17P Helping Babies to Fully Develop

Progesterone to **Prevent Repeat Preterm Birth**

Weekly intramuscular injections of 17P beginning between 16-21 weeks gestation has been associated with a 33% reduction in the rate of recurring preterm delivery.

Inside

About	2
Screening	2
Billing	3
Facilitative Treatment	4
About Auto-Injectors	6
Auto-Injectors vs IM Injection	6
Patient & Provider Resources	7
17P Contacts	8

NOTE References are available for healthcare professionals at MomBaby.org

UNC SCHOOL OF MEDICINE
Center for Maternal and Infant Health

About **17P**

Research has shown that injections of progesterone (17-hydroprogesterone) can result in a 33% reduction in the rate of preterm delivery (Meis et al., 2003). To date, no studies have shown an association between 17P and congenital anomalies or other neonatal developmental problems.

Who should use 17P?

Women with singleton gestations with a previous history of spontaneous preterm delivery of a single baby should be considered as candidates for 17P.

Progesterone is not effective in preventing premature delivery in pregnancies at low risk for prematurity, multiple gestations, or in patients for whom preterm contractions have occurred.

Is 17P safe for mom and baby?

There are minimal risks for mothers taking 17P. Most common side effects include soreness, irritation, bruising, itching, swelling, and pain at the injection site.

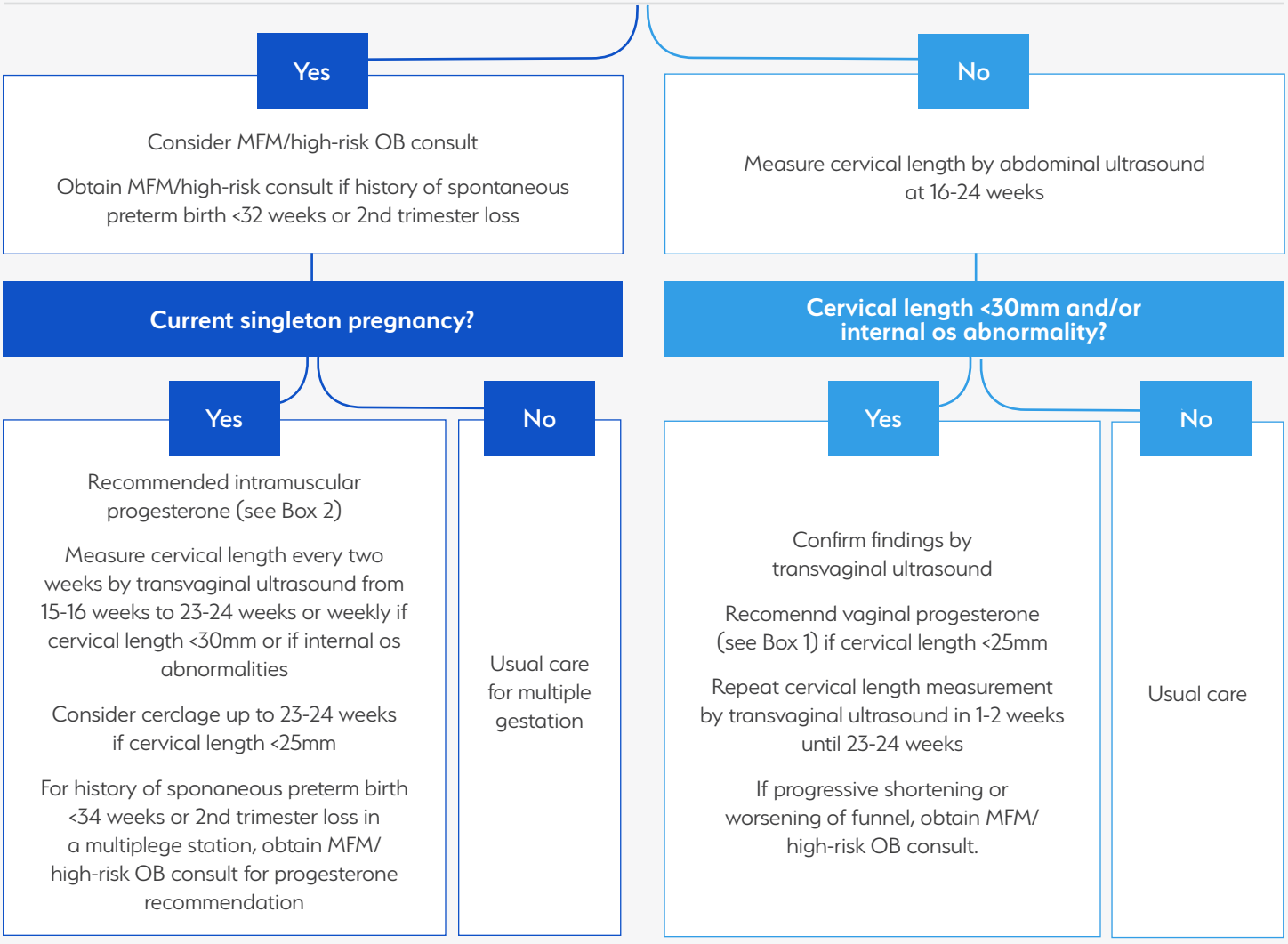
Randomized clinical trials have shown no increased risks of birth defects in babies born to mothers who have taken 17P and no differences in development of childhood health problems.

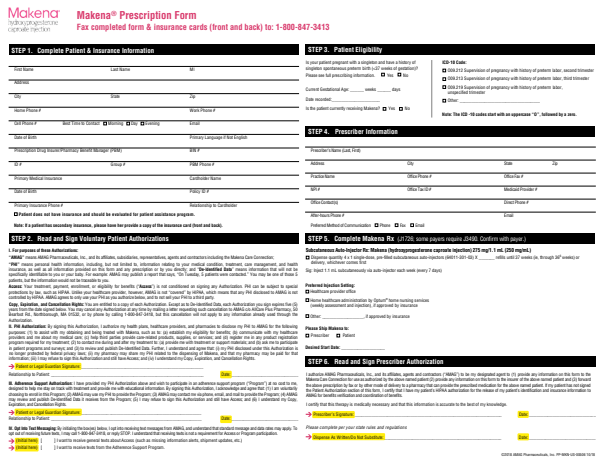
How should 17P be used?

Progesterone can used as a weekly intra muscular injection, ideally beginning at 16 weeks gestation and continuing to 36 weeks and 6 days.

Vaginal progesterone is recommended as a management option to reduce the risk of preterm birth in asymptomatic women with a singleton gestation without a prior preterm birth with an identified very short cervical length less than or equal to 20 mm before or at 24 weeks gestation.

History of spontaneous preterm birth (<37 weeks) or 2nd trimester pregnancy loss?





Makena® Prescription Form
Fax completed form & insurance cards (front and back) to: 1-800-847-3413

STEP 1. Complete Patient & Insurance Information

STEP 2. Read and Sign Voluntary Patient Authorizations

STEP 3. Patient Eligibility

STEP 4. Prescriber Information

STEP 5. Complete Makena Rx (J1726; some payers require J2480. Confirm with payer.)

STEP 6. Read and Sign Prescriber Authorization

Fax completed form and insurance cards (front and back) to: 1-800-847-3413

Makena® (hydroxyprogesterone caproate injection) Prescription Form Checklist

Help ensure patients have access to Makena + support via Makena Care Connection® and prescriptions are processed quickly by completing the steps below:

- ☐ Confirm the prescription form is completed and there is no missing information
- ☐ Include a copy of both sides of the patient insurance card(s), including secondary insurance if applicable
- ☐ Encourage patient to sign and initial patient authorizations (see Step 2) so that Makena Care Connection can work on their behalf
- ☐ Complete the *Dispense as Written* line as per your state requirements (see Step 6) to help protect the prescription from generic substitution
- ☐ Remind patient to respond to phone calls from Makena Care Connection and/or the pharmacy and confirm Makena is being shipped

Have questions? Connect with us.

1-800-847-3418 (Monday–Friday, 8 AM–8 PM ET)

info@makenacareconnection.com

Prescription Support | Financial Assistance | Education and Adherence | Home Injections by Healthcare Professionals

If you or your patients are ever in doubt regarding the status of their Makena prescription, please contact Makena Care Connection. We are committed to helping ensure your patients receive treatment in a timely and affordable manner. If a patient is concerned about their out-of-pocket cost for Makena, they should call Makena Care Connection at 1-800-847-3418 to see if they are eligible for financial assistance.

Billing Information

How do I bill for 17P for privately insured patients?

For patients with private health insurance, clinics should contact the insurance company to inquire about their protocol and procedures for purchasing and billing for this treatment.

What if my patient has Medicaid?

Several formulations of progesterone are covered by Medicaid under various structures, including compounded 17P through the Physician Drug Program and Makena through the Physician Drug Program and Point of Sale Pharmacy.

For more information about ordering progesterone for Medicaid insured patients, contact your Pregnancy Medical Home, OB Nurse Coordinator through your CCNC network.

What if my patient is un- or under-insured?

Clinics and providers can contact the Makena Patient Assistance Program through the Makena Care Connection to obtain medication for patients without insurance or with an unaffordable copay.

To begin the process, follow instructions on the Makena Referral/Prescription Form. This form can be accessed from **tinyurl.com/MakenaRxForm** It is very important to fully complete the form. Be sure to have patients sign the form before faxing. If the form needs to be processed very quickly, write RUSH on the top of the form. Once the form is completed it needs to be submitted to the company by fax to 1-800-847-3413.

NOTE If your patient is difficult to reach by phone, please make a note when completing the form and list your office number instead of her phone number.

Prior to approving, the Makena Care Connection team must speak with the patient. To speed up the process, call the Makena Care Connection team while faxing in the prescription form so that the patient may speak with customer assistance during that time. The Care Connection team is able to provide services in multiple languages, including Spanish.

Once approved, the medication will be sent to either the patient or the provider (as indicated on the form).

NOTE Medicaid reimbursement requires that the provider give the medication to the patient, so it is recommended that the medication be sent to the clinic.

Facilitative **Treatment**

Integrating 17P treatment into care requires thought across the treatment "cascade" from screening through treatment counseling, acceptance and adherence. There are many places across this continuum where improvements can be made.

Woman-Centered 17P Care

Research has shown that patients who perceive themselves as having a high-quality relationship with their clinicians are more likely to adhere to treatment recommendations. Studies show that the clinician-patient relationship is a crucial factor affecting adherence, especially as treatment continues over the long term.

Provider tips for supporting patient 17P adherence:

1. Providers should discuss possible adverse effects and share a benefit-risk profile.
2. Providers should take time to answer women's questions. Women who reported having received detailed answers to their questions also reported better adherence.
3. Providers should not rely on presenting written information but should mainly engage in giving answers.

The 17P Treatment Cascade

1. **Attend antenatal care**
2. **Be identified as eligible and offered 17P**
3. **Accept 17P**
4. **Receive 17P**
5. **Adhere to weekly injections**

Action Steps for Providers

Providers should provide ongoing encouragement and support during 17P treatment as adhering to weekly injections is difficult

Patients need to be continually reassured that 17P is safe for mom and baby

Providers should discuss 17P treatment during the postpartum visit with all patients who had spontaneous preterm births

Minimize the pain of injections by applying pressure to the gluteal area prior to giving the intramuscular injection and by administering the drug slowly; care in administering shots may motivate women to complete treatment

Assign the same nurse to administer the shot at each appointment – if she is good at giving the shot!

Incorporate injections into home visits or traveling nurse's responsibility

Increase awareness and marketing of 17P treatment and preterm birth to the general public and to reproductive age women

Focus groups conducted across the state have found the following barriers and facilitators to receiving 17P treatment:

17P Treatment Facilitators

- CMIH-produced 17P booklet content, resources, and tools were helpful in answering women's questions
- Care managers' praise, encouragement, counseling and continued education about 17P benefits aided treatment compliance
- Statewide marketing of preterm birth and of the benefits of 17P treatment boosted public awareness
- Adoption of best practices in care management in North Carolina's Pregnancy Medical Home program aided treatment compliance

17P Treatment Barriers

- Transportation, especially long distances or across counties
- Lack of perceived risk of preterm birth among women
- Competing stressors and priorities (no child care; not able to leave work for weekly appointments)
- Injection site discomforts and inconsistencies in injection administration
- Costs of 17P and payer billing issues
- Lack of provider buy-in toward the treatment

Auto-Injectors

Auto-injectors can be used as an alternative to the intramuscular injections given at the hip. These pre-filled, single-use injectors are ready-to-use and administered subcutaneously to the back of the arm. The needle is not visible at any point, and the full dose is administered within 15 seconds, compared to 1 minute or longer with intramuscular options.

As with intramuscular injections, initiation should begin at 16-20 weeks gestation, administered weekly, and continued through to delivery or 37 weeks and 6 days.

It is important to note that it is not possible to stop the device from administering the full dosage once injection has begun. Premature removal of the device could result in the patient receiving an incomplete dose of the medicine.

Auto-Injectors or Traditional Intramuscular Injections?

Standard progesterone treatment protocol has utilized a 21-gauge needle to intramuscularly deliver the hormonal dosage into the gluteus maximus. Auto-injectors were developed with the desired goals of increasing ease of administration as well as reducing patient-experience of injection-related pain or anxiety, without compromising the efficacy of the treatment.

Providers should discuss the pros and cons of both treatment methods with patients before prescribing.

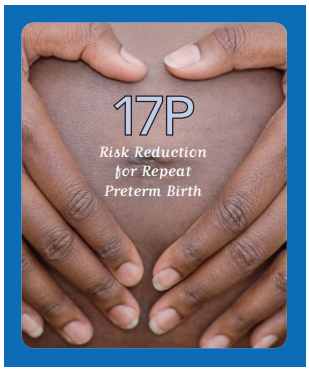
 **Auto-Injectors**	 **IM Injection**
Administered in arm	Administered in hip
27 gauge, 0.5 inch needle	21 gauge, 1 inch needle
Shorter injection time (15 seconds)	Full dose administered within 1 minute
More patients reported mild-moderate adverse experiences as a result of auto-injectors, including injection-site pain and diarrhea	Similar rates of adverse experiences of headache, nausea, and dizziness
Longer reported injection-site pain (up to 7 days)	Less mild-moderate injection site pain reported
Neither method has been approved for home administration.	
Both methods are covered by Medicaid, are the same price, and have the same treatment schedules.	

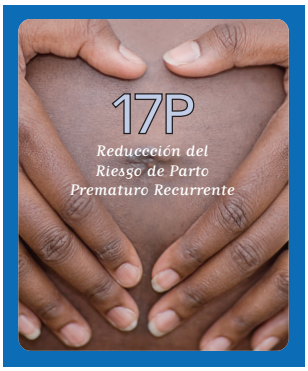
Krop, J., Kramer, W. G. (2017). Comparative bioavailability of Hydroxyprogesterone caproate administered via intramuscular injection or subcutaneous autoinjector in healthy postmenopausal women: A randomized, parallel group, open-label study. *Clinical Therapeutics* 39(12), 2345-2354.

Patient **Resources**

Displaying or dispensing the following resources in your office can be helpful when discussing 17P with a patient. These resources are available in English and Spanish and can be ordered for **free** from NC DHHS Women's Health Branch.

Is 17P Right For Me? is a one page handout that addresses the most common questions and concerns women have identified concerning 17P.

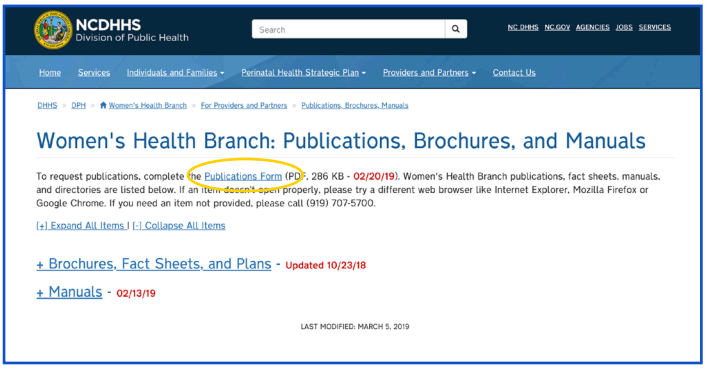




17P Risk Reduction for Repeat Preterm Birth Booklet is a self-help booklet for women considering 17P and includes helpful resources and injection-tracking tool sections.

Order All Materials for Free from the Women's Health Branch

1. Go to this link **tinyurl.com/WHBform**
2. Click the "Publications Form"
3. Print the form and fax in your order



Posters are also available to providers.

The following posters are designed to provide a general preterm birth message to help women who have had a prior preterm birth to initiate a conversation with their healthcare provider.

To receive posters, contact CMIH.

Resources for your Practice

A wealth of resources is available for providers and women on the Center for Maternal and Infant Health website.

mombaby.org/17-progesterone

17-Progesterone

A Women's Health Initiative to Reduce Recurring Preterm Delivery

The implementation of a strong 17P program requires the commitment of the full clinic team. Health care providers, patients, case managers, office managers and payers must come together to identify all eligible women, develop a collaborative plan to conveniently deliver and track 17P use, and assure that the woman and provider/clinic are reimbursed for this treatment.

It takes effort to establish a strong 17P program in your clinic. We are here to help! Please utilize and adapt the resources provided here and on our website for up-to-date information to assist your practice in the delivery of 17P to all eligible women.

Erin McClain, MA, MPH
UNC Center for Maternal and Infant Health

919-808-0989
erin_mcclain@unc.edu

UNC
SCHOOL OF MEDICINE
Center for Maternal and Infant Health

mombaby.org

17P Helping Babies to Fully Develop