

17P: Makena vs. Compounded and the New UUHSC Prescription Algorithm

**Erin Clark, MD
Maternal Fetal Medicine
University of Utah Health Care**



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17P: Level A evidence

- “A woman with a singleton gestation and a prior spontaneous preterm singleton birth should be offered progesterone supplementation starting at 16-24 weeks of gestation...to reduce the risk of recurrent spontaneous preterm birth.”
- Reduces risk by approximately 30%

ACOG Practice Bulletin #130, 2012 (reaffirmed 2014)

Makena

- FDA approved in February 2013
- Now made and marketed by *Lumara Health* (previously *KV Pharmaceuticals*)
- Compounding persisted widely due to concerns regarding cost

Drug Quality & Security Act

- Signed into law December 2013
- Followed the 2012 case of contaminated compounded steroid injections from a New England compounding pharmacy that led to 751 cases of fungal meningitis in 20 states (64 deaths)
- New law contains stricter provisions
 - Compounding pharmacies cannot compound a product that is identical to a commercial product
 - Gives FDA more authority to require recalls of poorly compounded drug and allows FDA inspections

Drug Quality & Security Act

- Over the past 2 years, the FDA has inspected hundreds of compounding pharmacies and found serious quality problems
- Utah:
 - Compounding pharmacies in Utah cited
 - Utah State law does not allow pharmacies to compound copies of commercial products

UUHSC

- Legal felt we were out of compliance with State and Federal law
 - UU Health Plans and Healthy U Medicaid need to cover Makena
 - Done- compounded now only covered if documented allergy to Makena or 'lack of efficacy'
 - Other Utah Medicaid providers should also cover Makena...
 - March 10, 2015, Utah Medicaid now covers commercial Makena and compounded

Other Payers

- Other Payers
 - Variable coverage
 - Variable co-pays (often very high)

Regardless of payor, there is going to be increasing pressure - for legitimate safety reasons - to prescribe Makena unless justifiable reason to do otherwise...

Prescribing 17P

- Requires that providers navigate:
 - Coverage
 - Medical or pharmacy pre-authorization
 - Co-pays
 - Makena co-pay assistance
 - Prescription to appropriate pharmacy
 - Medication pick-up
 - Medication teaching and administration

Prescribing 17P

- UUHSC needs a single point person!
 - Accessed by all prescribers
 - Easy, efficient prescription process
 - Take prescription and work through A-Z, without further prescriber involvement, culminating in the patient receiving the drug

Several meetings, involving 20+ multidisciplinary representatives, later....

17P Algorithm



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UNIVERSITY SPECIALTY &
HOME INFUSION PHARMACY

Makena Referral Process to University Specialty & Home Infusion Pharmacy (UHIP)

Referral

- Prescriber will write prescription for **Makena** first line for all patients
- EPIC E-Prescribe: U of Utah Specialty & Home Infusion
 - In notes section indicate that it may be substituted with compounded product
- Email: HomeInfusion@utah.edu w/patient information & any specific coordination or patient issues (timeline, ability to do self injections, etc.)

17P Algorithm

Minimum 2-3 business days

Benefit Check &
Clinical
Coordination

- UHIP will perform benefit check (pharmacy & major medical)
- If Makena is covered: 1st line: UHIP → 2nd line: UofU Retail Pharmacy → 3rd line: External Specialty Pharmacy (via Makena Care Connection)
- If Makena is NOT covered, UHIP will send prescription for compounded product to IHC Home Care Pharmacy (Fax 801-442-0711; Phone 385-887-7351) using IHC order form
- For unfunded patients: will utilize Makena Patient Assistance (if applicable) or pursue 17 OHP via IHC self-pay (\$60 per vial)
- Will email/call clinic to coordinate care
- EPIC Progress Note with "Pharmacy" as Service regarding final plan & pharmacy

17P Algorithm

Mini

Makena Delivery & Administration

- No clinic deliveries; will deliver direct to patient or have patient pick up near appointment date
- As default, patient will bring Makena to clinic for 1st injection & teaching, then self-administer all subsequent injections
- If unable to self-administer, weekly clinic visits or Home Health if insurance allows
- UHIP & UofU Retail pharmacies will provide all supplies necessary for self-injection (i.e. needles, syringes, etc.)
- UHIP will continue to coordinate care and monitor patient until end of therapy (week 36 or delivery)

17P Patient Information



17P FOR PREVENTING PRETERM BIRTH

Fact Sheet for Patients & Families ● ● ● ● ● ●

WHAT IS 17P?

The abbreviation "17P" stands for 17-alpha-hydroxyprogesterone caproate. It's a type of progesterone, a hormone naturally produced by the placenta during pregnancy. The medication 17P is prescribed by a doctor to help prevent preterm birth.