

Prior Spontaneous PTB assessment and treatment

- ❖ Confirm currently pregnant a singleton gestation with a prior history of a singleton spontaneous preterm birth less than 37 weeks of gestation.
- ❖ Counsel on the beneficial effects of progesterone therapy.
- ❖ Initiate progesterone therapy at 16 to 20 weeks and continue therapy to 36 weeks of gestation.
- ❖ Prior SPTB< 34 wks: Offer cervical length screening at 16-18 weeks and every 2 weeks up through 22 weeks.
- ❖ Cervical length < 25 mm candidate for cerclage.
- ❖ Patients with a visibly abnormal cervix should be referred to MFM specialist for evaluation.

Progesterone Formulations

Indications for Use	Progesterone formulation	Dosage	Trial reference
Prior sPTB	17 α-hydroxyprogesterone caproate*	250mg IM weekly	(Meis et al., 2003)
Prior sPTB or short cervical length (<20 mm)	Vaginal suppositories#	100 mg vaginal suppository every night	(da Fonseca et al., 2003)
Prior sPTB or short cervical length (<20 MM)	Micronized capsules†	200 mg vaginally daily	(Fonseca et al., 2007)
Short cervical length between 10 and 20 mm	8% vaginal progesterone gel	90 mg vaginally daily	(Hassan et al., 2011)

Progesterone Availability

*17-P is available through the Alabama Medicaid Pharmacy Plan as the commercial brand Makena®. For patients who have not yet received Medicaid approval, or who do not qualify for the Alabama Medicaid Maternity Care Program, 17-P can be obtained through the Makena Care Connection patient assistance program 1-800-847-3418. Compounded 17-P is available only with prior approval from Medicaid.

#Progesterone vaginal suppositories are not clinically available but can be obtained from compounding pharmacies for patients desiring that mode of therapy.

†Micronized progesterone capsules are marketed generically and are the same medication as the commercial brand Prometrium. Progesterone gel is marketed as 8% Crinone gel; it is not currently available generically. Neither of these formulations is currently FDA approved for a preterm birth prevention indication. Prometrium is covered by the Alabama Medicaid Pharmacy Plan, Crinone gel is not.

Quality Indicators/Benchmarks

- ❖ Progesterone treatment in women with a current singleton pregnancy and a prior singleton sPTB who present for care by 20 weeks of gestation.
- ❖ Cervical length ultrasound in women with a prior sPTB who present for care before 22 weeks.

APEC acknowledges that not all providers and patients will have equal access to cervical length screening according to the schedule outlined above. This indicator is being examined in order to identify opportunities to remove barriers to care and enhance resource provision to patients throughout the state.

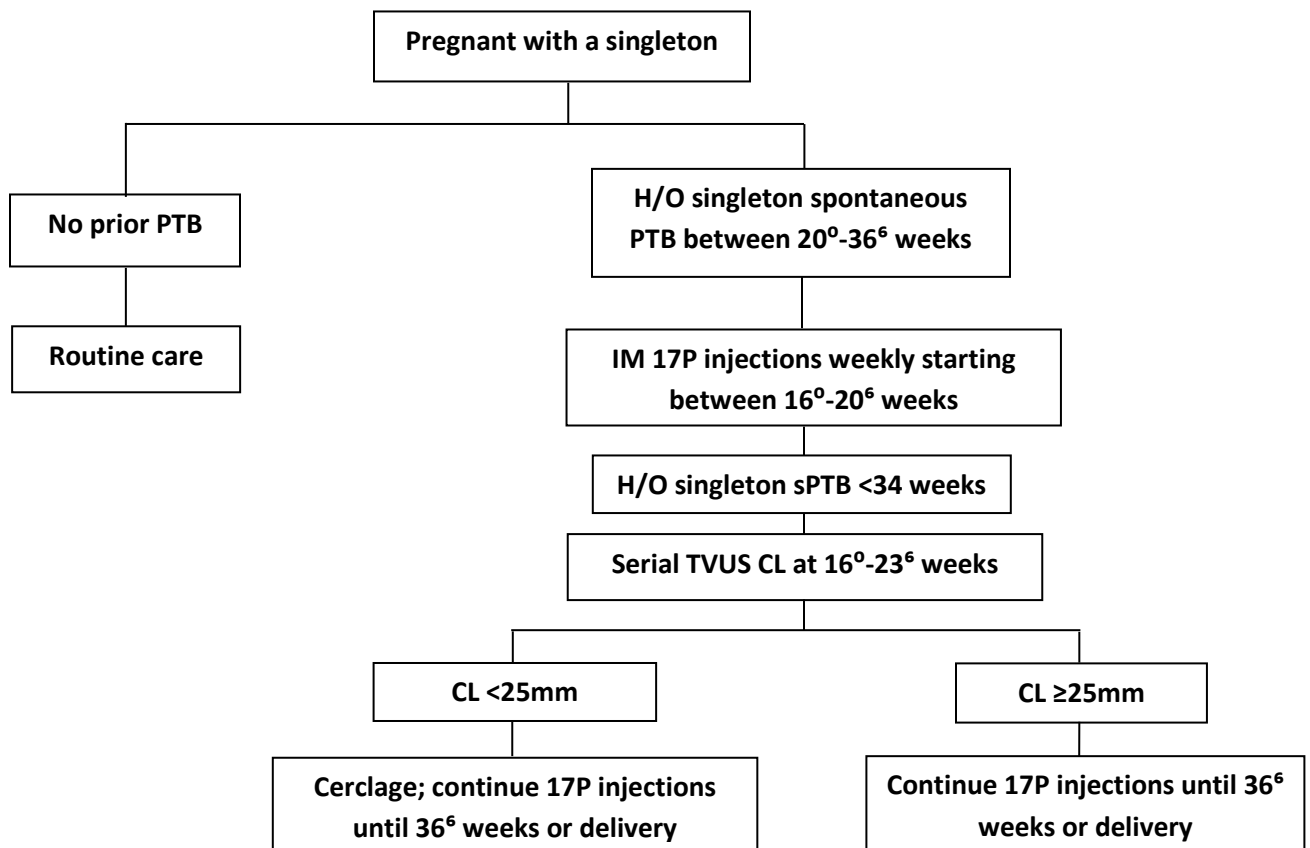
APEC Guidelines
Prior Spontaneous PTB

17 α -hydroxyprogesterone caproate clinical eligibility:

- Singleton pregnancy
- Prior singleton spontaneous preterm birth <37 weeks of gestation

Patients must meet the FDA-approved indication for 17-P defined as current singleton pregnancy with a **history of singleton spontaneous preterm birth less than 37 weeks** of gestation.

Risk factor for preterm birth	Injectable HPC	Comments
History of singleton spontaneous preterm birth	✓	IM 17-P has been shown to be effective in women with a history of singleton SPTB <37 weeks.(da Fonseca et al., 2003; Meis et al., 2003; O'Brien, Adair, Lewis, & al., 2007) Once initiated, patients should remain on 17P injections, regardless of detection of short cervical length or use of cerclage.
Short cervix with no history of preterm birth	Not indicated	IM 17-P has not demonstrated efficacy in women without a history of preterm birth who have a short cervix.(Grobman et al., 2012)
Multiples (twins, triplets, etc.)	Not indicated	IM 17-P has not demonstrated efficacy in women pregnant with multiples.(Caritis et al., 2009; Combs et al., 2011; Rouse et al., 2007)
History of preterm birth of multiple gestation	Not indicated	IM 17-P has not demonstrated efficacy in women with a prior preterm birth of multiples.



Alabama Perinatal Excellence Collaborative

This document should not be construed as dictating an exclusive course of treatment or procedure to be followed.