UFHealth
SHANDS HOSPITAL

Volume 27, Number 8 August/September 2013

Drugs & Therapy

B • U • L • L • E • T • I • N

FORMULARY UPDATE

The Pharmacy and Therapeutics Committee met August 20, 2013. 4 products were added in the *Formulary*, 6 drugs were deleted, and 15 drugs were designated nonformulary and not available. Criteria for use were established or changed for 4 drugs.

◆ ADDED

Combination Eye Drops – tropicamide, cyclopentolate, phenylephrine, ketorolac, and lidocaine [Compounded]

Ketorolac 0.5% Ophthalmic Solution (Generic)

Moxifloxacin (Avelox®)*

**Restricted to Infectious Diseases, Antimicrobial Management Team, and/or Mycobacteriology for the treatment of Mycobacterial infections.*

Prothrombin Complex Concentrate (Kcentra®)*

**Restricted to life-threatening bleed in patients receiving warfarin.*

◆ DELETED

BCG Live Vaccine (TICE® and Theracys®)†

†*Nonformulary and not available*

Buprenorphine – Naloxone (Suboxone®)^

^*Nonformulary and not available – Patient may **not** use own medication*

Hydroxyethyl Starch in Lactated Ringers (Hextend®)†

†*Nonformulary and not available*

Podophyllum Resin 25% Topical Solution (Generic)†

†*Nonformulary and not available*

Prothrombin Complex Concentrate (Profilnine®)†

†*Nonformulary and not available*

(continued on next page)

NEWS

Factor in the criteria

Factor products, alone or in combination with other blood products, have been used to correct coagulopathies associated with a number of causes including post-operative bleeding and anticoagulant overdose. These agents are primarily used for off-label indications, with supporting data existing only in the form of case series or retrospective case-control studies and minimal randomized controlled trials.[1-5] While rapid correction of coagulopathies is often seen, these products are not without risk. Notably, factor products have been associated with an increased risk of thromboembolic events, a finding supported by a 2012 Cochrane review.[1-2] In late 2011, due to the potential risks associated with factor product administration, the Pharmacy and Therapeutics (P&T) Committee established criteria for use for both Prothrombin Complex Concentrate (PCC) and Factor VIIa products.

Prothrombin Complex Concentrate is restricted to use in patients receiving warfarin with an INR > 1.7 who present with a life-threatening hemorrhage. The dosing of the product is weight-based and dependent upon the patient's INR at presentation. The maximum dosing weight is 100 kg.

Factor VIIa is restricted to hemophilia or life-threatening bleed associated with anticoagulation therapy in conjunction with a hematology consult, refractory intra-operative bleeding in a cardiothoracic surgery, or refractory post-operative bleeding in the CT-ICU as defined by chest tube output greater than or equal to 3 mL/kg/hr for 2 consecutive hours. Dosing of Factor VIIa is restricted to 45 mcg/kg in the absence of a hematology consult.

Evaluation of current prescribing trends has shown increasing utilization outside the P&T approved criteria for use. On September 1, 2013, concurrent evaluation of adherence to criteria for PCC and Factor VIIa was launched. This campaign has been organized by Dr. Timothy Flynn, Chief Medical Officer, and Dr. David Weiner, Chair of the Pharmacy and Therapeutics Committee. Implementation of this evaluation is being performed by Dr. Marc Zumberg, Department of Hematology, and Carrie Lagasse, Department of Pharmacy. Evaluation of PCC and Factor VIIa will occur within 24-48 hours of product administration. Each patient will be evaluated for adherence to the Pharmacy and Therapeutics Committee criteria for use. If it is determined that the clinical picture does not align with current criteria, a second evaluation will be performed by the hematology physician. If it is determined that the patient still falls outside established criteria for use, a letter will be drafted to the ordering physician as well as the attending of record at the time of factor administration.

"On September 1, 2013, concurrent evaluation of adherence to criteria for PCC and Factor VIIa was launched."

These letters will be sent electronically and are not meant to be punitive, but rather to educate the providers on use outside the P&T approved criteria. However, continued use outside the approved criteria may result in escalation of the case evaluation to Department Chairs and/or the Chief Medical Officer.

(continued on page 6)

INSIDE THIS ISSUE

◆ A New Plan for Plan B

Formulary update, *from page 1*

Scopolamine Hydrobromide Ophthalmic Drops (Isopto Hyoscine®)†

†*Non-formulary and not available*

◆ NON-FORMULARY AND NOT AVAILABLE

BCG Live Vaccine (TICE® and Theracys®)

Buprenorphine – Naloxone (Suboxone®)

Buprenorphine – Naloxone (Zubsolv®)

Canagliflozin (Invokana®)*

**Desvenlafaxine* (Khedezla®)§

§*Therapeutic Interchange*

Fluticasone – Vilanterol (Breo Ellipta®)*

Hydroxyethyl Starch in 0.9% Sodium Chloride (Hespan®)

Hydroxyethyl Starch in Lactated Ringers (Hextend®)

Hydroxyethyl Starch in Sodium Chloride (Voluven®)

Nafitine Hydrochloride Gel (Naftin®)*

Paroxetine (Brisdelle®)*

Podophyllum Resin 25% (Generic)

Prothrombin Complex Concentrate (Profilnine®)

Scopolamine Hydrobromide Ophthalmic (Isopto Hyoscine®)

Tobramycin Inhalation Powder (TOBI Podhaler®)*

◆ CRITERIA FOR USE CHANGES

Meperidine (Generic)*

Moxifloxacin (Avelox®)*

**Restricted to Infectious Diseases, Antimicrobial Management Team, and/or Mycobacteriology for the treatment of Mycobacterial infections.*

Zolpidem (Ambien®)*

Combination Eye Drops were requested for formulary addition by Florida Surgical Center (FSC). Eye procedures often require the administration of multiple ophthalmic agents pre-operatively. Nurses have noted that this is both a time-consuming and waste-prone activity. Individual ophthalmic preparations are applied in succession with a limited number of drops placed in the patient's eye prior to wasting the remainder of the bottle to avoid inter-patient contamination. This is a very costly practice. In addition, the time needed to administer a multitude of drops in succession can delay through-put in the OR.

The physicians and nurses have requested the addition of a compounded eye drop that would suit their needs and decrease the time and waste described above. After contacting JCB Laboratories, a list of possible combinations was disseminated to the ophthalmology physicians at FSC. After discussion in their division, the physicians have elected to add Item #841503 which contains tropicamide, cyclopentolate, phenylephrine, ketorolac, and lidocaine jelly. The Pharmacy and Therapeutics Committee voted to approve the addition of this compounded product.

Ketorolac 0.5% Ophthalmic Solution is a nonsteroidal anti-inflammatory agent with potent analgesic properties and modest anti-inflammatory actions. Ketorolac exerts its anti-inflammatory and analgesic effects though inhibition of the cyclooxygenase pathway. It is FDA approved for the reduction of pain and inflammation following cataract extraction as well as for relief of ocular itching secondary to allergic conjunctivitis. Ketorolac is also indicated for ocular pain, burning and stinging post-corneal refractive surgery.

Ketorolac ophthalmic solution has never been evaluated by the Pharmacy and Therapeutics Committee for inclusion in the *Formulary*. A request was made from FSC, to use a compounded, combination eye drop which includes topicamide 0.2%, cyclopentolate 0.2%, phenylephrine 0.5%, and ketorolac 0.1% suspended in lidocaine jelly 0.4%. All agents in this combination product are listed in the *Formulary* except ketorolac ophthalmic solution. The Pharmacy and Therapeutics Committee voted to add ketorolac ophthalmic solution in the *Formulary*.

Moxifloxacin is a fluoroquinolone antibiotic with activity against *Mycobacterium tuberculosis*. Fluoroquinolones (FQ) have excellent oral bioavailability and the ability to penetrate macrophages; essential features for activity against tuberculosis. While not FDA approved for this indication, FQ have been used to treat mycobacterial infections caused by multi-drug resistant organisms or for patients intolerant to other first line therapies. Published guidelines make no strong recommendation regarding which FQ is preferred, with both levofloxacin and moxifloxacin regarded as viable options. Both have been shown to have potent activity in-vitro and in animal models against *M. tuberculosis*.

While the available evidence does not show moxifloxacin should displace any first-line agents in the empiric therapy of tuberculosis, it may be reasonable to substitute moxifloxacin for isoniazid or ethambutol in patients who cannot receive either drug in the initiation phase of treatment.

Despite a lack of clinical evidence suggesting moxifloxacin to be superior to levofloxacin, clinicians may prefer moxifloxacin based on in-vitro susceptibility when managing mycobacterial infections. With the potential benefit of moxifloxacin as an alternative agent for managing mycobacterial infections, the Pharmacy and Therapeutics Committee voted to add moxifloxacin in the *Formulary* restricted to Infectious Diseases, Antimicrobial Management Team, and/or Mycobacteriology approval for the treatment of mycobacterial infections.

Prothrombin Complex Concentrate (Kcentra®) is a new 4-factor prothrombin complex concentrate (PCC) with a labeled indication for urgent reversal of acquired coagulation factor deficiency induced by warfarin therapy in adult patients with acute major bleeding. Fresh frozen plasma (FFP) is the only other product approved for this use in the US. Patients receiving chronic anticoagulation therapy with warfarin to prevent blood clotting sometimes develop acute bleeding. Like FFP, Kcentra® is used in conjunction with the administration of vitamin K to reverse the anticoagulation effect and stop bleeding. Unlike FFP, Kcentra® does not require blood group typing or thawing, and may be administered more quickly than FFP.

PCC products are associated with the occurrence of blood clots, and carry a boxed warning for this adverse event. The warning also explains that patients receiving PCC

(continued on next page)

Formulary update, *from page 2*

products should be monitored for signs and symptoms of thromboembolic events, as both fatal and non-fatal arterial and venous thromboembolic complications have been reported in clinical trials and post marketing surveillance.

The Pharmacy and Therapeutics Committee recommended that Kcentra® be added in the *Formulary* and that 3 factor PCC (Profilnine®) be deleted from the *Formulary*. Kcentra® will be restricted to patients receiving warfarin who present with a life-threatening bleed. Dosing weight for the 4 factor product will be capped at 100 kg and dosing will be based upon the package insert (INR and weight-based). P&T also approved continuation of rounding to vial size (within a 10% margin) and a therapeutic interchange allowing the pharmacist to automatically interchange the dosing of Kcentra® based on INR level when an INR is available.

Bacillus-Calmette-Guerin Live (BCG) Vaccine has been in the *Formulary* for many years. Previously, Theracys® had been the supplied brand of vaccine; however, TICE® recently replaced this product due to availability. There has been zero inpatient use, and UF Health – Shands Hospital is no longer supplying this medication to the UF Urology clinic. Due to lack of use, this agent was removed from the *Formulary* and designated non-formulary and not available.

Buprenorphine-Naloxone: Buprenorphine is an opioid agonist-antagonist that is restricted to opioid detoxification, opioid maintenance therapy or the treatment of chronic pain in patients with a history of opioid dependency. When combined with naloxone, this agent is preferred as the tablet, when crushed and injected, will not elicit an opioid response.

In 2007, this combination product was added in the *Formulary*, but restricted to UF Health Psychiatric Hospital (Shands Vista) or patients admitted to UF Health – Shands Hospital on buprenorphine-naloxone for opioid maintenance or chronic pain with a history of opioid dependency. Recently, the Vista partial hospitalization program moved offsite to the new UF Health Florida Recovery Center. Patients now obtain their Suboxone® via individual outpatient prescriptions from their retail pharmacy of choice. Vista inpatient pharmacy no longer dispenses this medication.

The Pharmacy and Therapeutics Committee approved the recommendation to delete Suboxone® from the *Formulary* and make it non-formulary and not available. Patients are unable to use their own medication because it is a controlled substance. On the inpatient side, patients will receive buprenorphine [alone] not in combination with any opioid antagonist.

A sublingual buprenorphine-naloxone product (Zubsolv®) was approved by the FDA in July 2013. This product was also designated non-formulary and not available in the *Formulary* by the Pharmacy and Therapeutics Committee.

Hydroxyethyl Starch (HES) Solutions are used primarily for the treatment of hypovolemia when plasma volume expansion is desired. They are non-protein colloid solutions which act as volume expanders. In March, 2005, hetastarch in lactated ringers [Hextend®] was added in the *Formulary*. A monograph for Voluven® (hetastarch in NS) was prepared although this agent was never formally requested.

In late June 2013, the FDA issued a MedWatch regarding the use of hydroxyethyl starch solutions. It was noted that the FDA analyzed recent data which indicated an increased risk in mortality and renal injury requiring renal replacement therapy in critically ill adults as well as excess bleeding particularly in patients undergoing open heart surgery in association with cardiopulmonary bypass. Due to these increases in morbidity and mortality, the FDA concluded that HES should not be used in critically ill adults. A boxed warning outlining these increased risks is being added to the package labeling.

After reviewing the FDA MedWatch as well as the monograph for Voluven®, the Pharmacy and Therapeutics Committee approved the removal of all hetastarch products from the *Formulary* and supported their designation of non-formulary and not available. This requires deletion of Hextend® with a new designation of non-formulary and not available, maintenance of the non-formulary and not available designation for Hespan®, and a new designation for Voluven® of non-formulary and not available. Anesthesia and Critical Care Medicine were supportive of this designation.

Podophyllum Resin 25% Topical Solution is FDA approved for external and urethral condyloma acuminatum (genital/perianal warts) mainly caused by the Human Papilloma Virus. Current distribution records indicate the product has not been utilized at UF Health – Shands Hospital in the past 3 years.

The Pharmacy and Therapeutics Committee voted to remove this agent from the *Formulary* and have it designated non-formulary and not available.

Scopolamine Hydrobromide Ophthalmic Solution (Isopto Hyoscine®) has been discontinued by the manufacturer (Alcon). There are no other manufacturers of this product. As such, the Pharmacy and Therapeutics Committee approved the recommendation to remove this item from the *Formulary*.

Canagliflozin (Invokana®) is sodium-glucose co-transport 2 (CGLT2) inhibitor with a labeled indication as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. It works by blocking the reabsorption of glucose by the kidney, increasing glucose excretion, and lowering blood glucose levels in diabetic patients. Its safety and efficacy were evaluated in 9 clinical trials that included over 10,000 patients with type 2 diabetes. These trials showed lower hemoglobin A1c levels and fasting plasma glucose levels compared with placebo.

The most common adverse effects are vulvovaginal candidiasis and urinary tract infections. Canagliflozin causes a diuretic effect, which can cause orthostatic or postural hypotension and result in dizziness or fainting, especially in the first 3 months of therapy. In May 2013, the P&T voted to designate this medication non-formulary and not available with patients unable to use their own home supply.

Dr. Kenneth Cusi with Endocrinology asked the Committee to reconsider allowing patients to continue canagliflozin if they are stable on chronic therapy and the physician identifies no problem with the continuation of the home medication. After discussion, the Committee decided that the risks associated with continuation of home therapy were minimal. The Committee recommended canagliflozin remain non-formulary and not available, with the designation changed to allow for patients to use their own medica-

(continued on next page)

Formulary update, *from page 3*

tions. The Committee will re-evaluate in 3-6 months to determine if there is any identified risk in patients receiving this medication as an inpatient.

Desvenlafaxine Extended-Release (Khedezla®) is a serotonin and norepinephrine reuptake inhibitor (SNRI) indicated for the treatment of major depressive disorder. This formulation is similar to desvenlafaxine marketed under the brand name Pristiq®. Both products are available in 50 mg and 100 mg extended release tablets.

In October, 2010 the Pharmacy and Therapeutics Committee evaluated Pristiq® and recommended it be designated non-formulary and not available. **A therapeutic interchange was proposed as follows:**

Venlafaxine XR 75 mg daily = Desvenlafaxine 50 mg or 100 mg daily

Venlafaxine XR 150 mg daily = Desvenlafaxine 150 mg daily

Venlafaxine XR 225 mg daily = Desvenlafaxine 200 mg or greater daily

Venlafaxine XR 75 mg every other day = Desvenlafaxine 50 mg every other day

After finding no additional rationale for the use of this medication, the Committee approved the designation of all desvenlafaxine products as non-formulary and not available with the above therapeutic interchange.

Fluticasone and Vilanterol inhaler contains the new long-acting beta 2-adrenergic agonist (LABA) vilanterol in combination with fluticasone. It has a labeled indication for use in adults with chronic obstructive pulmonary disease (COPD) to reduce exacerbations.

Fluticasone and vilanterol combination inhaler is the first once-daily inhaled therapy for COPD that contains a LABA and a corticosteroid. It is not intended for the treatment of asthma or the relief of acute bronchospasm and is contraindicated in people with severe hypersensitivity to the active ingredients, milk proteins, or magnesium stearate. The labeling states that the inhaler should not be used for the treatment of acute symptoms of COPD or in combination with another LABA. A boxed warning in the product's labeling states that LABA use increases the risk of death in patients with asthma. It is not known if patients with COPD face a similar risk.

Adverse effects include an increased risk of pneumonia, worsening of pre-existing infections, adrenal suppression, decreased bone mineral density, and disorders of the eye.

In clinical trials, the most common adverse events reported in patients were nasopharyngitis, upper-respiratory-tract infection, and oral candidiasis.

Due to the likely cost implications as well as lack of superiority over other agents in the class, the Pharmacy and Therapeutics Committee approved the designation of fluticasone and vilanterol as non-formulary and not available with patients able to use their own supply.

Nafitine hydrochloride gel is an allylamine antifungal topical agent indicated for the treatment of interdigital tinea pedis cause by susceptible organisms including *Trichophyton rubrum*, *Trichophyton mentagrophytes*, and *Epidermophyton floccosum* in patients 18 years or older.

As this is not typically an inpatient issue, the Committee designated nafitine hydrochloride non-formulary and not available. The Anti-Infective Subcommittee has provided their agreement with this recommendation.

Paroxetine is a selective serotonin reuptake inhibitor (SSRI) that is marketed under a number of brand names (Paxil® and Paxil CR®) for a number of psychiatric conditions. Paroxetine marketed under the brand name Brisdelle® is FDA approved for the treatment of moderate to severe vasomotor symptoms associated with menopause. It is not indicated for the treatment of any psychiatric condition. Dosing for this indication is 7.5 mg daily at bedtime.

After discussion, the Pharmacy and Therapeutics Committee approved the recommendation that Brisdelle® be designated non-formulary and not available with patients able to take their own medication. If patients are unable to supply their own medication, a recommendation to adjust the dose to 10 mg daily is suggested.

Tobramycin Inhaled Powder is an aminoglycoside antibiotic indicated for the management of cystic fibrosis patients with *Pseudomonas aeruginosa* infection. Tobramycin works by inhibiting protein synthesis which leads to altered cell membrane permeability, progressive disruption of the cell envelope and eventual cell death.

Inhaled tobramycin is also available in nebulized form (TOBI nebs®) which is already listed in the *Formulary*. In May 2013, inhaled tobramycin powder was designated non-formulary and not available by the Committee barring any dissent from the Anti-Infective Subcommittee (AIS). After evaluation of the medication at the August 8 AIS meeting, it was approved to maintain the formulary designation of non-formulary and not available.

Meperidine is an opioid agonist currently restricted in the *Formulary*. Criteria for use for the injectable product were developed and approved by the Pharmacy and Therapeutics Committee in May 2002. Current approved criteria for use limit meperidine to the treatment of rigors or for analgesia and sedation during short procedures as well as in conjunction with an IRB approved study protocol for an intravascular cooling device. These decisions were made based upon the recommendations of the Pain Committee and Pharmacy and Therapeutics Committee.

In June, 2013, the Pain Committee recommended changes to the criteria for meperidine utilization. The recommended change was as follows: Meperidine should be limited to use for the treatment of rigors and for analgesia and sedation during short procedures in patients not tolerating fentanyl and/or midazolam. These criteria amendments were approved by the Pharmacy and Therapeutics Committee.

Zolpidem (Ambien®) is a sedative/hypnotic which has been linked to a number of adverse events. In December, 2012, the FDA issued a labeling change for zolpidem to recommend initiation of 10 mg dosing in non-geriatric males only with 5 mg initial dosing recommended for females and all geriatric patients. This labeling change was secondary to a pharmacokinetic study outlining risks associated with the 10 mg in the female and geriatric population.

In January, 2013, an evaluation of zolpidem use at UF Health – Shands Hospital showed a large proportion of patients receiving 10 mg dosing. At that time, 10 mg zolpidem was removed from all order sets and the 10 mg order composer buttons were also eliminated from EPIC.

A repeat evaluation of zolpidem utilization in April, 2013, showed only modest reductions in 10 mg dosing (approximately 20%). The majority of patients receiving 10 mg dosing were also receiving this dose prior

(continued on next page)

Formulary update, *from page 4*

to admission. The Medication Safety Committee recommended further restriction of the medication to allow for use of zolpidem 10 mg in male, non-geriatric patients only. For the purposes of this restriction, geriatric was defined as greater than or equal to 65 years of age (as per Beer's Criteria designations).

The Pharmacy and Therapeutics Committee believed these restrictions to be too stringent and recommended alternative means to reduce the utilization of 10 mg dosing. The Committee voted to continue with the passive modes of decreasing 10 mg dosing via deletion of order composer buttons and removal of 10 mg doses from EPIC order sets. In addition, when zolpidem 10 mg is ordered, the Committee would like the following order composer questions to be answered by the physician: 1 – is this a continuation of the patient's home dose? 2 – Has the patient failed a 5 mg regimen? The Committee voted to approve this language.

NEWS

A New Plan for Plan B

On June 10, 2013, the Obama administration expanded the availability of the emergency contraception, Plan B One-Step®.[1] The Justice Department directed the manufacturer, Teva Pharmaceuticals, to submit a supplemental application to make the product available over-the-counter for all consumers regardless of age. The Food and Drug Administration (FDA) was instructed to approve the change "without delay."[1]

Prior to this mandate, Plan B One-Step® was available without a prescription for patients 17 years old and older; patients less than 17 could only obtain the medication with a valid prescription. The age restriction to limit access for young teenagers has been controversial. One United States district judge, Edward R. Korman, stated the restriction was a "reaction to political pressure" and the denial of nonprescription access to those less than 17 year old was "scientifically unjustified."[2]

The Plan B One-Step®, sometimes referred to as the "morning-after pill," is a single, large dose of the progestin, levonorgestrel. Contrary to its pseudonym, this product can be taken up to 72 hours after sexual intercourse to reduce the risk of an unwanted pregnancy.[3] In clinical trials, use of this product was associated with a variable reduction in the risk of pregnancy, anywhere from 52% to 100%.[2] Studies suggest emergency contraceptives are inferior in efficacy to routine use of oral contraceptives.[2]

The Plan B One-Step® and other agents in its class are not considered abortifacients, as defined by medical authorities, such as the FDA, the National Institutes of Health, and the American College of Obstetricians and Gynecologists.[2] The literature validates equal efficacy and safety among all age groups.[3] When taken incidentally by pregnant women, reports suggest no increased risk of birth defects.[3]

Given the plethora of efficacy and safety evidence in females of all ages, why the resistance to increasing access to minors? For many, there was concern for a negative behavioral impact, as well as a personal component. To paraphrase President Obama, "as the father of two young girls" the idea of making the drug available to them without a prescription made him uncomfortable.[1] Many believe parents or a doctor should be involved in aiding young females with the decision to use this agent.

Published studies should quell the concern that increasing access to minors will induce negative behaviors. In randomized controlled trials including young teens, the increased availability of emergency contraceptives has not correlated with changes in frequency of unprotected sex, use of regular hormonal contraception, or rate of sexually transmitted infections.[4]

Although the evidence suggests no increase in irresponsible behavior, there are negative consequences that are implied with increasing availability. Of particular concern are lost opportunities for physicians to counsel patients about the use of more effective, longer-term contraceptive methods when patients present for emergency contraception.

Most recent reports suggest approximately 3.2 million or 50% of all pregnancies in the United States are unintended.[5] The rate of unintended births is higher among teenagers (85%) and associated with hundreds of thousands of abortions yearly in this population.[5] Emergency contraception pills offer women of all ages a last chance to prevent pregnancy after unprotected intercourse.

The decision to expand access to emergency contraceptives is consistent with a worldwide trend. These agents are available over-the-counter in a number of countries, including Norway, Sweden, the Netherlands, and Canada.[2] In many other countries, this agent can be obtained directly from a pharmacist without a prescription.[2]

Of note, the two-dose emergency contraceptives will continue to require a prescription due to the slightly more complex administration instructions. These agents constitute a small fraction of the market share.

– Ji Lee, Pharm.D.

REFERENCES

1. Shear M and Belluck P. U.S. Drops Bid to Limit Sales of Morning-After Pill. Published June 10, 2013. New York Times.
2. Trussell J and Raymond E. "Emergency Contraception: A Last Chance to Prevent Unintended Pregnancy." Jun 2013. Last accessed: 24 Jul 2013. http://ec.princeton.edu/questions/ec-review.pdf.
3. Plan B One-Step [package insert]. Pomona, New York: Barr Pharmaceuticals, Inc; 2009.
4. Gold MA et al. The Effects of Advance Provision of Emergency Contraception on Adolescent Women's Sexual and Contraceptive Behaviors. J Pediatr Adolesc Gynecol. 2004; 17:87–96.
5. Finer LB, Zolna MR. Unintended pregnancy in the United States: incidence and disparities, 2006. *Contraception*. 2011;84:478-85.

Drugs & Therapy
B • U • L • L • E • T • I • N

Volume 27, No. 8 Aug./Sept. 2013
This publication is produced by the Drug Information and Pharmacy Resource Center under the direction of the Department of Pharmacy Services and the Pharmacy and Therapeutics Committee.

EDITOR,
DRUGS & THERAPY BULLETIN
Carrie A. Lagasse, PharmD

DIRECTOR,
PHARMACY SERVICES
Thomas E. Johns, PharmD

CHAIRMAN, PHARMACY & THERAPEUTICS COMMITTEE
I. David Weiner, MD
Professor of Medicine and Physiology and Functional Genomics
University of Florida, College of Medicine

EDITING, DESIGN, & PRODUCTION
UF Health Shands Publication Services

FOR MORE INFORMATION, VISIT US ONLINE
http://professionals.ufhealth.org/resources/drug-information-and-pharmacy-resource-center/bulletins/

UF Health Shands Hospital
University of Florida
DRUG INFORMATION SERVICE
PO Box 100316
Gainesville, FL 32610-0316

NON-PROFIT ORG.
U.S. POSTAGE
PAID
GAINESVILLE, FL
PERMIT NO. 94

Factor in the criteria, *from page 1*

As the physician, if you believe there is published data to support rationale for use which are not included in current criteria, a formal proposal should be made for addition of those criteria. This proposal should be submitted to the Secretary of the Pharmacy and Therapeutics Committee and include supporting literature as well as a signed disclosure form.

If there are any questions or comments regarding the campaign, please do not hesitate to contact Marc Zumberg or Carrie Lagasse.

REFERENCES

1. Hirschler B. Analysis: entering the age of the $1 million medicine. Business & Financial News, Breaking US & International News. Accessed online January 3, 2012 at www.reuters.com.
2. Rader RA. Approvals increase from last year, but innovations and health care and markets impacts are limited. BIOPHARMA: Biopharmaceutical Products in the US and Europena Markets. Accessed online January 3, 2013 at www.biopharma.com.
3. Edney A, Larkin C. Drug approvals reach 15-year high on smoother FDA reviews. Bloomberg. Accessed online January 2, 2013 at www.bloomberg.com.
4. Anon. Abbott drug tops sales as Lipitor, Plavix era ends. Reuters. Accessed online April 11, 2012 at www.reuters.com.
5. Wild D. Specialty drug market share set for solid growth. Specialty Pharmacy Continuum. Accessed online August 17, 2012 at www.specialtypharmacycontinuum.com.

Drug information questions?

Contact the Drug Information Service  **Call 265-0408**

Or submit your question online at http://professionals.ufhealth.org/resources/drug-information-and-pharmacy-resource-center/

- This service is for referring physicians and other healthcare professionals taking care of UF Health – Shands Hospital patients
- Phones are staffed from 9 am to 4:30 pm, Monday – Friday
- All answers are thoroughly researched and referenced

For emergent questions that do not need thorough research, go to the pharmacy servicing your area.