Student Clinical Digest

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Inside This Issue:

CAREER CLINICAL PHARMACIST SPOTLIGHT

Emergency Department Pharmacist, Wellstar North Fulton Hospital
Duy Vu, Pharm.D.

By Hyuna Kim, Pharm.D. Candidate

We interviewed emergency medicine pharmacist Dr. Duy Vu for this issue. Dr. Vu graduated from Belmont University College of Pharmacy in 2016 and completed a PGY1 residency at Dekalb Medical Center the following year.

What inspired you to become an ER Pharmacist?
I did not truly experience critical care or emergency medicine until my PGY1 residency. As part of the curriculum, we rotated through various areas and I naturally gravitated towards the excitement of the emergency department. I was also impacted on a personal level. On the second day of my ED rotation, my dad came in with a STEMI. He later had a full recovery and I was his medication advocate when he left the hospital. The role of a pharmacist in the emergency department resonated profoundly as a result.

What steps did you take to become a clinical pharmacist at your current hospital?
As a student pharmacist and even PGY1 resident, I participated in many organizations to try and explore all of the opportunities they offered. I weighed the pros and cons of everything I was involved in and tried to talk to as many people as possible. Staying well rounded and versatile helped me to take on new opportunities as they came.

How would you describe your typical day at the hospital?
There really is not a typical day when it comes to the emergency department. Some days are filled with ambulatory patients with minor fractures while others have their fair share of traumas, intubations, and cardiac arrests. If I had to distill my role to a few words, it would be making sure that we not only have the drug but that it is also used appropriately according to guidelines and hospital policies. Ultimately, the goal of every team member is to ensure the best possible patient outcome.

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Duy Vu, Pharm.D.

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What is your advice for students who are interested in clinical pharmacy in general?
There are many facets to clinical pharmacy and the approach that I've found success with was to keep an open mind and explore every opportunity that presented itself. It is also important to have a hunger for self-improvement and a willingness to change since best practices change frequently. What is regarded as best practice today might be improved upon tomorrow and it is important to not be confined to what feels like a comfortable way to do things.

What should students with an interest in specializing in emergency care keep in mind?
Many colleagues I've worked with or students I've precepted mention that the greatest barrier to working in the emergency department is the anxiety of performing under pressure. There is internal pressure to remember doses, contraindications, and algorithms and produce accurate answers promptly. This is expected and gets better with time. It is best to get all the jitters out through a good shadowing program or preceptor that provides hands-on experience.

Are you currently involved in any professional organization? If so, how do they help you grow as a pharmacist?
I am involved with Georgia Society of Health-System Pharmacists. The meetings provide updates about clinical practice and also raise awareness for issues such as pain management in conjunction with opioid stewardship, alternatives for drug shortages, and tools for practitioner self-improvement.

HIV Pre-exposure Prophylaxis (PrEP): Truvada®

By Stella Hur, Pharm.D. Candidate

Approximately 36.7 million people are living with human immunodeficiency virus (HIV) worldwide. HIV continues to be a major global public health issue with 1.8 million newly infected patients in 2016.[1] The World Health Organization (WHO) recommends that oral Pre-exposure Prophylaxis (PrEP) be considered for HIV-negative people who are in an ongoing sexual relationship with a partner that is HIV-positive or has an unknown HIV status but is at substantial risk of HIV infection. Only about 70% of HIV-infected individuals are aware of their HIV status; many are unaware of their status until later stages of the disease. Currently, there is no cure for HIV; therefore, prevention is very important in stopping the spread of HIV. Truvada, generically known as emtricitabine and tenofovir disoproxil fumarate, is the only medication that is currently approved by the US Food and Drug Administration (FDA) for HIV PrEP.

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Truvada is a once daily oral prescription medication that can help reduce the risk of contracting HIV-1. Truvada works by blocking HIV reverse transcriptase, which is used by HIV-infected cells to make new viruses. This prevents the virus from establishing itself and slows the spread of HIV in the body. Several studies showed that Truvada reduced the risk of HIV infection by more than 90% if patients were adherent to therapy.[2,3] Other studies suggest Truvada is beneficial to all high risk groups: homosexual men, heterosexual individuals with a HIV-positive sexual partner, and recreational IV drug users. The *iPrEx* study demonstrated that Truvada reduced HIV-1 risk by 99% when seven doses were taken per week among homosexual men.[4] Apart from sexual transmission, approximately 10% of newly diagnosed HIV in the United States is attributed to injection drug use. Truvada also effectively prevented HIV among injection drug users, with a 70% risk reduction.[5]

Truvada is approved for PrEP in HIV-negative individuals due to its efficacy and minimal side effect profile. Patients on Truvada for PrEP should have HIV testing performed every 3 months. Truvada alone is not for approved for HIV treatment because it increases the risk of developing resistance to the components, emtricitabine and tenofovir disoproxil fumarate, which would limit future treatment options. Despite prophylaxis with Truvada, there is still a risk of acquiring HIV. Those on PrEP should also use other forms of contraceptive protection such as condoms, hormonal contraceptives, or the copper IUD. It is important to discuss use of Truvada with healthcare providers before initiating other therapies.[1]

PrEP with Truvada is a promising step towards addressing the global health burden of HIV. Through access, education, and adherence, there will hopefully be a future decline in the rate of HIV transmission worldwide.

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New restrictions on opioid prescriptions from insurance companies

By Christy Hee Kyung Lee, Pharm.D. Candidate

"The best way to prevent drug addiction and overdose is to prevent people from abusing drugs in the first place. If they don't start, they won't have a problem."[1] This statement was released by the office of the press secretary of the white house on October 26, 2017. Opioid use and drug addiction have been critical ongoing health issues in the United States, where more than 200,000 people have died from overdoses related to prescription opioids from 1999 to 2017.[2] In 2017, the three largest pharmacy benefit managers (PBMs) - CVS Caremark, Express Scripts, and Optum Rx - analyzed new restrictions on opioid prescriptions.[3] While each PBM has individual preemptive programs to combat the opioid crisis, they all limit daily doses of controlled pain medications and require immediate-release formulations be dispensed before extended-release formulations for severe long-term pain treatment.[4] Express Scripts, the nation's largest PBM, has additionally begun limiting opioid naïve patients to seven-day prescriptions.[5] CVS also recently implemented this program to cover all clients, regardless of health plan.[4]

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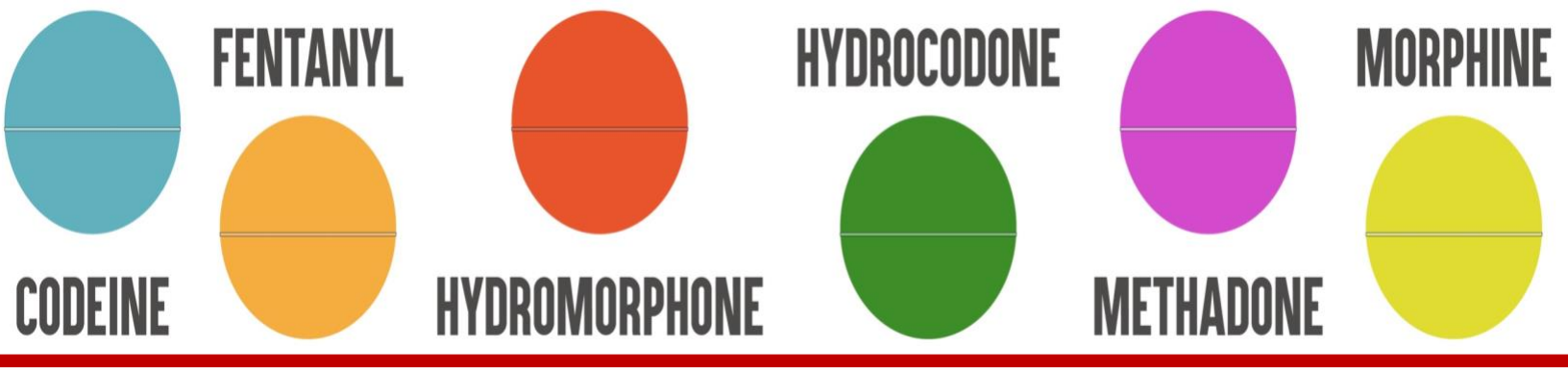

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A different program was previously implemented by the North Carolina division of Medical Assistance (NCDMA) and revealed interesting results. This recipient management "lock-in" program limited identified patients to one prescriber and one pharmacy in a 12-month period for benzodiazepine, opiate, and certain anxiolytic prescriptions. The program aimed to prevent misuse and reduce overutilization of Medicaid benefits. This Medicaid lock-in program focused on opioid and benzodiazepine prescriptions dispensed to beneficiaries using Prescription Drug Monitoring Program (PDMP) records between October 2010 and September 2012. The total number of dispensed controlled substance prescriptions covered by Medicaid was found to be lower during lock-in and after the program expiration. However, beneficiaries' average daily morphine milligram equivalents increased overall. Persistent patients were discovered to be using non-Medicaid out-of-pocket payments to obtain these medications.[6]

While combating the opioid crisis is important, can a health program intended to improve the lives of Americans actually backfire?

For example, people who are in dire need of medications may be deprived due to affordability and resort to unfavorable medication choices. In January 2017, when UnitedHealthcare stopped covering buprenorphine, a patient in excruciating abdominal pain faced an out of pocket cost of $342 for a four week supply. As a result, the patient and her doctor opted to use morphine instead. Although morphine was a more affordable option that was covered by the insurance and cost the patient only $29, it is actually in a higher risk category for abuse and dependence.[3]

One size does not fit all. Because every patient is unique, generalization by insurance programs could have significant impacts on patients' lives. While it is important to prevent addiction and misuse of opioids, people who are in need should not be deprived of vital medication. Trial and error is a possible solution to finding an optimal plan for individuals. This process requires cooperation from lawmakers, healthcare professionals, and patients. While no perfect solution exists, optimizing pain regimens should be a priority in order to improve individuals' care and quality of life.

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NEW DRUG UPDATE
Betrixaban (Bevyxxa®) Anticoagulant Agent

By: Seth Garner, Pharm.D. Candidate

Indication: Factor Xa (FXa) inhibitor for the prophylaxis of venous thromboembolism (VTE) in adult patients hospitalized for an acute medical illness who are at risk for thromboembolic complications.[1]

Comparable drug(s): Other FXa anticoagulant drugs, such as apixaban, edoxaban, rivaroxaban, and fondaparinux, have been used for venous thromboembolism (VTE) prophylaxis; however, none are FDA approved in adult hospitalized patients with acute medical illness.[2]

Disease State/Drug Class Summary: VTE is a blood clot that starts in a vein and can break apart to travel to other major organs of the body causing embolisms. VTE can be caused by an obstruction slowing or changing the flow of blood within the veins. The most common triggers are surgery, cancer, immobilization, and hospitalization. Women who become pregnant or use hormones, such as oral contraceptives or estrogen, are also at risk for developing VTE. Other patients at risk for clotting include those who are older, obese or overweight, or have other conditions, such as autoimmune disorders.[3] Betrixaban directly inhibits FXa and prothrombinase activity to decrease the generation of thrombin, which results in a decreased risk of blood clot formation.[4]

Efficacy: In a randomized, double-blind, multinational clinical trial (APEX) the development of deep venous thrombosis (DVT) was 6.9% vs 8.5% (P=0.054) in the first cohort and 5.6% vs 7.1% (P<0.05) in the second cohort in favor of betrixaban over enoxaparin. In the overall population, the development of DVT was 5.3% vs 7.0% (P<0.05) in favor of betrixaban over enoxaparin. The overall safety outcome for the population, major bleeding, occurred in 0.7% vs 0.6% (P=0.55) with betrixaban showing a non-significant increased risk of major bleeding over enoxaparin.[1,5]

Most important risks/adverse events: Major bleeding (weigh risk vs. benefit in patients with concomitant use of P-glycoprotein (P-gp) inhibitors and other anticoagulants; bleeding should be monitored during therapy)[4]

Most common adverse events: Bleeding (>5%), UTI (3%), constipation (3%), hypokalemia (3%), hypertension (2%), headache (2%), nausea (2%), diarrhea (2%)[1]

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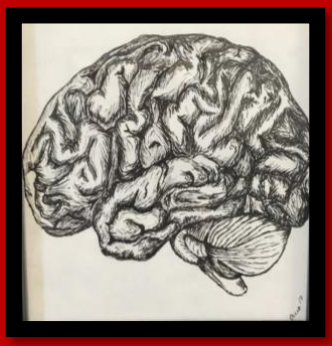
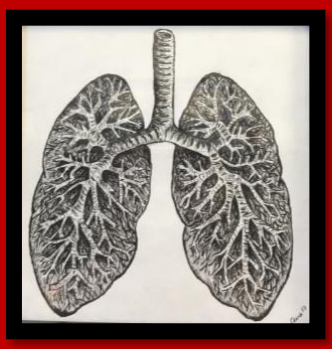
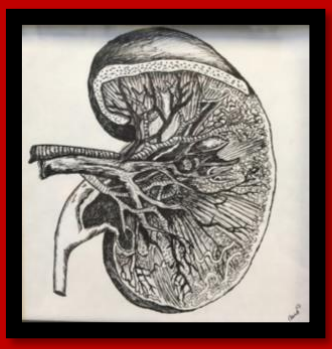
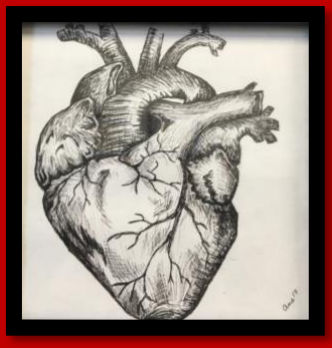
Artwork by Dr. Andrea Newsome









CAREER CLINICAL PHARMACIST SPOTLIGHT

Critical Care Pharmacist, Clinical Assistant Professor
Augusta University Medical Center, University of Georgia
Andrea Newsome, Pharm.D., BCPS, BCCCP

By: Alessia Jankowski, Pharm.D. Candidate

What education steps and opportunities did you pursue to get to where you are today?
As a member of the University of Georgia Honors Program, I was offered research opportunities through the Center for Undergraduate Research Opportunities (CURO) and awarded the CURO Honors Scholarship… A really cool experience, I studied abroad in Cortona, Italy where we studied art history, genetics and even biochemistry. Since I only did two years of undergraduate studies, most of my experiences were actually during pharmacy school… To be honest, I didn't know I wanted to do residency and thought I was going to be a community pharmacist after graduation. Then, I did my first IPPE and came home crying with the confirmation that community pharmacy was not for me. I had to completely retool what I was doing in pharmacy school and really ramp it up my third and fourth year.

How did your residency training at the University of North Carolina (UNC) Hospital and Clinics prepare you for your pharmacy career?
Well, it was probably one of the best experiences of my entire life. I love those people very much. As a whole, residency prepares you to become a clinical specialist because it allows you to practice the skills of a pharmacist while still in somewhat of a training environment. You have all this independence to make decisions and to see how those decisions impact patients. It definitely built up what I call my 'clinical knowledge base.' Just the amount of things I learned in 24 months is an exponential increase from what I had done in the previous four years. It was really hard – like working 12-hour days everyday. I would get there at 5 a.m. and stay until 5 p.m. every Monday through Friday, and then work every third weekend. I worked A LOT! I worked on projects on the weekends… so I really did a lot of hours! However, I figured out what I was capable of…Knowing that you are capable of that gives you a lot of confidence in yourself. Also, I chose UNC in particular for its focus on clinical care of patients and focus on teaching. Obviously, those two areas are extremely important to me. So I was able to do a lot of teaching with students, and that was really fun!

Why did you decide to pursue a career in critical care pharmacy?
Critical care is very fast paced and the evidence is not always as clear-cut. I felt that I was able to make really cool decisions, but also use my critical thinking skills, which I really enjoyed! I was not just following guidelines, although I am obsessed with guidelines and love evidence-based medicine. I really got to apply it all in practice…While I enjoy talking to patients, I admit that it never gave me great satisfaction. But I love working with the medical team and really like that teaching environment… I felt that I was a vital part of the team – it is awesome!

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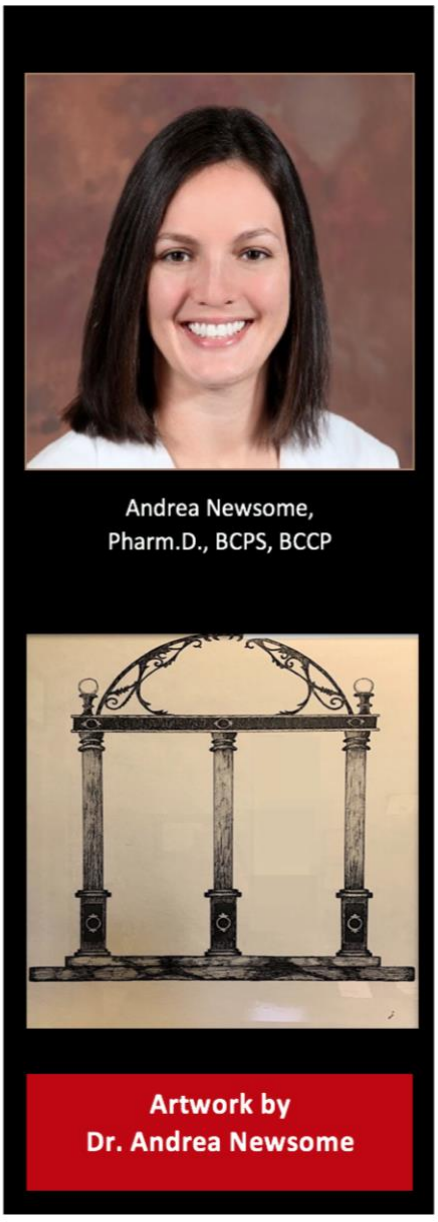
What steps did you take to become a Clinical Assistant Professor at The UGA College of Pharmacy?

I knew I wanted to be a professor before I knew I wanted to do anything else exactly and everyone said [I] had to do a residency… So, third year I worked on research with Dr. (Susan) Fagan and I was involved in creating the Student Diabetes Club… I just tried to be involved with the communities, research and writing, and all those types of resume builder activities. Then, I did a PGY1 and the question became, "what should I do at that point?" I was thinking about actually coming back and doing a fellowship, but I fell in love with patient care at that point and I really loved critical care. So, I thought…I want to hang out with patients more! Then, I did a PGY2 in Critical Care and there are different things you can do… You can do quality improvement, research, teach and be with students. Throughout my residency, and when I took my first position as the Cardiothoracic Intensive Care Unit pharmacist, I really tried to focus on the things that I thought would get me ready for this position. In academia, [they] talk about three things: service, scholarship, and teaching. Those are the three things that I am evaluated on, so when I started this job I took as many students as I could for IPPEs, APPEs, etc., and did as many lectures as they would give me. I tried to stay involved with research, so I did another project with Dr. Fagan, and I was involved in all of the Medication Use Evaluations (MUE). So, I just say be involved, and do not feel like you have to do something you don't like doing; you should always pursue your interests.



What are your best pieces of advice for students interested in residency and clinical pharmacy?

Be involved! Don't just say 'no' to things because you *think* you don't like it. If someone offers for you to come work in his or her lab for a little bit, even though you may not want to do lab research, I promise you will learn so much if you take advantage of these opportunities. You will be able to interpret literature better because you spent that time in the lab and even make some friends in the lab. Maybe you find out that you love it in which case you can be a pharmacist that does translational research. Just because you don't think that you can like organizations does not mean you should not be a part of an organization. Once I joined the Student Diabetes Club, I would go to sandwich luncheons and participate in informational talks, I realized that I really loved all of it once I gave it a chance. So, just try to say 'YES' to stuff! Finally, mentorship, mentorship, mentorship!! Do not think that you can do it on your own. I am not here today without the many people helping me to get here… Mentorship is so important and with pharmacy being such a small world, the more mentorship and the more things to be involved in, the better! Just realize that every rotation and experience can teach you something – there are always good things you can get from everything!

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New Methylphenidate Formulation for ADHD: COTEMPLA XR-ODT™

By Justine Nurse-McLeod, Pharm.D. Candidate

With approximately 20 to 40% of children unable to swallow a standard size pill or capsule, the pediatric population faces its own unique set of barriers to the administration and compliance of oral medications.[6] For children and adolescents diagnosed with Attention Deficit Hyperactivity Disorder (ADHD), a new formulation of methylphenidate has proposed a solution to this age-old problem. On June 19, 2017, the US Food and Drug Administration approved the first and only methylphenidate extended-release orally disintegrating tablet for the treatment of ADHD in children 6 to 17 years of age. This novel medication, known as Cotempla XR-ODT, was developed by Neos Therapeutics and introduced to market in October 2017.[5]

Presently, stimulant medications such as methylphenidate are used as first-line pharmacological therapies in the treatment of ADHD, with long-acting formulations allowing for convenient once-daily dosing. However, most existing options come in tablet or capsule form which necessitate being swallowed intact.[3] Cotempla XR-ODT offers health care providers and their patients a new treatment option by combining the convenience of once-daily dosing with an effortless orally disintegrating dosage form, which will ideally increase the rates of efficacy and adherence currently observed within this patient population.

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What are your current academic and research interests?
Currently, I am interested in the vascular and hemodynamic changes that occur in the critically ill. On the vascular side of things, Dr. (Somanath) Shenoy and I are doing a project on MMP3 in Acute Respiratory Distress Syndrome (ARDS). On the hemodynamic side, I am researching fluid management in critically ill patients. In the past, I have done a lot of research on stroke patients with Dr. Susan Fagan and specifically looked at IL-6, an inflammatory cytokine in ischemic stroke. I have looked at various cytokines in hemorrhagic stroke and authored multiple review papers on hemorrhagic stroke. My PGY1 research project evaluated how programs actually set up research in the residency year. Usually, residents pick a project, obtain IRB approval, and then conduct research. However [they] used a "Flipped Residency Research Model," where residents were given a project that had already been IRB approved. For the first half of the residency year, residents would collect data, analyze the results and present the findings. Then, for the second half of the residency year, residents would create and submit a project proposal for IRB approval for the incoming PGY1 residents. So a PGY1 resident would take your project, and if interested, you could still contribute to the project and participate in two research projects essentially. Then, my PGY2 project focused on iloprost in ARDS and burn patients.

Outside of pharmacy, what are your favorite hobbies?
I have a lot of hobbies actually. I love to read and average about one book a week. So, if you ever want a book recommendation, just let me know! I love to draw and can show you some of my drawings that I keep in my office! I do a lot of arts and crafts projects – paintings, drawings, and even building things. Actually, I built a coffee table and a bookshelf for my house! Also, I am a huge hiker. I hiked Mount LeConte in Tennessee last weekend, Black Balsam Knob in North Carolina two weekends ago, and even the Inca Trail in Peru back in August before starting this job! In the future, I really want to do a trek in the Grand Canyon! Of course, I love hanging out with my closest friends and love them all very deeply.

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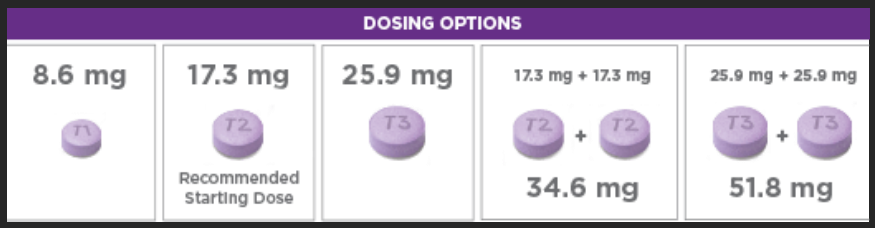
Final approval of the drug was supported by the results of a Phase 3 clinical trial in children in a laboratory classroom setting. Compared to placebo, a statistically significant improvement in ADHD symptom control was seen with Cotempla XR-ODT throughout the classroom day. Generally, the onset of effect was observed one hour subsequent to dosing, and symptom control continued throughout 12 hours. Overall, the adverse events profile of Cotempla XR-ODT is comparable to the established tolerability profile of other extended-release methylphenidate products. While there were no serious adverse events reported throughout the trial, common adverse events included decreased appetite, trouble sleeping, nausea, vomiting, indigestion, weight loss, irritability, mood swings, increased heart rate, and increased blood pressure.[1]

With regards to formulation, Cotempla XR-ODT contains approximately 75% extended-release and 25% immediate-release methylphenidate particles and is available in various strengths, including 8.6, 17.3, and 25.9mg of methylphenidate (equivalent to 10, 20, and 30mg methylphenidate hydrochloride). Currently, the recommended starting dose is 17.3mg once daily in the morning taken consistently with or without food. If needed, the dose can be titrated in weekly increments of 8.6 to 17.3mg to a maximum of 51.8mg per day. As with any orally-disintegrating dosage form, the tablet should be placed on the tongue and allowed to disintegrate with careful avoidance of chewing or crushing.[2,5]



Although the Cotempla XR-ODT formulation offers ease and convenience, it does come at a significant cost. While many insurance companies do not cover Cotempla XR-ODT, there is a manufacturer savings card offered for patients with commercial insurance. With the savings card, patients have a $0 copay for the first 30-day supply, followed by a $25 copay per prescription filled through 2018.[4] For uninsured patients, GoodRx offers a supply of thirty tablets (17.3mg) for approximately $350.00 depending on the pharmacy utilized. It should also be noted that some pharmacies may not honor associated coupons as Cotempla XR-ODT is a controlled medication. While price may initially prove a significant barrier to access, the ability of this drug to aid in the successful management of ADHD in the future is encouraging.

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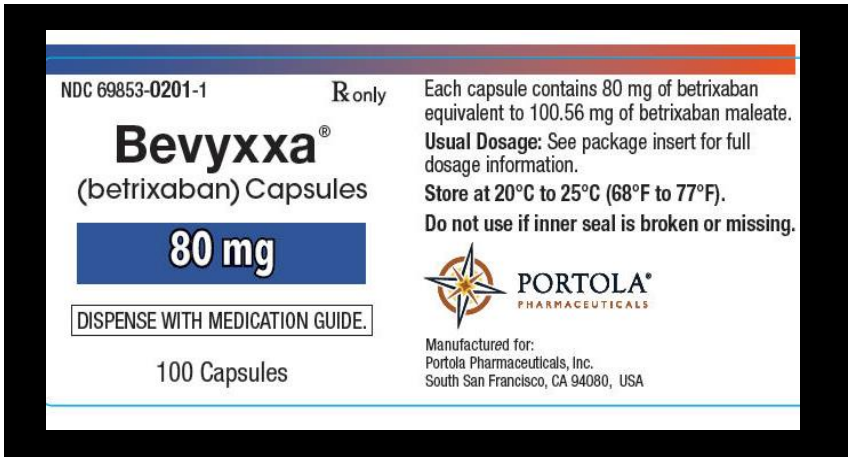

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Advantages: Currently the only FDA approved drug therapy to prevent VTE in adult patients hospitalized for an acute medical illness who are at risk for thromboembolic complications.[1,4] The only major side effect experienced by patients was bleeding. No dose adjustment necessary for patients greater than 65 years old.[4]

Disadvantages: Drug-drug interactions are likely with P-gp inhibitors, which can increase the blood levels of betrixaban. Patients with renal impairment will require a reduced dose, and it is recommended to avoid concomitant use in those taking other anticoagulants. Betrixaban should be avoided in patients with hepatic impairment as the drug is mainly cleared hepatically. Betrixaban is recommended to be taken with food daily at the same time each day.[4]

Usual dosage: Recommended initial single dose of 160 mg, followed by 80 mg once daily, taken at the same time each day with food. Recommended duration of treatment is 35 to 42 days.[4] In patients with renal impairment, CrCl ≥ 15 < 30 mL/min, and/or receiving or starting concomitant P-gp inhibitors, recommended initial single dose of 80 mg, followed by 40 mg once daily.[1,4]

Available Products: Capsules - 40 mg and 80 mg

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