



Understanding the Compounded 17P Administration Referral

Referring for the Alere Administration of Compounded 17P

Alere would like to share some information with you about **filling out the 17P administration referral form** and **requesting Alere administration of compounded 17P for your patients**.

If the form is not filled out correctly, the referral can be delayed significantly while we reach out to you for more information. We have tried to make this process as easy as possible while still complying with the law because we know having our 17P administration services for your patients makes a big difference to them and to you.

1. Why a medical reason for compounded 17P is needed.

The Alere compounding pharmacy requires that you indicate on the referral form the **medical reason for prescribing compounded 17P for your patient** and that you sign the referral form. Otherwise, the pharmacy **CANNOT** dispense compounded 17P to your patient. In enforcing this requirement, the pharmacy is following long-standing laws about compounding a drug. Those laws allow a pharmacy to compound a drug that is similar to but not “*essentially a copy of*” a commercially available FDA-approved drug, such as Makena®, as long as the prescribing physician has indicated that there is an individual medical need for the compounded drug rather than the FDA-approved drug. It is extremely important to both Alere and our pharmacy partner that we follow the compounding laws precisely so that you can be assured your patients are receiving an uninterrupted supply of safe and quality drugs.

2. What is “medical need?”

The decision to prescribe compounded 17P over Makena® must be medically-driven. The Alere referral form already lists some of the more common medical justifications for prescribing compounded 17P that could apply to your patient’s situation. If, in your medical judgment, you agree that one of them applies, simply check the applicable box.

If none of them applies, there is also a blank in which you can indicate your own MEDICAL reason for prescribing compounded 17P. You cannot use non-medical justifications, such as “I don’t like Lumara,” “Makena® is too expensive,” or “The patient doesn’t want preservatives.” You also cannot say “Hx of PTB” or something similar in that space because that is simply the criteria for prescribing hydroxyprogesterone caproate in any form, not a medical reason for prescribing compounded 17P instead of Makena®. Any justification other than a medical need cannot be accepted by our partner compounding pharmacy.

As an example...a physician written reason “reduce exposure to **benzyl alcohol**” **IS acceptable** while “reduce exposure to **preservatives**” is **NOT acceptable**.

3. What happens when the referral form is not filled out correctly?

THE WHOLE PROCESS STOPS. The Alere Center must attempt to obtain a MEDICAL reason and a signature from you before the compounding pharmacy can process the referral. Alere wants to avoid this situation whenever possible so that the care you want for your patient can be provided as promptly as possible.