17P Frequently Asked Questions

What are the criteria for treatment with 17P?	Women, with a *singleton* pregnancy who have a history of previous spontaneous singleton preterm delivery, between 20weeks 0days and 36weeks 6 days
How is 17P administered?	17Pcan be administered either intramuscularly or subcutaneously.
Can 17P be used for patients with history of singleton spontaneous preterm birth(s) who are currently pregnant with multiples?	17P is FDA approved for use only in *singleton* pregnancies *only*.
How well does 17P work?	In a large randomized, controlled trial, 17P lowered the recurrence risk of a repeat preterm birth by one-third (33%). (Meis PJ, et al, NEJM 2003) A second randomized, controlled trial (PROLONG) failed to demonstrate a reduction in recurrent PTB with use of 17P. (Blackwell SC, et al, Am J Perinatol 2019) In comparing the discordant results of the two trials, discordance in baseline demographic characteristics and obstetric history, including baseline PTB birth risk and number of recurrent PTB, may account for the differences is response to 17P.
Can vaginal progesterone be used instead of 17P?	Both formulations have been evaluated, but 17P has been more rigorously studied in women with a prior preterm birth and therefore is more commonly recommended. The choice of formulation may depend on the provider's interpretation of the literature and individualized assessment of other factors, such as insurance coverage, affordability, timely availability, and what formulation the patient will be most compliant with. Vaginal formulations can also be considered in cases of severe needle phobia or refusal of 17P.
Which vaginal progesterone formulations can be used?	Prometrium oral capsule (micronized progesterone USP) 200 mg* placed ***vaginally*** QHS through 36 weeks. These capsules should not be taken orally. (* some trials have use 100 mg) Compounded progesterone suppositories 200 mg vaginally QHS are also available (obtained from compounding pharmacies)

What if an otherwise eligible patient presents for care at 21 weeks?	You can place the order, which will be reviewed by the specific plan. Some plans may cover initiation of 17P up to 24 -27 weeks.
What if the patient misses a dose or will be out of town at the time of her next scheduled 17P injection?	The recommendation is for injections to be no sooner than 5 days and no later than 9 days apart. If no other options are available, a bridge of vaginal progesterone could be utilized from the day after the last injection until injections resume.
We ordered 17P at 15 weeks but are still waiting for insurance coverage at 20 weeks. What should we do?	Using vaginal products as a bridge is a reasonable solution while you contact the patient's insurance carrier to determine the cause for the delay.
Can an uninsured patient receive 17P? What if they cannot afford the copay?	The patient may be eligible to receive medication through the Makena Care Connection (www.Makena.com). If the patient is > 20 weeks 6 days gestation, she is not eligible for this assistance. The patient should call The Makena Care Connection 1-800-847-3418 and discuss her specific financial needs.
Is 17P safe for mother and baby?	There are minimal risks to this medication. The most common problems are soreness, irritation, itching, bruising, swelling and pain that can occur at the injection site. An increased risk for development of gestational diabetes has been reported in some studies. Studies have shown 17P to be safe for the fetus and it does not increase risks for birth defects. This medication is given in the second and third trimesters of pregnancy, after much of organogenesis has occurred. Results of both the Meis and PROLONG trial did not demonstrate an increase in congenital anomalies or evidence of teratogenic effects. Long-term outcomes are not known, although long-term adverse effects have not been reported.
Can the patient have a family member give the injection in the home?	Permission for home injections of 17P depends on the insurance plan.
Can 17P injections be discontinued prior to 36 weeks?	Discontinuation of 17P prior to 36 weeks may actually increase risk of preterm delivery in the current pregnancy

Should 17P be administered following preterm premature rupture of membranes (PPROM)?	Once PPROM has occurred, 17P should be discontinued.
Should 17P be administered to patients in preterm labor?	If the patient is not in active labor or delivery does not appear imminent, 17P should be continued on the weekly dose schedule.