

**Policy: MBP 127.0**

**Section: Medical Benefit Pharmaceutical Policy**

**Subject: Makena (hydroxyprogesterone caproate)**

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### **I. Policy:**

Makena (hydroxyprogesterone caproate)

### **II. Purpose/Objective:**

To provide a policy of coverage regarding Makena (hydroxyprogesterone caproate)

### **III. Responsibility:**

- A. Medical Directors
- B. Medical Management
- C. Pharmacy Department

### **IV. Required Definitions**

1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than
3. the department requiring/authoring the policy.
4. Devised – the date the policy was implemented.
5. Revised – the date of every revision to the policy, including typographical and grammatical changes.
6. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

### **V. Additional Definitions**

Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

- a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- b. provided for the diagnosis and the direct care and treatment of the Member's condition, illness disease or injury;
- c. in accordance with current standards good medical treatment practiced by the general medical community;
- d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
- e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient

### **Medicaid Business Segment**

Medical Necessity shall mean a service or benefit that is compensable under the Medical Assistance Program and if it meets any one of the following standards:

- (i) the service or benefit will, or is reasonably expected to, prevent the onset of an illness, condition or disability.
- (ii) the service or benefit will, or is reasonably expected to, reduce or ameliorate the physical, mental or development effects of an illness, condition, injury or disability.
- (iii) the service or benefit will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for members of the same age

**DESCRIPTION:**

Makena (hydroxyprogesterone caproate) is a synthetic progestin indicated for reducing the risk of preterm birth in women with a singleton pregnancy who have a history of singleton spontaneous preterm birth. It is not intended for use in women with multiple gestations or other risk factors for preterm birth and is contraindicated in women with current or history of thrombosis or thromboembolic disorder, 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 or uncontrolled hypertension

**CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee**

Makena (hydroxyprogesterone caproate) will be considered medically necessary for the commercial, exchange, CHIP and Medicare lines of business when all of the following criteria are met:

- The member is a pregnant female with a single fetus **AND**
- There is a documented history of a prior spontaneous preterm singleton birth (defined as prior to 37 weeks gestation) **AND**
- Is being initiated into treatment between 16 weeks 0 days and 20 weeks 6 days **AND**
- There is medical record documentation that the member does not have any of the following:
  - current or history of thrombosis or thromboembolic disorder **AND**
  - known or suspected breast cancer, other hormone-sensitive cancer, or history of these conditions **AND**
  - undiagnosed abnormal vaginal bleeding unrelated to pregnancy **AND**
  - cholestatic jaundice of pregnancy **AND**
  - liver tumors, benign or malignant, or active liver disease **AND**
  - uncontrolled hypertension

**AUTHORIZATION DURATION:** Approval will be for the quantity required for the member to receive a once weekly injection until week 37 of gestation. (Makena is supplied as a 5 mL vial, 1 mL vial, or 1.1 mL auto-injector – each dose is 1 mL [250 mg] for vials or 1.1 mL [275mg] for auto injector)

**LINE OF BUSINESS:**

**Eligibility and contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy.**

This policy will be revised as necessary and reviewed no less than annually.

**Devised:** 3/24/15

**Revised:** 1/16/23 (LOB carve out, supplied formulations update)

**Reviewed:** 3/31/16, 3/30/17, 3/29/18, 3/28/19, 2/1/20, 1/19/21, 1/18/22