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TO: FAMILY PACT (PLANNING, ACCESS, CARE, AND
TREATMENT) PROVIDERS

SUBJECT: FAMILY PACT PROGRAM LETTER 10-01, FAMILY PACT
CLINICAL PRACTICE ALERTS:

- URINARY TRACT INFECTIONS (UTI) IN WOMEN
- FAMILY PLANNING SERVICES FOR OBESE WOMEN
- UPDATE: EMERGENCY CONTRACEPTION (EC)

The California Department of Public Health, Office of Family Planning issues *Clinical Practice Alerts* to provide guidance to Family PACT providers on current clinical and programmatic issues. *Clinical Practice Alerts* provide an interpretation of the Family PACT Program Standards. Providers should refer to the *Policies, Procedures, and Billing Instructions* manual for the complete text of the standards, official administrative practices, and billing information. For the purposes of this and other *Clinical Practice Alerts*, the term “shall” indicates a program requirement while the term “should” is advisory and not required. The three enclosed *Clinical Practice Alerts* have been developed to provide new and updated information on the following topics:

- “Urinary Tract Infections in Women” is a new *Clinical Practice Alert* that details the use of diagnostic tests for UTI, as well as a listing of preferred drugs for treating UTIs.
- “Family Planning Services for Obese Women” is a new *Clinical Practice Alert* that examines the affect of body weight on the efficacy of each contraceptive method and the medical risks experienced by obese women who use oral contraceptives.
- “Update: Emergency Contraception” adds new recommendations beyond those contained in the *Clinical Practice Alert* published in December 2005, in addition to a review of new oral EC products and modifications in Food and Drug Administration dispensing regulations.

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You are encouraged to share this information with all of the clinicians, counselors, and health educators in your practice that provide care to Family PACT clients.

Additional copies of these documents and resources such as the Family PACT Benefit Grid can be downloaded from our Web site at:
<http://www.familypact.org/en/Providers/policies-procedures-and-billing-instructions.aspx>.
If you have questions or comments regarding these *Clinical Practice Alerts*, please contact Michael Policar M.D., M.P.H., Chair, Family PACT Clinical Practice Committee, at (916) 650-0424.

Thank you for participating in the Family PACT Program. We hope these *Clinical Practice Alerts* are useful to your practice.

Sincerely,

ORIGINAL SIGNED BY

Laurie Weaver, Chief
Office of Family Planning

Enclosures

UPDATE: EMERGENCY CONTRACEPTION (EC)

Emergency contraception (EC), including progestin-only products, combined oral contraceptive pills (OC) and the ParaGard[®] intrauterine contraceptive (IUC), is an effective intervention to prevent unintended pregnancy after unprotected sexual intercourse. Oral EC can be provided as a prepackaged product or as an accepted regimen of combined OCs. Please check the Family PACT Formulary at http://files.medi-cal.ca.gov/pubsdoco/publications/masters-mtp/fpact/pharmacy_f00.doc to determine which EC products currently are covered. This Alert replaces the December 2005 EC Alert.

KEY POINTS

- **EC provision is time sensitive and is most effective the sooner it is administered after unprotected intercourse. Providers should offer EC as soon as possible, but administration should be no later than 120 hours after an episode of unprotected intercourse.**
- **Progestin-only EC can be given as levonorgestrel 1.5 mg as one dose or levonorgestrel 0.75 mg taken as two doses 12 hours apart, with no difference in side effects between the two regimens. Oral contraceptives offered as EC must contain ethinyl estradiol with either levonorgestrel or dl-norgestrel given as two doses 12 hours apart.**
- **Advance provision of EC should be offered to women who rely on less effective methods of contraception or those who report having missed doses of combined hormonal contraceptives or progestin-only pills.**
- **A pregnancy test visit when the result is negative in a woman who does not desire pregnancy represents an additional opportunity to discuss contraception and to offer advance provision of EC.**

QUESTIONS AND ANSWERS**Is a comprehensive history, physical exam, or pregnancy test required before dispensing EC?**

No. A comprehensive health history or physical exam is not required for administration of EC. A pregnancy test should be performed only if 10 days or more have elapsed from the date of unprotected intercourse. Contraceptive counseling should be offered at EC visits and clients advised that EC is not recommended as a sole method of contraception.

What effect does advance provision of EC have on clinical outcomes?

Advance provision has been shown in clinical studies to increase actual EC usage with no decrease in the ongoing use of effective contraception or an increase in sexually transmitted infection rates.¹ However, in a large meta-analysis² advance provision of EC does not reduce overall pregnancy rates when compared to conventional EC provision.

Does the use of EC cause abortion?

No. EC does not cause an abortion because it works before implantation occurs. If a woman already is pregnant, EC will not cause a miscarriage or birth defects. By preventing pregnancy, EC reduces the need for induced abortion.

What are the specific indications for EC?

- When EC is requested by a client within five days of an episode(s) of unprotected intercourse
- As a component of a "quick start" regimen for off-cycle initiation of a hormonal regimen of contraception, if a woman has had unprotected intercourse in the past five days

When should EC use be considered by a woman already using contraception?

According to evidence-based guidelines for missed hormonal contraceptives,³ women who have had intercourse in the past five days should use a barrier back-up for the next seven days and consider the use of EC in the following circumstances:

- When a woman misses one or more days of OCs in week one or three or more days in week two or three of cyclic OC use
- After removal of the contraceptive ring for three or more hours in week one or longer than 72 hours in week two or three
- After detachment of the patch for 24 hours or longer in week one or longer than 72 hours in week two or three
- When progestin-only pill-taking is delayed for longer than three hours *OR* after missing one or more progestin-only pill(s)

Are there any age restrictions regarding the use of EC?

- Prepackaged EC products can be purchased without a prescription by women and men 17 years of age and older at most pharmacies. Clients should be reminded that proof of age will be requested.
- Women under 17 years of age either require a prescription or may obtain EC directly from a specially trained pharmacist participating in the EC Pharmacy Access Program without an advance prescription. A partial list of participating pharmacies (by city, county, or zip code) can be found at <http://www.ec-help.org/PharmacyLocations.asp>.
- Minors have the legal right to self-consent for pregnancy-related services, including the use of EC. California law does not require parental notification or consent for the provision of contraception (including EC) to minors.

EMERGENCY CONTRACEPTION (CONTINUED) MARCH 2010

Which oral contraceptive products can be used for EC?

The original Yuzpe Regimen for emergency contraception used Ovral[®] with two tablets as a first dose and two tablets 12 hours later. Consequently, only OCs containing levonorgestrel or dl-norgestrel + ethinyl estradiol in doses equivalent to the original Yuzpe regimen should be used. For example, Nordette[®] must be used as four tablets per dose.

Is there any advantage to progestin-only EC compared to using combined OCs?

There is significantly less nausea and vomiting in patients using progestin-only products compared with EC regimens that contain estrogen. In addition, randomized trials have demonstrated that the use of progestin-only EC results in even lower pregnancy rates than the combination OC method.⁴

How long after unprotected intercourse is EC effective??

The original Yuzpe regimen permitted the use of EC up to 72 hours after unprotected intercourse and all EC products are labeled with the same restriction. However, a number of studies^{5,6} have shown that EC are effective for up five days (120 hours) after unprotected intercourse.

Are there any women who should not be given EC?

The World Health Organization (WHO)⁷ states that the only contraindication to oral EC is a known pregnancy. A history of heart attack, angina, stroke, thromboembolic conditions, migraine, and severe liver disease are listed as WHO-category 2.

Can IUCs be used as EC?

ParaGard[®] (T380 Intrauterine Copper Contraceptive) can be used as EC if the client desires to continue the IUC for long-term contraception. ParaGard[®] may be relied upon as EC up to eight days after unprotected intercourse. The Mirena[®] Intrauterine System should not be used as EC, as there are no studies to support its use in this circumstance. When billed to Family PACT, IUCs cannot be used *solely* for the purpose of EC.

APPLICATION OF FAMILY PACT POLICY

Are there any restrictions on the dispensing of oral EC under Family PACT?

- Family PACT benefits include both clinic and pharmacy dispensing of oral EC when prescribed or furnished by a Family PACT provider or furnished by a pharmacist participating in the EC Pharmacy Access Program.
- EC is available to female clients under all primary diagnosis (S) codes except S60 (pregnancy testing).
- Reimbursement for pre-packaged EC is in accordance with current program policy as published in the Policies, Procedures, and Billing Instructions (PPBI) manual

How should EC visits be documented?

- Documentation of client education and counseling pertaining to EC must be contained in the medical record to support services billed for reimbursement.

Are all Family PACT providers expected to provide counseling and provision of EC?

- Program standards require providers to offer EC onsite or by prescription.
- All staff performing education and counseling services shall be knowledgeable about EC and the policies for use under the Family PACT Program.
- Specific instructions for the use of EC shall be provided both verbally and in written form. The client should be given the opportunity to ask questions and discuss personal concerns about EC.
- Female clients requesting EC must be offered contraceptive options counseling, including long-acting reversible contraceptives (LARC), if they are not using contraception or having difficulty with their current method.

Providers should refer to the Family PACT PPBI for the complete text of the Family PACT Standards, official administrative practices, and billing information.

RESOURCES FOR INFORMATION ON EMERGENCY CONTRACEPTION

References:

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2. Polis CB, Schaffer K, et al. Advance provision of emergency contraception for pregnancy prevention: a meta-analysis. *Obstet Gynecol* 2007 Dec;110(6):1379-88.
3. Guilbert E, Black A, et al. Missed Hormonal Contraceptives: New Recommendations. *JOGC* 2008;30(11):1050-62.
4. American Academy of Pediatrics Committee on Adolescence. Emergency Contraception. *Pediatrics* 2005;116:1026-35.
5. Ellertson C, Evans M, Ferden S, et al. Extending the time limit for starting the Yuzpe regimen of emergency contraception to 120 hours. *Obstet Gynecol* 2003 Jun;101(6):1168-71.
6. Rodrigues I, Grau F, et al. Effectiveness of emergency contraceptive pills between 72 and 120 hours after unprotected sexual intercourse. *Am J Obstet Gynecol* 2001;184:531.
7. WHO Medical eligibility criteria for contraceptive use Fourth edition 2009. Accessed at http://whqlibdoc.who.int/publications/2009/9789241563888_eng.pdf.

Helpful consumer resources:

- Princeton University Emergency Contraception website: <http://not-2-late.com>. Hotline: (888) NOT-2-LATE.
- California Pharmacy Access Partnership: <http://www.ec-help.org/>.
- Association of Reproductive Health Professionals: <http://www.arhp.org/healthcareproviders/resources/ecresources/index.cfm>.

FAMILY PLANNING SERVICES FOR OBESE WOMEN

Unplanned pregnancy and obesity constitute overlapping epidemics in the United States (U.S.). About half of all pregnancies are unplanned and nearly a third of all Americans are obese.¹ As obesity becomes more prevalent in the U.S., questions arise regarding the unique reproductive health needs of obese women.

KEY POINTS

- **Pregnancy and childbirth among obese women are far more dangerous than are either contraception or sterilization.**
- **Overweight and obese oral contraception (OC) users appear to be at a similar or slightly higher risk of pregnancy as compared to normal body mass index (BMI) women. At most, obesity increases the failure rate by two to four pregnancies per 100 woman-years of OC use. Even with this effect, OCs remain in the “middle tier” of contraceptive efficacy.***
- **Obesity is linked with a slightly higher failure rate among users of the transdermal contraceptive patch, especially those who weigh 90 kg (198 pounds) or more; however, this does not change “middle tier” efficacy ranking of this method.**
- **OCs have multiple benefits in obese women with polycystic ovary syndrome (PCOS), including contraception, cycle control (and prevention of anovulatory dysfunctional bleeding episodes), prevention of endometrial hyperplasia and endometrial cancer, and treatment of hirsutism.**

QUESTIONS AND ANSWERS

How is obesity defined?

Obesity is defined as a body mass index (BMI) greater than 30 kg/m.² More adult women are obese (33 percent) than men (28 percent), and higher rates in African-American women (49 percent) compared with Hispanic women (38 percent) and non-Hispanic White women (31 percent).

What are the reproductive risks associated with obesity?

Obese women have an increased risk of spontaneous abortion, fetal neural tube defects and cardiovascular anomalies (and lower detection rates of fetal anomalies on ultrasound), gestational hypertension and preeclampsia, gestational diabetes and fetal macrosomia, and an increased risk of cesarean delivery when compared with a BMI of less than 30. Obese women also are at greater risk for complications from cesarean, including hemorrhage, wound infection, endometritis, and anesthesia problems.

What are the major concerns regarding OC use in obese women?

- Because there are few good quality studies that evaluate OC failure relative to body weight, there is not a consensus opinion regarding OC efficacy in obese women. In a large prospective European study of over 59,000 women published in 2009,² BMI and weight had little or no impact on the effectiveness of OCs. A literature review by Trussel³ concluded that there is “no convincing evidence that very heavy or obese women have a higher risk of OC failure during perfect use than thinner women, even with the lowest dose formulations.” However, Grimes¹ states that, “OCs may be less effective in heavy women, with an extra two to four pregnancies per 100 woman-years of OC use, depending on the baseline rate of unplanned pregnancy among pill users. Despite this effect, the effectiveness of OCs in clinical use remains high.”
- Obesity is an independent risk factor for venous thromboembolism and OC users with a BMI ≥ 35 have an increased risk of venous thromboembolism compared with OC users of normal weight. Because of this concern, OC use by obese women is designated as a World Health Organization Medical Eligibility Criteria (WHO-MEC) “Category 2” rating.
- OCs do not cause significant weight gain beyond that expected in women who do not use hormonal methods of contraception

Is the higher failure rate of the contraceptive patch in obese women clinically significant?

In pooled clinical trials involving 3,319 women using the patch, there were 0.8 failures per 100 couples per year.⁴ However, of the 15 failures, one-third occurred in women weighing 90 kg or more. Consequently, in Food and Drug Administration patient package labeling, weight ≥ 90 kg is listed as a *precaution*, but not as a contraindication. Because of this concern, both the patch and ring have a WHO-MEC “Category 2” rating for use in obese women. Obese women should be counseled regarding this observation but reminded that the patch is still quite effective when used correctly and consistently.

What is the relationship between Depo-Provera® (DMPA) use and obesity?

- A 2009 review by Curtis⁵ concluded that overweight or obese adolescent DMPA users gain more weight than normal weight DMPA users, although this effect was not seen in adults. A study by Le, et.al.,⁶ showed that DMPA users who experience a five percent or greater increase in body weight increase within six months of DMPA initiation are most likely to gain excessive weight. They conclude that such women should be counseled regarding weight control or offered another method.
- There is no relationship between body weight and DMPA failure. In addition, DMPA reduces uterine bleeding in obese women and protects the endometrium against hyperplasia.
- DMPA has a WHO-MEC “Category 1” rating for use in obese women.

**The top tier of contraceptive effectiveness includes sterilization, intrauterine contraceptives (IUCs), Depo-Provera® (DMPA), and implants, while the bottom tier is comprised of barrier methods, fertility awareness methods, and withdrawal. The “middle tier” includes OCs, Patch, and Ring.*

FAMILY PLANNING SERVICES FOR OBESE WOMEN (CONT.) MARCH 2010

Will contraceptive implant (Implanon[®]) users gain weight?

- A comparative study found a mean increase in weight similar to that seen with non-hormonal IUCs. Clients should be advised that Implanon[®] use typically has a minimal impact on weight gain but that weight gain may occur for other reasons.
- There are no studies of Implanon[®] failure rates in relation to body weight, but two studies have shown that serum levels of etonogestrel remain above the ovulatory threshold across the range of body weights, including women weighing ≥ 90 kg.
- Implanon has a WHO-MEC "Category 1" rating for use in obese women.

Are intrauterine contraceptives (IUCs) a better choice for obese women?

- IUCs are a good contraceptive choice for obese women given their high efficacy irrespective of weight and the ability of the levonorgestrel intrauterine system (Mirena[®]) to prevent endometrial hyperplasia in obese anovulatory women.
- IUC insertion can be a challenge in obese women, since determining the size and direction of the uterus can be difficult and visualization of the cervix may be a challenge without special equipment. Use of a large speculum or placing a condom with the tip removed over the speculum blades provides better exposure.
- Both IUCs have a WHO-MEC "Category 1" rating for use in obese women.

What about contraceptive sterilization for obese women?

- The Centers for Disease Control and Prevention (CDC) Collaborative Review of Sterilization (CREST) study showed that among 9,475 women who had interval sterilization by laparoscopy, obesity significantly increased the risk of surgical complications (relative risk 1.7; 95 percent CI 1.2–2.6). Other large cohort studies conducted by Family Health International linked obesity with operative difficulties, technical failures in occluding the tubes, longer operating times, and prolonged hospital stays.
- Because general anesthesia and abdominal entry are not necessary, hysteroscopic sterilization may be associated with fewer complications in obese women than with laparoscopy.
- Vasectomy for the partner of an obese woman is often the best option when permanent contraception is desired.

Why are OCs often given as medical therapy to obese women with PCOS?

- Owing to a "first-pass" effect in the liver, OCs increase sex hormone binding globulin (SHBG) and decrease free testosterone. As a result, the hirsutism and acne often present in women with PCOS is effectively treated.
- Menstrual cycle control observed with the use of hormonal contraceptive methods can prevent the recurrent anovulatory dysfunctional bleeding episodes that commonly occur in women with PCOS.
- Premenopausal women with anovulation are at increased risk of endometrial hyperplasia and cancer. The progestin in combined hormonal contraceptives (and progestin-only methods) provides "opposition" to chronic estrogen exposure.
- Even though most women with PCOS are oligo-ovulatory, the timing of ovulation is difficult to predict and consequent pregnancy is a risk. It is important to offer effective contraception to obese women with PCOS so that measures to promote weight loss can be implemented before attempting pregnancy, and blood glucose can be normalized in women with PCOS and type 2 diabetes.

What advice about weight loss should be given to obese clients?

Since the provision of detailed weight control advice and management is beyond the scope of practice for many reproductive health providers, referral to a primary care provider for medical evaluation and weight loss services should be made available to Family PACT clients. However, the following counseling points are based upon recently published studies and guidelines.

- In a randomized comparison of various diets (Atkins[™], Ornish, Zone[®], etc.), weight loss was associated with adherence to the diet but not diet type. All diets work about equally well, but only if followed over the long term.
- Rapid weight loss or "yo-yo" dieting is ineffective for long term weight control.
- Successful weight loss maintenance is associated with high levels of physical activity, a diet low in fat and high in carbohydrate, and regular self-monitoring of weight.
- No matter which diet a person chooses, regular exercise is essential for successful weight loss (and cardiovascular health).
- Behavioral strategies (Weight Watchers[®], etc.) for weight loss are more effective than placebo but work even better when pairing diet with exercise.
- National Institutes of Health (NIH) guidelines for the use of prescription weight loss drugs (such as orlistat) include:
 - BMI >30 kg/m² or 27 kg/m² with a co-morbid medical condition
 - The client is motivated to begin structured exercise and low calorie diet
 - The medication is started at the completion of one month of successful diet and exercise
 - It is continued only if additional weight loss achieved in the first month of using medications
- Bariatric surgery is reasonably safe and should be considered by all patients with BMI over 40 kg/m² or BMI >35 kg/m² with other medical co-morbid conditions.

REFERENCES

1. Grimes DA, Shields, WC. Family planning for obese women: challenges and opportunities. *Contraception* 2005;72:1-4.
2. Dinger JC, Cronin M. et al. OC effectiveness according to BMI, weight, age, and other factors. *Am J Obstet Gynecol* 2009;201:263-9.
3. Trussel J, Schwartz EB, Guthrie K. Obesity and oral contraceptive pill failure. *Contraception* 2009;79:334-38.
4. Ziemann M, et al. Contraceptive efficacy and cycle control with the Ortho Evra transdermal system: the analysis of pooled data. *Fertil Steril* 2002 Feb;77(2 Suppl 2):S13-8.
5. Curtis KM, Ravi A, Gaffield ML. Progestin-only contraceptive use in obese women. *Contraception* 2009;80(4):346-54.
6. Le YL, et al. Early weight gain predicting later weight gain among DMPA users. *Obstet Gynecol* 2009;114(pt 2):279.

URINARY TRACT INFECTIONS (UTIs) IN WOMEN

More than one-half of women will have at least one UTI during their lifetime and three to five percent of all women will have multiple recurrences. Because UTIs often occur in relation to intercourse, they are a common problem in women of reproductive age.

KEY POINTS

- A detailed history, and in some cases physical exam, is necessary to differentiate lower UTIs (acute bacterial cystitis, also referred to as a “bladder infection”) from upper urinary tract infections (pyelonephritis).
- The initial diagnosis or treatment of a lower UTI does not routinely require a urine culture. The use of urine cultures in women with acute cystitis is limited to those with a recent history of recurrent UTI and those with treatment failures.
- Trimethoprim-sulfamethoxazole (TMP-SMX) given for three days is the preferred treatment regimen for UTIs, while ciprofloxacin given as a three-day regimen and cephalexin given for seven days are available as alternative regimens.
- Other effective antibiotic treatments for acute cystitis include nitrofurantoin, trimethoprim, fosfomycin, and multiple quinolone products but none are covered as Family PACT benefits.

QUESTIONS AND ANSWERS

What are the risk factors for urinary tract infection in premenopausal women?

The presence of risk factors may aid in the diagnosis of both acute and recurrent UTIs:

- Frequent or recent sexual activity, use of diaphragm and spermicidal agents, and increasing parity;
- A history of previous urinary tract infections;
- Medical conditions such as diabetes, obesity, sickle cell trait, anatomic congenital abnormalities, urinary tract stones;
- Neurologic disorders or medical conditions requiring indwelling or repetitive bladder catheterization.

Should asymptomatic women be screened with a dipstick urinalysis?

No. Screening for and treatment of asymptomatic bacteriuria is not recommended in nonpregnant, premenopausal women. Bacteriuria has not been shown to be harmful in this population nor does treatment decrease the frequency of symptomatic infections.

What are the presenting findings in women with UTIs?

History-taking is essential in differentiating uncomplicated from complicated urinary tract infection.

- Uncomplicated acute cystitis usually presents clinically as dysuria with symptoms of frequent and urgent urination, secondary to irritation of the urethral and bladder epithelium. Women also may experience suprapubic pain or pressure and rarely have hematuria. Fever is uncommon in women with uncomplicated lower UTI. Acute urethritis owing to infection from gonorrhea (GC) or *Chlamydia trachomatis* (Ct), or urethral pain secondary to genital herpes simplex virus, may present with similar clinical symptoms.
- In contrast, upper UTI (acute pyelonephritis) frequently occurs with a combination of fever and chills, flank pain, and varying degrees of dysuria, urgency, and frequency. Severe flank pain radiating to the groin is more indicative of kidney stones.
- Other factors that define complicated UTIs include diabetes, pregnancy, immunosuppression, previous pyelonephritis, symptoms lasting >14 days, recent hospitalization, presence of kidney stones, or structural abnormalities of the urinary tract.

How should women with UTI symptoms be evaluated?

Urine dipstick testing for pyuria with leukocyte esterase (LE) or nitrite (indicative of *E. coli* bacteriuria) is a rapid and inexpensive method with a sensitivity of 75 percent and specificity of 82 percent. While a dipstick is a good initial test, women with negative dipstick test results and characteristic UTI symptoms may be treated presumptively. In addition, if GC or Ct are suspected based on sexual history or symptoms, collect a sample for a GC and Ct nucleic acid amplification test (NAAT) from the beginning of the urine stream and a second sample for dipstick urinalysis from the mid-stream. GC and Ct NAAT tests are more accurate if the urine sample is obtained at least one hour after prior urination.

When is a urine culture necessary?

Urine culture is not indicated for the initial diagnosis or routine follow-up of an uncomplicated lower UTI. However, if clinical improvement does not occur within 48 hours, or in the case of a recurrent UTI, a urine culture is useful to help tailor treatment. Women with complicated UTIs also should have a urine culture performed (although it is not a Family PACT benefit; see below)

How should uncomplicated acute cystitis in women be treated?

A three-day antimicrobial regimen is the recommended treatment for uncomplicated lower UTI in women, with bacterial eradication rates consistently higher than 90 percent. Treatment decisions should follow a step-wise consideration of each antibiotic option.

- **First-line therapy:** Trimethoprim 160 mg and sulfamethoxazole 800 mg (TMP-SMX double strength) twice daily for three days is the preferred therapy for lower UTIs, with a 94 percent bacterial eradication rate.
- **Second-line therapy:** Ciprofloxacin 250 mg twice daily for three days.
 - Fluoroquinolones that have shown equivalency include ciprofloxacin, levofloxacin, norfloxacin, and gatifloxacin (only ciprofloxacin is included in the Family PACT formulary). Although highly effective, fluoroquinolones should not be used as a first-line agent as overuse will likely hinder the ability to effectively use this class of antimicrobials in patients with complicated UTIs and in those patients with respiratory and other non-urinary tract infections.

URINARY TRACT INFECTIONS IN WOMEN (CONT.) MARCH 2010

- **Third-line therapy:** Cephalixin 500 mg twice a day or 250 mg four times a day for seven days. Disadvantages include:
 - β -lactams, such as first-generation cephalosporins and amoxicillin, are less effective in the treatment of uncomplicated UTIs. This is because of increasing resistance among the common uropathogens, rapid excretion from the urinary tract, and the inability to completely clear gram-negative rods from the vagina, increasing the risk for recurrence.
 - Lower completion rates, since the regimen must be used for seven days instead of three days (vs. first and second line treatments).

Is a routine follow-up visit necessary after the treatment of a UTI?

Given the high cure rate after treatment for an uncomplicated UTI, a routine follow up visit or test-of-cure urinalysis is not necessary. However, if the client's symptoms do not respond to treatment, she should be re-evaluated for treatment failure or another condition.

How are recurrent (repeated) UTIs categorized and managed?

Recurrent UTIs are defined as three or more episodes per year and may be due to relapse (failure to completely cure an initial infection) or reinfection with the same or a different organism. In addition to a urine culture and consideration of whether an anatomic cause may be present, the following interventions should be considered:

- Discontinuation of vaginal spermicides.
- Drinking cranberry juice has been shown to decrease symptomatic UTIs. In a recent meta-analysis addressing the effectiveness of drinking cranberry juice and taking other formulations, it was reported that taking cranberry formulations was more effective compared with taking a placebo.
- Though not Family PACT benefits, the following interventions will reduce recurrent UTIs:
 - Intermittent (post-coital) or continuous prophylactic antimicrobial therapy prevent recurrences in 95 percent of cases.
 - Patient-initiated therapy with symptom onset. Women are given a prescription for one of the three-day dosage regimens and instructed to start therapy when symptoms develop. If symptoms do not improve in 48 hours, clinical evaluation should be performed.
- There is little evidence that aggressive hydration to prevent recurrences has any major effect, and this practice can theoretically worsen urinary retention issues, decrease urinary pH affecting the antibacterial activity of urine itself, and dilute antimicrobial concentrations in the urinary tract. It is currently not recommended for prevention of UTI recurrence.
- Post-coital voiding has not been proved effective, nor have douching or wiping techniques.

APPLICATION OF FAMILY PACT POLICIES

Can women with pyelonephritis or other "complicated" UTIs be treated under the Family PACT Program?

Management of women with complicated UTIs is beyond the scope of the program and is not a covered benefit. These clients often require referral for expert management, which on occasion includes hospitalization.

Is the diagnosis and management of cystitis in men a covered benefit?

No. Bladder infections in men rarely are sexually transmitted infections and therefore are outside the scope of the program.

How should UTI visits in women be coded?

UTI services are restricted to female clients who present with symptoms of infection. Therefore, all claims for evaluation and treatment of UTIs in women must contain a primary diagnosis (S-code) and a secondary diagnosis.

- If the diagnosis of UTI is made, use International Classification of Diseases, 9th Revision (ICD-9) code 595.0 (acute cystitis) for the secondary diagnosis.
- If a UTI is presumptively treated based on presenting symptoms, enter an ICD-9 code for the client's presenting symptom from the following list:
 - 599.71 Gross hematuria
 - 788.1 Dysuria
 - 788.41 Urinary frequency
 - 789.09 Abdominal pain, other specified site

Which laboratory tests does Family PACT cover?

With appropriate Clinical Laboratory Improvement Amendment certification and, in some cases, using test kits approved by the Centers for Medicare and Medicaid Services, dipstick urinalysis (CPT code 81000), urinary analysis (UA) dipstick with microscopy (81001) and without (81002), UA automated without microscopy (81003), and UA microscopy only (81015) are covered either as point of care office tests or when performed by a clinical lab. In addition, urinalysis qualitative (81005) is performed by a clinical lab, as well as urine culture (87086). If the culture is positive, reflex sensitivity testing (87181, 87184, or 87186) are benefits.

Are alternative antibiotic regimens available by Treatment Authorization Request if a formulary drug is not appropriate?

No. Only the drugs listed in the formulary will be covered by Family PACT. However, a clinician may prescribe a non-formulary antibiotic which can be purchased by the client, in some cases through pharmacy discount programs for generic drugs.

Providers should refer to the Family PACT Policies, Procedures, and Billing Instructions for the complete text of the Family PACT Standards, official administrative practices, and billing information.

RESOURCES FOR INFORMATION ON URINARY TRACT INFECTIONS IN WOMEN

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