



From the Front Lines

AlixaRx Clinical Pharmacists Address Everyday Challenges in Long-Term Care

AlixaRx Therapeutic Interchange Program

AlixaRx is pleased to announce that we have expanded our Therapeutic Interchange (TI) program. This program allows prescribers to preauthorize therapeutic substitution by drug class for all of their nursing home patients. Please note that each prescriber will need to fill out and sign an individual form for each facility.

Over the coming weeks, the new TI program will begin to roll out to the majority of our customers and will continue until the program is fully updated in each permitted facility. Due to regulatory constraints, we are not currently able to rollout an automatic TI program in VA, NE or MO.

For each interchanged medication order, you will receive both a fax notification as well as a notification in the medication tote delivered to your facility. It will be imperative that each facility checks the fax machine for all notifications before pulling any new orders from the Automated Dispensing Unit (ADU). The fax prompt you to update PCC with the correct order, ensuring appropriate medication administration and documentation.

Fluoroquinolones Restrictions from FDA

New Drug Update

These programs have several advantages including decreased facility drug spend for Medicare and Managed Care patients and a reduction in the number of drug claim rejections due to step therapy and prior authorization requests for patients covered by Medicare D or private insurance. Also, improved therapeutic and regulatory outcomes are achieved by limiting the use of potentially inappropriate medications in older adults.

A study reported in JAMA Internal Medicine on May 9, 2016 highlights the benefits of TI programs to health care organizations. In this study the drug classes where the greatest savings were realized included statins (Crestor, Lipitor), proton pump inhibitors (Prilosec, Prevacid, Protonix), SSRIs (Zoloft, Prozac, Lexapro), and angiotensin receptor blockers (Cozaar, Diovan).

Please don't hesitate to contact either your AlixaRx Clinical Pharmacist or AlixaRx Pharmacy with any questions regarding the process.

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FDA Recommends Restricting the Use of Fluoroquinolones Due to Potential Side Effects

The FDA has recently released a statement indicating that the use of systemic fluoroquinolones should be restricted due to the potential for serious "disabling and potentially permanent" side effects involving tendons, muscles, joints, nerves and the central nervous system.

Examples of Fluoroquinolone antibiotics include Avelox (moxifloxacin), Cipro (ciprofloxacin), Factive (gemifloxacin), Levaquin (levofloxacin) and Floxin (ofloxacin).

The FDA advised that the risk of serious side effects frequently outweighs the benefit in patients receiving fluoroquinolones for the treatment of sinusitis, bronchitis and uncomplicated urinary tract infections for which other treatment options are available. The use of fluoroquinolones should be reserved only for cases where other treatment options do not exist.

Potential side effects include tendon, joint and muscle pain, tendonitis, tendon rupture, peripheral neuropathy, confusion and hallucinations, exacerbation of Myasthenia Gravis, QT prolongation, phototoxicity and hypersensitivity. These side effects can occur together. If a patient experiences any of these side effects, treatment with the fluoroquinolone should be discontinued and the course of treatment should be completed with a non-fluoroquinolone antibiotic.

Any side effects should be reported to the FDA's MedWatch program at https://www.accessdata.fda.gov/scripts/medwatch/medcatch-online.htm

References: 1. FDA Drug Safety Communication "FDA Advises Restricting Fluoroquinolone Antibiotic use for Certain Uncomplicated Infection; Warns about Disabling Side Effects that Can Occur Together" http://www.fda.gov/downloads/Drugs/DrugSafety/UDM500591.pdf, accessed May 13, 2016. 2. Lowes, Robert "Limit Fluoroquinolone Use in Light of Risk, FDA Says" Mediscape Medical News. http://www.medscape.com/viewarticle/863256 - Accessed May 13, 2016.

New Drug Update - Repatha (Evolocumab)

Approved by the FDA in August 2015, Repatha (Evolocumab) is a subcutaneous injection used to treat high LDL (low density lipoprotein) cholesterol in patients who have not been able to adequately lower LDL levels with current treatment options.

Repatha is classified as a PCSK9 (proprotein convertase subtilisin kexin 9) inhibitor and is approved for use as an adjunct treatment for adult patients receiving maximally tolerated statin therapy or who are unable to tolerate statins diagnosed with heterozygous or homozygous familial hypercholesterolemia or clinical atherosclerotic cardiovascular disease.

Repatha targets PCSK9, a protein that decreases the number of receptors on the liver responsible for removing LDL cholesterol from the bloodstream. Repatha prevents PCSK9 from blocking these receptors, increasing the number of receptors available to remove LDL cholesterol from the bloodstream, resulting in a decrease in LDL levels. Clinical trials have shown an average decrease of LDL levels by 60 percent as compared to placebo.

Repatha is administered as a subcutaneous injection, given as 140mg every 2 weeks or 420mg every month. It is available in either a prefilled syringe or an autoclick injector. The medication should be stored in the refrigerator and should be left out to warm to room temperature for at least 30 minutes prior to injection. Repatha can be stored at room temperature for up to 30 days. If not used within 30 days at room temperature, the medication must be discarded. The needle cover of the prefilled syringes and the autoclick injector may contain latex. Use with caution in patients with a latex allergy.



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Common side effects include nasopharyngitis, upper respiratory infection, influenza, back pain and injection site reactions. No dosage adjustment is required for patients with mild to moderate renal or hepatic impairment. Rash and hives have occurred during treatment with Repatha. If symptoms of a serious allergic reaction occurs, the medication should be discontinued.

References: 1. FDA approves Repatha to treat certain patients with high cholesterol; http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm460082.htm; Accessed 5/12/2016. 2. Prescribing information Repatha injection http://pi.amgen.com/united_states/repatha/repatha_pi_hcp_english.pd; accessed 5/12/2016

New Oral Anticoagulants - Xarelto® (rivaroxaban)

For decades warfarin (Coumadin) was the only available oral anticoagulant on the market. Its use is complicated by a long list of drug interactions and requirements for frequent lab monitoring. Even under ideal situations, maintaining warfarin patients within the goal INR is challenging. In the past few years several new anticoagulant medications have come to market with fewer drug interactions and without the requirement for routine lab monitoring. While these agents are safer in some ways, they are still high risk medications that can result in serious adverse events, including bleeding. Errors in dosing, duration, and administration can put our residents at risk. With these medications being ordered more frequently it is important to review current recommendations for use.

Xarelto® (rivaroxaban) Approved Indications and Dosages:

Non-valvular A.Fib. - Stroke and embolism prevention: 20mg PO daily

DVT or PE Treatment: 15 mg PO twice daily with food for the first 21 days, then 20 mg PO once daily with food for a total of 6 months

DVT or PE Prevention in patients previously treated: 20 mg PO once daily with food at approximately the same time each day

DVT prevention post hip/knee surgery: 10 mg PO once daily for 12 days after knee replacement surgery or for 35 days after hip replacement surgery.

<u>Administration:</u> 15mg and 20mg tablets should be taken with food, the 10mg tablets can be taken with or without food. All tablet strengths can be crushed.

Dose adjustment for elderly:

In residents with A.fib. and CrCl 15-50ml/min the dose should be 15mg daily (this will be most of our elderly residents). Other indications: No dosage adjustments but avoid use if CrCl<30ml/min.

Challenge yourself to know the names and dosages of new oral anticoagulants. Ensure an accurate indication (diagnosis) is entered into your electronic health record. Utilize drug information resources to double check that the dose and duration are appropriate. Ask your AlixaRx Clinical Pharmacist for additional guidance on the use of these agents, we love drug information questions!

Don't miss a review of Eliquis® (apixaban) in the next addition of From the Front Lines.

Resources: Clinical Pharmacology accessed 5/10/16. Available at: http://www.clinicalpharmacology.com/

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