Putting New Family PACT Benefits to Work in Patient Care
Webinar Q & A
May 11, 2022

STI Testing & Treating

1. When a patient is seen for STI testing, should the claim also have the birth control ICD-10 code?

Answer: Yes. Services for the diagnosis and treatment of specified STIs must be billed with the diagnosis code that identifies the contraceptive method for which the client is being seen. Please refer to the *Benefits: Family Planning-Related Services* section of the Family PACT Policies, Procedures and Billing Instructions (PPBI) manual.

Gonorrhea and chlamydia (GC/CT)

2. Should the use of Azithromycin be discontinued?

Answer: Azithromycin is still the recommended treatment of chlamydia in certain situations, such as treating chlamydia during pregnancy. It is an alternative treatment for genital and pharyngeal chlamydia, mainly when the client declines to use the 7-day course of doxycycline. It should not be used for rectal chlamydia because of a 20% failure rate. Due to resistance, it has no role in the treatment of gonorrhea.

3. Are self-rectal swabs comparable to provider collected swabs? (b) Can you please speak to the efficacy of self-collection for rectal and pharyngeal GC/CT? (c) Do you recommend AGAINST rectal self-swab?

Answer: A number of studies have been performed and published comparing clinician-sampling to patient self-sampling for both gonorrhea and chlamydia. The 2021 CDC STI Treatment Guidelines (pages 71-72) state that "patient-collected samples can be used in place of provider collected samples in clinical settings when testing by NAAT for urine (men and women), vaginal swabs, rectal swabs, and oropharyngeal swabs after patient instructions have been provided. Patient-collected specimens are reasonable alternatives to provider-collected swabs for gonorrhea screening by NAAT."

If you decide to offer this alternative to clients, *be sure* to ask the client if they prefer self-sampling over clinician sampling and provide explicit instruction in how to collect the samples.

Partner treatment for GC/CT

4. Prescribing antibiotics for STIs for partners that I have never met always has made me feel uncomfortable. Knowing nothing about their medical history, their allergies, etc. makes me a bit concerned. Can you elaborate some thoughts on this?

Answer: Every state in the US has made expedited partner therapy (EPT) for gonorrhea and chlamydia an "exception to the rule" regarding the need for a visit before a person is treated. This is because the

public health benefit of having partners treated to prevent reinfection of the patient (and others) outweighs the risk of not examining the partner(s). California's regulations state that patients may deliver treatments to partners for gonorrhea, chlamydia and trichomoniasis, which in turn is reflected in Medi-Cal and Family PACT policy.

Per the 2021 CDC STI Treatment Guidelines, "provision of medication by EPT should be accompanied by written materials for educating partners about gonorrhea and chlamydia, their exposure to gonorrhea and/or chlamydia, and the importance of therapy. These materials should also educate partners about seeking clinical evaluation for adverse reactions or complications and general follow-up when able. Educational materials for female partners should include information about the importance of seeking medical evaluation for PID, especially if symptomatic; undertreatment of PID among female partners and missed opportunities for diagnosing other STIs among women are of concern.

5. If a partner is treated based on the patient sharing the information, do you still do a CMR to report the STI?

Answer: No, since the CMR is intended to report *confirmed cases* of specific conditions. Partner treatment is based on the probability of infection, but not the certainty of it.

6. What directions would you write on the client's prescription if you are treating their partners?

Answer: Per the *Benefits: Family Planning-Related Services* section of the PPBI (page 24), "If a Family PACT provider diagnoses a Family PACT client with gonorrhea, chlamydia and/or trichomoniasis and determines that offering the client EPT is medically necessary to prevent reinfection of the client, then the provider may either dispense medication directly to the Family PACT client to provide to his/her partner(s) or may provide the Family PACT client with a prescription, written in the name of the client, for medications with a quantity and duration of therapy sufficient to treat the acute infection in the client and to prevent reinfection of the client by treating the client's partner(s)."

7. What diagnosis code is required for partner treatment? We've been getting some denials with only CT or GC code. Do we need to add "exposure to STI" code to cover?

Answer: Family PACT uses **Z20.2** [Contact with and (suspected) exposure to infections with a predominantly sexual mode of transmission (M and F)]. This code is used for an asymptomatic partner exposed to a person with chlamydia and/or gonorrhea.

8. Will Family PACT cover patient-delivered partner treatment medicine for CT, GC or Trichomoniasis if dispensed from a clinic and billed on the encounter form (Superbill)?

Answer: Yes. Family PACT covers dispensing of PDPT (patient delivered partner therapy) for up to five partners. The Superbill is a billing "tool." It is not a required form of the program. You may use any template that adequately documents medical records for services billed for reimbursement under the Family PACT Program.

Lab issues for GC/CT

9. Can a person come in today and get tested for all 3 sites for CT/GC today as a Family PACT benefit and then again tomorrow?

Answer: Reproductive health screening tests may be provided, **if clinically indicated**. For a CT and GC screening test(s) to be reimbursed, **the ordering provider must indicate the medical necessity for the test** with the ICD-10-CM code, as appropriate, on the laboratory order. The laboratory provider must include the ICD-10-CM diagnosis code that identifies the contraceptive method for which the patient is being seen. Please refer to the *Benefits: Family Planning Services* section of the PPBI.

10. Is the test of cure at the 7-14 day paid for by Family PACT? Is there a specific ICD code for the test of cure?

Answer: Yes, the test-of-cure for *pharyngeal gonorrhea* 7-14 days after treatment is covered by Family PACT. The ICD-10 diagnosis code that should be used is **Z86.19** [Personal history of certain other infectious and parasitic diseases].

Remember that in most circumstances, a test-of-cure after treatment of gonorrhea or chlamydia is not indicated. The indications for test-of-cure listed by the 2021 CDC STI Treatment Guidelines include post-treatment for pharyngeal gonorrhea, pregnancy, noncompliance with therapy, persistent symptoms despite therapy, suspicion of early reinfection after adequate therapy, and multi-day antibiotics with high failure rate.

11. We have a reference lab. Would we be paid for chlamydia testing three times if we test the 3 areas?

Answer: Family PACT benefits include up to three GC/CT tests (each from a different site) per day.

12. CT 87491 for three sites same date has not been a covered benefit. Family Pact is only covering one sometimes two but never three. What should we bill as to get it covered?

Answer: Family PACT <u>does not</u> cover any point-of-care tests for gonorrhea or chlamydia, so clinics should not be billing for the tests themselves. It is the clinical lab that performed the test that should be billing Family PACT. When these samples are sent to a clinical lab that is contracted with Medi-Cal, Family PACT benefits include up to three GC/CT tests (each from a different site) per day.

13. What about if the testing is done by laboratory in our health department, will Family PACT cover the 3-site testing?

Answer: See answer to Question 12, above.

Mycoplasma and Ureaplasma

14. Is Mycoplasma *genitalium* testing covered by Family PACT?

Answer: Yes. It is covered for the purpose of *diagnosis* of recurrent urethritis in females and males, cervicitis, and in some cases of pelvic inflammatory disease (PID). It is not covered as a screening test in either females or males.

15. Is Moxifloxacin covered?

Answer: Yes. The CDC regimen of doxycycline for 7 days *followed by* moxifloxacin for 7 days is covered for treatment of *M. genitalium*. However, prior authorization with a pharmacy treatment authorization request (TAR) must be submitted and approved before the dispensing of moxifloxacin.

16. Why not testing for Ureaplasma, too? We are seeing it quite a bit.

Answer: It is not covered because the CDC does not recommend screening for *Ureaplasma urealyticum* and there are limited reasons to order it as a diagnostic test. It is sometimes included in the evaluation of cervical factor infertility, but evaluating this condition is not a Family PACT benefit.

17. Should we treat sex partners of Mycoplasma *genitalium* positive patients?

Answer: According to the CDC STI Treatment Guidelines [page 82]: "Recent studies report a high concordance of *M. genitalium* among partners of males, females, and MSM; however, no studies have determined whether reinfection is reduced with partner treatment. Sex partners of patients with symptomatic *M. genitalium* infection can be tested, and those with a positive test can be treated to possibly reduce the risk for reinfection. If testing the partner is not possible, the antimicrobial regimen that was provided to the patient can be provided."

Partner treatment for *M genitaliu*m is not a Family PACT benefit.

18. The *Mycoplasma genitalium* policy of our department is to test symptomatic individuals not wait for recalcitrant/unresolved symptoms, is this correct?

Answer: If *M. genitalium* is prevalent in your patient population, that may be a reasonable policy. However, the CDC recommendation, which is reflected in Family PACT policy, is to test for *M. gen* only in the case of recurrent urethritis, recurrent cervicitis, or in some cases of pelvic inflammatory disease.

19. After Doxycycline, if client is allergic to Moxifloxacin, what is recommended for *Mycoplasma genitalium?*

Answer: According to the 2021 CDC STI Treatment Guidelines [page 82]: "when moxifloxacin cannot be used, an alternative regimen can be considered, based on limited data: doxycycline 100 mg orally 2 times/day for 7 days, followed by azithromycin (1 g orally on day 1 followed by 500 mg once daily for 3 days) and a test of cure 21 days after completion of therapy. Because of the high prevalence of macrolide resistance and high likelihood of treatment failure, this regimen should be used only when a test of cure is possible, and no other alternatives exist."

20. Is Medi-Cal also covering Mycoplasma *genitalium* as a diagnostic test?

Answer: Yes. Please refer to the *Pathology: Microbiology* section of Part 2 of the Medi-Cal manual.

Trichomoniasis

21. Can you talk a little more about Trichomoniasis? Screening?

Answer: According to the 2021 CDC STI Treatment Guidelines, the indications for screening for vaginal trichomoniasis include:

- Cis women living with HIV: screen annually
- Cis women in corrections institutions: opt-out screening
- *Consider screening* if "at risk" for vaginal trichomoniasis: new/multiple sex partners, history of STI, inconsistent condom use, sex work, and intravenous drug use

Family PACT covers a number of diagnostic tests for trichomoniasis (please refer to the *Laboratory Services* section of the PPBI). As of the publication date of this document, trichomoniasis screening is not a Family PACT benefit.

22. Will Family PACT ever cover Trichomoniasis testing in people with a penis?

Answer: If there is a policy change, it will be announced in a future *Family PACT Update*.

Syphilis

23. Given the congenital syphilis rate, will Family PACT be considering covering point of care syphilis testing to aim early diagnosis and treatment in reproductive age people?

Answer: Not at this time. All Family PACT covered syphilis tests are performed in clinical labs only.

24. Is doxycycline an alternate for Syphilis or not anymore?

Answer: Yes. According to the 2021 CDC STI Treatment Guidelines, "for nonpregnant persons with penicillin allergy who have primary or secondary syphilis, doxycycline (100 mg orally two times/day for 14 days) and tetracycline (500 mg orally 4 times/day for 14 days) have been used for years and can be effective. Compliance is likely to be better with doxycycline than tetracycline because tetracycline can cause more gastrointestinal side effects and requires more frequent dosing. The only acceptable alternatives for treating late latent syphilis or syphilis of unknown duration are doxycycline (100 mg orally two times/day) or tetracycline (500 mg orally 4 times/day), each for 28 days. Because of *T. pallidum* chromosomal mutations associated with azithromycin and other macrolide resistance and documented treatment failures in multiple U.S. geographic areas, azithromycin should not be used as treatment for syphilis."

25. For vaginitis, is there consideration for NuSwab coverage?

Answer: No. NuSwab *screens* for BV (3 different tests), trich, candida (two types), gonorrhea, and chlamydia from a single swab. There is no CDC recommendation to screen for so many pathogens from a single swab. In most cases, an asymptomatic client will require screening for only a few *specific* pathogens, based on her sexual history, or in some cases, none.

Annovera

26. How do patients store Annovera when out for hormone free/withdrawal bleed/ 7 days out time?

Answer: The following recommendations are made in the Annovera patient package insert:

- During the hormone-free interval, your vaginal system should be cleaned with warm water and mild soap, dried with a clean cloth towel or paper towel, and stored in the case provided, away from children, pets, and extreme temperatures.

- Protect ANNOVERA from direct sunlight. Do not refrigerate or freeze and avoid excessive heat.
- Always put the vaginal system in or take it out on your vaginal system change day at about the same time of day. For example, if you put your vaginal system in on Monday at 9:00 in the morning, always take it out or put it back in on Monday at about 9:00 in the morning.
- You do not have to take the vaginal system out when you have sex. If you decide to remove it, remember to reinsert it within 2 hours after removing it or you may not be protected from pregnancy.

27. Why would someone use Annovera when one of the side effects is migraine headaches, and migraines with aura increase stroke risk?

Answer: The contraindications to the use of Annovera are the same as those of other combined hormonal methods like the combined OC, contraceptive patches, and the contraceptive vaginal ring. The FDA approved labelling is almost identical among the three combined hormonal methods, based on what is referred to as a "class effect."

28. Can Annovera be used continuously?

Answer: As noted in the presentation, a pharmacologic study showed that if Annovera is used continuously over the course of a year, the blood levels of segesterone should remain high enough throughout the year to prevent ovulation and consequent pregnancy. However, there are *no studies* in human subjects yet that track the safety or efficacy of Annovera used continuously for a year.

29. If a patient has a vaginal yeast infection or Bacterial Vaginosis and wants to use vaginal cream or gel, do they need to remove the hormonal ring during the treatment?

Answer: No, the ring does not have to be removed if the cream or gel is water-based. The patient package insert states: "Do not use any vaginal products such as oil-based suppositories, oil-based creams, or oil-based gels while the vaginal system is in the vagina. Do not use any vaginal lubricants that have silicone or oil in them." Water-based lubricants are ok to use. Patients should read the ingredients on the labels carefully before buying a vaginal lubricant.

30. The package inserts for NuvaRing states only to give four rings at a time. Are you saying you can give 12-13 EluRyng/NuvaRing at a time?

Answer: The Family PACT benefit is up to one Annovera ring per year or 13 NuvaRing/EluRyng units per year if a client requests a full year dispensing *and* the clinician has prescribed the method for a year. However, the clinician is under no obligation to prescribe any method for a year. You can and should use your clinical judgement in deciding the duration of prescription of a given medication for a given client.

Phexxi

31. Does Medi-Cal cover Phexxi?

Answer: Yes. Both Medi-Cal and Family PACT cover Phexxi.

32. Can Phexxi be used on a diaphragm prior to insertion or just inserted for subsequent acts of intercourse?

Answer: Phexxi has not been studied as *a substitute* for a spermicidal cream or gel to be used with a diaphragm. Studies show that the use of Phexxi is compatible with a diaphragm, but there has not been a comparative study of failure rates with diaphragm + Phexxi compared to diaphragm + spermicide.

Available evidence does not support advising clients who use a diaphragm that Phexxi can be substituted for spermicide.

33. Is Phexxi reimbursable with hormonal methods at the same visit?

Answer: Yes, if clinically indicated.

34. Has this been looked at with condom use?

Answer: Not specifically to determine if there is improved efficacy. The following is excerpted from the patient package insert for Phexxi:

- Phexxi may be used concomitantly with hormonal contraceptives; latex, polyurethane, and polyisoprene condoms; and vaginal diaphragms. Avoid PHEXXI use with vaginal rings.
- Phexxi may be used concomitantly with other products for vaginal infections including miconazole, metronidazole, and tioconazole.

Twirla

35. Is there a BMI threshold for Twirla or Xulane patches in which they become less effective?

Answer: Yes. A BMI of $\geq$30 kg/m^2 is associated with an increased failure rate for both patches. However, even with the greater failure rate in this circumstance, both patches are still within the "middle tier" of contraceptive effectiveness, which includes OCs, ring(s), patches, and DMPA.

36. How does the risk of thromboembolism with Twirla and Xulane compare to Ortho Evra?

Answer: Xulane and OrthoEvra are the same product. The risk of venous thromboembolism (VTE) with OrthoEvra is slightly higher than with a corresponding dose of oral contraceptives but is far lower than the risk of VTE in pregnancy. The risk of VTE with Twirla *may* be slightly less than with Xulane owing to the lower release rate of ethinyl estradiol, but they have not been compared "head-to-head" yet. Nonetheless, the Patient Package Inserts for both Twirla and Xulane have "Black Box" warnings regarding the risk of VTE.

37. You mentioned using the Patch continuously. I learned that continuous use was not recommended due to increasing levels of estrogen in the bloodstream, and a week off was necessary to let those levels drop. Has that changed?

Answer: Neither Xulane nor Twirla have been evaluated for continuous use. As noted in the presentation, Family PACT providers *may* dispense up to 52 patches (one-year supply) for clients on a continuous cycle.

38. Can the birth control patch be used as "as needed" birth control for patients who do not have sex regularly?

Answer: No. This has never been studied and very likely would not be effective.

DepoProvera

39. Can the clinic charge Family PACT for injection of DMPA-SQ if patient picks up from pharmacy and brings to clinic? Seems like less pain with SQ and may be preferrable to some patients.

Answer: No.

40. Does Depo SQ still have weight gain issues? And delayed return to fertility issues?

Answer: In most respects, expect the side effects of DMPA-SQ to be similar to those of DMPA-IM. With both versions of DMPA, the likelihood of rapid weight gain (beyond what would be experienced normally) is an issue mainly with overweight adolescents. Delay of return to fertility should be the same with both products. With DMPA-IM, the average time to pregnancy is 9 months after the final injection.

41. Is it true that Depo cannot be covered by Family PACT if it is given earlier than 84 days from last injection?

Answer: No. Both strengths are limited to one per client, per 80 days.

42. How long do you use Depo Provera as birth control? Can you use it for more than 2 years?

Answer: It can be used for contraception for as long as someone wants to use it. However, given that there may be a small amount of bone loss due to low estrogen levels while using DMPA (an average of 7% of bone density), some experts caution about its use in women in their late 40's, given that there may not be enough time to regain bone mineral density after DMPA discontinuation but before menopause. Consequently, it is important to discuss the issue of benefits and risks with clients in the older age group.

43. Do we use a regular E&M code when the MA is administering Depo?

Answer: Clinics may not bill for a medical assistant administering Depo.

Pharmacy

44. So, the pharmacies will dispense birth control for 1 year?

Answer: Per state law, "[a] pharmacist *shall* dispense, at a patient's request, up to a year-long supply of an FDA-approved, self-administered hormonal contraceptive pursuant to a valid prescription that specifies an initial quantity followed by periodic refills." Please refer to Senate Bill 999, signed September 23, 2016.

45. What is the rationale for NOT covering SLYND, purely financial?

Answer: No. For a drug to be approved to be included in the Medi-Cal and Family PACT formularies, the manufacturer must request that it be added. All new medications must be approved through this process to be included in the Med-Cal and Family PACT formularies.

Other

46. What is IDU next to sex work?

Answer: IDU: intravenous drug use

47. Can you clarify the term receptive oral intercourse?

Answer*: Receptive* oral sex is when a person has contact of their mouth and lips with a partner's penis or vulva/vagina. *Insertive* oral sex is when a person with a penis inserts their penis into another person's mouth or throat.

48. Does Medi-Cal cover Gardasil 9 beyond age 18? (b) It was mentioned Gardasil covers from 18 yrs. and older with Medi-Cal, but I did not hear up to what age? 40 years old? 50 years old?

Answer: Consistent with FDA labelling and CDC recommendations, Gardasil can be prescribed to Medi-Cal patients through 45 years of age for both females and males.

49. How about checking blood pressure while using hormonal contraception for 1 year at a time?

Answer: There is no need to routinely check blood pressure annually in users of combined hormonal contraception. While annual screening may be indicated for some people with cardiovascular risk factors, those who are normotensive when they start hormonal contraceptives should have their blood pressure checked every 2 years.

50. Which hormonal birth control does not give mood swings or depression as side effect?

Answer*: In general*, hormonal contraceptives do not cause depression or exacerbate pre-existing depression. This may occur in a small percentage of hormonal contraceptive users; in which case a different product could be tried, or the client could switch to a non-hormonal method such as a copper IUD or a barrier method. If mood swings occur at the time of the transition to the hormone-free interval, switching to a continuous regimen of OCs or a contraceptive vaginal ring may prevent the mood swings from occurring.

51. Any updates/recommendations for taking a "break" when using continuous pill/patch/ring?

Answer: This practice is not recommended by the CDC or any other national body.

52. We have patients that have frequent menstruation, breakthrough spotting after the IUD insertion, Depo, or when started OCPs. Patients want to see the provider and the provider codes the visit with Dx code N92.0 do we need an authorization? Is this considered a complication that requires a TAR.

Answer: No. The bleeding patterns that you described are side effects, not complications, of contraceptive methods. As such, management visits do not require preauthorization or a treatment authorization request (TAR). In coding for these visits, the primary diagnosis is always the ICD-10 **Z30x code** that corresponds to the person's method of contraception.