



CONFIDENTIAL

FOR ALERE USE ONLY:
Faxed to Contract Pharmacy INITIALS
DATE TIME

Physician Plan of Treatment / Statement of Medical Necessity
Pharmacy-Compounded, Preservative-Free
17 Alpha-Hydroxyprogesterone Caproate (17P) Therapy

Center #: _____

Patient ID#: _____

Patient Name:
Address:
Phone(H): Phone (C):
DOB:
Hospital Start Date:
Home Care Service Dates Covered:
PPOT Expiration Date: Est. Date of Disch:
Primary Diagnosis:
Secondary Diagnosis:
Prog: GA: Ht: Wt:
Allergies:
Treatment Goal:

Nursing Service(s)
Medication Administration Per Rx
Other:
Other:

Equipment
Other:

Physician Orders
PHYSICIAN PREFERENCE ORDERS FOLLOWED
Provide anaphylaxis kit at initiation of service and administer for allergic reaction/anaphylaxis per protocol. Kit to include:
1 ea. - Epinephrine 0.3mg auto-injector 2 ea. - Diphenhydramine 25 mg capsules 1 ea. - Sterile alcohol pad
Dispense pharmacy-compounded 17 alpha-hydroxyprogesterone caproate 250mg/ml in a unit dose, preservative-free formulation. Clinical assessment of patient demonstrates preservative-free 17P is medically indicated for this patient based upon documented individual medical need:
Documented history of previous spontaneous preterm birth Current pregnancy at risk for preterm-birth
Sensitivity to preservatives Specific sensitivity to benzyl alcohol
Other:
Administer pharmacy-compounded 17 alpha-hydroxyprogesterone caproate (preservative-free) 250mg (1ml) IM weekly beginning
(date) until (date).
Weekly skilled nursing visit for medication administration and preterm labor / high-risk pregnancy assessment.
Physician to receive skilled nursing visit summary weekly OR upon request
NOTE: At end of service, physician will receive an injection record, a discharge summary, and the final medications list.
Additional Orders:

NOTE: Start of service will occur upon completion of benefits and eligibility verification, patient acceptance of service, and completion of administration consent forms.

Activity Level
No restrictions Daily activities with rest periods Modified bed rest Strict bed rest Other:

Table with 2 columns: Medications (prescription, OTC, nutraceuticals) and Drug, Dose, Route, Frequency.

Functional Limitations: None Hearing Speech Language Vision Other
Mental Status: Alert Oriented Other
Precautions / Safety Measures:
Diet:
For CA &/or Medicaid certified agencies only: Rehab. Potential: Ref./Discharge Plan:

I certify that this patient is under my care and that the above services are medically necessary and are authorized by me with the above written plan of treatment. My signature acknowledges that (i) I have received and reviewed the protocol that accompanies this plan of treatment and understand and accept responsibility for the patient's care, and (ii) my state medical license is current and valid as indicated below.
RBV Verbal Orders Dr. / , RN Date Time:
PHYSICIAN SIGNATURE License #/State: Date
Orders Reviewed / Received By ,RN Date: Time:

Pharmacy-Compounded, Preservative-Free 17 Alpha-Hydroxyprogesterone Therapy Protocol

1. The Physician Plan of Treatment (PPOT) is automatically discontinued upon patient's delivery.
2. Any patient-specific deviations from protocol should be noted on the original copy of the PPOT.
3. The physician will be notified on a weekly basis or upon request regarding the patient's status.
4. The physician will be notified and documentation completed per Alere policy if the patient demonstrates non-compliance with their plan of treatment.
5. Alere is to be notified of the hospital to be used for emergency care, alternate medical coverage when the primary physician is not available, and any referrals to specialty physicians or organizations that affect the patient's care.

Intervention for Adverse Drug Reactions (ADR)/Allergic Reactions/Anaphylaxis:

- a. For all adverse drug reactions while patient is on Alere service, clinicians will notify the physician and will follow Alere policy on adverse drug reaction reporting.
- b. **Suspected Mild Allergic Reaction** (symptoms: itching, rash, nausea, vomiting, abdominal cramps, diarrhea and/or anxiety):
 - Instruct patient/caregiver to stop infusion of medication immediately.
 - Instruct patient to take one diphenhydramine 25 mg capsule initially; repeat in 30 minutes if symptoms persist.
 - Notify physician.
- c. **Suspected Moderate to Severe Allergic Reaction** (symptoms: respiratory distress (wheezing, dyspnea, cyanosis), hypotension, thready pulse, swelling of eyes, lips or tongue, slurred/difficult speech, fever and/or vomiting):
 - Instruct patient/caregiver to stop infusion of medication immediately.
 - Contact emergency medical systems (e.g., "911") if warranted.
 - Instruct patient/caregiver to administer 0.3 mg of 1:1000 epinephrine IM into the patient's thigh or upper deltoid area.
 - Instruct patient to take two diphenhydramine 25 mg capsules (total dose 50 mg) if able.
 - Instruct patient to remain recumbent until paramedics arrive (if called).
 - Notify physician as soon as possible as to the events of the reaction and actions taken. The patient is instructed to notify the Alere center or physician for perceived decreases in fetal movement. The physician is notified immediately if the patient reports absent fetal movement.