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

*FHK- Florida Healthy Kids

Makena (hydroxyprogesterone caproate injection)

CG-DRUG-19

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 Makena (hydroxyprogesterone caproate injection) may be approved if the if the following criteria are met:

I. Weekly injections of 17 alpha-hydroxyprogesterone caproate between 16 and 36 weeks of gestation **may be approved** in pregnant women who meet the following criteria:

   A. A singleton pregnancy; **AND**

   B. Absence of preterm labor within the current pregnancy; **AND**

   C. A prior history of a preterm delivery before 37 weeks gestation due to either of the following:

      1. Spontaneous preterm labor; **OR**

      2. Premature rupture of membranes.

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

I. Progesterone therapy as a technique to prevent preterm labor **may not be approved** in pregnant women who do not meet the above criteria, or those with other risk factors for preterm delivery in the current pregnancy, including, but not limited, to: multiple gestation pregnancy, cervical cerclage, a uterine anomaly, positive tests for cervicovaginal fetal fibronectin, or preterm labor.

II. Injections of 17 alpha-hydroxyprogesterone caproate in a home setting by or through a licensed home health agency **may not be approved**, except when criteria for home health services are met. (See CG-MED-23 - Home Health.)

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

*FHK- Florida Healthy Kids

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. Additional press release information about the FDA new approval of Makena. February 4, 2011. Available at: http://www.prnewswire.com/news-releases/fda-approves-makena-the-first-and-only-treatment-to-reduce-the-risk-of-preterm-birth-in-women-with-a-singleton-pregnancy-who-have-a-history-of-singleton-spontaneous-preterm-birth-115271964.html. Accessed on September 15, 2015.
2. United States Food and Drug Administration (FDA). Additional information about approval of Makena. February 4, 2011. Available at: http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm242234.htm. Accessed on September 24, 2015