Authorization for Release of Personal Health Information

To ensure enrollment, please fax to Makena Care Connection® (1-800-847-3413)
Telephone 1-800-847-3418 • www.makena.com

Makena®
hydroxyprogesterone
caproate injection

STEP 1 — Complete Your Personal Information

First Name | Last Name | MI | Date of Birth

Address

City | State | ZIP

Home Phone | Work Phone | Cell Phone

STEP 2 — Read and Sign Voluntary Patient Authorizations

I. For purposes of these Authorizations:

"**AMAG**" means AMAG Pharmaceuticals, Inc., and its affiliates, subsidiaries, representatives, agents and contractors including the Makena Care Connection; "**PHI**" means personal health information, including, but not limited to, information relating to your medical condition, treatment, care management, and health insurance, as well as all information provided on this form and any prescription or by you directly; and "**De-Identified Data**" means information that will not be specifically identifiable to you or your baby. For example: AMAG may publish a report that says, "On Tuesday, 5 patients were contacted." You may be one of those 5 patients, but the information would not be traceable to you.

Access: Your treatment, payment, enrollment, or eligibility for benefits ("**Access**") is not conditioned on signing any Authorization. PHI can be subject to special protections by law, such as HIPAA. Unlike your healthcare provider, however, AMAG is not "covered" by HIPAA, which means that any PHI disclosed to AMAG is not controlled by HIPAA. AMAG agrees to only use your PHI as you authorize below, and to not sell your PHI to a third party.

Copy, Expiration, and Cancellation Rights: You are entitled to a copy of each Authorization. Except as to De-Identified Data, each Authorization you sign expires five (5) years from the date signed below. You may cancel any Authorization at any time by mailing a letter requesting such cancellation to AMAG c/o AllCare Plus Pharmacy, 50 Bearfoot Rd., Northborough, MA 01532, or by phone by calling 1-800-847-3418, but this cancellation will not apply to any information already used through the Authorization.

II. PHI Authorization: By signing this Authorization, I authorize my health plans, healthcare providers, and pharmacies to disclose my PHI to AMAG for the following purposes: (1) to assist with my obtaining and being treated with Makena, such as to: (a) establish my eligibility for benefits; (b) communicate with my healthcare providers and me about my medical care; (c) help third parties provide care-related products, supplies, or services; and (d) register me in any product registration program required for my treatment; (2) to contact me during and after my treatment to: (a) provide me with treatment or support materials; and (b) ask me to participate in patient programs and surveys; and (3) to review and publish De-Identified Data. Further, I understand and agree that: (i) my PHI disclosed under this Authorization is no longer protected by federal privacy laws; (ii) my pharmacy may share my PHI related to the dispensing of Makena, and that my pharmacy may be paid for that information; (iii) I may refuse to sign this Authorization and still have Access; and (iv) I understand my Copy, Expiration, and Cancellation Rights.

→ Patient or Legal Guardian Signature: _____

Relationship to Patient: _____ Date: _____

III. Adherence Support Authorization: I have provided my PHI Authorization above and wish to participate in an adherence support program ("Program") at no cost to me, designed to help me stay on track with treatment and provide me with educational information. By signing this Authorization, I acknowledge and agree that: (1) I am voluntarily choosing to enroll in this Program; (2) AMAG may use my PHI to provide the Program; (3) AMAG may contact me via phone, email, and mail to provide the Program; (4) AMAG may review and publish De-Identified Data it receives from the Program; (5) I may refuse to sign this Authorization and still have Access; and (6) I understand my Copy, Expiration, and Cancellation Rights.

→ Patient or Legal Guardian Signature: _____

Relationship to Patient: _____ Date: _____

IV. Opt Into Text Messaging: By initialing the box(es) below, I opt into receiving text messages from AMAG, and understand that standard message and data rates may apply. To opt out of receiving future texts, I may call 1-800-847-3418, or reply STOP. I understand that receiving texts is not a requirement for Access or Program participation.

→ (Initial here) ☐ I want to receive general texts about Access (such as missing information alerts, shipment updates, etc.)

→ (Initial here) ☐ I want to receive texts from the Adherence Support Program.

Please see Important Safety Information for Makena (hydroxyprogesterone caproate injection) on reverse.

Please Fax Completed Form to Makena Care Connection at 1-800-847-3413.

Makena (hydroxyprogesterone caproate injection) is a progestin indicated to reduce the risk of preterm birth in women with a singleton pregnancy who have a history of singleton spontaneous preterm birth. The effectiveness of Makena is based on improvement in the proportion of women who delivered <37 weeks of gestation. There are no controlled trials demonstrating a direct clinical benefit, such as improvement in neonatal mortality and morbidity.

Limitation of use: While there are many risk factors for preterm birth, safety and efficacy of Makena has been demonstrated only in women with a prior spontaneous singleton preterm birth. **It is not intended for use in women with multiple gestations or other risk factors for preterm birth.**

Important Safety Information for Makena (hydroxyprogesterone caproate injection)

Makena should not be used in women with any of the following conditions: blood clots or other blood clotting problems, breast cancer or other hormone-sensitive cancers, or history of these conditions; unusual vaginal bleeding not related to your current pregnancy, yellowing of the skin due to liver problems during pregnancy, liver problems, including liver tumors, or uncontrolled high blood pressure.

Before you receive Makena, tell your healthcare provider if you have an allergy to hydroxyprogesterone caproate, castor oil, or any of the other ingredients in Makena; diabetes or prediabetes, epilepsy, migraine headaches, asthma, heart problems, kidney problems, depression, or high blood pressure.

In a clinical study, certain complications or events associated with pregnancy occurred more often in women who received Makena. These included miscarriage (pregnancy loss before 20 weeks of pregnancy), stillbirth (fetal death occurring during or after the 20th week of pregnancy), hospital admission for preterm labor, preeclampsia (high blood pressure and too much protein in your urine), gestational hypertension (high blood pressure caused by pregnancy), gestational diabetes, and oligohydramnios (low amniotic fluid levels).

Makena may cause serious side effects including blood clots, allergic reactions, depression, and yellowing of your skin and the whites of your eyes. Call your healthcare provider right away if you think you have symptoms of a blood clot (leg swelling, redness in your leg, a spot on your leg that is warm to touch, or leg pain that worsens when you bend your foot) or symptoms of an allergic reaction (hives, itching, or swelling of the face). The most common side effects of Makena include injection site reactions (pain, swelling, itching, bruising, or a hard bump), hives, itching, nausea, and diarrhea.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit **www.fda.gov/medwatch** or call 1-800-FDA-1088.

For full Prescribing Information please visit www.makena.com/pi

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