WASHINGTON STATE UNIVERSITY HEALTH SCIENCES

Drug Information Center
College of Pharmacy

Highlights of FDA Activities – 3/1/17 – 3/31/17

FDA Drug Safety Communications & Drug Information Updates:

Balloon angioplasty devices to treat autonomic dysfunction: Safety Communication - FDA concern over experimental procedures 3/8/17

The FDA is warning the public about Transvascular Autonomic Modulation, an experimental procedure that is promoted to treat a variety of conditions. This procedure has not been thoroughly studied in clinical trials. Also, the use of the balloon angioplasty device within the procedure is within the scope of its FDA-approved indications.

SPS-1 Statistic Prevention Solution distributed by Organ Recovery Systems: Safety Communication - FDA warns of Potential Contamination and Advises of Recall 3/9/17

The FDA warned of the potential of bacterial contamination of SPS-1 Static Preservation Solution (SPS-1), a solution used in the flushing and cold storage of kidney, liver and pancreas at the time of organ removal in preparation for storage, transportation, and transplantation into the recipient. Voluntary recall and random testing of sterility have been initiated on SPS-1 bags following confirmed contamination of one bag with *Pantoea* and *Enterococcus* bacteria. The manufacturer has suspended production and distribution until additional test results are available. Lots PBR-0060-392, PBR-0074-330, PBR-0074-337, and PBR-0060-386 have been recalled.

Increased Risk of Serious Pancreatitis In Patients Without A Gallbladder With Viberzi (eluxadoline) Use: Drug Safety Communication 3/15/17

The FDA warned that Viberzi (eluxadoline), a medicine used to treat irritable bowel syndrome with diarrhea (IBS-D), should not be used in patients who do not have a gallbladder. An FDA review found these patients have an increased risk of developing serious pancreatitis that could result in hospitalization or death.

Absorb GT1 Bioresorbable Vascular Scaffold (BVS) by Abbott Vascular: Safety Communications - FDA Investigating Increased Rate of Major Adverse Cardiac Events 3/18/17

The FDA warned health care providers treating patients with Absorb GT1 BVS that the rate of major adverse cardiac events observed in patients receiving the BVS is higher, when compared to patients treated with the approved metallic XIENCE drug-eluting stent. Monitoring and testing is currently being conducted in order to know why there are higher risk of cardiac events.

Major Product Recalls Announced Through MedWatch:

Herbal and Dietary Supplement Products by Regeneca Worldwide: Recall - Not Manufactured in Compliance with Current Good Manufacturing Practices 3/7/17

Regeneca recalled its entire line of herbal and supplement products nationwide following a court order.

SynchroMed ll and SynchroMed EL Implantable Drug Infusion Pumps by Medtronic: Recall- Failure of Priming Bolus 3/14/17

Medtronic recalled its SynchroMed Implantable Infusion Pumps due to a software problem that can cause the unintended delivery of drugs during a priming bolus procedure. Manufacturer representatives are exchanging the software application cards.

HeartStart MRx Monitor/Defibrillator by Phillips Healthcare: Class l Recall - Electrical Issues 3/24/17

Due to an electrical issue, Phillips Healthcare is recalling the HeartStart MRx Monitor/Defibrillator. The electrical problems prevent the device from powering up, charging, and delivering an electrical shock therapy. A delay in therapy could potentially cause permanent organ damage, brain injury or death.

Prelude Short Sheath Introducer by Merit Medical Systems: Recall – Sheath May Separate 3/31/17

Merit7F Prelude Short Sheath Introducer, used to guide the placement of catheters, grafts, and other medical devices into veins and arteries, recalled due to potential for the tip to separate during the procedure. Affected lots (H1041469, H1041473, H1036880, and H1041464) were distributed from December 15, 2016 to January 18, 2017.

Mylan's EpiPen and EpiPen Jr Auto-injectors: Recall – Failure to Activate 3/31/17

Thirteen lots have been recalled due to the potential that these devices may contain a defective part that may result in the devices failure to activate. The 13 lots were distributed between December 17, 2015 and July 1, 2016.

Product/Dosage	NDC	Lot Number	Expiration Date
EpiPen Jr Auto-Injector, 0.15mg	49502-501-02	5GN767	April 2017
EpiPen Jr Auto-Injector, 0.15mg	49502-501-02	5GN773	April 2017
EpiPen Auto-Injector, 0.3mg	49502-500-02	5GM631	April 2017
EpiPen Auto-Injector, 0.3mg	49502-500-02	5GM640	April 2017
EpiPen Jr Auto-Injector, 0.15mg	49502-501-02	6GN215	September 2017
EpiPen Auto-Injector, 0.3mg	49502-500-02	6GM082	September 2017
EpiPen Auto-Injector, 0.3mg	49502-500-02	6GM072	September 2017
EpiPen Auto-Injector, 0.3mg	49502-500-02	6GM081	September 2017
EpiPen Auto-Injector, 0.3mg	49502-500-02	6GM088	October 2017
EpiPen Auto-Injector, 0.3mg	49502-500-02	6GM199	October 2017
EpiPen Auto-Injector, 0.3mg	49502-500-02	6GM091	October 2017
EpiPen Auto-Injector, 0.3mg	49502-500-02	6GM198	October 2017
EpiPen Auto-Injector, 0.3mg	49502-500-02	6GM087	October 2017

Dietary Supplement Recalls & Public Notifications

In March, the FDA issued notifications to the public regarding undeclared active ingredients in the following products. Patients are advised not to purchase or use these products.

Product	***Promoted Use***	***Hidden/Undeclared Drug Ingredient(s)***
African Viagra	Sexual Enhancement	Sildenafil[1]
Arouse-Plus	Sexual Enhancement	Tadalafil[1]
Bazook Bullet	Sexual Enhancement	Aminotadalafil[1]
Black Ant*	Sexual Enhancement	PDE-5 inhibitor[1]
Black 3K Plus Male Sexual Enhancement Capsules	Sexual Enhancement	Sildenafil[1]
Clalis*	Sexual Enhancement	PDE-5 inhibitor[1]
Dadiyongshi –Xiangganglongshengwu*	Sexual Enhancement	PDE-5 inhibitor[1]
Evil Root*	Sexual Enhancement	PDE-5 inhibitor[1]
Germany Black Gold*	Sexual Enhancement	PDE-5 inhibitor[1]
Germany Niubian*	Sexual Enhancement	PDE-5 inhibitor[1]
Gold Vigra*	Sexual Enhancement	PDE-5 inhibitor[1]
Hard Ten Days*	Sexual Enhancement	PDE-5 inhibitor[1]
Hu Hu Sheng Wei*	Sexual Enhancement	PDE-5 inhibitor[1]
Indian God Lotion*	Sexual Enhancement	PDE-5 inhibitor[1]
LaBri's Body Heath Atomic*	Weight Loss	Sibutramine[2]
Lang Yi Hao (Chaonogsuopian)*	Sexual Enhancement	PDE-5 inhibitor[1]
Lien Chan for Seven Days*	Sexual Enhancement	PDE-5 inhibitor[1]
Maca Gold*	Sexual Enhancement	PDE-5 inhibitor[1]
Max Man*	Sexual Enhancement	PDE-5 inhibitor[1]
Power Male Sexual Stimulant	Sexual Enhancement	Sildenafil[1]
Power V8 Viagra*	Sexual Enhancement	PDE-5 inhibitor[1]
Rhino 7K 9000 Male Performance Booster	Sexual Enhancement	Sildenafil[1]
Rhino 8 Platinum 8000	Sexual Enhancement	Sildenafil[1]
Stree Overload*	Sexual Enhancement	PDE-5 inhibitor[1]

Product	***Promoted Use***	***Hidden/Undeclared Drug Ingredient(s)***
Tiger King*	Sexual Enhancement	PDE-5 inhibitor[1]
Viagra 100*	Sexual Enhancement	PDE-5 inhibitor[1]
Ye Lang Shen*	Sexual Enhancement	PDE-5 inhibitor[1]
Zhansheng Weige Chaoyue Xilishi*	Sexual Enhancement	PDE-5 inhibitor[1]
Zhonghua Niubian*	Sexual Enhancement	PDE-5 inhibitor[1]

*Recalled

[1]Sildenafil/tadalafil/vardenafil may interact with nitrates to lower blood pressure to dangerous levels

[2]Sibutramine has been associated with increased cardiovascular events; discontinued 2010[FDA]

New Product Shortages Reported by the FDA:	***Date Initially Posted***
Sincalide (Kinevac) Lyophilized Powder (Bracco Diagnostics) 5 mcg/vial	3/1/17
Sodium Bicarbonate Injection, USP 4%, 4.2%, 7.5%, and 8.4% solution in vials and syringes	3/1/17
Labetalol Hydrochloride Injection 5 mg/ml multi-dose vials and prefilled syringe	3/1/17
Belatacept (Nulojix) Lyophilized Powder for injection (Bristol Myers Squibb Co.) 250 mg lyophilized powder per vial	3/6/17
Promethazine Injection 25 mg/mL and 50 mg/mL vials and ampules	3/23/17
Rocuronium Bromide Injection 50 mg/5 mL and 100 mg/10 mL multi-dose vials	3/22/17

Product Discontinuations/Withdrawals	***Date Posted***
Nitroglycerin transdermal (NITRO-DUR) (Merck Sharp & Dohme) All strengths; generics remain available	3/2/17
Ammonium Chloride Injection (Hospira, Inc) 5 mEq/mL; 20 mL vial discontinued by Hospira; no other source available	3/8/17
Cefotaxime Sodium Injection (Sanofi-Aventis) 500 mg single dose vial, 1 g single dose vial and single dose ADD-Vantage vial, 2 g single dose vial and single dose ADD-Vantage vial, 10 g bulk package vials discontinued by Sanofi-Aventis and Hospira; product remains available in limited supply from West-Ward	3/9/17
Montelukast Sodium Oral Granules (Mylan Pharmaceuticals, Inc.) 4 mg packets discontinued by Mylan; remains available from other manufacturers	3/23/17
Risperidone Orally Disintegrating Tablets (Mylan Pharmaceuticals, Inc) All strengths (0.25 mg, 0.50 mg, 1 mg, 2 mg, 3 mg, 4 mg) discontinued by Mylan; remains available from other manufacturers.	3/28/17

New Drug Approvals:	***Description***	***Date Approved***
House dust mite allergen extract tablet / Odactra / Merck Sharp & Dohme Corp.	Allergen extract sublingual tablets for house dust allergy immunotherapy in adults	3/1/17
Ribociclib / Kisqali / Novartis Pharms Corp.	See attached drug summary	3/13/17
Safinamide / Xadago / Newron Pharmaceuticals US Inc.	See attached drug summary	3/21/17
Avelumab / Bavencio / EMD Serono Inc.	See attached drug summary	3/23/17
Naldemedine / Symproic / Shionogi Inc	See attached drug summary	3/23/17
Niraparib / Zejula / Tesaro Inc.	See attached drug summary	3/27/17
Dupilumab / Dupixent / Regeneron Pharmaceuticals, Inc.	See attached drug summary	3/28/17
Ocrelizumab / Ocrevus / Genentech, Inc.	See attached drug summary	3/28/17

New Indications:	***Description***	***Date Approved***
Pembrolizumab / Keytruda / Merck and Co.	FDA has approved this drug for adult and pediatric patients with refractory classical Hodgkin lymphoma (cHL), or those who have relapsed after three or more prior lines of therapy.	3/14/17
Topiramate extended-release / Qudexy XR / Upsher-Smith Laboratories Inc.	Prophylaxis of migraine in adults and adolescents	3/29/17

New Dosage Forms or Formulation:	***Description***	***Date Approved***
Desmopressin acetate / Noctiva / Serenity Pharmaceutical, LLC	Nasal spray, 0.83 mcg/0.1 mL and 1.66 mcg/0.1 mL; indicated for adults who awaken at least two times per night to urinate (nocturnal polyuria)	3/3/17
Hyaluronic acid gel / Juvederm Vollure XC / Allergan	Formulation approved for injection into the facial tissue for the correction of moderate to severe facial wrinkles and folds in adults over the age of 21	3/20/17

Compiled by:

Terri Levien, Pharm.D.
Zaynah K. Ali, Pharm.D., PGY1 Drug Information Resident
Andrew Pascal, Pharm.D. Candidate 2017
Pierce Robledo, Pharm.D. Candidate 2017
Katlin Cormier, Pharm.D. Candidate 2017
Alice Knotts, Pharm.D. Candidate 2018
Uzoma Mbogu, Pharm.D. Candidate 2018

Drug Information Center
College of Pharmacy
Washington State University
PO Box 1495
Spokane, WA 99210-1495
(509) 358-7662
Pharmacy.druginfo@wsu.edu

Ribociclib / Kisqali / Novartis Pharmaceuticals	
Generic Name / Brand Name / Company	Ribociclib/Kisqali/Novartis Pharmaceuticals
Date of approval	March 13, 2017
Drug Class (Mechanism of Action if novel agent)	Cyclin-dependent kinase 4/6 inhibitor
Indication	In combination with an aromatase inhibitor as initial endocrine-based therapy for the treatment of postmenopausal women with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer
Comparative agent – Therapeutic interchange?	Palbociclib
Dosage forms/strengths. Common Dose/sig	Tablets: 200 mg; Recommended starting dose: 600 mg orally (three 200 mg tablets) taken once daily with or without food for 21 consecutive days followed by 7 days off treatment
DEA Schedule	Not scheduled
Date of market availability	March 17, 2017
Similar Medications (Look-Alike Sound-Alike)	Riboflavin, Ribavirin
CLINICAL USE EVALUATION	
Common Adverse Effects	Most common adverse reactions (incidence ≥ 20%) are neutropenia, nausea, fatigue, diarrhea, leukopenia, alopecia, vomiting, constipation, headache, and back pain; (incidence ≥ 10%) are UTI, anemia, lymphopenia, decreased appetite, insomnia, dyspnea, stomatitis, abdominal pain, rash, pruritus, pyrexia and edema
Severe Adverse Effects	QT prolongation, hepatobiliary toxicity, neutropenia and embryo-fetal toxicity

Severe Drug-Drug Interactions	CYP3A4 Inhibitors: Avoid concomitant use with strong CYP3A inhibitors. If strong inhibitors cannot be avoided, reduce ribociclib dose CYP3A4 Inducers: Avoid concomitant use with strong CYP3A inducers CYP3A substrates: The dose of sensitive CYP3A substrates with narrow therapeutic indices may need to be reduced when given concurrently with ribociclib Drugs known to prolong QT interval: Avoid concomitant use of drugs known to prolong QT interval such as anti-arrhythmic medicines
Severe Drug-Food Interactions	Avoid pomegranate or pomegranate juice, and grapefruit or grapefruit juice
Important Labs Values to assess prior to order entry or at point of clinical follow up. (Need Pop Up?)	Perform Complete Blood Count (CBC) before initiating therapy, every 2 weeks for the first 2 cycles, at the beginning of each subsequent 4 cycles, and as clinically indicated Perform Liver Function Tests (LFTs) before initiating treatment, every 2 weeks for the first 2 cycles, at the beginning of each subsequent 4 cycles, and as clinically indicated Monitor electrocardiograms (ECGs) and electrolytes prior to initiation of treatment. Repeat ECGs at approximately Day 14 of the first cycle and at the beginning of the second cycle, and as clinically indicated. Monitor electrolytes at the beginning of each cycle for 6 cycles, and as clinically indicated.
Used in Pediatric Areas	Safety and efficacy not established
Renal or Hepatic Dosing	No dose adjustment is necessary in patients with mild hepatic impairment (Child-Pugh class A); the recommended starting dose is 400 mg once daily for patients with moderate (Child-Pugh class B) and severe hepatic impairment (Child-Pugh class C).
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	No contraindications Can cause fetal harm. Advise patients of potential risk to a fetus and to use effective contraception during therapy; If the patient vomits after taking the dose, or misses a dose, no additional dose should be taken that day and the next prescribed dose should be taken at the usual time
Special administration technique or considerations	Ribociclib tablets should be swallowed whole (tablets should not be chewed, crushed or split prior to swallowing), no tablet should be ingested if it is broken, cracked, or otherwise not intact
Prepared by	Andrew Pascal, Pharm. D. Candidate of 2017, Washington State University
Source	Ribociclib (Kisqali) prescribing information. East Hanover, NJ: Novartis Pharmaceuticals Corp.; March 2017.

Safinamide / Xadago / US WorldMeds, LLC	
Generic Name / Brand Name / Company	Safinamide/Xadago/US WorldMeds, LLC
Date of approval	March 21, 2017
Drug Class (Mechanism of Action if novel agent)	Monoamine Oxidase B Inhibitor
Indication	An adjunctive treatment to levodopa/carbidopa in patients with Parkinson's disease experiencing symptom breakthrough or "off" episodes
Comparative agent – Therapeutic interchange?	Rasagiline, selegiline
Dosage forms/strengths. Common Dose/sig	Tablets: 50 mg and 100 mg; Recommending starting dose: 50 mg once daily at the same time of day. After two weeks may increase dose to 100 mg once daily, based on individual need and tolerability.
DEA Schedule	Not scheduled
Date of market availability	2nd Quarter
Similar Medications (Look-Alike Sound-Alike)	Rufinamide

CLINICAL USE EVALUATION	
Common Adverse Effects	>2%: Dyskinesia, fall, nausea, and insomnia
Severe Adverse Effects	Hypertension, serotonin syndrome, falling asleep during activities of daily living, hallucinations or psychotic behavior, impulse control or compulsive behaviors, withdrawal-emergent hyperpyrexia and confusion, retinal pathology
Severe Drug-Drug Interactions	• MAO Inhibitors – Contraindicated. Combination increases the risk of non-selective MAO inhibition which may result in increased blood pressure, including hypertensive crisis. • Opioids-Contraindicated. Combination could result in life-threatening serotonin syndrome • Serotonergic Drugs-Contraindicated. Combination could result in life-threatening serotonin syndrome. • Dextromethorphan-Contraindicated. Combination has been reported to cause episodes of psychosis or abnormal behavior • Sympathomimetics- combination has resulted in severe hypertension or hypertensive crisis. • Substrates of Breast Cancer Resistance Protein- Combination may inhibit BCRP which could in turn increase plasma concentrations of BCRP substrates. • Dopaminergic Antagonists – Combination may decrease the effectiveness of safinamide and exacerbate symptoms of Parkinson's disease.
Severe Drug-Food Interactions	Aged, fermented, cured, smoked and pickled foods containing tyramine could lead to severe hypertension or hypertensive crisis; patients should be advised to avoid food with large amounts of tyramine
Important Labs Values to assess prior to order entry or at point of clinical follow up. (Need Pop Up?)	Liver Function Tests – Contraindicated in patients with severe hepatic impairment
Used in Pediatric Areas	Safety and effectiveness have not been established
Renal or Hepatic Dosing	• Hepatic Dosing: Maximum dose of 50 mg once daily for patients with moderate (Child-Pugh class B) impairment. Has not been studied in patients with severe hepatic impairment (Child-Pugh class C), and is contraindicated in these patients. • Renal dosing adjustments are not necessary.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	• May cause or exacerbate existing hypertension. • Caution regarding daytime sleepiness and episodes of falling asleep during activities of daily living. • May lead to an intense urge to gamble, partake in sexual urges, spend money, binge eating, and the inability to control these urges. May require a dose reduction or discontinuation of medication • Rapid dose reduction, or withdrawal of medication has led to a symptom complex resembling neuroleptic malignant syndrome (eg. elevated temperature, muscular rigidity, altered consciousness, and autonomic instability)
Special administration technique or considerations	• Effective only when used in conjunction with levodopa/carbidopa • May take without regard to meals
Prepared by	Katlin Cormier, Pharm.D. Candidate 2017, Washington State University
Source	Safinamide (Xadago) prescribing information. Louisville, KY: US WorldMeds, LLC.; March 2017.

Avelumab / Bavencio / EMD Serono Inc. & Pfizer Inc.	
Generic Name / Brand Name / Company	Avelumab/Bavencio/EMD Serono Inc. & Pfizer Inc.
Date of approval	March 23, 2017
Drug Class (Mechanism of Action if novel agent)	Programmed death ligand-1 (PD-L1) blocking antibody
Indication	Treatment of adults and pediatric patients 12 years and older with metastatic Merkel cell carcinoma
Comparative agent – Therapeutic interchange?	None
Dosage forms/strengths. Common Dose/sig	Injection: 200 mg/10 mL (20 mg/mL) solution in single-dose vial. Administer 10 mg/kg as an intravenous infusion over 60 minutes every 2 weeks. Premedicate with acetaminophen and an antihistamine for the first 4 infusions and subsequently as needed.
DEA Schedule	Not scheduled
Date of market availability	March 29, 2017
Similar Medications (Look-Alike Sound-Alike)	Atezolizumab, Avelox
CLINICAL USE EVALUATION	
Common Adverse Effects	>20%: Fatigue, musculoskeletal pain, diarrhea, nausea, infusion-related reaction, rash, decreased appetite, and peripheral edema.
Severe Adverse Effects	Infusion-related reactions, pneumonitis, colitis, hepatitis, nephritis, immune-mediated adverse effects
Severe Drug-Drug Interactions	None known
Severe Drug-Food Interactions	None known
Important Labs Values to assess prior to order entry or at point of clinical follow up. (Need Pop Up?)	Renal function tests, liver function test, blood glucose, and thyroid function tests
Used in Pediatric Areas	Safety and effectiveness of avelumab have not been established in pediatric patients less than 12 years of age.
Renal or Hepatic Dosing	No dosing adjustments are required for renal or hepatic impairment.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	• Immune-mediated pneumonitis: Withhold for moderate pneumonitis; permanently discontinue for severe, life-threatening or recurrent moderate pneumonitis. • Immune-mediated hepatitis: Monitor for changes in liver function. Withhold for moderate hepatitis; permanently discontinue for severe or life threatening hepatitis. • Immune-mediated colitis: Withhold for moderate or severe colitis; permanently discontinue for life-threatening or recurrent severe colitis. • Immune-mediated endocrinopathies: Withhold for severe or life-threatening endocrinopathies. • Immune-mediated nephritis and renal dysfunction: Withhold for moderate or severe nephritis and renal dysfunction; permanently discontinue for life threatening nephritis or renal dysfunction. • Infusion-related reactions: Interrupt or slow the rate of infusion for mild or moderate infusion-related reactions. Stop the infusion and permanently discontinue for severe or life-threatening infusion-related reactions. • Embryo-fetal toxicity: can cause fetal harm. Advise of potential risk to a fetus and use of effective contraception.
Special administration technique or considerations	Premedicate with antihistamine and acetaminophen prior to first 4 infusions, and subsequent infusions as clinically indicated.
Prepared by	Uzoma Mbogu, Pharm.D. Candidate 2018, Washington State University
Source	Avelumab (Bavencio) prescribing information. New York, NY: EMD Serono Inc & Pfizer Inc; March 2017.

Naldemedine / Symproic / Shionogi Inc.	
Generic Name / Brand Name / Company	Naldemedine / Symproic / Shionogi Inc.
Date of approval	March 23, 2017
Drug Class (Mechanism of Action if novel agent)	Opioid Antagonist
Indication	For the treatment of opioid-induced constipation in adult patients with chronic non-cancer pain.
Comparative agent – Therapeutic interchange?	Naloxegol, methylnaltrexone
Dosage forms/strengths. Common Dose/sig	Tablet: 0.2 mg; Dose: 0.2 mg once daily
DEA Schedule	Currently C-II; DEA currently re-evaluating
Date of market availability	Mid-summer
Similar Medications (Look-Alike Sound-Alike)	Nilotinib, nilutamide
CLINICAL USE EVALUATION	
Common Adverse Effects	≥2%: Abdominal pain, diarrhea, and nausea
Severe Adverse Effects	Opioid withdrawal
Severe Drug-Drug Interactions	• Strong CYP3A inducers – decreases naldemedine concentrations, potentially decreasing effectiveness. • Other opioid antagonists – has potential for additive effect and increased risk of opioid withdrawal, avoid use with other opioid antagonist. • Moderate and Strong CYP3A4 inhibitors – increases naldemedine concentrations, could increase risk of adverse reactions. • P-gp inhibitors – increases naldemedine concentrations, could increase risk of adverse reactions.
Severe Drug-Food Interactions	None known
Important Labs Values to assess prior to order entry or at point of clinical follow up. (Need Pop Up?)	Liver function tests – avoid use in severe hepatic impairment
Used in Pediatric Areas	Safety and effectiveness have not been established.
Renal or Hepatic Dosing	Hepatic Dosing: effect of severe hepatic impairment (Child-Pugh Class C) has not been evaluated; avoid use in patients with severe hepatic impairment. No dose adjustment is required in mild or moderate hepatic impairment. Renal Dosing: No dose adjustment required.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications: • Patients with known or suspected gastrointestinal obstruction or at an increased risk of recurrent obstruction. • Patients with a history of hypersensitivity reaction to naldemedine. • Consider the overall risk benefit in patients with known or suspected lesions of the GI tract. Monitor for severe, persistent, or worsening abdominal pain; discontinue naldemedine if symptoms develop • Consider the overall risk benefit in patients with disruptions to the blood-brain barrier, monitor for symptoms of opioid withdrawal. • Use during pregnancy may precipitate opioid withdrawal in a fetus due to the undeveloped blood-brain barrier. • Breast feeding during is not recommended or for 3 days after final dose.
Special administration technique or considerations	• Does not require alteration of analgesic dosing regimen prior to initiation. • Patients receiving opioids for less than 4 weeks may be less responsive. • Discontinue naldemedine if treatment with opioid pain medication is discontinued.
Prepared by	Katlin Cormier, Pharm.D. Candidate 2017, Washington State University
Source	Naldemedine (Symproic) prescribing information. Florham Park, NJ: Shionogi Inc.; March 2017.

Niraparib / Zejula / Tesaro	
Generic Name / Brand Name / Company	Niraparib / Zejula / Tesaro
Date of approval	March 27, 2017
Drug Class (Mechanism of Action if novel agent)	Niraparib is an inhibitor of poly(ADP-ribose) polymerase (PARP) enzymes, PARP-1 and PARP-2, which play a role in DNA repair which leads to DNA damage, apoptosis and cell death
Indication	Maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy
Comparative agent – Therapeutic interchange?	None
Dosage forms/strengths. Common Dose/sig	Capsules: 100 mg Monotherapy as 300 mg (three 100 mg capsules) taken orally once daily
DEA Schedule	Not scheduled
Date of market availability	April 19, 2017
Similar Medications (Look-Alike Sound-Alike)	Neratinib
CLINICAL USE EVALUATION	
Common Adverse Effects	>10%: Thrombocytopenia, anemia, neutropenia, leukopenia, palpitations, nausea/vomiting, diarrhea, dyspepsia, abdominal pain, mucositis, fatigue, decreased appetite, myalgia, back pain, headache, insomnia, nasopharyngitis, dyspnea, cough, rash, hypertension
Severe Adverse Effects	Myelodysplastic syndrome/acute myeloid leukemia, bone marrow suppression, cardiovascular effects
Severe Drug-Drug Interactions	Weak inhibitor of BCRP
Severe Drug-Food Interactions	Not studied
Important Labs Values to assess prior to order entry or at point of clinical follow up. (Need Pop Up?)	CBC weekly for the first month, monthly for the next 11 months, and periodically thereafter
Used in Pediatric Areas	Safety and effectiveness have not been studied
Renal or Hepatic Dosing	• No dose adjustments for patients with mild to moderate renal impairment (Clcr: 30-89 mL/min) • Safety of drug has not been established for patients with severe renal impairment or ESRD undergoing hemodialysis
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	• Monitor for hematologic toxicity including myelodysplastic syndrome and bone marrow suppression • Monitor blood pressure and heart rate monthly in the first year of treatment • Due to its mechanism of action, this may cause fetal harm when administered to pregnant women; advise females of reproductive potential to use effective contraception during treatment and for at least 6 months after receiving the last dose
Special administration technique or considerations	Start treatment no later than 8 weeks after the most recent platinum-based regimen. Administer at the same time each day; bedtime administration may help manage nausea. Swallow capsules whole. Take with or without food.
Prepared by	Pierce Robledo Pharm. D. Candidate of 2017, Washington State University
Source	Niraparib (Zejula) prescribing information. Waltham, MA: Tesaro, Inc.; March 2017.

Dupilumab / Dupixent / Regeneron & sanofi-aventis	
Generic Name / Brand Name / Company	Dupilumab / Dupixent / Regeneron & sanofi-aventis
Date of approval	March 28, 2017
Drug Class (Mechanism of Action if novel agent)	Interleukin-4 receptor alpha antibody
Indication	Treatment of adult patients with moderate-to-severe atopic dermatitis whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable
Comparative agent – Therapeutic interchange?	None
Dosage forms/strengths. Common Dose/sig	Injection: 300 mg/2 mL in a single-dose pre-filled syringe Dose: 600 mg (two 300 mg injections in different injection sites) subcutaneously, followed by 300 mg subcutaneously every other week
DEA Schedule	Not DEA scheduled
Date of market availability	March 2017
Similar Medications (Look-Alike Sound-Alike)	None identified
CLINICAL USE EVALUATION	
Common Adverse Effects	>1%: Injection site reaction, conjunctivitis, blepharitis, oral herpes, keratitis, eye pruritus, dry eyes
Severe Adverse Effects	None known
Severe Drug-Drug Interactions	Live vaccines
Severe Drug-Food Interactions	None known
Important Labs Values to assess prior to order entry or at point of clinical follow up. (Need Pop Up?)	None required
Used in Pediatric Areas	Safety and efficacy in have not been established
Renal or Hepatic Dosing	No formal trial of the effect of hepatic or renal impairment on the pharmacokinetics of dupilumab was conducted.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	• Contraindicated in patients who have known hypersensitivity to dupilumab or any of its excipients
Special administration technique or considerations	• For the initial 600 mg dose, administer each of the two 300 mg injections at different injection sites. • Administer subcutaneous injection into the thigh or abdomen, except for the 2 inches (5 cm) around the navel. The upper arm can also be used if a caregiver administers the injection • Rotate the injection site with each injection. Do not inject into skin that is tender, damaged, bruised, or scarred.
Prepared by	Pierce Robledo, Pharm. D. Candidate of 2017, Washington State University
Source	Dupilumab (Dupixent) prescribing information. Bridgewater, NJ: sanofi-aventis U.S. LLC; March 2017.

Ocrelizumab / Ocrevus / Genentech USA, Inc	
Generic Name / Brand Name / Company	Ocrelizumab / Ocrevus / Genentech USA, Inc
Date of approval	March 28, 2017
Drug Class (Mechanism of Action if novel agent)	CD20-directed cytolytic antibody
Indication	Treatment of patients with relapsing (RMS) or primary progressive (PPMS) forms of multiple sclerosis (MS).
Comparative agent – Therapeutic interchange?	None; rituximab similar pharmacology but not indicated for use in MS
Dosage forms/strengths. Common Dose/sig	Injection: 300 mg/10 mL (30 mg/mL) in a single-dose vial. Administer by intravenous infusion • Starting dose: 300 mg IV, followed two weeks later by a second 300 mg IV infusion • Subsequent doses: 600 mg IV every 6 months
DEA Schedule	Not scheduled
Date of market availability	April 2017
Similar Medications (Look-Alike Sound-Alike)	None identified
CLINICAL USE EVALUATION	
Common Adverse Effects	• RMS (incidence ≥10% and > REBIF): upper respiratory tract infections and infusion reactions • PPMS (incidence ≥10% and > placebo): upper respiratory tract infections, infusion reactions, skin infections, and lower respiratory tract infections
Severe Adverse Effects	Infusion reactions, infections, malignancies
Severe Drug-Drug Interactions	• Immunosuppressive or Immune-modulating therapies • Live vaccination
Severe Drug-Food Interactions	None known
Important Labs Values to assess prior to order entry or at point of clinical follow up. (Need Pop Up?)	Screen for hepatitis B virus
Used in Pediatric Areas	Safety and effectiveness havehas not been established
Renal or Hepatic Dosing	No dosing adjustments are required for renal or hepatic impairment.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	• Contraindicated in patients with active hepatitis B virus infection or a history of life-threatening infusion reaction to ocrelizumab. • Infections: Delay administration in patients with an active infection until the infection is resolved. • Vaccination with live-attenuated or live vaccines is not recommended during treatment and after discontinuation, until B-cell repletion. • Infusion reactions: Management recommendations for infusion reactions depend on the type and severity of the reaction. Permanently discontinue if a life-threatening or disabling infusion reaction occurs. • Malignancies: An increased risk of malignancy, including breast cancer, may exist.
Special administration technique or considerations	• Hepatitis B virus screening is required before the first dose • Pre-medicate with methylprednisolone (or an equivalent corticosteroid) and an antihistamine prior to each infusion • Must be diluted prior to administration • Monitor patients closely during and for at least one hour after infusion • Advise patients to complete any required vaccinations at least 6 weeks prior to initiation of ocrelizumab
Prepared by	Uzoma Mbogu, Pharm.D. Candidate 2018, Washington State University
Source	Ocrelizumab (Ocrevus) prescribing information. South San Francisco, CA: Genentech, Inc.; March 2017.