



MEDICAID POLICY STATEMENT		
Original Effective Date	Next Annual Review Date	Last Review / Revision Date
09/29/2004	08/24/2017	10/17/2016
Policy Name		Policy Number
17 alpha hydroxyprogesterone caproate (Makena)		SRx-0029
Policy Type		
<input checked="" type="checkbox"/> Medical	<input type="checkbox"/> Administrative	<input type="checkbox"/> Payment

Medicaid Policy Statements prepared by CSMG Co. and its affiliates (including CareSource) apply to Medicaid health benefit plans administered by CSMG and its affiliates and are derived from literature based on and supported by applicable federal or state coverage mandates, clinical guidelines, nationally recognized utilization and technology assessment guidelines, other medical management industry standards, and published MCO clinical policy guidelines. Medically necessary services include, but are not limited to, those health care services or supplies that are proper and necessary for the diagnosis or treatment of disease, illness, or injury and without which the patient can be expected to suffer prolonged, increased or new morbidity, impairment of function, dysfunction of a body organ or part, or significant pain and discomfort. These services meet the standards of good medical practice in the local area, are the lowest cost alternative, and are not provided mainly for the convenience of the member or provider. Medically necessary services also include those services defined in any federal or state coverage mandate, Evidence of Coverage documents, Medical Policy Statements, Provider Manuals, Member Handbooks, and/or other policies and procedures.

Medicaid Policy Statements prepared by CSMG Co. and its affiliates (including CareSource) do not ensure an authorization or payment of services. Please refer to the plan benefit document (i.e., Evidence of Coverage) for the service(s) referenced in the Medical Policy Statement. If there is a conflict between the Medicaid Policy Statement and the plan benefit document, then the plan benefit document will be the controlling document used to make the determination. In the absence of any applicable controlling federal or state coverage mandate, benefits are ultimately determined by the applicable plan benefit document.

A. SUBJECT

17 alpha hydroxyprogesterone caproate (Makena)

B. BACKGROUND

The American College of Obstetricians and Gynecologists (ACOG) Congress has recommended that progesterone supplementation for the prevention of recurrent preterm birth should be offered to women with a singleton pregnancy and a prior spontaneous preterm birth due to spontaneous preterm labor or premature rupture of membranes. Current evidence does not support the routine use of progesterone in women with multiple gestations.

C. DEFINITIONS

N/A

D. POLICY

I. CareSource will approve the use of Makena and consider the use as medically necessary when the following criteria have been met:

- Reducing the risk of preterm birth in women with singleton pregnancies who have a history of singleton spontaneous preterm birth

A. 17 alpha hydroxyprogesterone caproate (Makena)

17 alpha hydroxyprogesterone caproate (Makena) is indicated as a treatment to reduce the risk of preterm birth in women with singleton pregnancies 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.

Prior Authorization Criteria:

1. Current singleton pregnancy
2. 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
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
4. 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.
5. Initiation of injections during the period of 16-24 weeks and can be administered through 36 weeks 6 days gestation
6. Not currently in labor

NOTE: Prior Authorization Criteria for Continued Coverage after 36 weeks will **NOT** be considered.

NOTE: Documented diagnosis must be confirmed by portions of the individual's medical record which will confirm the presence of the condition or disease and will need to be supplied with a prior authorization request. These medical records may include, but are not limited to test reports, chart notes from provider's office or hospital admission notes.

ALL other uses of 17 alpha hydroxyprogesterone caproate are considered experimental/investigational and therefore, fall under CareSource's Off-Label policy.

CONDITIONS OF COVERAGE

Quantity Limitations 250mg/once weekly until 36 weeks of gestation

Place of Service Office, Outpatient, Home

**Preferred place of service is in the home setting.

Ohio and Kentucky Medicaid Members Only: No prior authorization is required for Makena or hydroxyprogesterone caproate, but should only be administered to patients who meet the guidelines established above. All prior authorization requests (if applicable) will be reviewed according to the guidelines noted above.

NOTE: CareSource supports administering injectable medications in various settings, as long as those services are furnished in the most appropriate and cost effective setting that are supportive of the patient's medical condition and unique needs and condition. The decision on the most appropriate setting for administration is based on the member's current medical condition and any required monitoring or additional services that may coincide with the delivery of the specific medication. CareSource prefers Makena to be billed on the medical benefit through the buy and bill process. Requests for coverage on the pharmacy benefit will be reviewed on a case by case scenario.

HCPCS J1725 – Makena, J3490 hydroxyprogesterone caproate
CPT

AUTHORIZATION PERIOD



Approved initial authorizations are valid for the period of the pregnancy up to 36 weeks of gestation. **ALL** authorizations are subject to continued eligibility.

E. RELATED POLICIES/RULES

N/A

F. REVIEW/REVISION HISTORY

Date Issued: 09/29/2004

Date Reviewed: 09/29/2004, 04/01/2006, 07/01/2007, 03/04/2009, 07/01/2009,
08/15/2012, 08/22/2013, 08/24/2014

Date Revised: 08/24/2014 – Changed metric for short cervix; added advanced cervical dilation or effacement to criteria.
07/31/2015- Removed short cervix diagnosis, updated references, added preferred POS, added Home Health Services information
4/5/2016 – Removed compounded 17-P, revised for Makena SDV update.
10/17/2016- Added medical conditions to the prior authorization criteria and J-Code for hydroxyprogesterone caproate

G. REFERENCES

1. 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.
2. Tita ATN, Rouse DJ. Progesterone for preterm birth prevention: an evolving intervention. *American Journal of Obstetrics & Gynecology* 2009; March, pp 219-224.
3. Makena Package Insert. Lumara Health, 12/20/2015
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.

The Medicaid Policy Statement detailed above has received due consideration as defined in the Medicaid Policy Statement Policy and is approved.
