Gateway Health

Updated: 09/2019
PARP Approved: 07/2019

Prior Authorization Criteria

Makena (hydroxyprogesterone caproate injection)

All requests for Makena (hydroxyprogesterone caproate injection) require a prior authorization and will be screened for medical necessity and appropriateness using the criteria listed below.

Makena (hydroxyprogesterone caproate injection) Prior Authorization Criteria:

Coverage may be provided with a diagnosis of prophylaxis of preterm birth and the following criteria is met:

- Member must be 16 years of age or older
- Must have a singleton pregnancy (i.e. one fetus)
- Must have a history of singleton spontaneous preterm birth defined as delivery prior to 37 weeks gestation
- Is being, or was, initiated into treatment between 16 weeks 0 days and 26 weeks
- The requested dose and frequency is in accordance with FDA-approved labeling, nationally recognized compendia, and/or evidence-based practice guidelines
- The member must not have any of the following contraindications to Makena:
    - 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
- **Initial Duration of Approval:** coverage is provided until week 37 (through 36 weeks, 6 days) of gestation or delivery, whichever occurs first.

Coverage may be provided for any non-FDA labeled indication if it is determined that the use is a medically accepted indication supported by nationally recognized pharmacy compendia or peer-reviewed medical literature for treatment of the diagnosis(es) for which it is prescribed. These requests will be reviewed on a case by case basis to determine medical necessity.

When criteria are not met, the request will be forwarded to a Medical Director for review. The physician reviewer must override criteria when, in their professional judgment, the requested medication is medically necessary.

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MAKENA (HYDROXYPROGESTERONE CAPROATE) PRIOR AUTHORIZATION FORM

Please complete and fax all requested information below including any progress notes, laboratory test results, or chart documentation as applicable to Gateway Health[SM] Pharmacy Services. **FAX:** (888) 245-2049
If needed, you may call to speak to a Pharmacy Services Representative.
PHONE: (800) 392-1147 Monday through Friday 8:30am to 5:00pm

PROVIDER INFORMATION

Requesting Provider:	NPI:
Physician Specialty:	Office Contact:
Office Address:	Office Phone:
	Office Fax:

MEMBER INFORMATION

Member Name:	DOB:
Gateway ID:	Member weight: _____pounds or _____kg

REQUESTED DRUG INFORMATION

***** Please note BRAND is formulary *****

Check desired formulation below:

☐ **Makena 250mg/1mL Vial**

☐ **Makena 275mg/1.1mL Auto-Injector**

☐ **Other (specify):**_____

If requesting the generic or the compound please provide an explanation for why the member cannot use the brand:

_____

_____

Frequency:

Length of Therapy:

BILLING INFORMATION

This medication will be billed: ☐ at a pharmacy **OR**
☐ medically (if medically please provide a JCODE:_____

Place of Service: ☐ Hospital ☐ Provider's office ☐ Member's home ☐ Other

PLACE OF SERVICE INFORMATION

Name:	NPI:
Address:	Phone:

MEDICAL HISTORY

Is the current pregnancy singleton (i.e. one fetus)? ☐ Yes ☐ No

Is Makena being prescribed for the prevention of preterm singleton birth? ☐ Yes ☐ No

Does the member have a history of spontaneous preterm birth (delivery prior to 37 weeks gestation)?
☐ Yes ☐ No

Is the pregnancy between 16 weeks, 0 days and 26 weeks gestation? ☐ Yes ☐ No

Contraindications: Does the patient have current or history of thrombosis or thromboembolic disorders, known or suspected breast cancer, undiagnosed abnormal vaginal bleeding unrelated to pregnancy, cholestatic jaundice or pregnancy, liver tumors or active liver disease, or uncontrolled hypertension? ☐ Yes ☐ No

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MAKENA (HYDROXYPROGESTERONE CAPROATE)
PRIOR AUTHORIZATION FORM - page 2 of 2

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MEMBER INFORMATION	
Member Name:	DOB:
Gateway ID:	Member weight: _____pounds or _____kg

SUPPORTING INFORMATION or CLINICAL RATIONALE - continued

Prescribing Provider Signature	**Date**