



Progesterone FAQ's

This frequently asked questions document was created to serve as an aid in overcoming barriers to ordering Progesterone. Each question/answer is created as a hyperlink for your convenience. This feature helps to ensure you get your questions answered in a timely manner. To use this sheet, simply click on the question in the Table of Contents box. The link will take you directly to the question/answer within the document.

Table of Contents

- Makena Ordering**..... 3
 - How is Makena; Hydroxyprogesterone caproate ordered?..... 3
 - How are vaginal preparations ordered?..... 3
 - How do we bill for Medicaid PIP Communication/Order form? 3
 - Can the patient receive Makena in the office? 3
 - Can the patient have a family member give the injection in the home?..... 3
 - Is Home Care administration of Makena covered by insurance? 3
 - What is the earliest gestational age Makena can be ordered?..... 3
 - We ordered Makena at 13 weeks. What do we do since the patient is now 17 weeks and the home care company hasn't initiated treatment? 4
- For Non-Medicaid Patients**..... 4
 - Can an uninsured patient receive Makena?..... 4
 - Are there any treatment options if the patient presents at 21 weeks and has no insurance? 4
 - Can our office purchase Makena?..... 4
 - Can our office order hydroxyprogesterone caproate (HPC) for office administration? 5
 - Is cost assistance available for the office? 5
 - Does the office have to purchase the 5 dose vial or is single dose available?..... 5
 - Is it possible to return unused Makena?..... 6
 - Is there any assistance for those who cannot afford the copay? 6
- Clinical Q&A** 6
 - What are the criteria for Makena Treatment?..... 6
 - Why would I choose to order injectable over vaginal?..... 6
 - Can we obtain Makena for patients with history of singleton spontaneous preterm birth(s) currently pregnant with multiples?..... 6



The patient first presented at 20w6d. Does this mean she can't receive Makena? 7

If the patient presents at 21 weeks is Makena unavailable? 7

What is the procedure if the patient wants to switch from Makena to vaginal treatment?..... 7

What is the procedure if the patient wants to switch from vaginal treatment to Makena?..... 7

What is the procedure if the patient is on injectable and will be out of town the date of her next scheduled injection? 7

What is the suggested treatment for those who are needle phobic or refuse the injectable product?7

What vaginal products are available? 8

For the uninsured, or for those with high copays, are there any financial resources for vaginal products? 8

Is it appropriate to order Makena *and* a vaginal treatment for the patient with a history of preterm birth and a short cervix? 8

If a patient is allergic to castor oil can compounded 17P still be obtained?..... 8

If compounded 17P is available in our area, is it covered by insurance plans? 8

If a patient has a short cervix but doesn't wish to use a vaginal product, can she be prescribed intramuscular? 9

What should be prescribed for patients with a prior preterm birth who refuse injections but complain vaginal treatment is messy? 9

Why would I choose single over the multi-dose vial? 9

How is HPC/Makena stored?..... 9

How are vaginal products stored?..... 9

Can our office purchase Makena?..... 9

Special Populations of Patients 10

What happens to a Medicaid patient currently on Makena who just moved to Ohio? 10

How do we obtain progesterone for patients with Medicaid *and* Medicare?..... 10

How can progesterone be obtained if a patient has been 'sanctioned' by Medicaid?..... 11

If a patient is on Makena or needs to be initiated but is incarcerated during pregnancy can she be treated at the facility? 11



Makena Ordering

How is Makena; Hydroxyprogesterone caproate ordered?

Complete the 2 page Medicaid PIP Communication/Order form that is available on the OPQC website. www.opqc.net

For problems email specifics to Progesterone_PIP@medicaid.ohio.gov

How are vaginal preparations ordered?

Complete & fax the Medicaid PIP Communication/Order form to the patient's MCP and order the vaginal form from patient's pharmacy of choice.

How do we bill for Medicaid PIP Communication/Order form?

If you are not paid at an FQHC bundled rate and completed the form for a Buckeye member, use CPT code 59899 with U1 for first trimester, U2 for second and U3 for third trimester. If completing for CareSource, Molina, Paramount, United Community or Medicaid Fee-for-Service members, use HCPCS code H1000.

Can the patient receive Makena in the office?

Yes. The office can 'Buy and Bill' through the insurance plans. This covers the cost of the drug and the administration fee. Confirm codes with the individual plans.

Can the patient have a family member give the injection in the home?

Home injections of Makena depend on the insurance plan. Vials of HPC can be purchased, and a family member/friend instructed on administration.

Is Home Care administration of Makena covered by insurance?

Yes. Check with the patient's specific plan for the home care company that they contract with.

What is the earliest gestational age Makena can be ordered?

The order can be placed as early as 13 weeks. It will be held as an 'early bird' until 16 weeks at which time it can be initiated.



We ordered Makena at 13 weeks. What do we do since the patient is now 17 weeks and the home care company hasn't initiated treatment?

Using vaginal products as a bridge is a reasonable solution while you contact the patient's insurance carrier and make them aware the contracted home care company has not initiated treatment. Request the Insurance plan follow-up with the specialty pharmacy and the home health agency.

For Non-Medicaid Patients

Can an uninsured patient receive Makena?

Yes. The patient has to be between 16w 0d and 20w 6 days. Complete Makena Care Connection form (www.Makena.com) with patient signature, check 'NO INSURANCE' box and fax to 1-800-847-3413. Place a follow up call to 1-800-847-3418 to be sure order was received.

If the patient is > 20weeks 6 days gestation she is not eligible for free drug or financial assistance.

Are there any treatment options if the patient presents at 21 weeks and has no insurance?

Vaginal products are a reasonable option or generic Delalutin (HPC).

Can our office purchase Makena?

Yes. Contact Specialty Pharmacies to place order for shipment:

- CuraScript 1-877-599-7748
- Optum RX 1-800-788-4863
- Acaria SP 1-800-535-1815
- CVS Caremark 1-800-237-2767
- Option Care 1-866-827-8203
- TheraCom 1-888-214-8313
- Briova Rx 1-800-707-8194*note WV office takes care of OH
- Central Compounding of OH 1-614-847-0109



- Duncan's Pharmacy in KY 1-270-247-3345

Can our office order hydroxyprogesterone caproate (HPC) for office administration?

Yes. 5ml vials (minimum order of 5 vials) can be ordered directly from ANI Pharmaceuticals (302)482-8644 and shipped to your office. You can also contact these *Specialty Pharmacies*:

1. OptionCare – www.optioncare.com - (855) 275-9647
2. Panther Specialty – www.pantherspecialty.com – 1-855-726-8479

Or from *major wholesalers*:

1. AmerisourceBergen Customer Care Line – 1-844-222-2273
(AmerisourceBergen Ordering Number: 10166914)
2. Cardinal Pharmaceutical Customer Service – 1-800-926-3161
(Cardinal Item Number: 5260393)
3. McKesson Pharmacy Customer Service – 1-855-625-7385
(McKesson item number: 3568656)

Is cost assistance available for the office?

Yes. If your facility, clinic or hospital pharmacy is 340B eligible Makena can be obtained from *CuraScript* or *TheraCom*. Volume Discounts are available. If your facility is affiliated with a GPO (Group Purchase Organization) this can help lower the purchase price. ANI Pharmaceuticals has a discounted price.

Does the office have to purchase the 5 dose vial or is single dose available?

The office can purchase either. You can choose what works best and is most economical in your practice. Generic Delalutin (HPC) is only available in 5ml vials.



Is it possible to return unused Makena?

A return request form needs to be completed. When purchased through a specialty distributor returns can be made under certain circumstances. See *Makena Returns Policy* for specifics.

Is there any assistance for those who cannot afford the copay?

Yes. The patient will need to call The Makena Care Connection 1-800-847-3418 and discuss her specific financial needs. There are no upper level income caps.

Other options include generic HPC, or generic vaginal product.

Clinical Q&A

What are the criteria for Makena Treatment?

Women, with a *singleton* pregnancy who have a history of delivery of a *singleton*, between 20weeks 0days and 36weeks 6 days without a medical indication, are eligible. Most insurance plans consider a preterm birth as 16weeks 0 days through 36weeks 0 days and cover off label use.

Why would I choose to order injectable over vaginal?

This will usually depend on the provider's interpretation of the literature. There are other factors that could be considered such as current gestational age, history, insurance coverage, affordability, timely availability, and what product will the patient be most compliant with.

Can we obtain Makena for patients with history of singleton spontaneous preterm birth(s) currently pregnant with multiples?

FDA has approved Makena for use in *singleton* pregnancies only. Vaginal products are a reasonable alternative, require no prior authorization and are readily available at local pharmacies. Another option would be off label use of generic Delalutin (HPC).



The patient first presented at 20w6d. Does this mean she can't receive Makena?

As long as the order was placed on the date the patient was 20w 6d and meets the criteria she is eligible.

If the patient presents at 21 weeks is Makena unavailable?

You can place the order which will be reviewed by the specific plan. Most will cover initiation up to 24 weeks and some up to 27 weeks. (For specific plan coverage information see *OPQC Progesterone Coverage Chart* located on the OPQC website www.opqc.net) Generic Delalutin (HPC) is not subject to gestational age restriction, is covered by the Medicaid, MCP's and Optum/Alere.

What is the procedure if the patient wants to switch from Makena to vaginal treatment?

Vaginal treatment would initiate 7 days after the last Makena injection.

What is the procedure if the patient wants to switch from vaginal treatment to Makena?

Nightly vaginal treatment needs to continue until the day of Makena injection.

What is the procedure if the patient is on injectable and will be out of town the date of her next scheduled injection?

The recommendation is for injections to be no closer than 5 days and no further than 9 days apart. This was the procedure followed in the Meis, Progesterone Trial. Alternatively, a bridge of vaginal could be utilized from the day after the last injection until injections resume.

What is the suggested treatment for those who are needle phobic or refuse the injectable product?

Vaginal products are a reasonable alternative.



What vaginal products are available?

Generic 200 mg prometrium (generic is micronized progesterone USP) an oral capsule placed Vaginally QHS;

Compounded suppositories usually 200 mg QHS obtained from compounding pharmacies

Various gels 90mg QHS and First Progesterone® a compounded suppository both available at most local pharmacies. (See *OPQC Progesterone Coverage Chart*)

For the uninsured, or for those with high copays, are there any financial resources for vaginal products?

Yes. www.GoodRx.com or www.helprx.com has coupons available for anyone. Coupons cannot be used concomitantly with insurance, but may be cheaper than copays and do lower the cost for those without insurance. Enter patients purchase area zip code and specific drug to obtain cheapest cost in the area specified.

Is it appropriate to order Makena *and* a vaginal treatment for the patient with a history of preterm birth and a short cervix?

No. There is no research to support both treatments simultaneously.

If a patient is allergic to castor oil can compounded 17P still be obtained?

Yes. If the patient has a true allergy, compounded 17P can be ordered in a different oil such as sesame.

If compounded 17P is available in our area, is it covered by insurance plans?

Yes, it is covered.



If a patient has a short cervix but doesn't wish to use a vaginal product, can she be prescribed intramuscular?

There is currently no strong evidence to support 17P use for those with short cervix and not prior preterm birth.

What should be prescribed for patients with a prior preterm birth who refuse injections but complain vaginal treatment is messy?

It is reasonable to encourage use of vaginal pill as it is the 'least messy' available product.

Why would I choose single over the multi-dose vial?

This will depend on a variety of individual factors for example cost, affordability, place of administration, billing, ease of storage and who will be administering.

How is HPC/Makena stored?

The single or multi-dose vial should be stored at room temperature and protected from light.

How are vaginal products stored?

Vaginal products are also stored away from light and at room temperature. Some patients prefer to store suppositories in the refrigerator to make them firmer and easier to place.

Can our office purchase Makena?

Yes. Contact Specialty Pharmacies to place order for shipment:

- CuraScript 1-877-599-7748
- Optum RX 1-800-788-4863
- Acaria SP 1-800-535-1815
- CVS Caremark 1-800-237-2767
- Option Care 1-866-827-8203
- TheraCom 1-888-214-8313
- Briova Rx 1-800-707-8194*note WV office takes care of OH



- Central Compounding of OH 1-614-847-0109

Duncan's Pharmacy in KY 1-270-247-3345

Special Populations of Patients

What happens to a Medicaid patient currently on Makena who just moved to Ohio?

Contact the county OJFS office where she resides and notify them of pregnancy. Order Makena via the Medicaid PIP Communication/Ordering form and note the change of residence in the comments section. Route to Medicaid FFA/MedicaidMCP. Note continuation of treatment that originated in another state. Include the date the next injection is due. If delay, order vaginal product as a bridge.

How do we obtain progesterone for patients with Medicaid and Medicare?

Contact patient's County ODJFS office and advise them of pregnancy. Order vaginal Prometrium under Medicare Part D as a bridge. Enter Makena; Hydroxyprogesterone caproate order per Medicaid Communication Order form. Note that patient is "dually eligible" for Medicaid and Medicare. Fax to Medicaid. Makena; Hydroxyprogesterone caproate needs to be billed to Medicare Part B if administered in the office and Medicare Part D plan if administered at home. Note: Medicare is the primary payor and has to be billed first. *Medicaid cannot cover any drug that may be covered by Medicare, even if Medicare denies the claim.*

Also available is an FDA approved *generic* Delalutin (this was Makena in the 1970's & 1980's) or **HPC**. It is currently approved for uterine adenomas and irregular vaginal bleeding but can be prescribed off label. It is only available in a 5 dose vial. It can be shipped to the patient or your office within 48 hours. You can do buy and bill with the patient returning weekly to your office. If this isn't possible, a family member can be taught to administer in the home.

HPC is available for purchase from the following major *wholesalers*:

AmerisourceBergen Customer Care Line – 1-844-222-2273



(AmerisourceBergen Ordering Number: 10166914)

Cardinal Pharmaceutical Customer Service – 1-800-926-3161

(Cardinal Item Number: 5260393)

McKesson Pharmacy Customer Service – 1-855-625-7385

(McKesson item number: 3568656)

How can progesterone be obtained if a patient has been ‘sanctioned’ by Medicaid?

Sanctions are filed if the individual is subject to a 3rd occurrence r/t work activity. To lift this sanction, the individual has to agree to comply with their work activity. If the pt is sanctioned before pregnancy is known the pt would need to contact the CDJFS and agree to comply with their Self Sufficiency contract to lift this. Medicaid’s eligibility team will ask the counties to lift sanctions for those women they are notified about through the Progesterone Project then progesterone can be ordered per the Communication/Order form.

If a patient is on Makena or needs to be initiated but is incarcerated during pregnancy can she be treated at the facility?

The facility will have to purchase and administer Makena, generic Delalutin (HPC), initiate or switch to a vagina product.