

PHARMACY POLICY STATEMENT Indiana Medicaid

DRUG NAME	Makena (hydroxyprogesterone caproate)
BILLING CODE	J1726 (1 unit = 10 mg)
BENEFIT TYPE	Medical
SITE OF SERVICE ALLOWED	Outpatient/Office/Home
COVERAGE REQUIREMENTS	No prior authorization is required for Indiana Medicaid. However, Makena (hydroxyprogesterone caproate) should only be administered to members who meet the established criteria below. QUANTITY LIMIT – 250 mg weekly
LIST OF DIAGNOSES CONSIDERED NOT MEDICALLY NECESSARY	Click Here

Makena (hydroxyprogesterone caproate) is a **non-preferred** product and will only be considered for coverage under the **medical** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

REDUCTION OF RISK OF PRETERM BIRTH

For **initial** authorization:

1. Member has current singleton pregnancy; AND
2. Member has documented history of one or more preterm births occurring between 16 and 36 weeks gestation due to spontaneous preterm labor, rupture of membranes, or advanced cervical dilation or effacement; AND
3. No evidence that preterm birth was secondary to defined medical indications, such as induction for hypertension, IUGR, fetal compromise or distress, placenta abruption or previa, Rh or other blood group incompatibility, fetal anomaly; AND
4. Member has no history of the following: blood clots or other blood clotting problems, breast cancer or other hormone sensitive cancers, liver problems or liver tumors, uncontrolled high blood pressure; AND
5. Member is not currently in labor; AND
6. Medication is initiated during the period of 16-24 weeks and can be administered through 36 weeks 6 days gestation.
7. **Dosage allowed:** 250 mg weekly initiating between 16 and 24 weeks gestation and continuing up to 36 weeks 6 days gestation.

If member meets all the requirements listed above, the medication will be approved for the period of the pregnancy up to 36 weeks and 6 days gestation.

CareSource considers Makena (hydroxyprogesterone caproate) not medically necessary for the treatment of the diseases that are not listed in this document.

DATE	ACTION/DESCRIPTION
01/08/2018	New policy for Makena created. New format established, no changes in criteria from previous policy version.



References:

1. Makena [package insert]. Waltham, MA; AMAG Pharmaceuticals, Inc: Lumara Health, April, 2016.
2. How, MD, H. Y., Batron, MD, J.R., Istwan, RN, N. B. , Rhea, MPH, D. J., & Stanziano, MD, G.J. (2007). Prophylaxis with 17-alpha-hydroxyprogesterone caproate for prevention of recurrent preterm delivery: does gestational age at initiation of treatment matter? American Journal of Obstetrics & Gynecology. 2007.07.013, 260.e1-260.e3.
3. Tita ATN, Rouse DJ. Progesterone for preterm birth prevention: an evolving intervention. American Journal of Obstetrics & Gynecology 2009; March, pp 219-224.
4. Progesterone and preterm birth prevention: translating clinical trials data into clinical practice American Journal of Obstetrics & Gynecology, 2012, Volume 206, Issue 5, 376 - 386.

Effective date: 01/31/2018

Revised date: 01/08/2018