

# Superior HealthPlan Clinical Edit Criteria



## Drug/Drug Class

### Makena

The intent of the algorithm is to ensure that patients meet medical necessity through a Clinical Edit for Makena. Superior has received approval for a clinical edit on Makena via the Texas Vendor Drug Program.

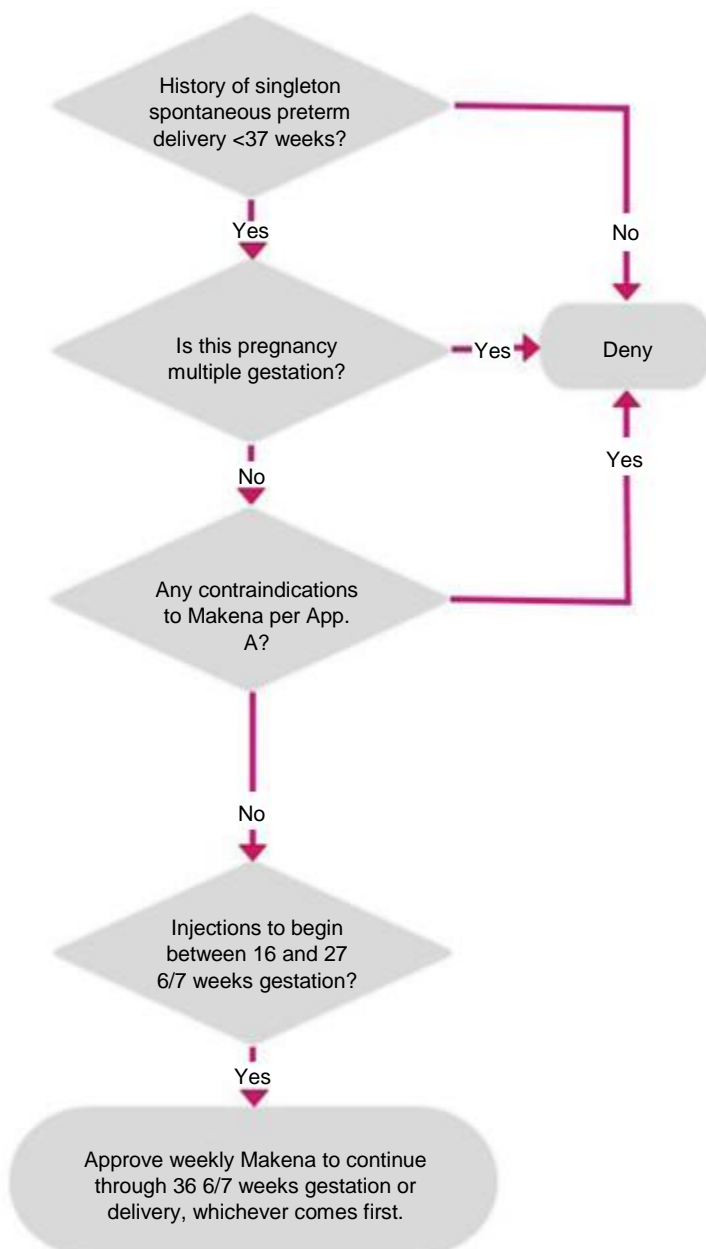
### Clinical Edit Information Included in this Document

- **Drugs included in the edit:** a list of medications included in this clinical edit logic
- **Logic diagram:** a visual depiction of the clinical edit algorithm
- **Diagnosis and step logic:** a list of diagnosis and additional step logic, claims and look back period information
- **Clinical Edit References:** references used to create the criteria
- **Publication history:** a log that tracks when the clinical edit was implemented and any revisions to the publication

## Superior HealthPlan Clinical Edit - Makena

Drugs Included in the Edit	
Label Name	NDC
Makena 1,250 mg/5ml vial	64011024301
Makena 250mg/ml vial	64011024702

### Logic Diagram



<b>Diagnosis Information which qualifies for approval &amp; look back period</b>
History of singleton spontaneous preterm delivery before 37 weeks
Current singleton pregnancy between 16 weeks 0 days to 20 weeks 6/7 days
No contraindication listed in Appendix A

<b>Diagnosis Information which does not qualify for approval &amp; look back period</b>
Current pregnancy with multiple fetuses at any point in pregnancy
History of singleton non-spontaneous delivery before or after 37 weeks
History of a multiple fetus spontaneous or non-spontaneous birth before or after 37 weeks
Any contraindication listed in Appendix A
Current gestation outside 16 weeks 0 days to 20 weeks 6/7 days

<b>Appendix A-Contraindications for Makena</b>
History of or current thrombosis or thromboembolic disorder
Known or suspected breast cancer, other hormone-sensitive cancer or a history of these conditions
Undiagnosed abnormal vaginal bleeding, not related to pregnancy
Cholestatic jaundice of pregnancy
Benign or malignant liver tumors, or active liver disease
Uncontrolled hypertension

*Please note: Superior will review prior authorization before 16 weeks gestation to allow medication supply to be received in a timely manner, if approved per criteria.*

## Clinical Edit References:

1. ACOG Committee Opinion. Number 419. October 2008. [file:///C:/Users/PSP19/Downloads/17P\\_Committee\\_Opinion%20\(2\).pdf](file:///C:/Users/PSP19/Downloads/17P_Committee_Opinion%20(2).pdf). Accessed September 3, 2014.
2. Hugo Gonzalez-Quintero, V. et al. Gestational age at initiation of 17- $\alpha$  Hydroxyprogesterone caproate and rate of preterm births in singleton gestations with a history of preterm delivery. *Journal of maternal-fetal and neonatal medicine*. 2007; 20: 249-52.
3. Johnson, J. et al. Efficacy of 17 $\alpha$ -Hydroxyprogesterone caproate in the prevention of premature labor. *The New England Journal of Medicine*. 1975; 293: 675-680.
4. Mackenzie, R., Walker, M., Armson, A., Hannah, Mary. Progesterone for the prevention of preterm birth among women at increased risk: a systematic review and meta-analysis of randomized controlled studies. *American Journal of Obstetrics and Gynecology*. 2006; 194: 1234-42.
5. Makena [package insert]. McPherson, KS: Hospira, Inc.; August 2013.
6. Mason, M. et al. Optimizing the use of 17-P in pregnant managed care Medicaid members. *Managed Care*. January 2008.
7. Meis, P. 17 Hydroxyprogesterone for the prevention of preterm delivery. *Obstetrics and Gynecology*. 2005; 105: 1128-1135.
8. Meis, P., Lekbanoff, M., Thom, E., et al. Prevention of recurrent preterm delivery by 17 alpha-hydroxyprogesterone caproate. *The New England Journal of Medicine*. 2003; 348: 2379-85.
9. *Preterm Birth*. Atlanta, GA: Centers for Disease Control and Prevention; December 2013. <http://www.cdc.gov/reproductivehealth/maternalinfanthealth/pretermbirth.htm>. Accessed September 3, 2014.
10. Progesterone Drug Information. In: UpToDate, Post TW (Ed), UpToDate. Waltham, MA. (Accessed September 3, 2014).
11. Society for Maternal-Fetal Medicine Publications Committee, with the assistance of Vincenzo Berghella, MD. Progesterone and preterm birth prevention: translating clinical trials data into clinical practice. *American Journal of Obstetrics and Gynecology*. 2012; 206: 376-386.
12. The American College of Obstetricians and Gynecologists. Prediction and Prevention of Preterm Birth: Clinical Management Guidelines for Obstetrician-Gynecologists. *Obstetrics and Gynecology*. 2012; 120: 964-73.

## References for Additional Information

1. ACOG, AAP and Society for Maternal Fetal Medicine. Ob-Gyns Respond to High Cost of Makena. March 14, 2011. [http://www.acog.org/from\\_home/misc/20110311GoedekelTr.pdf](http://www.acog.org/from_home/misc/20110311GoedekelTr.pdf)
2. Armstrong, J. M.D. Unintended Consequences — The Cost of Preventing Preterm Births after FDA Approval of a Branded Version of 17OHP. *The New England Journal of Medicine*. March 16, 2011.

Publication Date	Notes
6/15/15	Clinical edit added
2/14/17	Added reference tables, references and publication table per UMCM Chapter 3 requirements.
10/2/17	Updated gestational age consideration to relax edit further from 16 weeks 0 days -20 weeks 6 days to 27 weeks 6 days. Literature supports such update.