



## MAKENA™ PA SUMMARY

**In accordance with a recent preliminary injunction issued by a United States District Court, DCH is issuing this temporary policy relating to the use of Makena during the time of the pending litigation.**

**STATUS:** Non-Preferred

**LENGTH OF AUTHORIZATION:** Up to 21 weeks

**NOTE:** *If medication is being administered in a physician's office, then it must be billed through the DCH physician's injectable program and not the outpatient pharmacy program. Information regarding the physician's injectable program can be located at [www.mmis.georgia.gov/portal](http://www.mmis.georgia.gov/portal).*

### PA CRITERIA:

❖ Approvable if administered in member's home by home health or in a long-term care facility

AND

❖ Member must be 16 years of age or older and have a confirmed pregnancy with one fetus of gestational age between 16 weeks, 0 days and 20 weeks, 6 days

AND

❖ Member must have a history of at least one singleton spontaneous preterm birth

AND

❖ Member must not have a current or history of thrombosis or clotting disorders; known, history of, or suspected breast cancer or other hormone-sensitive cancer; undiagnosed abnormal vaginal bleeding unrelated to pregnancy; cholestatic jaundice of pregnancy; benign or malignant liver tumors; liver disease; or uncontrolled hypertension.

### EXCEPTIONS:

❖ Exceptions to these conditions of coverage are considered through the prior authorization process.

❖ The Prior Authorization process may be initiated by calling **Catamaran at 1-866-525-5827**.

❖ Compounded hydroxyprogesterone (CHC) or 17-P is available in the event that the treating physician documents that the patient has a specific medical need for a compounded variation over Makena. The compounded product must be requested using the Compound PA Request Form found on the DCH website at <http://dch.georgia.gov/prior-authorization-process-and-criteria>. The reason for the use of the compounded product should be documented in box 3 of the form. The Department does not intend to mandate that physicians must switch to Makena™ for patients who already have embarked on a course of treatment with compounded 17P for an existing pregnancy, nor does the Department intend to mandate that physicians must prescribe Makena for patients where the physician has documented medical need for the compound.

❖ DCH's prior authorization policy favoring CHC over Makena™ is no longer in effect.



**PA and APPEAL PROCESS:**

❖ For online access to the PA process please go to [www.mmis.georgia.gov/portal](http://www.mmis.georgia.gov/portal), highlight Pharmacy on the top right side of the page, and click on Prior Approval Process.

**QUANTITY LEVEL LIMITATIONS:**

❖ For online access to the current Quantity Level Limit please go to [www.mmis.georgia.gov/portal](http://www.mmis.georgia.gov/portal), highlight Provider Information and click on Provider Manuals. Scroll to the page with Pharmacy Services Part II and select that manual.