POLICY AND PROCEDURE

POLICY NAME: Makena Clinical Criteria for Authorization via Medical Benefit	**POLICY ID:** TX.PHAR.15
BUSINESS UNIT: Superior HealthPlan	**FUNCTIONAL AREA:** Pharmacy
EFFECTIVE DATE: 06/01/15	**PRODUCT(S):** STAR, STAR HEALTH, STAR PLUS, STAR Kids, CHIP
REVIEWED/REVISED DATE: 03/2016, 11/2016, 09/02/17, 09/2018, 06/2019, 03/15/20, 03/10/21, 10/01/21, 10/01/22	
REGULATOR MOST RECENT APPROVAL DATE(S): N/A	

POLICY STATEMENT:
Clinical policies are intended to be reflective of current scientific research and clinical thinking. This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care and are solely responsible for the medical advice and treatment of members.

PURPOSE:
The purpose of this Clinical Policy is to provide a guide to medical necessity reviews for Makena under the medical benefit.

Subject
Prior authorization of Makena® (hydroxyprogesterone caproate injection) for the prevention of recurrent pre-term delivery.

Description
The intent of the criteria is to ensure that patients follow selection elements established by Superior HealthPlan policy, this policy will be required for coverage of Makena under the medical benefit.
Consistent with the regulation at 42 CFR Section 438.210 and 42 CFR Section 457.1230(d), services covered under managed care contracts, including clinician-administered drugs, must be furnished in an amount, duration, and scope that is no less than the amount, duration, and scope for the same services specified in the state plan.

While MCOs may place appropriate limits on drugs, MCOs may not use a standard for determining medical necessity that is more restrictive than what is used in the state plan, i.e., developed by the Vendor Drug Program (VDP). For example, if a member is denied a clinician administered drug in managed care because of the MCO's prior authorization criteria, but would have received the drug under the criteria specified in the state plan, then the MCO's prior authorization criteria would violate the amount, duration, and scope requirements cited above. HHSC intends to amend the Managed Care Contracts at the next opportunity to include this requirement. This same standard applies to CHIP formulary and CAD coverage.

Refer to the Outpatient Drug Services Handbook of the Texas Medicaid Provider Procedure Manual for more details on the clinical policy and prior authorization requirements.
Compared to VDP criteria for Makena through the medical benefit, the allowable time to start therapy has been extended.

FDA Approved Indications
Makena is indicated to reduce the risk of preterm birth in women with a singleton pregnancy and a history of singleton spontaneous preterm birth. Makena is not intended for use in women with multiple gestations or other risk factors for preterm birth.

Safety
Makena works as a long acting progestin when administered intramuscularly. Although the exact mechanism by which Makena reduces the risk of preterm birth is unknown, mechanisms of endogenous progesterone include relaxation of uterine smooth muscle, blocking the action of oxytocin, and maintenance of pregnancy.[10]

Preterm birth is defined as birth occurring before 37 weeks gestation and it occurs in approximately 12% of all live births in the US. It is a leading cause of infant death and long-term disability. Preterm birth related healthcare costs reached approximately $26 billion in 2005. Women who have had a spontaneous preterm delivery are at a greatly increased risk for preterm delivery in subsequent pregnancies. The earlier in the pregnancy a preterm delivery occurs, the greater the chance of preterm delivery in a subsequent pregnancy.[9]

Studies have shown that administration of a weekly intramuscular injection of 17-alpha-hydroxyprogesterone caproate (17P) in patients with a previous spontaneous singleton preterm delivery resulted in a significant reduction in the rate of recurrent preterm delivery and decreased neonatal intensive care unit admissions. The studies demonstrating the greatest benefit show that 17P should be initiated between 16 and 20 6/7 weeks gestation. Studies have shown some benefit with initiation up to ≤ 27 6/7 weeks gestation, but the likelihood of preventing an early premature delivery is reduced and the current FDA labeled indication is for initiation between 16-20 6/7 weeks.[11] *Superior will allow the prolonged window to start the drug.* There is no current evidence to support starting 17P after 28 weeks gestation.[2,4,6,7,8] Makena should be considered an option to reduce the risk of premature birth in singleton gestation women with a history of spontaneous preterm singleton birth.[1,11] It should be initiated between 16 and 20 6/7 weeks gestation and continued until 36 6/7 weeks gestation or delivery, whichever occurs first.[12]

Carefully monitor for and consider recommendations if any of the following conditions occur during use:[5]

Safety Concern	Recommendation
Thromboembolic events	Discontinue Makena
Allergic reactions (urticaria, pruritus, angioedema)	Consider discontinuing Makena
Decreased glucose tolerance	Monitor in pre-diabetic and diabetic women
Fluid retention	Monitor in women with conditions that may be adversely effected by fluid retention (cardiac or renal dysfunction, preeclampsia, epilepsy, migraine, asthma)
Depression	Monitor in women with a history of depression. Discontinue Makena if depression recurs.
Jaundice	Monitor and consider benefits vs. risk of continuing treatment
Hypertension	Monitor women who develop hypertension while receiving Makena and consider benefits vs. risks of continuing

SCOPE:
Pharmacy, Medical Directors

DEFINITIONS: N/A

POLICY:
It is the policy of Superior HealthPlan that Makena is **medically necessary** in the prevention of preterm delivery for women who meet the following criteria as applied to the medical benefit.

Please note, approval prior to 16 weeks gestation: Makena requests may be submitted for approval just prior to 16 weeks, 0 days gestation to allow time for the prior authorization approval process and shipping from the pharmacy.

PROCEDURE:

I. Approval Criteria

1. Does the Member have a diagnosis of singleton pregnancy?
[ ] Yes (Go to #2)
[ ] No (Deny)

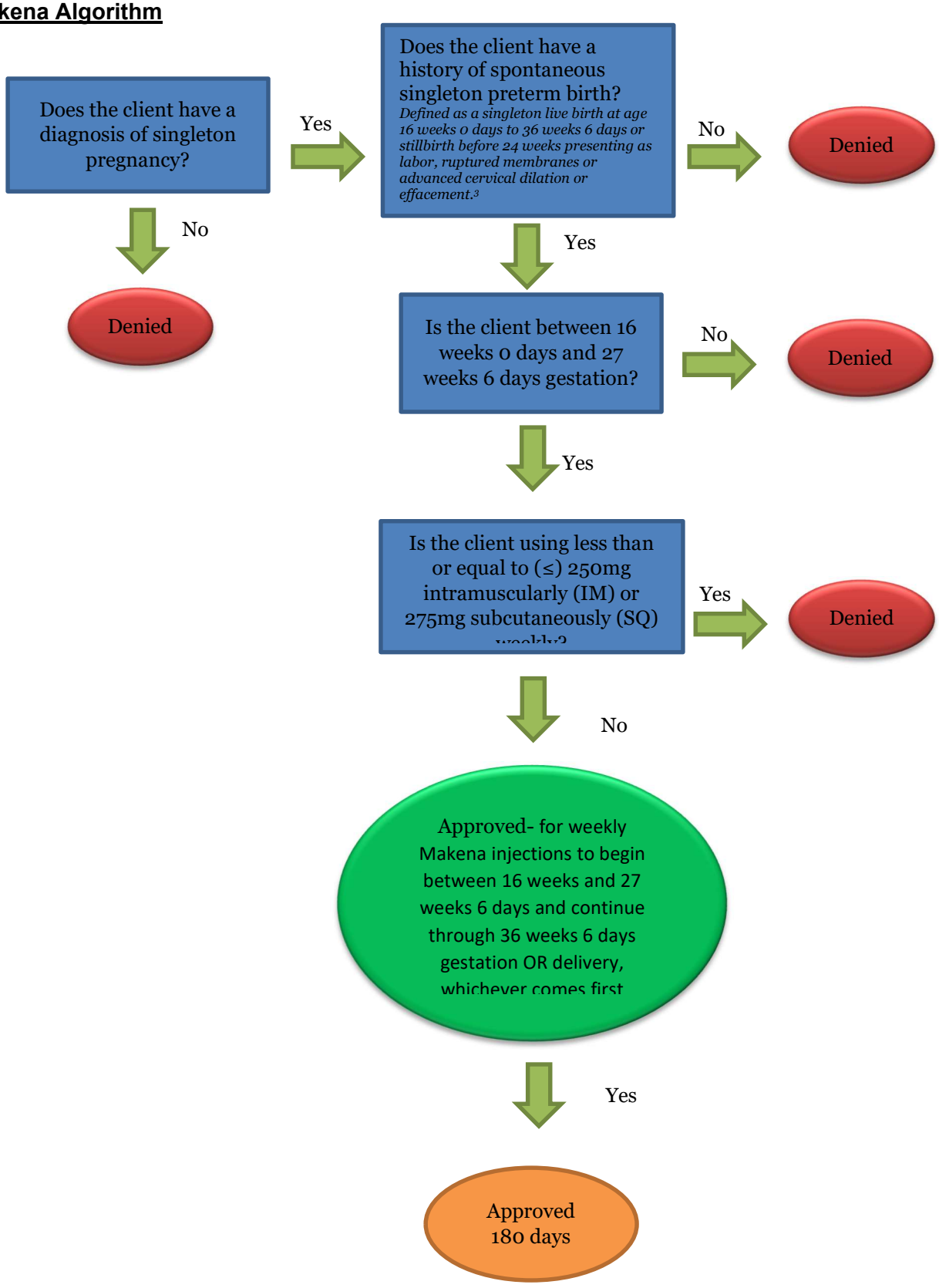
2. Does the Member have a history of spontaneous singleton preterm birth? *Defined as a singleton live birth at age 16 weeks 0 days to 36 weeks 6 days or stillbirth before 24 weeks presenting as labor, ruptured membranes or advanced cervical dilation or effacement.*[3]
[ ] Yes (Go to #3)
[ ] No (Deny)

3. Is the Member between 16 weeks 0 days and 27 weeks 6 days gestation?
[ ] Yes (Go to #4)
[ ] No (Deny)

4. Is the Member using less than or equal to (≤) 250mg intramuscularly (IM) or 275mg subcutaneously (SQ) weekly?
[ ] Yes (Approve for weekly Makena injections to begin between 16 weeks and 27 weeks 6 days and continue through 36 weeks 6 days gestation OR delivery, whichever comes first)
[ ] No (Deny)

**This policy is adapted from Texas Medicaid Provider Procedures Manual criteria for hydroxyprogesterone caproate. The original clinical criteria can be located at https://www.tmhp.com/resources/provider-manuals/tmppm.*

Makena Algorithm



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References for Additional Information

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9. U. S. Food and Drug Administration. FDA Statement on Makena. March 30, 2011. http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm249025.htm

ATTACHMENTS: N/A

ROLES & RESPONSIBILITIES: N/A

REGULATORY REPORTING REQUIREMENTS: N/A

REVISION LOG

REVISION TYPE	REVISION SUMMARY	DATE APPROVED & PUBLISHED
New Policy Document	N/A	06/01/15
Ad Hoc Review	Added statement to allow processing just prior to gestational week 16 day 0	10/2015
Ad Hoc Review	Added statement to “criteria as applied to the pharmacy benefit” to the Policy/Critera section	03/2016
Ad Hoc Review	Removed Gayle Dichter and added Justin M. Weiss on Approval Added STAR Kids to Product Type	11/16/16
Annual Review	Changed Makena algorithm to allow injections to begin up to 27 6/7 weeks gestation Added “David” to Dr. David Harmon as an approver	09/20/17
Annual Review	Added “and Medical” to the name and body of document. Updated Makena algorithm to condense content of boxes 4 and 5 to a single box	09/2018
Ad Hoc Review	Updated Policy/Criteria and Makena Algorithm sections to reflect VDP guidance. VDP permits the criteria to be voluntary and thus less strict than VDP has written. Age edit on VDP criteria omitted. Lengthened window to start Makena is approved per PA. Also defined previous spontaneous birth for internal reference. Updated description section regarding applying criteria to medical and pharmacy benefit. Updated references to include TX VDP criteria references, ACOG and Iams article added. Removed Justin Weiss and added Karen Tadlock on Approval	06/2019
Annual Review	No changes	03/15/20
Annual Review	No changes	03/10/21
Annual Review	Removed pharmacy benefit references and cross referenced Texas Medicaid Provider Procedures Manual criteria for hydroxyprogesterone caproate Removed step checking for contraindications	10/01/21
Ad Hoc Review	Updated references	10/01/22

POLICY AND PROCEDURE APPROVAL

The electronic approval retained in RSA Archer, the Company’s P&P management software, is considered equivalent to a signature.