
Makena[®]
hydroxyprogesterone
caproate injection



Personalized Patient Support.
Healthcare Professional Resources.
More Than Makena.

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.**

Please see Important Safety Information on the back and full Prescribing Information for Makena (hydroxyprogesterone caproate injection) in pocket.

Connecting you, your staff, & your patients to personalized support for Makena® (hydroxyprogesterone caproate injection)

When you choose Makena for your patients, you get more than the medicine. You get one centralized resource that's designed specifically to assist your patients throughout their Makena experience.

At Makena Care Connection®, we offer personalized support that helps make filling prescriptions easier, addresses your patients' financial concerns, and encourages adherence to therapy. Your patients won't just get Makena to help reduce the risk of recurrent preterm birth; they'll also get support when they need it.



We speak your patients' language

We're ready to help your patients with translation services in more than 20 languages. So communicating with moms on Makena isn't a barrier.

Connecting your patients to support

Together we can work toward one goal—helping your patients achieve a full-term pregnancy. Our dedicated staff at Makena Care Connection is ready to provide an extra layer of personalized support.

Have Questions? [Connect with us.](#)

1-800-847-3418 • 7 AM-7 PM CST makena@sonexushealth.com

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“We’ve been able to connect moms to the Makena Care Connection® for education, financial assistance, and adherence support. They’ve made the process easy and allowed me to focus on taking care of my patients.”

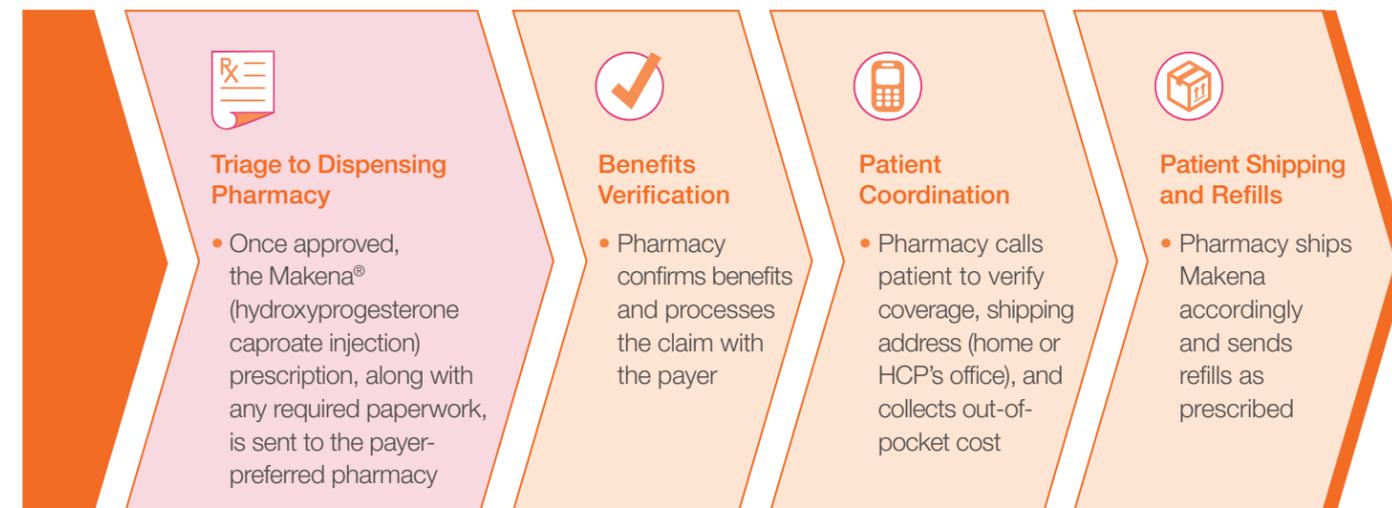
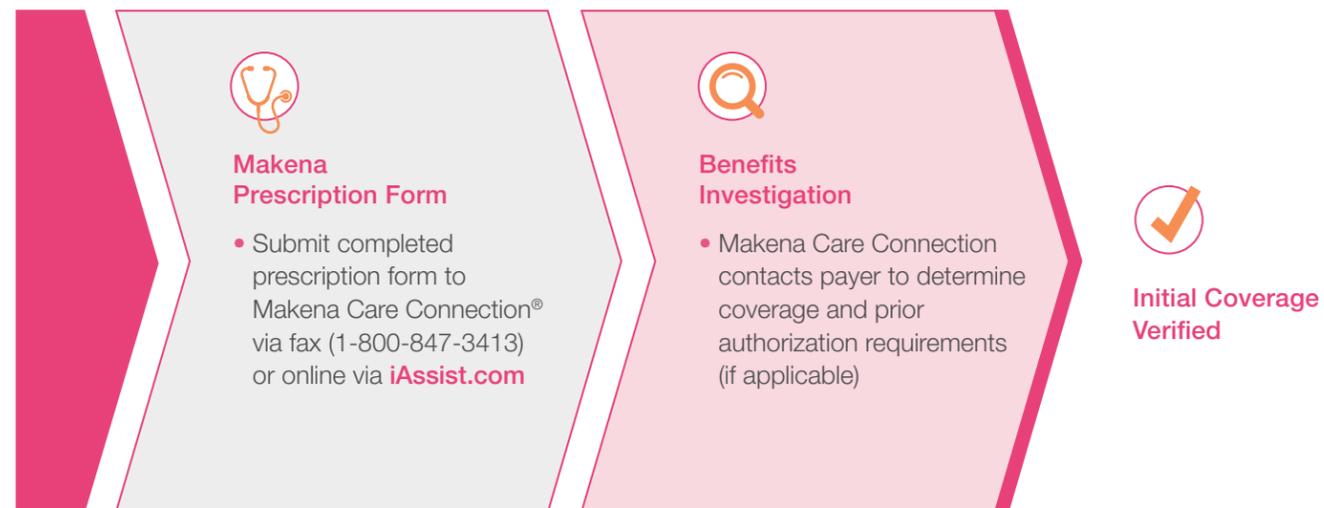
—Deborah Carpenter, WHNP-BC*



*Deborah Carpenter is a speaker for AMAG Pharmaceuticals Inc.

Working together to help ensure moms get off to a good start with Makena® (hydroxyprogesterone caproate injection) as prescribed

Goal of 24 HOURS



Roles and responsibilities

- HCP
- Makena Care Connection®
- Pharmacy



Prescription form tips:

- Include a copy of both sides of the patient insurance card(s) when you submit the prescription form
- If patient does not have insurance, check “uninsured”
- Encourage patient to sign the HIPAA waiver*

Medicine delivery tips:

- If the prescription is submitted before 13 weeks' gestation, it may be held and processed once the patient reaches 13 weeks' gestation†
- Patient needs to respond to the pharmacy's phone call in order to ship medicine

Financial assistance tips:

- If a patient is concerned about her out-of-pocket cost for Makena, she should call Makena Care Connection at **1-800-847-3418** to see if she is eligible for financial assistance

eMakena makes things easier

Prescribe online. Connect patients to support programs. All in one place.

You can prescribe Makena through our online portal. This added resource lets you submit the prescription and prior authorization form (when applicable), track progress, and connect patients to support programs. To get started, [visit iAssist.com](https://www.iassist.com).

*By signing the HIPAA waiver, the patient allows the Makena Care Connection to communicate with the HCP, insurer, and pharmacy on her behalf. If the patient does not sign the HIPAA waiver, the Makena Care Connection will not have the ability to check the patient's status with the pharmacy.

†Some insurance companies will not approve Makena until a patient reaches 13 weeks' gestation. In those cases, the Makena Care Connection holds the prescription until the patient reaches 13 weeks, at which point they will triage the prescription to the payer-preferred pharmacy.

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Personalized support that helps Makena® (hydroxyprogesterone caproate injection) moms access therapy and encourages adherence

Financial Assistance

We believe patients should be able to focus more on their pregnancy than the cost of their medication. To support that, AMAG Pharmaceuticals is committed to ensuring affordable access to Makena. We proactively screen and offer eligible patients financial assistance with no income caps.

Commercially insured moms whose health plan covers Makena	Helps lower out-of-pocket costs associated with copays, coinsurance, and deductibles.*
Uninsured and commercially underinsured moms	A free course of therapy.*

*Each patient's eligibility is evaluated on an individual basis. To be eligible, patients must meet the FDA-approved indication (pregnant with a single baby with a history of singleton spontaneous preterm birth). In compliance with federal regulations, patients insured by a government-funded program (eg, Medicaid, TRICARE, etc) are not eligible.

Home Injections by Healthcare Professionals

We can help coordinate Makena injections through a home healthcare organization. Once approved by insurance, moms prescribed Makena can choose to receive their injections by a healthcare professional in the comfort of their home or another location that's convenient for them. Benefits may include:

- Supporting compliance with weekly injections
- Addressing logistical barriers for patients
- Simplifying scheduling challenges for your office

Education and Adherence

We understand that moms receiving Makena injections may need some encouragement and support to stick to their weekly injection schedule, and we want to help. This free service offers educational and adherence support to encourage women to make Makena part of their pregnancy and take an active role in their health.

A level of personalized support you and your patients can expect:

- Injection reminders that support weekly treatment
- Educational materials to address topics during pregnancy
- Encouragement so patients can take an active role in their health

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Giving you an extra layer of support with the Makena Care Connection®

When you start Makena® (hydroxyprogesterone caproate injection), you get more than the medicine. You'll get personalized resources that are specifically designed to help you throughout your experience with Makena. Think of us as an extra layer of support.



Rx Support You're unique and so are your insurance benefits. Because getting your medicine in a timely manner is important, we're here to lend a hand. We have a dedicated team who understands the coverage policies for Makena. Our experts can handle the details between your healthcare professional, your insurance company, and your pharmacy so that you receive your Makena when you need it.



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Ready to Refill? About 1 week before you are scheduled to start your next Makena vial, your pharmacy will call you to confirm shipment and arrange payment. Your Makena prescription cannot ship until you speak with the pharmacy to arrange payment and delivery. Your pharmacy's number may show up as an "unknown number," or an 800 number on caller ID. So if you do not receive this call, please call the Makena Care Connection at 1-800-847-3418, and we'll help.

Please see Important Safety Information on the back and full Prescribing Information for Makena (hydroxyprogesterone caproate injection) in the pocket and at www.makenapi.com.

Important Safety Information for Makena[®] (hydroxyprogesterone caproate injection)

- Do not use Makena in women with any of the following conditions:
 - Current or history of thrombosis or thromboembolic disorders
 - Known or suspected breast cancer, other hormone-sensitive cancer or history of these conditions
 - Undiagnosed abnormal vaginal bleeding unrelated to pregnancy
 - Cholestatic jaundice of pregnancy
 - Liver tumors, benign or malignant, or active liver disease
 - Uncontrolled hypertension
- Makena should be discontinued if thrombosis or thromboembolism occurs
- Allergic reactions, including urticaria, pruritus and angioedema, have been reported with use of Makena or with other products containing castor oil
- Women receiving Makena should be monitored if they:
 - Are prediabetic or diabetic
 - Have conditions that may be affected by fluid retention, such as preeclampsia, epilepsy, cardiac or renal dysfunction
 - Have a history of clinical depression; Makena should be discontinued if depression recurs
 - Develop jaundice; consider whether benefit of use warrants continuation
 - Develop hypertension
- Certain pregnancy-related fetal and maternal complications or events were numerically increased in Makena-treated subjects as compared to placebo subjects, including miscarriage (2.4% vs. 0%) and stillbirth (2% vs. 1.3%), admission for preterm labor (16% vs. 13.8%), preeclampsia or gestational hypertension (8.8% vs. 4.6%), gestational diabetes (5.6% vs. 4.6%), and oligohydramnios (3.6% vs. 1.3%)
- The most common adverse reactions reported in $\geq 2\%$ of subjects and at a higher rate in the Makena group than in the control group were injection site reactions (pain [35% vs. 33%], swelling [17% vs. 8%], pruritus [6% vs. 3%], and nodule [5% vs. 2%]), urticaria (12% vs. 11%), pruritus (8% vs. 6%), nausea (6% vs. 5%), and diarrhea (2% vs. 1%)

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Waltham, MA 02451

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Rx Support You're unique and so are your insurance benefits. Because getting your medicine in a timely manner is important, we're here to lend a hand. We have a dedicated team who understands the coverage policies for Makena. Our experts can handle the details between your healthcare professional, your insurance company, and your pharmacy so that you receive your Makena when you need it.



Financial Assistance We believe that you should be able to focus on your pregnancy more than the cost of your medication. To support that, AMAG Pharmaceuticals is committed to making sure that moms like you have affordable access to Makena. We offer eligible patients financial assistance, which helps to lower out-of-pocket costs.*

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Injection Tracker

Write down the date and the side of your body of your weekly injection. Please note that your results and duration of therapy may vary.

START DATE:	DATE: L R									
DATE: L R										

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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.

