Market Applicability														
Market	**DC**	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	NA	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	NA

*FHK- Florida Healthy Kids

Makena (hydroxyprogesterone caproate injection)

Override(s)	Approval Duration
Prior Authorization Quantity limit	6 months

Medications	Quantity Limit
Makena (hydroxyprogesterone caproate injection)	May be subject to quantity limit

APPROVAL CRITERIA

Requests for weekly Makena (hydroxyprogesterone caproate injection) for the prevention of preterm birth may be approved if the if the following criteria are met:

I. Individual is between 16 weeks, 0 days and 36 weeks, 6 days of gestation; **AND**
II. Therapy is initiated between 16 weeks, 0 days and 20 weeks, 6 days of gestation; **AND**
III. Individual has a singleton pregnancy; **AND**
IV. Individual has absence of preterm labor within the current pregnancy; **AND**
V. Individual has a prior history of a preterm singleton delivery before 37 weeks gestation due to either of the following:
    A. Spontaneous preterm labor; **OR**
    B. Premature rupture of membranes.

Requests for Makena (hydroxyprogesterone caproate) injection may **not** be approved for the following:

I. Individual has other risk factors for preterm delivery *in the current pregnancy*, including, but not limited to the following:
    A. Multiple gestation pregnancy,
    B. Cervical cerclage,
    C. A uterine anomaly,
    D. Positive tests for cervicovaginal fetal fibronectin, or
    E. Preterm labor;

OR

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.
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Market Applicability														
Market	**DC**	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	NA	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	NA

*FHK- Florida Healthy Kids

II. Injections are administered in a home setting by or through a licensed home health agency, except when criteria for home health services are met.

State Specific Mandates		
State name	Date effective	Mandate details (including specific bill if applicable)
Louisiana		**This policy does not apply.** 6.13.1.2 Provision of injectable or vaginal progesterone for every eligible pregnant woman with a history of pre-term labor or a short cervix found in the current pregnancy. The MCO shall not require prior authorization of progesterone.

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2018. URL: http://www.clinicalpharmacology.com. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: June 14, 2018.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2018; Updated periodically.
5. Society for Maternal-Fetal Medicine (SMFM). The choice of progestogen for the prevention of preterm birth in women with singleton pregnancy and prior preterm birth. *Am J Obstet Gynecol.* 2017 March;216(3):B11-B13.
6. Society for Maternal-Fetal Medicine (SMFM). Progesterone and preterm birth prevention: translating clinical trials data into clinical practice. *Am J Obstet Gynecol.* 2012 May;206(5): 376-86.
7. The American College of Obstetricians and Gynecologists (ACOG). Prediction and prevention of preterm birth. Practice Bulletin 130. October 2012.

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