Operational Guidance Regarding 17-P

As part of the Health and Human Services Commission (HHSC) initiative to reduce the number of pre-term births in Texas, HHSC has added Makena, the name-brand version of 17-alpha hydroxyprogesterone caproate (often referred to as 17P), to the pharmacy formulary effective June 15, 2015. Makena will be available as both a Medicaid pharmacy and medical benefit. The compounded version of 17P will continue to be available only as a Medicaid medical benefit.

The primary benefit of adding Makena to the formulary is enabling doctors to prescribe the drug and submit the prescription to a pharmacist who will then submit the claim and mail the drug to the physician's office without the physician having to purchase, stock, and submit a claim for the drug.

Makena as a Pharmacy Benefit

As a pharmacy benefit, Makena® will require a clinical prior authorization (PA) in fee-for-service (FFS) Medicaid and managed care organizations (MCOs) may elect to require the same PA. A link to the Makena PA form is available at http://www.txvendordrug.com/news/#makena. As discussed at the Pharmacy Director's Meeting on May 7, 2015, and documented in a notice to the MCOs on May 8, 2015, MCOs are expected to adjudicate claims for this drug by June 15, 2015, and use their HHSC-approved PA criteria.

Makena and Compounded 17P as Medicaid Medical Benefits

Current medical policy:

Compounded 17-Alpha Hydroxyprogesterone Caproate:

For 17-alpha hydroxyprogesterone caproate that has been compounded by a pharmacy provider, PA is not required, and providers are not required to include documentation that supports medical necessity with the claim; however, the provider must keep the documentation in the client's medical record. Providers must submit claims for a compounded drug using procedure code J1725. Procedure code J1725 is restricted to diagnosis code V2341.

Makena:

PA requests and claims for trademarked 17-alpha hydroxyprogesterone caproate (such as Makena) must be submitted with procedure code J1725, modifier U1, and the NDC number 64011-0243-01.

Makena and 17P as Medicaid Medical Benefits - Changes **Effective September 1, 2015**

Effective September 1, 2015, HHSC will be eliminating the PA requirements for both the compounded version and Makena as Medicaid medical benefits. If an MCO elects to implement

a PA on the medical side, it must not disadvantage the branded Makena product. In other words, if a PA is used for Makena, that same PA must be used for compounded 17P also. It is important to note that PA will continue to be required on pharmacy claims after this date.

Additionally, effective September 1, 2015, the current FFS billing practices will reverse and all claims billed for compounded version of the drug must be billed using modifier U1. Makena should no longer be billed with a modifier.

Contact Information

If you have further questions or comments, please contact Amanda Hudgens, Senior Policy Analyst, at amanda.hudgens@hhsc.state.tx.us.