HARVARD PILGRIM HEALTH CARE
RECOMMENDED MEDICATION REQUEST GUIDELINES

HYDROXYPROGESTERONE CAPROATE (MAKENA)

Generic	Brand	HICL	GCN	Exception/Other
HYDROXYPROGESTERONE CAPROATE	MAKENA		39946	
HYDROXYPROGESTERONE CAPROATE/PF	MAKENA	43985		

GUIDELINES FOR USE

1. Is the request for the prevention of preterm birth for a patient who meets all of the following conditions?
   - The current pregnancy is a singleton pregnancy
   - The patient has a history of singleton spontaneous preterm birth, defined as delivery at less than 37 weeks gestation
   - Hydroxyprogesterone (Makena) will be initiated between 16 weeks, 0 days and 24 weeks, 6 days of gestation
   - The patient does **NOT** have any of the following contraindications to therapy:
     - Current or history of thrombosis or thromboembolic disorders
     - Known or suspected breast cancer, other hormone-sensitive cancer, or a 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

   If yes, **approve by HICL up to four 250mg vials per 28 days OR one 5mL vial per 35 days for up to 21 weeks or through 36 weeks, 6 days gestational age, whichever is less.** Please use status code #056 and the approval text provided.
   APPROVAL TEXT: Your request for **[hydroxyprogesterone (generic Makena)/Makena]** has been approved for a quantity of **[__-vials(s) or auto injectors]** per week for a **[__-week]** period.

   If no, do not approve. Please use status code #238 and the denial text provided.
   DENIAL TEXT: Per your health plan's Hydroxyprogesterone Caproate (Makena) guideline, this medication is only covered when prescribed for the prevention of preterm birth for a patient who meets all of the following conditions:
   - The current pregnancy is a singleton pregnancy
   - You have a history of singleton spontaneous preterm birth, defined as delivery at less than 37 weeks gestation
   - The medication will be initiated between 16 weeks, 0 days and 24 weeks, 6 days of gestation
   - You do not have one of the following contraindications to therapy:
     - Current or history of thrombosis or thromboembolic disorders
     - Known or suspected breast cancer, other hormone-sensitive cancer, or a 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

   (Denial text continued on next page)

GUIDELINES FOR USE (CONTINUED)

Your provider did not indicate that you **[specify criteria not met]** and therefore your request was not approved.

RATIONALE

Ensure appropriate utilization of Makena for the prevention of preterm birth.

FDA APPROVED INDICATIONS

Makena is indicated to reduce the risk of preterm birth in women with a singleton pregnancy who have a history of singleton spontaneous preterm birth. The effectiveness of Makena is based on improvement in the proportion of women who delivered < 37 weeks of gestation. There are no controlled trials demonstrating a direct clinical benefit, such as improvement in neonatal mortality and morbidity.

Limitations of use: While there are many risk factors for preterm birth, safety and efficacy of Makena has been demonstrated only in women with a prior spontaneous singleton preterm birth. It is not intended for use in women with multiple gestations or other risk factors for preterm birth.

REFERENCES

- Makena [package insert]. Waltham, MA: AMAG Pharmaceuticals, Inc.; February 2018.
- American College of Obstetricians and Gynecologists Committee on Practice Bulletins-Obstetrics. ACOG practice bulletin no. 130: prediction and prevention of preterm birth. *Obstet Gynecol*. 2012;120(4):964-973.

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