MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

I. Requirements for Prior Authorization of Progestational Agents

A. Prescriptions That Require Prior Authorization

A prescription for a Progestational Agent that meets any of the following conditions must be prior authorized:

1. A prescription for a non-preferred Progestational Agent. See the Preferred Drug List (PDL) for the list of preferred Progestational Agents at: www.providersynergies.com/services/documents/PAM_PDL.pdf

2. A prescription for a Progestational Agent with a prescribed quantity that exceeds the quantity limit. See Quantity Limits for the list of drugs with quantity limits at: http://www.dpw.state.pa.us/provider/doingbusinesswithdpw/pharmacyservices/quantitylimitslist/index.htm

3. A prescription for Makena

B. Review of Documentation for Prior Authorization

In evaluating a request for prior authorization of a prescription for a Progestational Agent, the determination of whether the requested prescription is medically necessary will take into account whether the recipient:

1. For a non-preferred Progestational Agent - Has a documented history of therapeutic failure, intolerance, or contraindication of the preferred Progestational Agents

2. For Makena:

   a. Is a pregnant female with a single fetus

   AND

   b. Is between 16 weeks 0 days and 36 weeks 6 days gestation

   AND

c. Has a documented history of a prior spontaneous preterm singleton birth (defined as prior to 37 weeks gestation)

AND

d. Is being, or was, initiated into treatment between 16 weeks 0 days and 26 weeks

AND

e. Does not have a contraindication to use of Makena as per the "Prescribing Information/Contraindications"

AND

f. Does not have a:

i. History of, or plans for, a cervical cerclage, **OR**
ii. Known fetal anomaly, **OR**
iii. History of seizure disorder

C. Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B, above, to assess that the patient meets the clinical requirements for prior authorization of a Progestational Agent. If the guidelines in Section B are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the recipient.

D. Dose and Duration of Therapy

Approvals of requests for prior authorization of prescriptions for Makena will be limited to 250 mg weekly not to exceed a total of 21 injections.

References:

1. FDA Statement on Makena, November 8, 2011. http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm279098.htm

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(Replacing May 14, 2012)

2. ACOG Committee Opinion Number 419, October 2008, Reaffirmed 2011. http://www.acog.org/~/media/Committee%20Opinions/Committee%20on%20Obs tetric%20Practice/co419.ashx?dmc=1&ts=20120118T0911074525

3. Information Update on 17a-Hydroxyprogesterone Caproate (17P) from The American College of Obstetricians and Gynecologists and the Society for Maternal-Fetal Medicine. http://www.acog.org/~/media/Announcements/20111013MakenaLtr.ashx?dmc=1&ts=20120118T0911074515

4. Makena® (package insert), Ther-Rx Corporation 2011. http://www.makena.com//media/PDFs/full-pi.pdf

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