

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

I. Requirements for Prior Authorization of Makena®

A. Prescriptions That Require Prior Authorization

All prescriptions for Makena must be prior authorized.

B. Review of Documentation for Prior Authorization

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

1. Is a pregnant female with a single fetus

AND

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

AND

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

AND

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

AND

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

AND

6. Does not have a:

- a. History of, or plans for, a cervical cerclage, **OR**
- b. Known fetal anomaly, **OR**
- c. History of seizure disorder

May 14, 2012
(Replacing July 11, 2011)

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 Makena. 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>
2. ACOG Committee Opinion Number 419, October 2008, Reaffirmed 2011.
<http://www.acog.org/~media/Committee%20Opinions/Committee%20on%20Obs%20tetric%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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