date Last Reviewed/Revised: 5/01/2018

GPI Code: 2600001010

Prior Authorization Criteria (may be considered medically necessary when criteria I through VI are met):

- I. Documented diagnosis of singleton pregnancy.
- II. Documented history of singleton spontaneous preterm birth.
- III. Treatment must begin between 16 weeks, 0 days and 20 weeks, 6 days of gestation.
- IV. Minimum age requirement: 16 years old.
- V. Prescriber must be an OB-GYN specialist.
- VI. Refer to plan document for the preferred product. If prior authorization is not for the preferred product, prescriber must also demonstrate medical necessity for the nonpreferred product, justifying both why the preferred product cannot be used and how the nonpreferred product is clinically different than the preferred product.

Exclusion Criteria:

- Current or history of thrombosis or thromboembolic disorders.
- Known or suspected breast cancer, other hormone-sensitive cancer, or history of these conditions.
- Undiagnosed abnormal vaginal bleeding unrelated to pregnancy.
- Cholestatic jaundice of pregnancy.
- Liver tumors, benign or malignant, or active liver disease.
- Uncontrolled hypertension.

Other Criteria:

- N/A

Disclaimer: Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgment in providing the most appropriate care for their patients.



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Quantity/Days Supply Restrictions:

- One 250 mg injection once weekly (every 7 days). (Single and Multi use vials)
- One 275 mg injection once weekly (every 7 days). (Auto-Injector)

Approval Length:

- **Authorization:** Up to 21 weeks [until week 37 (through 36 weeks, 6 days) of gestation or delivery, whichever occurs first].
- **Re-Authorization:** N/A

Appendix:

N/A

References:

1. http://www.makena.com/pdf/makena_pi.pdf.
2. [Medi-Span](#).
3. https://regence.myprime.com/content/dam/prime/memberportal/forms/AuthorForms/Cambia/Program_Summaries/dru255reg.pdf
4. https://www.healthnet.com/static/general/unprotected/html/national/pa_guidelines/makena_natl.html.
5. <https://tuftshealthplan.com/documents/providers/guidelines/pharmacy-medical-necessity-guidelines/makena>.

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<i>Historical Tracking Of Changes Made To Policy</i>	
5/1/2018	<p>1. Added “(Single and Multi-use vials)” and “One 275 mg injection once weekly (every 7 days), (Auto-Injector) under Quantity/Days Supply</p> <p>2. Deleted http://blue.regence.com/trgmedpol/drugs/dru255.pdf and Added/updated link to https://regence.myprime.com/content/dam/prime/memberportal/forms/AuthorForms/Cambia/Program_Summarie_s/dru255reg.pdf , Deleted https://www.healthnet.com/static/general/unprotected/html/national/pa_guidelines/makena_natl.html under Deleted http://www.network-health.org/uploadedFiles/pdfs/medication_necessity_guidelines/makena_hydroxyprogesterone_caproate_en.pdf Added/updated link https://tuftshealthplan.com/documents/providers/guidelines/pharmacy-medical-necessity-guidelines/makena Under References</p>
7/18/2017	<p>1. Policy reviewed: no changes made.</p>

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