# Putting New Family PACT Benefits to Work in Patient Care Webinar Transcript May 11, 2022

## Nicole Nguyen:

Hi everyone. Good afternoon. Thank you for joining us today for our webinar titled Putting New Family PACT Benefits to Work in Patient Care. We hope you are all doing well and staying safe. My name is Nicole Nguyen. I'm the Program Manager of the Family Planning program here at the California Prevention Training Center, the CAPTC under contract with the California Department of Health Care Services Office of Family Planning is sponsoring today's event. We welcome you. Before we get started, let's just go over some really quick housekeeping slides. So first please check your audio and select your desired settings to join either through your computer audio or through your phone. If your internet connection is shaky, we highly recommend that you call it in so that you can get the best possible sound and there's no interruptions.

## Nicole Nguyen:

Second, please check that you're able to see the viewer screens with the slides on your left and the go-to webinar control panel on the right. And then there's this orange box with the white arrow, this is how you can hide or show your dashboard. If you don't want to see it, or you accidentally clicked it in, this is how you can make it appear again. Under that is the audio setting where you can change your audio preference at any time. And also please submit all your comments and questions via the questions box. So before I introduce our presenter, I want to acknowledge that we're really excited to be working with the University of Nevada, Reno School of Medicine to provide CME for this event. So, this webinar will qualify for a 1.5 CME credit, and it's only available to those who watch the entire webinar live today.

## Nicole Nguyen:

So those who watch the recordings afterwards will not be eligible for the CME credits, or if you watch in groups and didn't register yourself, unfortunately, we won't be able to give you those credits either. And we'll make sure everyone get the link to access your CME certificate in the follow-up email, along with all the materials that we share today, like the recordings, the slides, and then the evaluation survey. And then of course, for transparency, we want to state that all of our presenters, planners, anyone in a position to control the content of this CME activity have indicated that they nor their spouse legally recognize domestic partners have any financial relationships with the commercial interest to the content of this activity. All right, so now I'd like to introduce you our two presenters, our first one will be Lamont Weaver. Lamont is our Health Program Specialist for the Office of Family Planning.

## Nicole Nguyen:

He has been with OFP for three years. He works for the Research Evaluation and Data Section of the program, and his experience has afforded him the ability to work on everything from enrollment and compliance to policy and provider training. He'll be sharing with us some updates regarding the Public Health Emergency wind down. So thank you Lamont for joining us today. And then next, as always,

we're really excited to have Dr. Michael Policar with us, Dr. Policar serve as clinical professor of Obstetrics, Gynecology and Reproductive Sciences at the University of California, San Francisco School of Medicine. From 2005 to 2014 he was the Medical Director of Program Support and Evaluation for the Family PACT Program. And he also administered by the California Department of Public Health Services, Office of Family Planning. He currently serves as Professor Emeritus of Obstetrics, Gynecology and Reproductive Sciences at UCSF. So we're always excited to have him share all his new fa knowledge with us. And so with that, Lamont and Mike the floor is yours.

Lamont Weaver:
Okay. So...

Nicole Nguyen:
So let me touch here so you can...

Lamont Weaver:
... I'll just go in first.

Dr. Michael Policar:
Yes, sir.

Nicole Nguyen:
All right.

Dr. Michael Policar:
Hang on.

Nicole Nguyen:
Let me make...

Dr. Michael Policar:
Okay. Here we go.

Nicole Nguyen:
There, you should be able to share your screen now.

Lamont Weaver:
Okay, good.

## Dr. Michael Policar:
And here. Okay. What, can you see that?

## Lamont Weaver:
Yes, I can.

## Dr. Michael Policar:
Okay.

## Lamont Weaver:
Yes, I can. And I will go. So regarding the Public Health Emergency Unwinding, just a little background. Of course, during the National Public Health Emergency in Response to COVID 19, Medi-Cal standard operations of... which consisted of annual evaluations of medical and eligibility was temporarily halted to ensure that beneficiaries had ongoing access to health coverage during the pandemic. Now that the Public Health Emergency is starting to unwind, which as currently stated, the PHE is currently extended to July 15th of this year. After that date, Medi-Cal, for the next 14 months, will be returning to normal eligibility and enrollment operations, which, and this involves the conducting the full renewal of enrollment for all beneficiaries, which during the time period from the beginning of the public health emergency to now Medi-Cal enrollment increased about 16% actually.

## Lamont Weaver:
So from 12,500,000 in March 2020, to 14,500,000 today. The Department of Health Care Services, they've been working to prepare for this unwinding for a while now, and the department has reached out to provide information and guidance to healthcare plans and counties, and actually begun direct outreach to beneficiaries to help build that outreach to be able to either ensure that they keep their current medical coverage or be able to help and guide for those who could potentially lose their coverage, to ensure that they be able to receive either low cost coverage from Covered California, or other government programs or transition to their employer-sponsored health coverage, if need be. So the Department of Health Care Coverages has begun the coverage, ambassador campaign, as part of this initiative.

## Lamont Weaver:
And these ambassadors can include the Department of Health Care Service providers, managed care plans, local health offices, health navigators, advocates, community organizations, stakeholders, healthcare facilities, clinics, and other state agencies. Along with this initiative, they've implemented a two-phased communication campaign to reach the beneficiaries across the line. So during this phase one approach, which is going on right now, ambassadors in this program will reach out to beneficiaries to update their contact information if they haven't done so already. So they can be contacted with important information about keeping their benefits. There is currently, and I'll offer in the resource slides in the chat-box later, there is actually a toolkit, a Medi-Cal toolkit, and a site on the department's webpage to help the ambassadors with communications to the beneficiaries. This toolkit includes social media prompts, calls, scripts, website banners. And during this phase one so...

## Lamont Weaver:

Just really encouraging to reach out to beneficiaries during this time period. So they can have this most up-to-date information possible. Now, I mentioned the PHEs expected to extend to July 15th. Phase two of this communication approach, which will continue to include reaching out to beneficiaries to update their contact information as well as report any changes in their circumstances, as well as checking for ensuring that the beneficiaries are checking. That's why we want to have those latest contact information on file. So when the Medi-Cal renewal packets go out through mail, they can be received. And this next phase that approach will begin about 60 days prior to the end of public health emergency. So we're getting to that time period right now. In addition to the resources that I'm going to have, DHS will actually have a webinar the week after next on the 24, I believe on the 24th and 25th. Webinar to go over the entire campaign in full, the toolkit and other resources are also available on the website and will be provided through this as well.

## Dr. Michael Policar:

Okay, great. Thank you. And we'll address your questions later when we do the Q&A. And just let me emphasize something that Lamont was talking about. During the public health emergency, there were just so many people who were not Medi-Cal beneficiaries before the public health emergency who became enrolled in Medi-Cal. And it's such a wonderful program, I'd say better than just about every state Medicaid programs. That being the case, given the broad range of services that people get with Medi-Cal, by all means they should make every attempt to continue to obtain their coverage in that way. One in three Californians who have insurance are covered in Medi-Cal. Okay. Well, let's move on to our major topic today, which are 'new benefits in Family PACT'.

## Dr. Michael Policar:

These are our learning objectives. We're going to talk about a number of new contraceptive benefits that have been added as Family PACT benefits that'll be available to you. We'll talk about a couple of new diagnostic tests for sexually transmitted infections, specifically focusing on Mycoplasma genitalium. And then the second half of the talk will be a little bit of a repeat of the presentation that Ina Park and I did about a year ago on the 2021 CDC STD treatment guidelines. But the reason that I've added it in this time is because the Office of Family Planning has now adopted most of the antibiotic regiments that are contained in the 2021 CDC STD treatment guidelines. So we're going to start with the new contraceptive benefits, but I do want to tell you about some initial information that I think is really important to know relative to how the benefits were structured.

## Dr. Michael Policar:

One of the things you might not realize about family practice, that it was one of the first family programs nationally to make it a benefit for people to get a full-year supply of their hormonal contraceptives. Of course, that started with the full-year supply of oral contraceptives and then was extended to other hormonal contraceptives afterwards. So it is currently a state law in California, based on California Senate Bill 999, which was signed about five years ago, and then embedded in a number of different state regulations regarding the fact that in both Family PACT Medi-Cal, as well as commercial health plans, that people have the right to get access to a full year of hormonal contraceptives. So you can see that this is contained in the Business and Professions Code, the Health and Safety Code, the Insurance Code for Commercial Insurance and the Welfare and Institution's Code. It all basically says the same thing.

## Dr. Michael Policar:

And that is that, a pharmacist shall dispense at a patient's request up to a year-long supply of an FDA-approved self-administered hormonal contraceptive. Basically, what that refers to is pills, patches, rings progestin mini pills and so on, because they are self-administered and now of course, that even includes Depo-subQ, as well, as we'll get to a little bit later. But at any rate, if a patient asks, then the pharmacist has to basically make available a full-year supply of the prescribed contraceptive. And it's not only true in Medi-Cal and in Family PACT, but it also applies to commercial insurance as well in the Insurance Code. So basically, people in California for the last five years have been guaranteed a full-year supply of their contraceptive choice. Now, the reason for that has to do with a number of studies that were published in the early 2000s, actually based on the Family PACT population.

## Dr. Michael Policar:

First was in 2006, that looked at family planning outcomes when a full-year supply of oral contraceptives was made available and then five years after that, another article that had to do with pregnancy outcomes for people who were dispensed a full year supply of hormonal contraceptives. Since then there have been four more studies that have been published about the cost effectiveness of this approach, which I won't go through in regard to time. But I do want to tell you about the two Family PACT studies that we did years ago to validate this approach.

## Dr. Michael Policar:

Diana Greene Foster being the primary author of these articles. So the first looked at, of people who had their first visit in January, 2003, women who were dispensed to full 13 cycles of oral contraceptives used 14 and a half cycles during the year, in comparison to people who were dispensed three cycles who only used about nine cycles during the year. Of course we used paid claims data in order to be able to compute this. Now, compared with the women who only received three cycles of oral contraceptives, those who were given a full-year supply were almost 30% more likely to have oral contraceptive pills on hand and twice as likely to have a sufficient supply of oral contraceptives for 15 months of continuous use. So with that full-year supply, obviously people had that immediately available to them. And despite having one fewer clinician visit during the year, women who were dispensed 13 cycles were actually more likely to have cervical cancer screening with cervical cytology test and Chlamydia test, and less likely to have a pregnancy test than women who were initially dispensed fewer recycled.

## Dr. Michael Policar:

So one of the concerns initially was that if we gave people a full year of oral contraceptives, that they wouldn't come back and get the screening test that they needed for Cervical cancer, and for Chlamydia. But it turns out that among the women who were dispensed a year of oral contraceptives they were actually more likely to come back for those screening tests and less likely to mute a pregnancy test. Now, another thing that we were concerned about, was if you gave someone 13 cycles of pills in advance, how likely were they to actually use those pills as opposed to just wasting them, throwing them away, not using them. And what Dr. Foster Greene was able to compute was the fact that for those people who used 13 cycles, about 6.5% of cycles were not used. If they were dispensed three cycles and about 2% of cycles were not used, but in a way, this was really good news for us because it told us that in the large majority of circumstances, when people were dispensed 13 cycles, they actually used 13 cycles.

## Dr. Michael Policar:

So it was fairly uncommon for people to be dispensed cycles of oral contraceptives that they didn't use in either case. And then that first study also showed that it was cost savings compared to women who received 13 cycles of oral contraceptives over a year, Family PACT actually paid almost $100 more for women who received three cycles and about $44 more for people who received one cycle. So that was the first study made it pretty clear about the fact that, by giving people a full-year of pills, they were more likely to use them, low likelihood of wastage and it was actually cost saving. Five years later that led to a second study. And in this second study, Dr. Foster Greene was able to do the most incredible work. She and Dennis Hulett. They were able to link the Family PACT claims database with the Medi-Cal claims database.

## Dr. Michael Policar:

So they were able to follow tens of thousands of people over a period of time, during which time they were members of Family PACT, and then later might have gotten services through Medi-Cal, particularly in regard to pregnancy care. So what this looks at is, in the first row, people who got one cycle of pills, then three cycle of pills, then the people who got a whole year of pills, 12 or 13 cycles, what we find, if you look in that third line with the red numbers, is that their continuation rate was much higher at 15 months in comparison to people who only got one or three cycles of pills. They were less likely to switch to another method, only about 7% of people did. The likelihood that they would have a claim for anything related to pregnancy was only about a third, in other words, people who got one cycle of pills, 3% had a pregnancy fright, but of people who got 12 or 13 cycles of pills, only 1% of people had a pregnancy fright.

## Dr. Michael Policar:

And then finally, for those people who got 13 cycles of pills, they were substantially less likely to have abortion services paid for. So this was profoundly important because it showed that this approach of 13 cycles all at once was not only safe and cost savings, but that it actually changed longer-term outcomes so that there were fewer undesired pregnancies and a lower abortion rate for people who were able to get 13 cycles. It was that kind of study, that kind of information that came from the Family PACT program that led the state legislature to subsequently approve that Senate Bill 999, that I mentioned, so that now people can get a full-year supply of their hormonal contraceptives. You'll see a lot more of that once we go through each individual method. So here are the methods that we're going to talk about that are all new Family PACT benefits with the exception of the one at the bottom, Drospirenone progestin-only pill with a brand name of Slynd. It's not a Family PACT benefit, it's not a Medi-Cal benefit.

## Dr. Michael Policar:

But the ones which have been added as both Family PACT and Medi-Cal benefits are a one year contraceptive vaginal ring called Annovera, a new contraceptive vaginal gel called Phexxi, a lower dose contraceptive patch called Twirla. I'll tell you about all of those in detail. Next is a generic version of NuvaRing, which is called EluRyng, and some pharmacies are now starting to stock that. And of course, that would be covered by Family PACT. I'll remind you of a topic that we talked about in earlier webinars, which is DMPA or Depo-Provera subQ, which is self-injected by patients, which is now a permanent benefit in Family PACT. And then I'll tell you a little bit about Slynd, even though it's not a Family PACT benefit or a Medi-Cal benefit. I think it would be helpful for you to know about that as one of the newer products, which is on the market.

## Dr. Michael Policar:

So let's start with the FAL estradiol Segesterone Annovera, Contraceptive Vaginal Ring. And I've tried to make clear what these various abbreviations mean, and you can see the ring there. So the basics about Annovera is that one ring will prevent ovulation for a whole year, 13 cycles. So person obtains this ring, learns how to use it, and then can use that same ring over a full-year period. It's components are ethinyl estradiol, which is the same estrogen which is in the pill, the patch, the ring, nothing new there. But there is a brand new progestin, which is called Segesterone acetate, the trade name which is Nestorone, that is uniquely suited for this idea of having it in a ring for a period of a full year. It's used in a 28 day cycle, so that it's in for 21 days, it's out for seven days during which time a person will have a withdrawal bleed menses. The side effect profile and the bleeding profile is quite similar to the NuvaRing, which of course is a once-a-month ring.

## Dr. Michael Policar:

And it has the same diameter as the new ring, but it is twice as thick. I will show you some photographs of that in just a moment. It was developed by an organization in New York called the Population Council that sponsored almost all the clinical trials about the Annovera ring. It is currently licensed and owned by a company called TherapeuticsMD, and it was approved by the FDA in August of 2018. So it's been out for a little over three years. It works well in perfect use, in other words, in the clinical trials that were done with Annovera, the pregnancy rate was three pregnancies per 100 couples per year, which puts it in that same level or the same tier of efficacy as pills, patches, the NuvaRing and DMPA, which is considered to be the middle level of efficacy, not as effective as the long-acting reversible contraceptive methods like IUDs and implants, but certainly on the upper end of that middle tier of contraceptive efficacy.

## Dr. Michael Policar:

Now, another logical question is, well that was in clinical trials, how about in real world use? And unfortunately, those failure rates haven't been published yet, but they'll probably be around the same ballpark as oral contraceptives, patches, rings somewhere around five, six or seven up to nine failures per 100 couples per year, but that's just a guess. We know that in the studies, it was three pregnancies per 100 couples per year. Who can use it? Basically, anyone who can use oral contraceptives, who can use the NuvaRing, who can use contraceptive patches, can also use Annovera given the fact that it's a combined hormonal method with estrogen and progestin. How it's used. It's pretty much the same as other hormonal contraceptives in terms of when it's started and how quickly it works. And that is, once the ring is inserted, it has a fairly rapid onset of action in terms of providing protection against ovulation and pregnancy.

## Dr. Michael Policar:

So the way that Annovera is intended to be used is that it's in place in the vagina for 21 days, then it's removed for seven days, the idea being a hormone-free interval to induce a scheduled withdrawal bleed. But of course, one question that we all ask is, "Well, if it's ring that lasts for a whole year, could a person use it continuously? Just every single day without taking it out, without having a withdrawal bleed, without having any menstrual periods?" And at least at this point, there's only a single study that had looked at this. It was published in contraception last year, and it was basically a modeling study that looked at levels of the Segesterone acetate after 36 months... I was having difficulty seeing what was in

the slide there. And so it looked at predicted Segesterone levels after 364 days, a full year of hypothetical continuous use.

## Dr. Michael Policar:

And it was comparable to the levels at which no pregnancy happens. Now, again, this is not a study in a big population of people using Annovera continuously for a year. It was much more of a modeling study that looked at Segesterone acetate levels for a year, hypothetically for continuous use, and that level was high enough that no ovulation and therefore no pregnancy would be predicted to have occurred. So we have this modeling study that says, "Yes, it can be used continuously for a year, but we don't have that study done yet in populations of patients." Other things about Annovera is that, as opposed to the new ring, this one does not require refrigeration while it's being stored. It can be removed for up to two hours for intercourse or for cleaning. And so the advice is to wash the ring with mild soap, lukewarm water, rinse it, dry it off, and then put it back in, but try not to have it outside of the body any longer than two hours.

## Dr. Michael Policar:

... and not to have it outside of the body any longer than two hours. And a person can use water-based creams and lubricants in the vagina at the same time that the Annovera ring is being used. However, the patient should not use oil-based or silicone-based lubricants because of the fact that it changes the blood levels of ethinyl estradiol in Segesterone. Examples of particularly silicone-based lubricant might be various kinds of so-called intimate lubricants, things like Astroglide and others. Astroglide, of course, has both a water-based version and a silicone-based version, but the point is, is that a person should not use vaginal products that either has oil or a silicone base to it, only water-based creams and lubricants. This slide is a comparison of the ring that you are familiar with, the NuvaRing, and the new ring, Annovera.

## Dr. Michael Policar:

So obviously, the big difference is the lifespan, where the NuvaRing is active for 30 days, while the Annovera is active for one year. There are different progestins, but the doses are about the same. Both of them have ethinyl estradiol as the estrogen component. The daily release rate is almost identical between the NuvaRing and Annovera. They both have almost identical diameters, but the Annovera is significantly thicker, and then there's also a different kind of plastic used to release both the ethinyl estradiol and the Segesterone acetate. Okay, so the big difference, again, is the thickness. So here's the comparison of what NuvaRing looks like, 54 millimeters across, four millimeters is the thickness of the ring itself. The middle picture compares the diameter to a dime. And then, you see on the right side, the photograph of Annovera, showing that it's exactly the same diameter, more or less, as the NuvaRing, but twice as thick.

## Dr. Michael Policar:

And this is kind of the same thickness as some of the estrogen rings that are used for menopausal hormonal therapy as well. Now, if you look at some of the marketing literature about the Annovera contraceptive vaginal ring, they will tell you that it's marketed as the, "First woman controlled, procedure-free, long-acting, reversible birth control product, putting the woman in control of her fertility menstruation." So what they seem to be saying is, this is a LARC, a long-acting, reversible

method of contraception, kind of in the same vein as the implant and the IUD. But is it really a LARC? And the answer is, "Yeah, it's description is accurate because a person can use the same ring for a full year, but in some ways, it really is not a LARC, because of the fact that it has to be removed every month in order to have that withdrawal bleed over a seven-day period.

## Dr. Michael Policar:

And number two, it has to be replaced within two hours after cleaning. And therefore, it's not a for forgettable contraceptive like an IUD or an implant. Obviously, with IUDs and implants, there's just one effort to do the insertion of the IUD or the implant. Following that, it's forgettable for years at a time. That won't be true with the Annovera because of the need to at least remove it and wash it, if not to remove it and have a withdrawal bleed. So Family PACT has made this a contraceptive benefit. It became a benefit on October 1st of 2021. So the way that it's billed, if you dispense it in the clinic, is J7294. One ring per dispensing, basically, because it lasts for a whole year. And by the way, the reimbursement rate, just to give you some sense of what Family PACT is paying for these methods, is just about $2,100 for the full year.

## Dr. Michael Policar:

And there's a maximum of two dispensings of the ring during a 12-month period, taking into account, the fact that some people might use it for 11 months, and then they're going on vacation, they need their next ring a little early, so that's why there can be two dispensing within a 12-month period. The next one down is the NuvaRing. The reimbursement rate for that is $121 and change. That is per cycle, per month, basically, and up to 13 rings can be dispensed, because there is an assumption that some people are going to use the NuvaRing continuously, but put it in on the first of the calendar month, use it until the end of the calendar month, take out the old ring, put in a new ring on the first of the next calendar month, so it's basically continuous use of the NuvaRing without a hormone-free interval, without a withdrawal bleed, which for the patient, is like a menstrual period.

## Dr. Michael Policar:

And therefore, you would need 13 rings in order to be able to have a whole year of continuous use. And again, a maximum of two dispensings during a 12-month period. If a person needs a third dispensing during that 12-month period, then a treatment authorization request or a TAR, is necessary. Okay, so that tells you about Annovera. Next is a contraceptive vaginal gel, which is called Phexxi. And so, the content of Phexxi is a combination of lactic acid, citric acid, and potassium bitartrate, in a unique vehicle, which has adherence characteristics, such that it sticks to the vaginal side walls well, to keep the vaginal environment acidic for an extended period of time. A person could have used some kind of water-based, vaginal gel that dropped the pH, but in the past, those only worked for a few hours.

## Dr. Michael Policar:

This one works for somewhat longer, given the sort of high-tech approach to the adhesive that's contained within Phexxi. So what it does is to induce an acidic pH in the environment, between 3.5 and 4.5. And what that does is that it's toxic to sperm. It reduces sperm motility. Now, it's effective only if it's used before intercourse. If it's put in after intercourse, it doesn't work at all. It has to be before. And it can be put in anywhere between immediately before intercourse, all the way up to one hour before each episode of intercourse. So the person can put an application of it into the vagina, have sex two

minutes from now, 20 minutes from now, all the way up until an hour from now, but if more than an hour has elapsed, rather, than you have to put in another applicator, because it will only work for a period of about an hour. Number two, and you wouldn't normally expect this, it's available only by prescription only.

## Dr. Michael Policar:

So I actually asked the people from the company that made it, "Why is that? Does it have anything in it, which is particularly dangerous? Why not make it over-the-counter? And their response was that because of the fact that this is a brand new product, it doesn't have hormones in it, it has a really different mechanism of action, it doesn't contain the same sorts of detergents of the nonoxynol-9, which is in other spermicides, they felt strongly that people needed to be counseled by a clinician about how to use these correctly, so that's why it's prescription-only. It's not a safety issue, it's a way of enforcing the fact that patients will need to be counseled by clinicians or health educators about how to use Phexxi. Now, how well does it work? Well, the published failure rate over seven cycles of typical use is roughly 14 pregnancies per 100 couples, per year.

## Dr. Michael Policar:

Okay? I rounded that up. It's 13.7 failures, which... per seven months, which is equivalent to that of a diaphragm. And of course, that's the figure that the FDA looked at in approving that figure. The thing is, is that when you look at the effectiveness of most other contraceptive methods, it looks at the failure rate per 100 couples, per 12 months for a whole year, okay? And in the package insert, they estimate the Pearl Index and the failure rate for a full year, and they say it comes out to about 27 failures per 100 couples, per year. So, that means it's in that bottom tier in the third tier of efficacy. Of course, the better people are about using it in a highly effective way, according to the rules, the lower the pregnancy rate is going to be. This 14%, seven cycle failure rate is typical use. Some people using it correctly, some people using it incorrectly. But basically, it fits close to the level of other spermicides and other barrier methods in that third tier of efficacy.

## Dr. Michael Policar:

So who can use Phexxi? There are no absolute contraindications. The package insert says that we should avoid use in people who have recurrent urinary tract infections, or who have had recurrent pyelonephritis, only because of the fact that in the clinical studies, there was a minor relationship between the use of Phexxi and the development of urinary tract infections. And so, there's concern that it might aggravate the situation in people who have recurrent UTIs. And also, we should avoid using Phexxi when a person's using a vaginal ring. For the most part, there'd be no reason to use it at the same time as a person who's using a contraceptive vaginal ring. So how to use it.

## Dr. Michael Policar:

It can be used with diaphragms, with latex or polyurethane condoms. There are also studies looking at using Phexxi and a variety of other vaginal medications at the same time. So Miconazole, Tioconazole, which are both antifungal drugs, Metronidazole vaginal gel, which of course, would be used for bacterial vaginosis. It can be used at the same time as Phexxi. And again, I'll emphasize that when it needs to be used is immediately before intercourse or up to an hour before intercourse, and then an additional dose before each subsequent act of vaginal intercourse. It comes in a box with 12 applicators. Up in the right

hand corner, you'll see what those applicators look like. They're similar in size to a tampon applicator. Now, what about side effects? Well, this comes directly from the patient package insert, with a sample size of about 2,500 females. So there was vulvovaginal burning in 18%, vulvovaginal itching in roughly 14%, a vulvovaginal mycotic infection, which actually refers to a vaginal candidiasis, in about 9%, an association with a urinary tract infection or pyelonephritis in about 9%.

## Dr. Michael Policar:

And then, partners complained of local discomfort on their penis about 10% of the time, but it was usually minor and almost never a reason to discontinue the use of Phexxi. So this gives you an idea about the kinds of things that you might expect in terms of complaints that patients may have once they start using the medication, particularly the itching and burning. Now, one last thing to say about Phexxi, which is kind of forward looking. We're definitely not at this point yet, but we may be at some point. And that is that there was a study published last year in the American Journal of Obstetrics and Gynecology, the one we refer to as the gray journal, about using Phexxi as a way of reducing the likelihood of chlamydia and gonorrhea infections, okay? And this article refers to the product as EVO100, okay? And the reason why is, Evofem is the name of the company that makes it, so the investigational name for Phexxi in this study was EVO100.

## Dr. Michael Policar:

So they enrolled patients between 18 and 45 years of age, who had been diagnosed as having had and treated for either chlamydia or gonorrhea, six weeks before enrollment in the study. There were 376 people in the treatment group with EVO100, 388 people who were in the placebo group. And you can see the racial and ethnic distribution that has reported in this particular study, about an equal number of African American and White patients. So again, they got either the treatment product of Phexxi or a placebo vaginal gel, and they were instructed to apply the drug up to an hour before each sexual act. So what was the outcome? Well, thing to do was to jump to visit five, because there were multiple visits in follow up. And the figure on the left refers to rates of chlamydia in this high-risk population.

## Dr. Michael Policar:

So for people who used the treatment drug, EVO100, the rate of chlamydia was about 5%. For people who received the placebo, it was almost 10%. So the point is, using this medication actually reduced the likelihood of acquiring chlamydia by 50%. It was even more profound with gonorrhea. For people who used the study drug, the rate of gonorrhea was a little under 1%, but for people in the placebo group, the rate of gonorrhea was 3.2%. So look, here what we see is an even more profound reduction... Oops, there, go ahead. Sorry... in gonorrhea rate, so almost 80%. So what we might be looking at in the future is a multipurpose technology. It may be that this product can be used both as a contraceptive and as a way of preventing the likelihood of gonorrhea and chlamydia, but I want to emphasize, it is not FDA approved for the latter purpose yet.

## Dr. Michael Policar:

That's because there's another big clinical trial that's going on right now to look at the ability of Phexxi to prevent chlamydia and gonorrhea. That's the kind of information that's going to be presented to the FDA, and at some point, we may see it labeled, "Both for pregnancy prevention and STD protection," but we're not quite there yet. I just wanted you to know about it. Okay, so what is Family PACT... What is the

Family PACT benefit, as it relates to the contraceptive vaginal gel? It's available since July of last year, with HCPC Code of A4269-U5. When it's dispensed, it's dispensed in a box of 12 single-use applicators. There can be up to three dispensings, which means three boxes, for a 75-day period. And the reimbursement rate to clinics who dispense it is $257 per box of 12, which comes to about $21 per applicator.

## Dr. Michael Policar:

So again, I thought this was important information to let you know about Phexxi, because compared to other vaginal spermicides, they are all in the ballpark of somewhere around 10 or $12 for an entire tube of a spermicide, which may last for many, many acts of intercourse. On the other hand, with Phexxi, it's basically $21 for every act of intercourse, per applicator, but it's still... it is covered. There are some people who will be attracted to being able to use a vaginal contraceptive that is not a spermicide and does not have the irritant effect of a nonoxynol-9, and of course, a product which has no hormones in it. Okay, the next method to discuss is a new contraceptive patch. So this is one with ethinyl estradiol and levonorgestrel. Its trade name is Twirla. Excuse me for a second to get a sip of water.

## Dr. Michael Policar:

Okay, so you may know about the other contraceptive patch, which has been available for a while, which is called Xulane. That is actually the successor to the first contraceptive patch, which was called Ortho Evra. So Ortho Evra and Xulane are the same thing, but basically, Xulane is 35 micrograms of ethinyl estradiol and 150 micrograms of Norelgestromin, while Twirla has a little less ethinyl estradiol and it uses a different progestin, levonorgestrel, which you know all about. Levonorgestrel is in a number of oral contraceptives, as well as being the progestin which is in all the progestin-bearing IUDs like Mirena, Liletta, Kyleena, and so on. Now, with Twirla, there are two black box warnings, but I will say that this is true for both patches, both for Xulane and for Twirla. It is contraindicated in women who have a body mass index of 30 kilograms per meter squared or more, and that's true for two reasons.

## Dr. Michael Policar:

Number one is that, based on an increased body weight, the effectiveness starts to drop off significantly. And number two, there's a concern that the estrogen provided to a woman with a BMI of 30 or more would lead to an increased risk of venous thromboembolic events. And otherwise, it has the same cardiovascular contraindications for arterial events as the oral contraceptive and the ring. Now, how effective is Twirla? In typical use, overall, it's roughly six pregnancies, per 100 couples, per year. For people who have a body mass index of under 25, it drops to a... it's actually improved to a failure rate of about 3.5 pregnancies, per 100 couples, per year. And for people who have a body mass index between 25 and 30, the failure rate is about 5.7 pregnancies, per 100 couples, per year. So as you can see, if you round that up to six failures, per 100 couples, per year, that's very comparable to the oral contraceptive, to the ring, and to the other patch, which is available.

## Dr. Michael Policar:

So how is Twirla used? Very much in the same way as Xulane. It's approved for cyclic use, for the patch to be on for 21 days, and then off for seven in order to have a withdrawal bleed. Of course, it's one patch per week for each of three weeks, and then one week off. The patch can be applied to the abdomen, the buttocks, the torso, rather, like the rib cage, but not the breasts because of a concern that

the hormone leaving the patch would go straight into the breast. And then, of course, it has to be applied to clean skin. When to use it is that it is initiated the same as any other combined hormonal method. And for new starters who are not using anything, it really needs to be applied within the first 24 hours after the menses, or if not applied in that first day after the onset of the menstrual period, then seven days of a backup is needed. And it, again, the efficacy onset is the same as any other combined method, where it becomes effective quite quickly.

## Dr. Michael Policar:

So again, we have a comparison of the older patch to the newer patch, a comparison of progestins, which are different, but similar doses, a comparison of estrogens where the Twirla has a lower estrogen dose than does Xulane.. I'll show you a photograph of the size in just a moment, but the size of Twirla is double that of Xulane. It's used in exactly the same way, one patch per week for each of three weeks, and then a week off. And then, there is a different delivery system. In Twirla, it's called this Skinfusion system that has no latex. So I wish I had dimensions on here. I'm sorry I don't, but it gives you an idea about the sort of square appearance of Xulane, as opposed to Twirla, which is a greater diameter and is circular in its appearance. So what about coverage by Family PACT? So this is covered by Family PACT. Xulane has a billing code, the HPPC code of J7304-U1. And basically, the reimbursement rate is $13.57 cents per patch.

## Dr. Michael Policar:

And for Twirla, the HPPC code is J7304-U2, and its reimbursement rate is a little higher, about 17.75 per patch. Now, you can dispense, either prescribe or dispense, up to 52 patches, and it's fairly easy to make that computation, because the thought is that someone may be using the patch continuously. Instead of three weeks on, one week off, they use the patch every week, and they use a patch every week for the 52 weeks of the year. So that's why you can dispense up to 52 patches of either Xulane or Twirla, which would give a person a full year of protection. A 12-month supply of the same product of patches can be dispensed twice in a year. Again, the logic being that if a person was given a year's supply, has now used 11 months of it, and won't be available next month to get her new supply, that that new supply can be started a little bit early, but if you need to use a third supply in the same year, then that has to be approved by TAR.

## Dr. Michael Policar:

Okay, next topic. And this is quick because of the fact that we've talked about this before, and this has to do with Depo-Provera-SubQ. So remember during the pandemic, there was a lot of concern by patients who were using Depo-Provera-IM to actually leave their home, drive to the clinic, come into the clinic to get their Depo shots, so we did a whole webinar two years ago on the topic of alternatives to Depo-IM. So the alternatives were, you just bite the bullet and come into the clinic anyway, to get your Depo-150 injection. Number two is that some clinics were very creative and said, "Come to our clinic, stay in your car, and we will literally give you your Depo shot while you're in your car."

## Dr. Michael Policar:

The third was to have an in-person visit where you went to a pharmacy and got an IM injection of Depo-150 in a pharmacy, given by a pharmacist. That was a Family PACT benefit as of September 1st, 2020. Or you could switch to self-injected Depo-Provera-104-SubQ, or we recommended that a person could

switch to what was called a bridge method, progestin-only pills, pill, patch, ring, a barrier method, until the public health emergency was over and people could come back into clinic, so those were all available. But at any rate, two years ago, Depo-SubQ became a Family PACT benefit, as long as it was dispensed by a pharmacy. And so, remember, the differences between the two are the Depo-SubQ is in a prefilled syringe, ready-to-use at home, so the client's in control.

## Dr. Michael Policar:

It uses a shorter, smaller, 26-gauge, 3/8-inch needle, with only a small amount of fluid being injected SubQ by the patient herself. But the point is, is the tiny, short needle, about what you would expect with an insulin syringe, for example, so potentially less pain than Depo-IM, which is an IM injection. Remember that Depo-SubQ has 30% less hormone, 104 milligrams, in comparison to 150 milligrams in Depo-IM. And there are fairly similar side effects between the two. Local site irritation and soreness on the first and second self-injection, but that has a tendency to get better over time.

## Dr. Michael Policar:

Okay, so yet another comparison of Depo-SubQ on the top, and the intramuscular, Depo-150 on the bottom. It just gives you an idea of the differences between the two, and points out the fact that for Depo-SubQ, there is no generic version. Pfizer is the only company that is allowed to make it. So who are the people that are the best candidates to learn how to self-inject Depo-SubQ? Well, people who have heard about this and said, "Yeah, I really like the idea of being able to inject myself every 13 to 15 weeks at home." Second, clients who currently receive Depo-IM, and after counseling, say, "Yeah, sure, I'd be willing to learn how to inject this at home and not have to come into the clinic and get my Depo-IM injections," and it's also a good choice for people who already know-

## Dr. Michael Policar:

So IM injections. And it's also a good choice for people who already know how to self-inject. So, if you've taken ovulation induction drugs for In-vitro fertilization, you're a diabetic who uses insulin, you've had to use heparin or drugs for multiple sclerosis, you know how to do those self-injections already.

## Dr. Michael Policar:

The contraindications and side effects for DMPA-SQ are about the same for DMPA-SQ and DMPA-IM. There's no reason to do any sort of dosage adjustment with either one based on a person's body weight. And whenever a person decides to use DMPA-SQ, it's always a good idea to document why that was the case in the patient's medical record, just for the availability of other clinicians in the future to see why that particular choice was made. Now, the reason I brought this up is because of the fact that there has been an evolution of DMPA-SQ 104 as a Family PACT benefit.

## Dr. Michael Policar:

So it can be dispensed by a pharmacy directly to a Family PACT client for self-administration at home. That became a temporary pharmacy benefit in September 2020, which was really in the first few months after the pandemic started, but it was made a permanent pharmacy benefit as of June 2021. So Family PACT doesn't pay for this to be dispensed in clinics, but it does pay for you to transmit a prescription to a pharmacy, and then the pharmacy can provide it to a patient. In the earliest refill of a dose of DMPA-SQ

is 80 days. Remember it can be injected anywhere between 13 weeks and 15 weeks to work. Now I'm going to use this moment as an opportunity to remind you that there have been some major changes in how you get at the Family PACT Pharmacy Formulary.

## Dr. Michael Policar:

Remember you could go to thefamilypact.org website. Then what you could do is to go to the provider section, click on the Family Pact Formulary, and that's where you would find the drugs covered by Family PACT. That is no longer the case. There is a new program that you've probably heard about called Medi-Cal RX. This is for the entirety of the whole Medi-Cal program, whether it's Medi-Cal managed care, Medi-Cal Fee for Service, but it includes Family PACT as well. So this is the Medi-Cal RX website. I'm sure most of you also have Medi-Cal patients in addition to Family PACT patients. So it's really important to have a look at this. So basically the interaction of Medi-Cal RX and Family PACT is that the administration of all Medi-Cal pharmacy benefits, fee-for-service in Medi-Cal, Medi-Cal managed care, and Family PACT is now through this program. It includes all pharmacy services billed as a pharmacy claim.

## Dr. Michael Policar:

So in other words, whenever a licensed pharmacy dispenses it right to a Family PACT patient, they will do their pharmacy claims through the Medi-Cal RX portal. Okay, but it does not include pharmacy services that are billed as clinic-dispensed drugs or institutional claims. Those claims are done the way that they used to be done. But I just want to remind you that if you want to get an up-to-date copy of the Medi-Cal formulary, you would no longer go to the Familypact.org website, you're not going to use that one anymore. Instead, you're going to use Medi-Cal RX. It's very easy when you go to that website. And again, I'm going to show you the... Oops, there we go. It's up at the top here, medi-calrx.dhcs.ca.gov/home/. So you go to the welcome to Medi-Cal RX. In the question box type in Family PACT.

## Dr. Michael Policar:

It will take you right to the Family PACT Formulary in a very slick, easy-to-understand way. So that's how you're going to find out what's covered by Family PACT. And by the way, you can also go to this particular link and it will take you straight to the Family PACT Formulary as well. All right. Last topic in regard to contraceptives is to tell you about a new progestin-only pill, but again, I want to emphasize it's not a Family PACT or Medi-Cal benefit. It is a Drospirenone progestin-only pill called Slynd. It has four milligrams of Drospirenone, which is the same progestin, which is in Yaz, Yazmin, Ocella. And it has some of the same things that you're aware of regarding Drospirenone. It has an anti-androgenic effect at the hair follicle and therefore may be beneficial for reducing facial hair and acne.

## Dr. Michael Policar:

It has a diuretic effect like spironolactone. And so since people are urinating more, it may make their premenstrual distress disorder, PMDD, less. And then for a person who's got a medical condition that makes their potassium levels high, the recommendation is to check a person's potassium level during the first cycle of using Slynd, just to make sure it hasn't gone up even more, but that's only for people who have had a problem with high potassium months to start with. The way that this one is used is with a 24/4 dosing regimen, 24 days on four days off for the hormone-free interval. But this one has a full 24-hour missed pill window, which is not true of most of the other progestin-only pills. Also, it has no

estrogen and therefore there's no thromboembolic risk and no black box warning, as there are with combined oral contraceptives.

## Dr. Michael Policar:

So remember the other progestin-only pill or mini pill, which is out there is norethindrone, Micronor, and generic versions of that in comparison to Slynd. So in the case of bleeding people who use norethindrone progestin-only pills are relatively more likely to have breakthrough bleeding. On the other hand with the Drospirenone progestin-only pill, the four-day hormone-free interval allows much more scheduled bleeding. Number two is that the Norethindrone progestin-only pill really doesn't inhibit ovulation. It only thickens cervical mucus while with the Drospirenone pill. It actually inhibits ovulation. And then the third point is that Micronor and the generics, because of the short half-life of Norethindrone have to be taken exactly the same time every day while with Slynd, because it has a long half-life of 30 hours, you have that sort of brace period where you don't have to take the pills at exactly the same time every day.

## Dr. Michael Policar:

So it's more forgiving if you don't take it at the same time every day. So its efficacy is that it's typically use failure rate is four pregnancies per hundred couples per year. It is expensive. And again, because it's not covered by Medi-Cal or Family PACT, I can't give you a reimbursement rate, but my benchmark for prices are to go to an app, which is called Good RX, which gives you the lowest retail price in your community. And at least where I live in San Rafael, it's $196 per cycle. Although I think that coupons are available for that. So it is marketed basically to females who can't, or won't use estrogen, who want to use a progestin-only pill that is more forgiving of not taking it at exactly the same time. What I do want to remind you is that there is no generic version.

## Dr. Michael Policar:

Okay. One last thing about contraceptives, and then we're going to switch very quickly to an STD topic that is that hopefully, you followed the fact that the labeling for a number of different, long-acting contraceptive methods have been changed in the last year to make them more realistic and more evidence-based. So what I'm comparing in the middle column is now the FDA-approved duration of action in comparison to the evidence-based duration of action. All of these things on the list, by the way, are Family PACT benefits. So Paragard is approved for 10 years. The evidence says it works for 12 years. Mirena works for seven years. Now, the package insert has been changed to say that it works for seven years. It might even work for eight years, but at least the packaging asset seven years for Liletta evidence says it works seven years. It's now labeled for six years. Kyleena has

## Dr. Michael Policar:

Evidence for five years of efficacy and it's labeled for five years. And then down at the bottom, both DMPA-IM and DMPA-SQ are FDA approved for injection every 13 weeks. But there's really good evidence that the injection rate can actually be every 15 weeks and it'll still be equally efficacious. So an important update in terms, of the label of these various IUDs. So in the last 10 minutes or so, because I do want to give you time for Q and A. Of course, this is not a repeat of my whole talk, talk that we did a year ago with [inaudible 01:01:34] but just a quick update about updates regarding antibiotics that are covered by Family PACT for sexually transmitted infections. So first question is does Family PACT cover

multi-site sampling? And of course, what I'm referring to here is that we should always be asking when we take a sexual history for patients, males, and females, not only do you have genital sex, but do you have anal sex or do you have oral sex?

## Dr. Michael Policar:

And you can break that down into insertive sex or receptive sex, but you want to know about those sites basically. Okay. Now one of the reasons that's important is that in order to find chlamydia and gonorrhea, not only in the penis of men, in the vagina or cervix of females is the fact that we also don't want to miss rectal infections or oral pharyngeal infections. And in the case of men having sex with men, 70% of gonorrhea and chlamydia infections of the rectum or the throat are going to be missed, if you only do a urine sample for males. And this comes from the new CDC guidelines, which basically says that for people who have insertive anal sex, or I'm sorry, insertive intercourse, that is penis to vagina sex, that a male should be screened with [inaudible 01:03:07] application test for chlamydia and gonorrhea, for a receptive anal course, a rectal GC/CT for acceptive oral intercourse, a pharyngeal gonorrhea NAAT they say, you really don't need a pharyngeal chlamydia test.

## Dr. Michael Policar:

But the point is that all the tests for gonorrhea also include chlamydia. So there's really no way to split them out. Okay. So that has been guideline for at least 10 years. That for men having sex with men, we should screen all three sites. What is relatively new has to do with multi-site screening in females. So what the new CDC guidelines say is that for Cis-Women based on sexual history in the preceding year, not routinely for a person who's had receptive anal course do a rectal GC chlamydia NAAT, for people who had receptive oral intercourse, do a pharyngeal gonorrhea chlamydia NAAT based on a shared decision with the patient. And again like the study, I showed you a moment ago in males, the same is true, a female. So this is a big study done in a number of STD clinics with 5,500 women who are at high risk.

## Dr. Michael Policar:

And they were screened orally in the vagina and in the rectum. And it turns out that if chlamydia was found in the rectum, the vaginal chlamydia test was positive 65% of the time, but it was negative a third of the time. And if gonorrhea was found in the rectum, basically in a majority of circumstances, the two-thirds of cases, the genital, in other words, the vaginal sample was negative. So in other words, if we only screen the vagina in females, we may miss a significant amount of let's say rectal chlamydia and rectal gonorrhea. Okay. So that's why you always have to ask about which orifices you're having sex with if sex in or what body parts you're using to have sex. Okay. This slide goes through a little bit more detail about current anatomy and gender of sex partners, transgender females who have had a vaginoplasty, and transgender men who have had a metoidioplasty, which is basically surgery in order to create a penis.

## Dr. Michael Policar:

Okay. Now just also a quick reminder about where to take these samples when you're sampling oropharyngeal, get it from the tonsil pillars. When you're sampling the rectum, put the swab in three or four centimeters, and don't just like twist it. What you want to do instead is to twirl your wrist 360

degrees. So that you're sampling the entirety of the rectal sidewalls. Not just whatever stool happens to be in the rectum, you get a much more accurate sample that way. Okay.

## Dr. Michael Policar:

So what does this have to do with Family PACT? That is multi-site gonorrhea and chlamydia screening is covered both by Family PACT and Medi-Cal, where you can do up to three tests for gonorrhea and chlamydia per day. As of September 2018, one in the throat, one in the genital tract, one in the rectum as clinically indicated, be sure to use a separate NAAT test kit for each of the genital sample, the anal sample, and the oropharyngeal sample to get questions all the time about when you sample those three different sites, are they three different tests, three different CPT codes. And the answer is no, it's all the same test. It's all the same CPT code. You just have to label your samples very clearly for where the sample came from. And remember on the lab slips to include the ICD-10 diagnosis code for why you did that screening in the first place.

## Dr. Michael Policar:

Okay, next question. There has been a switch in how we treat chlamydia infections. So the new CDC guidelines say that the recommended regimen for treating chlamydia is Doxycycline a hundred milligrams orally twice a day for a week. The alternative is to use Azithromycin one gram orally in a single dose. So you might recognize that the old guideline with Azithromycin, Doxycycline with was an alternative. Now that's flipped on itself. So that Doxycycline twice a day for a week is the preferred approach. Okay. That's because it works better, particularly for chlamydia in the rectum.

## Dr. Michael Policar:

Now the old recommendation for pregnancy is still in place. Of course, we don't like to use Doxycycline in pregnancy because it effects that it has on fetal bone development. So during pregnancy, we still use Azithromycin in a single dose. So I think in a part for this flow chart, but basically what it says is if you think a person may have rectal chlamydia, they have to be treated with Doxy, because it works better. If a person's pregnant, they have to be treated with Azithro because we can't use Doxy. And if anyone else let's say, for example, you tell a patient that she or he has chlamydia. The recommendation is a week of Doxy and a person might say, I've taken that before, it makes me sick or I can't remember to take two pills a day for a week. And in that circumstance, it's acceptable to use Azithromycin we'd rather... Sorry. We would rather... We would rather see them use Doxycycline, but if not, it would be acceptable to use Azithromycin.

## Dr. Michael Policar:

Okay. What about gonorrhea infections? Here's a reminder that the treatment for uncomplicated gonorrhea in the cervix, in the urethra, and in the rectum is Ceftriaxone 500 milligrams IM for people who weigh under 150 kilograms and it's a Ceftriaxone a full gram IM for people who weigh more than 150 kilograms. Now that's the treatment for gonorrhea. And if you have not ruled out chlamydia, then you follow that with Doxycycline a 100 milligrams twice a day for seven days. So if you do a gonorrhea and chlamydia NAAT test, the gonorrhea test is positive. The chlamydia test is negative. Then you use Ceftriaxone 500 milligrams as the sole treatment. But on the other hand, let's say a patient comes in and says, my boyfriend was diagnosed as having gonorrhea. I need to be treated. You don't have a chlamydia

result at that point. So in that circumstance, you use 500 milligrams of Ceftriaxone followed by Doxycycline for a week.

## Dr. Michael Policar:

Okay. And you can see at the bottom that the CDC is no longer recommending Ceftriaxone plus Azithromycin for a number of reasons. Now, what if in your clinic you don't stock injectable Ceftriaxone. So here are the guidelines that say that an alternative for gonorrhea treatment is Cefixime. You may know that by its trade name of Suprax, but there are many generic versions. So it's Cefixime 800 milligrams given orally once to treat gonorrhea again, if you're, if you haven't ruled out chlamydia, then you would add Doxycycline for a week. So here are two oral medications that you can use to treat gonorrhea. Okay. Now finally, there's one exception to that rule and that's pharyngeal gonorrhea because pharyngeal gonorrhea has a... Does not have a good treatment success rate with that oral medication in order to treat pharyngeal gonorrhea, you have to use injected Ceftriaxone 500 milligrams IM given once, higher dose for people who have a heavier body weight. And not only that, but the CDC recommends doing a test-of-cure after treating pharyngeal gonorrhea, seven to 14 days after treatment.

## Dr. Michael Policar:

Now remember that within NAAT test for gonorrhea, you may pick up dead organisms for a week or even 10 days, that would give you a false positive test-of-cure. So Ina Park and others like to say, wait, at least 10 days or so before you do the test-of-cure after treating pharyngeal gonorrhea with Ceftriaxone just to make sure that you don't get a false positive test. Okay, let me just skip over this. It's why the change was made and that is less there... there are more Azithromycin-resistant strains of gonorrhea. As far as Family PACT goes, the PPBI has been updated to... To include all of these CDC recommendations for treating chlamydia and gonorrhea that I just mentioned.

## Dr. Michael Policar:

Okay. Were there any changes in the guidelines regarding patient delivered partner therapy, a few, and remember that when you diagnose a patient with gonorrhea or chlamydia, it used to be that the contact tracing of partners might be done by the local health department that definitely cannot be done anymore. The reason why is that the county health departments are so busy with work around the pandemic and COVID 19 that they just can't chase down partners for gonorrhea and chlamydia anymore. So the CDC in the 2021 guideline makes it really clear that it's up to the provider and the patient to get in touch with partners. Now, how can you get partners treated? Well, one is to have the patient bring the partner with her. It's called "BYOP", or bring your own partner works great. But most of the time a partner won't come.

## Dr. Michael Policar:

So alternatively, and in this order, the CDC recommends what's called patient-delivered partner therapy. So number one is provide the patient with antibiotics intended for the partner and then many clinics that's called a partner PACT. You just hand the patient extra medication for up to five partners, or you can prescribe extra doses in the index patient's name, or you can write prescriptions in the partner's name. All of those are acceptable, that kind of in that order. So what Family PACT says about that is that if a Family PACT client is diagnosed with gonorrhea, chlamydia, or trichomoniasis and expedited partner therapy is necessary to prevent reinfection. Either you can dispense medication to the client to give to

their partner, all the way up to five partners, or you can provide the client with a prescription in the client's name, not the partner's name, but the client's name with enough quantity and duration to be able to treat the acute infection, not only in the client but in her partners as well.

## Dr. Michael Policar:

Okay. And that's been a Family PACT benefit since August of 2020, it's also a Medi-Cal benefit. So the public health value of getting partners treated is so high. You don't need to see the partner in Family PACT and Medi-Cal will pay for those antibiotics to treat partners. Next, is what about treatment of pelvic inflammatory disease? And here are the guidelines have changed as well, based on Randomized Controlled Trial of women who had PID and they got shot of Ceftriaxone, Doxycycline for two weeks and then they were randomized either to the addition of Metronidazole or Placebo.

## Dr. Michael Policar:

Okay. Here's what the findings were that whether or not you got Metronidazole, by three days it was an equal response rate. But for people who also got Metronidazole, they were less likely to have anaerobes in the endometrium, less likely to have Mycoplasma genitalium, and reduce cervical motion tenderness and pelvic tenderness. And therefore they concluded that Metronidazole should be routinely added for treatment at PID. So this is the current recommendation for treatment of PID. It is a Family PACT benefit and all these are covered, particularly Ceftriaxone, 500 milligrams IM, and then a prescription for Doxycycline for 14 days with Metronidazole for 14 days.

## Dr. Michael Policar:

Okay. Next is the question of Mycoplasma genitalium has come up. Okay. Which is an organism that in particular can cause a problem with recurrent cervicitis and recurrent [inaudible 01:15:40] threats. Okay. About 2% of sexually active people have Mycoplasma genitalium, it's significantly higher in STD clinics. And there seems to be an association between having a Mycoplasma genitalium infection with having Cervicitis, PID, pre-term birth, and spontaneous abortion. We know it's an epidemiologic association, but we're not sure whether or not it's a cause-and-effect relationship. So there is a NAAT test available called the Aptima Mycoplasma genitalia assay, which is available for both males and females. It's very accurate in terms of sensitivity and specificity. So the CDC guidelines published last year, basically have recommendations for the use of the Mycoplasma genitalia NAAT, mainly for the diagnosis of recurrent urethritis in both females and males, Cervicitis, and PID. But they... They did not issue any recommendation regarding using the Mycoplasma genitalia assay as like general screening. And I've got many questions about this. I know it's also true in the [inaudible 01:16:54] can we use the M gen test just to screen high-risk people?

## Dr. Michael Policar:

And the answer to that is definitely not. At least it's a Family PACT benefit because it's not recommended by the CDC. CDC says you can use the Mycoplasma genitalia NAAT for people who have recurrent urethritis, recurrent Cervicitis, or who have pelvic inflammatory disease. They also pointed out that there's a new treatment for Mycoplasma genitalium it's Doxycycline for a week followed by Moxifloxacin for a week. So it is sequential and they basically got rid of Azithromycin as a treatment for Mycoplasma genitalium because there's a very high rate of resistance. So the Mycoplasma genitalium test is covered as a diagnostic test in Family PACT and that's been a benefit for all of about a week and a

half ever since the 1st of May of this year. And it's available as a diagnostic test for persistent or recurrent Cervicitis, nongonococcal urethritis of the penis that has not responded to Doxycycline.

## Dr. Michael Policar:

Urethritis of the penis that has not responded to doxycycline or azithromycin and Family PACT covers both of the drugs that are used. Skip over syphilis. I'm going to get to one last thing. Sorry again, for all the noise outside. And I will remind you about what's going on with vaginal trichomoniasis, by the way, I skipped over syphilis just because the Family PACT benefits for syphilis haven't changed and the CDC recommendations regarding syphilis haven't changed much. Other than the fact that they say that in anybody, in whom you diagnose syphilis, you really ought to have a conversation with them about PrEP. And of course, PrEP is not a Family PACT benefit at this point. So in regard to vaginal trichomoniasis, basically the CDC and the 2021 guidelines say that we should screen Cis-Women having HIV once a year. Screen Cis-Women in corrections, like in the jail or prison annually and then consider screening for trichomoniasis in people who are in increased risk of sexually transmitted infections, which they define as new or multiple partners, history of sexually transmitted infections and so on.

## Dr. Michael Policar:

But boy, this is really an unsatisfying recommendation because what do they mean by consider screening rather than either do it or don't do it? Well, the point is that in Family PACT, we do have some new tests that are available, but we haven't actually adopted those CDC recommendations yet about screening everyone for trichomoniasis. Now the tests that are covered by Family PACT is the Aptima Trichomonas vaginalis Assay and the OSOM Rapid Trich test. And of course microscopy is covered but they are only covered as diagnostic tests. And then again, once you've treated person for trichomoniasis, they need to be retested three months after treatment. Now, the other thing that's changed is the recommended treatment for vaginal trichomoniasis. Remember it used to be two grams of Metronidazole as a single dose. Now this study was published in 2018, which are that the success rate in treating vaginal trichomoniasis with a single dose is 81%.

## Dr. Michael Policar:

The cure rate of a seven day treatment is 89%. So now the CDC guidelines recommend treating females who have vaginal trichomoniasis with metronidazole 500 milligrams twice a day for a week. They've also changed the recommendation about metronidazole use in alcohol. And they say based on this study from Scandinavia that having people refrain from alcohol use is unnecessary during treatment. That's also a change in the 2021 guidelines. So finally then the recommendation regarding treatment for trichomoniasis is that females should be treated with metronidazole 500 milligrams twice a day for a week. Males can be treated with metronidazole two grams as a single dose and the alternative is tinidazole two grams as one dose. And again, the Family PACT benefits are the Trich NAAT test and the OSOM Rapid Trich as diagnostic test. And all of these CDC recommendations are covered. The last two slides I'm going show you are where to get more information.

## Dr. Michael Policar:

So Family PACT has an absolutely wonderful website at Familypact.org and just recently the California prevention training center has updated this page that has to do with clinical resources. So to get the monthly Family PACT update, you can go to this section on policy to see the full policy procedures and

billing instructions. You can go here if you want to download a table that has all of Family PACT benefits, download the Family PACT benefit grid. You can see the Family PACT standards, reimbursement rates for onsite medication dispensing and so on. Okay. So very, very last slide. And that is just to remind you, if you have an STD question that the prevention training centers, there are a number of them in that in the United States. And of course ours is the California prevention training center.

## Dr. Michael Policar:

They have a STD consultation network where if you've got a question about a complicated case, go to the website, put in your zip code, they'll tell you how to get in touch with the infectious disease clinician who is an STD expert who will be able to answer your questions about sexually transmitted infections. So with that, I'm going to try to answer a couple of questions, but I will tell you that as with other webinars, what I don't get to, we will do a written Q&A, and you'll be able to see the answers to all these questions, including the ones that I could get to. So can, Annovera be used continuously. The answer to that is, yes, a person can but you should really tell the individual that's just based on a single modeling study. We don't have a whole lot of clinical trials of that yet, but it's reasonable to believe that Annovera can be used nonstop. Even, even more noise. Next question, if a patient has vaginal candidiasis or bacterial vaginosis and wants to use a vaginal cream or gel, do they need to remove the hormonal ring during treatment?

## Dr. Michael Policar:

The answer to that is, no. As I mentioned during the talk, there have been studies done with a couple of different antifungal drugs, as well as metronidazole vaginal gel. And they work well, even though a ring is in place. And number two, they don't cut down on the hormone levels that are released from the ring. So yes, you can use those treatments for a vaginal infection and the ring at the same time. So what's the best way to store the Annovera ring when it's out for a withdrawal leak? Amanda, you stumped me on that. I don't know the answer, but I will put that into the written Q&A. The next question after that is exactly the same thing. And that is basically what's done with the Annovera during the hormone free interval. Let's see. Does Medi-Cal cover Phexxi? The answer to that is yes. Is Phexxi reimbursable with hormonal methods at the same time.

## Dr. Michael Policar:

I didn't see anything as I looked at the Phexxi benefit that said that it would not be, but I will certainly give you an opinion about that. I think that is not a really good idea. Now, is it safe to use a hormonal method and Phexxi at the same time? Sure. Why not? On the other hand, I got the question is why would you do that? I mean, because you could see that Phexxi is really quite expensive, $21 for every applicator. So I don't understand what the logic would be of using Phexxi at exactly the same time that you would be using hormonal method. Yeah, I get the idea about using a spermicide and using oral contraceptives at the same time. But I think for a person who's using their method quite effectively, they probably don't need a vaginal method as a backup.

## Dr. Michael Policar:

And if you were to do that, I would do that with one of the Nonoxinol spermicides, rather than doing that with Phexxi. And of course, let's wait until we get even more evidence about gonorrhea and chlamydia. And then, then we might have a different attitude at that time. Can a clinic charge Family

PACT for injection of the MPA subQ, if a patient picks it up from a pharmacy and brings it to the clinic. Seems like less payment, et cetera, with subQ and that might be preferable to some patients. The answer to that is, yeah, I don't see why not. In other words, it would be a low level E&M code for that visit, or it would be the injection code actually Family PACT doesn't cover injection code. So it would be a low level injection code, like a 99211 or a 99212.

## Dr. Michael Policar:

For example, of course she can't build for the drug itself. A person has gone to the pharmacy, picked up the drug, takes it back to the clinic, if that's where she wants it injected. And then that would be a low level E&M code for that. It just sort of defeats the purpose. It seems to me that if a person's going to come in, why not just do the Depo 150, but on the other hand, if they like the idea of the lower dose, they like the idea of the smaller needle, but they can't learn how to inject it themselves. Then I think it's reasonable for them to come to the clinic and have it done.

## Dr. Michael Policar:

So I know that this is a contraception talk, but how does Drospirenone affect lactation? Most of my patients are infants with breastfeeding mothers. And the answer is that, I've got to say again, I apologize for this because of the fact that it's not a Family PACT or Medi-Cal benefit, I haven't read through the entirety of the Drospirenone/Slynd patient package insert that would give you an idea about whether or not it's safe to use it with breastfeeding mothers.

## Dr. Michael Policar:

I will tell you this, that there's obviously decades of information about using Norethindrone. In breastfeeding women, we know that's entirely safe and it doesn't cut down on the amount of breast milk. On the other hand with Slynd, it's probably so new that those studies have not been done yet in regard to looking at the safety of Slynd in breastfeeding women. Well, let alone the fact that it's so hard to get because of the fact that it's not covered by Medi-Cal and it's not covered by Family PACT. So that's a topic which is likely to evolve over time when we learn, number one, when slim becomes a more widely available benefit, particularly in Medi-Cal and Family PACT. And number two, we'll probably see some things that have to about it, safety and breastfeeding. I just don't think that's out there yet.

## Dr. Michael Policar:

Next, do I recommend against a rectal self-swab? That's a really good question [inaudible 01:29:02] but I've got to tell you that unless a person is able to do that trick with really flipping their wrist in such a way that they're actually swabbing the rectal sidewalls. I think that this is going to be much more accurate if it's done by a clinician than if it's done by a patient. Now, there may be information in the STI literature about self-rectal swabs. I'm not entirely familiar with it, but I think to the degree that we're doing rectal swabs, they need to be done correctly, which is that wide swing of the wrist that you do to get the rectal sidewalls. Okay, so we are getting demand from Family PACT for doing multi-site testing. You shouldn't be and email the office of family planning and let them know about what you're running into, is a problem. So next question is, should you.

## Nicole Nguyen:

I'm sorry. I just wanted make sure to be on time to be respectful for time. We're right at 1:30, but I know in the past you've been able to stay like an extra 15 minutes to answer questions. So would you like to do that? And then that way, if you need to drop off, they're welcome to, but then that way you give a little extra time to answer more questions.

## Dr. Michael Policar:

So, the answer is I'm fine with staying another 10 minutes.

## Nicole Nguyen:

Okay, perfect. Yes. All right. And then again, everyone's recorded, so we'll get

## Dr. Michael Policar:

If you have to leave and get back to patients of course, feel free, and you'll be able to see all these answers in writing, but for those of you who can stay for another 10 minutes, I'll try to answer more questions. Let's see. Can I speak to the efficacy of self-collection for rectal and pharyngeal gonorrhea and chlamydia? I just did to the degree that I know about, I would definitely not be a fan of pharyngeal gonorrhea chlamydia collection that way. Because for people to use the swab, to swab their tonsil or pillars almost always causes a gag reflex. So I can't imagine how a patient themselves, even if they're looking at a mirror is going to be able to get a good oral pharyngeal sample without gagging. That really needs to be done by someone by a clinician and MA and so on.

## Dr. Michael Policar:

And I've already answered that for, for a rectal sample that you need that wide swing. Okay. All right. Let's see. Should the use of azithromycin be discontinued and the answer is no. Azithromycin is still an alternative therapy for chlamydia, perfectly fine for that, but it, but it's not first choice. The treatment of choice for chlamydia is seven days of doxycycline, but for the patient who can't, or won't take doxycycline, for the person who's pregnant then is azithromycin for chlamydia is completely appropriate. Now, when it comes to gonorrhea, 5% of gonorrhea isolates are no longer sensitive to azithromycin, and that number is going up, up and up and up every year. So that's why azithromycin is not considered to be an appropriate drug for gonorrhea, any longer. So if for gonorrhea, you're going to use either ceftriaxone or cefixime. Next question, is the test-of-cure at the 7 to 14 day mark paid for by Family PACT?

## Dr. Michael Policar:

The answer to that is, yes, that's an important question because remember previously Family PACT and I think even Medi-Cal had an edit where, when you did a gonorrhea or chlamydia nucleic acid application test, basically you could only do one for 30 days. That requirement has now gone away. And the point is you can do up to three a day, and then you can do follow-ups soon after that as clinically indicated, and that would include a test-of-cure. So the point is that if a person is treated for pharyngeal gonorrhea,

they come back 10 days later in order to have a test-of-cure for the pharyngeal gonorrhea, then that one will be covered by Family PACT. It will not hit a 30 day edit and be denied.

## Dr. Michael Policar:

Okay. I want to go back for a moment, for these questions from Jessica, I was feeling pressed for time, but I really want to be able to answer this. We are being denied from Family PACT for multi-site testing. What I just mentioned that is genital oral and rectal. That doesn't make sense. Then you would be denied because you're not doing those test. It's laboratory, that's doing the test. So if you take three different samples for NAATs test, those three samples are sent to Quest or to another laboratory. If they're denied, it's Quest, that's being denied. It's not your clinic. Okay. So unless Jessica actually works for Quest or actually works for a clinical lab, and you're asking the question of why those three samples are being denied payment to the laboratory.

## Dr. Michael Policar:

Then I think that's a completely reasonable question, although I don't know why the laboratory would be denied. But as far as your clinic goes, you should not be billing for those nucleic acid amplification test. The one sort of exception to that rule is planned parenthood, which has its own sort of reference lab. But most time in family planning clinics, even though you can do point-of-care test on-site, that doesn't include gonorrhea and chlamydia, you send those out. And therefore the group that's being denied is the laboratory. It's not your clinic. So what diagnosis code is required for partner treatment, we've been getting some denials with only the gonorrhea or the chlamydia code. Do we need to add exposure to STI code [inaudible 01:34:56]? Well, all of that is contained in the PPBI, which unfortunately is not in front of me, but there are about 10 different codes that can be used for a variety of circumstances of treating sexually transmitted infections.

## Dr. Michael Policar:

So sometimes it's because you're in a high risk hotspot, sometimes it's because of a fact that the patient had a high risk contact. Sometimes it's because the patient has had one STD and STI and now you're screening for other STIs. But the PPI should be clear. It is quite clear in terms of which codes you're going to use, in which circumstances I'll certainly put that into the written responses, but you shouldn't be getting denials as it relates to treating partners, because that very clearly is a Family PACT benefit.

## Dr. Michael Policar:

Okay. So again, I'm saying the same test. This one is from Shannon who left that the chlamydia test from three sites, same day of service has not been a covered benefit. Family PACT is only covering one, sometimes two, but never three. Again, something's wrong there unless you are a laboratory, because otherwise you should not be billing Family PACT for gonorrhea and chlamydia tests since they are sent out to a laboratory. You're not doing them on-site. Okay. So how do you provide a client with prescriptions for their partners in their electronic health records, such as Epic? Sorry Kim, I really can't answer that. I don't know how you go about doing that because of course, an HR, like epic is like tweaked for each place that it is used. So I don't have a good answer for you there.

## Dr. Michael Policar:

Let's see. Next one. This is pure true. Pharmacies no longer want to take written prescriptions, which is how we used to prescribe rather for partners and for family members. So the way to do that, as I mentioned earlier is nicely described in the PPBI is you write, or you take into account the fact that you're providing partner treatment by increasing the number of tablets, for example, that you're prescribing for the patient. So let's say for example, your patient has gonorrhea. Okay. And you don't have injectable Ceftriaxone. So, you're going to be using cefixime and maybe doxycycline for a week. All right. Actually has three partners. So therefore you have to treat the patient and the three partners. So the way that you do your prescription, and I understand it's electronically transmitted is basically for four doses it's for the patient and three of her partners, but it's all in her name.

## Dr. Michael Policar:

Medi-Cal and Family PACT, through the Medi-Cal RX website are now set up to be able to pay for that. Particularly by electronic transmission of those prescriptions, it doesn't have to be written, but that makes, that makes it a lot easier than having to write a separate prescription for a partner. Instead, what you do is you write it for the patient. You just double it, triple it, quadruple it, and all of that. And of course, document that. And all of that is going to be covered by Family PACT. Next is Medi-Cal also covering Mgen as a diagnostic test. Well, I can tell you that the medical website says that it is covered. What I don't know the answer to is how individual Medi-Cal managed care health plans are covering. So let's say your patient has medical coverages through Cal Optima or through the San Francisco health plan or through partnership health plan.

## Dr. Michael Policar:

You would have to look at those individual Medi-Cal managed care health plans to see if they're covering. But if the person is state fee for service, medical, it's covered, and of course in Family PACT is covered. Okay another question is in one of the slides, I used the abbreviation IDU next to sex work. What does that mean? It refers to intravenous drug use. So if the person is a needle user or a needle sharer, that is a significantly increased risk for HIV, syphilis, hepatitis B. So I realize we're almost at 1:40, so let me just take one or two more. So, given the congenital syphilis rate, Family PACT, be considering covering point of care, syphilis testing to improve the early diagnosis in treatment of reproductive age people. And the answer is yes, that is being considered right now.

## Dr. Michael Policar:

So one of the things I didn't have time for, we did cover this last year in the STD webinar with Dr. Park was that there are some labs that are still doing, what's called the traditional algorithm of screening for syphilis, which is a nontreponemal test, like a VDRL or an RPR, which is then followed by a treponemal test. Now, many labs have flipped that, and they're doing something else, which is called the reverse sequence algorithm, which is actually to start with a treponemal test, like an enzyme immunoassay. And if that's positive, then to back that up with a nontreponemal test. So you really need to know what your lab is doing. And the point that Katherine is making here is that there are now a couple of point of care tests for syphilis, which are treponemal tests looks directly for the Spirochete, okay.

## Dr. Michael Policar:

That are available in clinic. And wouldn't that be a really good way to make an early diagnosis of syphilis? Well, yes and no. Yes. You can get certainly a positive test of that EIA, which implies that the person may have syphilis, but it still has to be confirmed in the next step, which is the non-treponemal test. And that's got to be sent out to a lab. But at some point we should be able to have point of care testing for syphilis, which is both a screening test and a confirmatory test. We don't have that yet. All right. I'm just going to see if there's one more quick one, can Depo be billed when the MA delivers the depo shot? The answer to that is yes. It is clearly outlined in the PPBI, about how to do that. How about checking blood pressure when using hormonal contraception for a year?

## Dr. Michael Policar:

The answer is it's unnecessary. There's no reason that you should have to do that. If you had an initial blood pressure, which showed that was normal in a person with no history of hypertension, perfectly fine to go ahead and prescribed for a year. Okay. A few others they're kind of repetitive given the fact that, well, let me answer one more, very fast, because it's such an easy answer and that is, does Medi-Cal cover Gardasil 9 beyond age 18? The answer is Medi-Cal does. And the other question is, does Family PACT cover Gardasil 9? And the answer to that is not yet, but it's being considered.

## Dr. Michael Policar:

So it's another one of those things like the syphilis test that I mentioned a moment ago, where the office of family planning is considering coverage. And that's something that we'll be talking about later this summer or potentially in the fall. So anyway, thank you for hanging in there for an extra 12 minutes and probably by the middle of next week, I will have all these questions answered in writing, and they will be available for you with both the recording of what we just did as well as the answers to all your questions. So Nicole I'll handle hand the microphone back to you.

## Nicole Nguyen:

Yes, Doc, thank you so much. That was quite a lightning round notable car, and there's still so many questions, but yes, we'll collect them and get those answers out for you. Please make sure you ask that survey at the end for us. That really helps us a lot. And again, CMEs link recording slides, the Q&A will get them all out to you in about two weeks. And then thank you again for our wonderful presenters Lamont and then Dr. Policar, this was like definitely one of your superstar present presentation, for sure. Lots of information you were able to pack in. So thank you all for joining us, and I hope we all, you all stay safe and have a great rest of your week. Right? Bye.