PHARMACY POLICY STATEMENT

Original Effective Date	Next Annual Review		Last Revision
09/29/2004	08/24/2017		11/23/2016
Policy Name			**Policy Number**
Hydroxyprogesterone caproate			SRx-0074
Policy Type			
Medical	Administrative	**PHARMACY**	Reimbursement

Pharmacy Policy Statements prepared by CSMG Co. and its affiliates (including CareSource) are derived from literature based on and supported by 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 Evidence of Coverage documents, Pharmacy Policy Statements, Provider Manuals, Member Handbooks, and/or other policies and procedures.

Pharmacy 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 contract (often referred to as the Evidence of Coverage) for the service(s) referenced in the Pharmacy Policy Statement. If there is a conflict between the Pharmacy Policy Statement and the plan contract (i.e., Evidence of Coverage), then the plan contract (i.e., Evidence of Coverage) will be the controlling document used to make the determination

Contents of Policy

PHARMACY POLICY STATEMENT 1
A. INTRODUCTION 2
B. DEFINITIONS 2
C. POLICY COVERAGE CRITERIA 2
1. Site of Service 2
2. Coverage Criteria 3
3. Dosage and Quantity Limits (listed if applicable) 4
4. Authorization Period 4
5. Coding 4
D. RELATED POLICIES 4
E. REVIEW/REVISION HISTORY 4
F. REFERENCES 5

A. INTRODUCTION

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.

The intent of CareSource Pharmacy Policy Statements is to encourage appropriate selection of patients for therapy according to product labeling, clinical guidelines, and/or clinical studies as well as to encourage use of preferred agents. The CareSource Pharmacy Policy Statement is a guideline for determining health care coverage for our patients with benefit plans covering prescription drugs. Pharmacy Policy Statements are written on selected prescription drugs requiring prior authorization or step therapy. The Pharmacy Policy Statement is used as a tool to be interpreted in conjunction with the member's specific benefit plan.

NOTE: The Introduction section is for your general knowledge and is not to be construed as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals and is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider can also be a place where medical care is given, like a hospital, clinic or lab. This policy informs providers about when a service may be covered.

B. DEFINITIONS

1. None applicable.

C. POLICY COVERAGE CRITERIA

1. Site of Service

Site of Service Administration	Coverage Criteria
Office, Outpatient, Home	**Preferred place of service is in the home.** CareSource supports administering injectable medications in various settings, as long as those services are furnished in the most appropriate and cost effective settings that are supportive of the patient's medical condition(s) and unique needs and condition(s). The decision on the most appropriate setting for administration is based on the member's current medical condition(s) and any required monitoring or additional services that may coincide with the delivery of the specific medication.

2. Coverage Criteria

CareSource will approve the use of Makena (hydroxyprogesterone caproate) and consider its use medically necessary when the criteria have been met for each condition listed below. **No prior authorization is required for Makena (hydroxyprogesterone caproate) for Indiana Medicaid.** However, Makena (hydroxyprogesterone caproate) should only be administered to members who meet the established guidelines below. All prior authorization requests (if applicable) will be reviewed according to the guidelines below.

Condition	Makena (hydroxyprogesterone caproate) Coverage criteria:
Reduction of risk of preterm birth	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) Not currently in labor 6) Initiation of injections during the period of 16-24 weeks and can be administered through 36 weeks 6 days gestation

All other uses of Makena (hydroxyprogesterone caproate) are considered experimental/investigational; and therefore, will follow CareSource's off-label policy.

Please note that this policy is reviewed on an annual basis. New drugs and indications receiving FDA approval may not be reflected in this policy immediately.

Notes:

- Documented diagnosis must be confirmed by portions of the individual's medical record which need to be supplied with 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.
- Member is required to have completed the trial(s) listed in the above criteria unless the member is unable to tolerate or has a contraindication to trial medications. Documentation such as chart notes or pharmacy claims may be requested to verify trial(s), intolerance, or contraindication(s).
- Refer to the product package insert for dosing, administration and safety guidelines.

- Prior authorization request for continued coverage after 36 weeks will **NOT** be considered.

3. Dosage and Quantity Limits (listed if applicable)

Information for patients with renal or hepatic impairment is not included. See package insert for individual agents.

Condition	Dosage and Quantity Limit of Makena (hydroxyprogesterone caproate)
Reduction of risk of preterm birth	250 mg weekly initiating between 16 and 24 weeks gestation and continuing up to 36 weeks 6 days gestation

4. Authorization Period

Condition	Approval Period
Reduction of risk of preterm birth	The initial authorization for Makena is valid for the period of the pregnancy up to 36 weeks and 6 days gestation. **ALL** authorizations are subject to continued eligibility.

5. Coding

HSPCS	
J1725	Makena

D. RELATED POLICIES

AD-0004: Medical Necessity - Off-Label, Approved Orphan and Compassionate Use Drugs

E. REVIEW/REVISION HISTORY

DATE	ACTION/DESCRIPTION
09/29/2004	Issued, reviewed
04/01/2006	Reviewed
07/01/2007	Reviewed
03/04/2009	Reviewed
07/01/2009	Reviewed
08/15/2012	Reviewed
08/22/2013	Reviewed
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.
04/05/2016	Removed compounded 17-P, revised for Makena SDV update.

10/17/2016	Added medical conditions to the prior authorization criteria and updated coding
11/23/2016	Separated by line of business, updated coding, changed title (removed 17 alpha)

F. 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 Pharmacy Policy detailed above has received due consideration and is approved.

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