

Makena

Clinical Edit Criteria

Drug/Drug Class:



Makena

Superior HealthPlan follows the guidance of the Texas Vendor Drug Program (VDP) for all clinical edit criteria. Superior has adjusted the clinical criteria to ease the prior authorization process regarding this clinical edit. Criteria question requiring age 16 or older has been removed and the allowable time to start therapy has been extended. Criteria question regarding diagnosis has been adjusted to include an expanded definition of single spontaneous preterm birth and removes ICD-10 requirement. Adjusted criteria steps are outlined/highlighted in yellow.

The original clinical edit can be referenced at the Texas Vendor Drug Program website located at <https://paxpress.txpa.hidinc.com/makena.pdf>.

Clinical Edit 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 edit 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

Please note: All tables are provided by original Texas Vendor Drug Program Edit.

Superior HealthPlan Clinical Edit – Makena

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 275 MG/1.1 ML AUTOINCT	44459

Clinical Criteria Logic Makena (hydroxyprogesterone caproate)

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 Member have a history of spontaneous singleton preterm birth? *Defined as a singleton live birth at age 16 weeks 0 days to 36 weeks 6 days or stillbirth before 24 weeks presenting as labor, ruptured membranes or advanced cervical dilation or effacement. (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 16 weeks 0 days and 20 27 weeks 6 days 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)

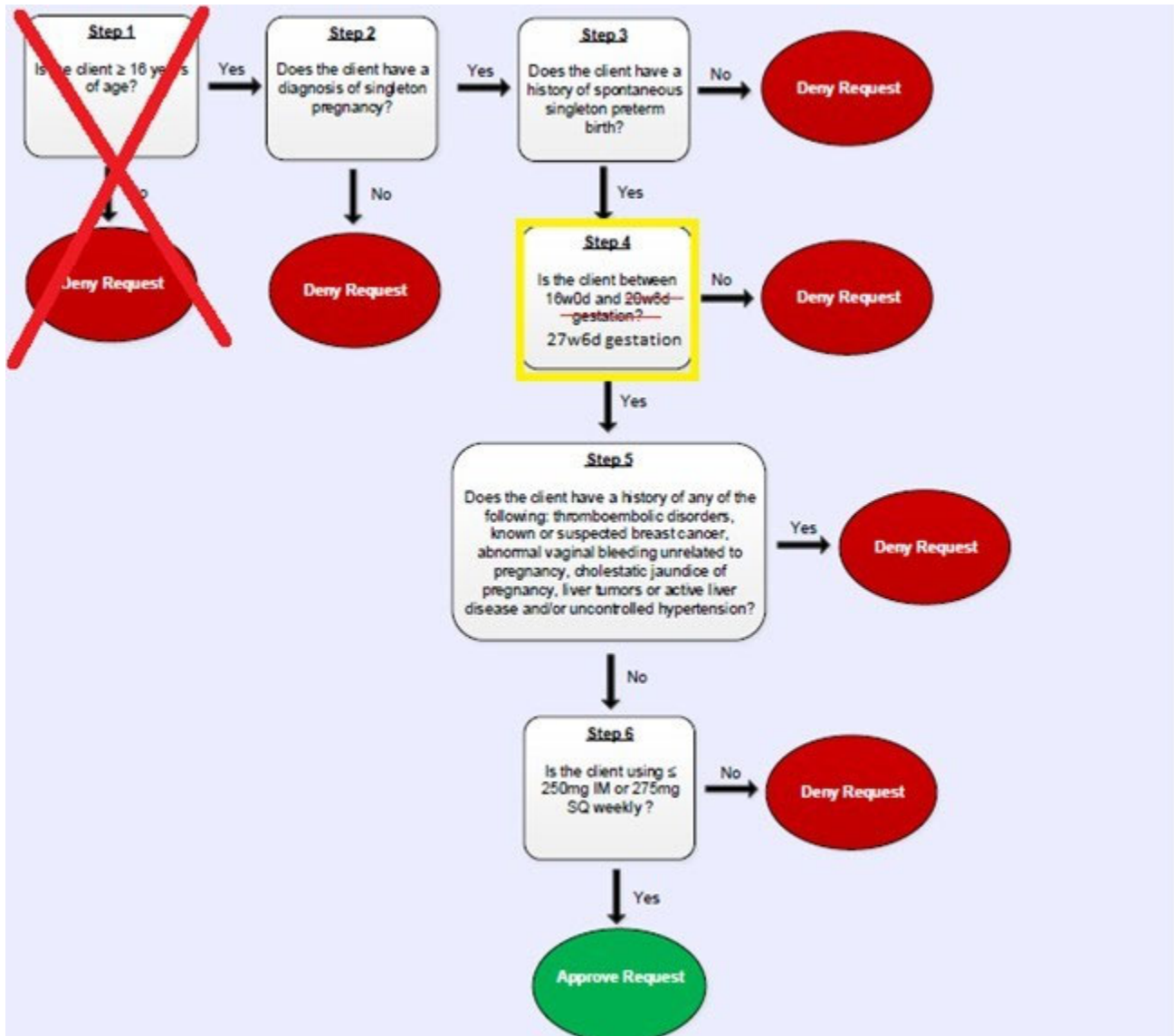
☐ No (Go to #6)

6. Is the client using less than or equal to (\leq) 250mg intramuscularly (IM) or 275mg subcutaneously (SQ) weekly?

☐ Yes (Approve)

☐ No (Deny)

Clinical Edit Logic Diagram Makena (hydroxyprogesterone caproate)



* Superior has adjusted the clinical criteria to ease the prior authorization process regarding this clinical edit. Criteria question one requiring age 16 or older has been removed and criteria question 4, regarding the allowable time to start therapy, has been extended.

Clinical Criteria References:

1. Clinical Pharmacology [online database]. Tampa, FL: Elsevier/Gold Standard, Inc.; 2018. Available at www.clinicalpharmacology.com. Accessed on September 29, 2021.
2. Micromedex [online database]. 2018. Available at www.micromedexsolutions.com. Accessed on September 29, 2021.
3. Makena Prescribing Information. Waltham, MA. AMAG Pharmaceuticals, Inc. February 2018.
4. Hydroxyprogesterone caproate Prescribing Information. Baudette, MN. ANI Pharmaceuticals Inc. June 2016.
5. 2019 ICD-10-CM Diagnosis Codes, Volume 1. 2019. Available at www.icd10data.com. Accessed on May 16, 2019.
6. Rundell K and Panchal B. Preterm Labor: Prevention and Management. Am Fam Physician. 2017 Mar;95(6):366-372.
7. Norwitz, ER. (2021) Progesterone supplementation to reduce the risk of spontaneous preterm birth. In CJ Lockwood (Ed), UpToDate. Accessed September 29, 2021.

Publication History:

Publication Date	Notes
6/15/2015	Clinical edit added
2/14/2017	Added reference tables, references and publication table per UMCM Chapter 3 requirements.
10/2/2017	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.
11/5/2018	Added Makena Auto injector and generics to available products, consolidated references, updated clinical steps to make the final step easier to read and adjusted gestation period.
6/24/19	Criteria cross referenced to newly released VDP criteria. Again original clinical edit was approved by HHSC several years ago. Criteria logic and diagram updated to match VDP with plan exceptions to question 1 (removed) and 4 (time extended on when Makena can be initiated). Supporting Tables section added. References updated to match VDP criteria.
4/5/20	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.
4/14/20	Updated URL link to VDP
10/5/21	Criteria question regarding diagnosis has been adjusted to include an expanded definition of single spontaneous preterm birth and removes ICD-10 requirement.
4/15/22	Removed GCNs for Makena (39946 and 40784) Updated references