Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	September 27, 2011 May 8, 2012; July 7, 2014, December 22, 2016, November 6, 2017, November 6, 2018, May 27, 2020, September 3, 2020, September 29, 2020

MAKENA® (hydroxyprogesterone caproate injection)

Clinical PA required (preferred): Makena® auto-injector 275mg and hydroxyprogesterone caproate (single dose vial) 250mg.
Clinical PA required (non-preferred): Makena® (single dose vial) 250mg.

LENGTH OF AUTHORIZATION: UP TO 5 MONTHS (THROUGH 36 WEEKS, 6 DAYS GESTATION)

CLINICAL NOTES:
Makena is a progestin indicated to reduce the risk of preterm birth in women with a singleton pregnancy (a pregnancy with only one baby) who have a history of singleton spontaneous preterm birth. Makena is not intended for use in women with multiple gestations or other risk factors for preterm birth.

Florida Medicaid covers prescribed drugs that combine two or more drugs when all of the following are met:

- At least one of the drugs in the compound drug is covered by Florida Medicaid.
- The compounded drug is not otherwise commercially available.
- The drug is compounded as prescribed for the recipient to treat his or her specific condition. (Prescribed Drug Services Coverage Policy, 2017)

REVIEW CRITERIA:

- Must be ≥ 16 years of age.
- Must be currently pregnant with only one baby (a singleton pregnancy) at 16 to 37 weeks gestation confirmed by supporting documentation or diagnosis code(s).
- Begin treatment between 16 weeks, 0 days and 20 weeks, 6 days of gestation.
- Documentation of having a history of singleton spontaneous preterm birth must be submitted.
- Makena is not intended for use in women with multiple gestations or other risk factors for preterm birth.

DOSING AND ADMINISTRATION:

- Administer once weekly.
- Begin treatment between 16 weeks, 0 days and 20 weeks, 6 days of gestation.
- Continue administration once weekly until week 37 (through 36 weeks, 6 days) of gestation or delivery, whichever occurs first.

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Dosage Forms:

- Available as Makena auto-injector 275mg administered subcutaneously once weekly.
- Available as Makena or hydroxyprogesterone caproate (single or multi-dose vials) 250mg administered intramuscularly once weekly.