

Texas Prior Authorization Program Clinical Criteria

Drug/Drug Class

Makena (hydroxyprogesterone caproate)

This criteria was recommended for review by the Texas Medicaid Vendor Drug Program to ensure appropriate and safe utilization.

Clinical Information Included in this Document

Makena Injection

- **Drugs requiring prior authorization:** the list of drugs requiring prior authorization for this clinical criteria
- **Prior authorization criteria logic:** a description of how the prior authorization request will be evaluated against the clinical criteria rules
- **Logic diagram:** a visual depiction of the clinical criteria logic
- **Supporting tables:** a collection of information associated with the steps within the criteria (diagnosis codes, procedure codes, and therapy codes); provided when applicable
- **References:** clinical publications and sources relevant to this clinical criteria

Note: Click the hyperlink to navigate directly to that section

Revision Notes

Updated 'Drugs requiring PA' table to include generic products, page 2
Removed question 1 (Is client female?) and added dosing for 275mg SQ auto-injector in question 6 in logic and logic diagram, pages 3-4
Added Table 3, to include ICD-10s for preterm birth, page 5
Updated references, page 6



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Drugs Requiring Prior Authorization

The listed GCNS may not be an indication of TX Medicaid Formulary coverage. To learn the current formulary coverage, visit TxVendorDrug.com/formulary/formulary-search.

Drugs Requiring Prior Authorization	
Label Name	GCN
HYDROXYPROGEST 1250 MG/5 ML	39946
HYDROXYPROGEST 250 MG/ML VIAL	40784
MAKENA 1250 MG/5 ML VIAL	39946
MAKENA 250 MG/ML VIAL	40784
MAKENA 275 MG/1.1 ML AUTOINCT	44459



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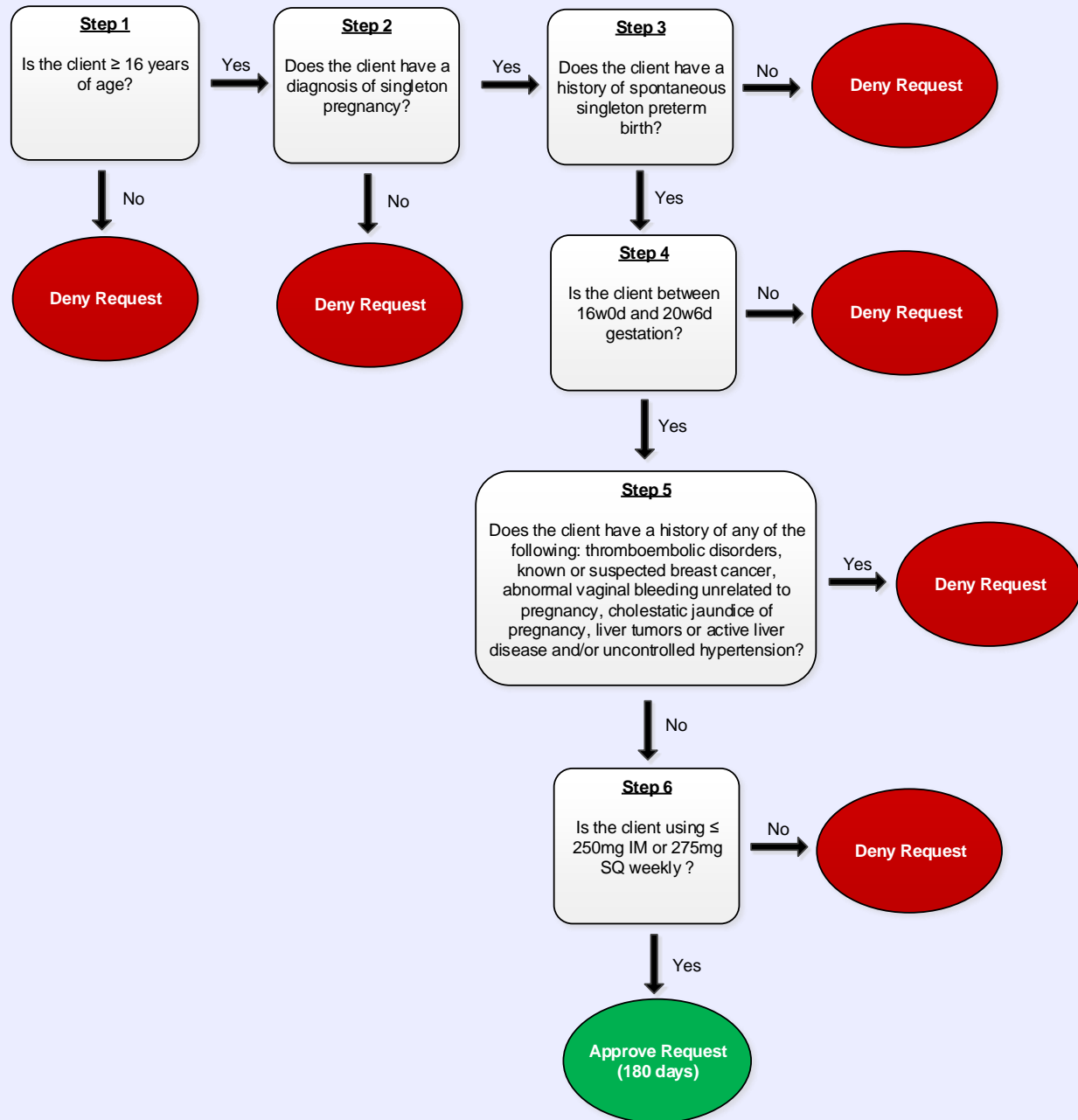
Clinical Criteria Logic

1. Is the client greater than or equal to (\geq) 16 years of age?
 Yes (Go to #2)
 No (Deny)
2. Does the client have a diagnosis of singleton pregnancy?
 Yes (Go to #3)
 No (Deny)
3. Does the client have a history of **spontaneous singleton preterm birth**?
(Note: ICD-10 codes for spontaneous singleton preterm birth can be found in Table 3)
 Yes (Go to #4)
 No (Deny)
4. Is the client between 16w0d and 20w6d gestation?
 Yes (Go to #5)
 No (Deny)
5. Does the client have a history of any of the following: thromboembolic disorders, known or suspected breast cancer, abnormal vaginal bleeding unrelated to pregnancy, cholestatic jaundice of pregnancy, liver tumors or active liver disease and/or uncontrolled hypertension?
 Yes (Deny)
 No (Go to #6)
6. Is the client using less than or equal to (\leq) 250mg intramuscularly (IM) or 275mg subcutaneously (SQ) weekly?
 Yes (Approve – 180 days)
 No (Deny)



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Clinical Criteria Logic Diagram



**Makena (hydroxyprogesterone caproate)****Clinical Criteria Supporting Tables**

Step 3 (diagnosis of spontaneous singleton preterm birth)	
Required diagnosis: 1	
ICD-10 Code	Description
O09212	SUPERVISION OF PREGNANCY WITH HISTORY OF PRE-TERM LABOR SECOND TRIMESTER
O09213	SUPERVISION OF PREGNANCY WITH HISTORY OF PRE-TERM LABOR THIRD TRIMESTER
O09219	SUPERVISION OF PREGNANCY WITH HISTORY OF PRE-TERM LABOR UNSPECIFIED TRIMESTER



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Clinical Criteria References

1. Clinical Pharmacology [online database]. Tampa, FL: Elsevier/Gold Standard, Inc.; 2018. Available at www.clinicalpharmacology.com. Accessed on August 22, 2018.
2. Micromedex [online database]. 2018. Available at www.micromedexsolutions.com. Accessed on August 22, 2018.
3. Makena Prescribing Information. Waltham, MA. AMAG Pharmaceuticals, Inc. February 2018.
4. 2019 ICD-10-CM Diagnosis Codes, Volume 1. 2019. Available at www.icd10data.com. Accessed on May 16, 2019.

Publication History

The Publication History records the publication iterations and revisions to this document. Notes for the *most current revision* are also provided in the **Revision Notes** on the first page of this document.

Publication Date	Notes
08/22/2018	Initial publication
03/29/2019	Updated to include formulary statement (The listed GCNS may not be an indication of TX Medicaid Formulary coverage. To learn the current formulary coverage, visit TxVendorDrug.com/formulary/formulary-search .) on each 'Drug Requiring PA' table
05/14/2019	Updated 'Drugs requiring PA' table to include generic products, page 2 Removed question 1 (Is client female?) and added dosing for 275mg SQ auto-injector in question 6 in logic and logic diagram, pages 3-4 Added Table 3, to include ICD-10s for preterm birth, page 5 Updated references, page 6