College of Pharmacy and Pharmaceutical Sciences
WASHINGTON STATE UNIVERSITY

Drug Information Center

Highlights of FDA Activities – 9/1/18 – 9/30/18

FDA Drug Safety Communications & Drug Information Updates:

Enteral Device Connectors 9/7/18

To reduce the risk of misconnections and patient injury, the FDA recommends hospitals and clinicians use enteral devices with connectors that meet International Organization for Standardization (ISO) 80369-1 or ISO 80369-3 standard, or that are otherwise deigned to reduce the risk of misconnections. Misconnections between enteral devices and other medical devices, such as tracheostomy tubes, have been associated with patient death and serious injuries.

Kratom statement 9/11/18

The FDA issued an update on its' ongoing concerns about kratom, including marketers actively selling kratom with unsubstantiated or fraudulent health claims. It has issued additional warning letters to vendors marketing kratom to treat opioid withdrawal and other serious medical conditions.

Years to Your Health Products – Infection Risk 9/14/18

The FDA advised consumers not to use any products produced by Years to Your Health of Irving, Texas. The products are made in a facility with poor manufacturing practices and with no testing of incoming ingredients or finished products.

Immediate-Release Opioid Analgesics – Risk Evaluation and Mitigation Strategy (REMS) 9/18/18

The FDA approved a REMS for immediate-release opioids, that also applies to extended-release and long-acting opioid analgesics. The new REMS requires training be made available to health care providers involved in the management of patients with pain including nurses and pharmacists, requires the education cover broader information about pain management including treatment alternatives, and new labeling containing information about health care provider education. The FDA also approved a new education blueprint for upcoming programs; continuing education training under the modified REMS will be available to providers by March 2019.

FDA Completes Pimavanserin (Nuplazid) Review 9/20/18

The FDA reported that after completion of a review of postmarketing reports of death or serious adverse effects with the use of pimavanserin, no new or unexpected safety findings were detected. The observed events were consistent with the safety profile described in the current product label. Although no new safety risks were identified, the FDA did report some potentially concerning prescribing patterns with pimavanserin, such as concomitant use with other antipsychotics or drugs that can cause QT prolongation.

Valsartan Update 9/24/18 & 9/28/18

The FDA provided additional updates on valsartan products not under recall and placed an import alert blocking all importation of pharmaceutical ingredients from Zhejiang Huahai Pharmaceuticals until the manufacturer determines how impurities were introduced into the valsartan and remediates its' quality control systems. Additional information can be found at FDA updates on valsartan recalls

Compounding Research Projects 9/27/18

The FDA announced new agreements with institutions to conduct studies to inform policies regarding compounded drugs. One study will examine the clinical utility of treating patients with compounded bioidentical hormone replacement therapy products. Another will examine evidence of the safety and effectiveness of multi-ingredient compounded topical pain creams. In addition, collaborations are continuing to gather information for developing the list of bulk drug substances used in compounding.

Caution with Pen Needles to Inject Prescription Medications 9/28/18
The FDA issued a safety communication regarding the use of pen needles with pen injectors, recommending health care providers show patients how to use the pen needles, and educate patients about the types of pen needles and the type they should use. Pharmacists should make sure patients know how to use the type of pen needle being dispensed when dispensing a new box.

Dosing Errors Due to Differences in Strength Expression of Compounded Products 9/28/18
The FDA advised it has received reports of dosing errors and confusion due to differences in labeled strength expression for compounded injectable products compared with conventional manufactured products. Conventional manufacturers label small volume injectable products with the strength per total volume as the primary and prominent expression of strength on the label. Examples were provided of multiple compounded products labeled with different prominent expression of strength, most commonly expressed as strength per milliliter. The FDA suggests that compounded injectables should be labeled using the strength convention adopted by conventional manufacturers to reduce the risk of medication errors: strength per total volume as the primary and prominent expression followed in close proximity by strength per milliliter enclosed by parenthesis.

Major Medication/Drug-Related Product Recalls Announced Through MedWatch:

Sterile Compounded Products from Pharm D Solutions: Recall – Lack of Sterility Assurance 9/11/18
Pharm D Solutions recalled all sterile compounded drug products to the consumer level due to concerns raised following FDA inspection. Recalled products were distributed nationwide and directly to customers and medical facilities. The recall does not affect the pharmacy's non-sterile compounded products or retail pharmacy operations.

Methocarbamol 750 mg tablets (Robaxin, Endo Pharmaceuticals): Recall – Incorrect Dosing on Label 9/28/18
Endo Pharmaceuticals recalled two lots of methocarbamol (Robaxin) 750 mg tablets (Lot# 216702P1, expiration 9/2020 and lot#220409P1, expiration 1/2021) due to incorrect dosing information on the label. Instead of displaying the correct dose of 2 tablets 3 times daily, the recalled product displays a dosage of 2 to 4 tablets 4 times daily.

Dietary Supplement Recalls & Public Notifications

Notifications were issued regarding undeclared active ingredients or contaminants in the following products. Patients are advised not to purchase or use these products.

Product	***Promoted Use***	***Undeclared Ingredient(s) or Contaminants***
Allergy & Hay Fever Relief (Lot 050216X) homeopathic/Beaumont Bio Med*	Allergy symptoms	Microbial contaminants
Arthritis Pain Relief (Lot 112317K) homeopathic/Beaumont Bio Med*	Joint pain	Microbial contaminants
Cold & Flu Response (Lot 042816C & 112317K) homeopathic/Beaumont Bio Med*	Aches & pain, nasal congestion, headache and fever	Microbial contaminants
Diarrhea Response (Lot 090915) homeopathic/Beaumont Bio Med*	Upset stomach & diarrhea	Microbial contaminants
Muscle & Joint Pain Relief (Lot 012916F) homeopathic/Beaumont Bio Med*	Pain relief	Microbial contaminants
NeoRelief (Lot 1138,1139, 1146 &1160) homeopathic/BioLyte Laboratories*	Muscle cramping and restless leg	Microbial contaminants
Skin Irritation & Itch Response (Lot 091515C & 050118S) homeopathic/ Beaumont Bio Med*	Skin irritation; pruritus	Microbial contaminants

Product	***Promoted Use***	***Undeclared Ingredient(s) or Contaminants***
Sinus Response (Lot 100316A) homeopathic /Beaumont Bio Med*	Nasal congestion, sinus pressure, sinus headaches	Microbial contaminants
Sore Throat & Laryngitis Response (Lot 100316G & 050118R) homeopathic/ Beaumont Bio Med*	Minor throat pain, irritation, inflammation & laryngitis	Microbial contaminants

*Recalled

New Product Shortages	***Date Initially Posted***
Diphenhydramine injection	9/14/18

Product Discontinuations/Withdrawals	***Date Posted***
Meropenem for Injection (Sagent), meropenem injection remains available from other manufacturers	9/5/18
Daclatasvir 90 mg tablets (Daklinza, Bristol Myers Squibb), other strengths remain available	9/13/18
Testosterone 1% gel (Perrigo Pharmaceuticals), remains available from other manufacturers	9/13/18
Ketoconazole 2% Shampoo (Nizoral, Janssen), remains available from generic manufacturers	9/18/18
Apraclonidine 0.5% ophthalmic solution (Iopdine, Novartis), remains available from other manufacturers	9/21/18
Altretamine capsules (Hexalen, Eisai), alternative sources are not available; patients will require alternative palliative ovarian cancer therapy	9/26/18

New Drug Approvals:	***Description (See Attached Drug Summaries)***	***Date Approved***
Moxetumomab pasudotox-tdfk / Lumoxiti / AstraZeneca	CD22-directed cytotoxin for treatment of adults with relapsed or refractory hairy cell leukemia who have received at least 2 prior systemic therapies	9/13/18
Fremanezumab-vfrm / Ajovy / Teva	Calcitonin gene-related peptide antagonist for migraine prevention	9/14/18
Duvelisib / Copiktra/ Verastem	Kinase inhibitor for relapsed or refractory chronic lymphocytic leukemia, small lymphocytic lymphoma, and follicular lymphoma	9/24/18
Dacomitinib / Vizimpro / Pfizer	Kinase inhibitor for first-line treatment of metastatic non-small cell lung cancer with EGFR exon 19 deletion or exon 21 L858R substitution mutation	9/27/18
Galcanezumab-gnlm / Emgality / Eli Lilly	Calcitonin gene-related peptide antagonist for migraine prevention	9/27/18
Amikacin liposome inhalation suspension / Arikayce / Insmed	Inhaled antibiotic for the treatment of refractory Mycobacterium avium complex lung disease	9/28/18
Cemiplimab-rwlc / Libtayo / Regeneron Pharmaceuticals	Treatment of advanced cutaneous squamous cell carcinoma	9/28/18

New Indications:	***Description***	***Date Approved***
Tocilizumab solution for subcutaneous injection / Actemra SC / Genentech	Treatment of active systemic juvenile idiopathic arthritis alone or in combination with methotrexate in patients 2 years of age and older	9/12/18
Midazolam injection / Seizalam / Meridian Medical Technologies	Treatment of status epilepticus in adults	9/14/18
Perampanel / Fycompa / Eisai	Indication expanded to include use of tablets and oral suspension for the treatment of partial onset seizures in patients 4 years of age and older	9/27/18

New Dosage Forms or Formulation:	***Description***	***Date Approved***
Riluzole / Tiglutik / ITF Pharma, Inc	Oral suspension, 50 mg/10 mL in 300 mL multiple-dose bottle for the treatment of amyotrophic lateral sclerosis	9/5/18
Buprenorphine and naloxone sublingual film / Cassipa / Teva	New strength (16 mg/4 mg) for maintenance treatment of opioid dependence	9/7/18
Latanoprost ophthalmic emulsion 0.005% / Xelpros / Sun Pharma	Benzalkonium chloride-free latanoprost formulation for the reduction of intraocular pressure in open-angle glaucoma and ocular hypertension; contains potassium sorbate preservative	9/12/18
Epinephrine 0.15 mg pre-filled syringe / Symjepi / Adamis	Reduced dosage strength approved for treatment of allergic reactions in patients weighing between 33 and 65 pounds	9/28/18
Testosterone enanthate / Xyosted / Antares Pharma	Subcutaneous autoinjector for testosterone replacement therapy in adult males with conditions associated with deficiency or absence of endogenous testosterone	9/28/18
Omallizumab / Xolair / Genentech	Liquid pre-filled syringe in 75 mg and 150 mg strengths; to be administered by a health-care professional	9/28/18

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New Drug Approvals

Moxetumomab pasudotox-tdfk / Lumoxiti / AstraZeneca Pharmaceuticals	
Generic Name / Brand Name / Company	Moxetumomab pasudotox-tdfk / Lumoxiti / AstraZeneca Pharmaceuticals
Date of approval	9/13/18
Drug Class (Mechanism of Action if novel agent)	CD22-directed cytotoxin MOA: It comprises the CD22 binding portion of an antibody fused to a truncated bacterial toxin; the toxin inhibits protein synthesis and ultimately triggers apoptotic cell death
Indication	Relapsed or refractory hairy cell leukemia in adult patients who have received at least two prior systemic therapies, including treatment with a purine nucleoside analog
Comparative agent – Therapeutic interchange?	None
Dosage forms/strengths. Common Dose/sig	Injection: 1 mg in a single-dose vial Dose: 0.04 mg/kg infused intravenously over 30 minutes on days 1, 3 and 5 of each 28-day cycle, up to 6 cycles
DEA Schedule	Not applicable
Date of market availability	Available
Similar Medication Names	Mogamulizumab
Clinical Use Evaluation	
Common Adverse Effects	>20%: Infusion related reactions, edema, nausea, fatigue, headache, fever, constipation, anemia and diarrhea
Severe Adverse Effects	Capillary leak syndrome, anemia, hemolytic uremic syndrome, decreased renal function and electrolyte abnormalities
Severe Drug-Drug Interactions	Unknown
Severe Drug-Food Interactions	Unknown
Important Labs Values to assess prior to order entry or at point of clinical follow up.	Monitor blood chemistry, serum electrolytes, and complete blood counts prior to each infusion and on day 8 of each cycle. Monitor renal function prior to each infusion.
Used in Pediatric Areas	Safety and efficacy not established
Renal or Hepatic Dosing	Avoid use in severe renal impairment (CrCl 29 mL/min or less)
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Not recommended in severe renal impairment. Avoid use in patients with a history of severe thrombotic microangiopathy or hemolytic uremic syndrome. Monitor for capillary leak syndrome, hemolytic uremic syndrome, renal toxicity, electrolyte abnormalities,
Special administration technique or considerations	Hydrate with IV solutions over 2-4 hours before and after each dose and advise patients to hydrate with oral fluids on days 1-8 of each cycle. Consider low-dose aspirin on days 1-8 of each cycle. Premedicate with antihistamine (hydroxyzine or diphenhydramine), acetaminophen, and a histamine-2 antagonist (ranitidine, famotidine, or cimetidine) prior to each infusion. If severe infusion related reaction occurs, interrupt infusion and administer oral or IV corticosteroid before resuming and before each subsequent dose. Post-infusion consider administration of oral antihistamines and antipyretics for up to 24 hours, and an oral corticosteroid to decrease nausea and vomiting.
Prepared by	Kayla Mielke
Source	Lumoxiti (moxetumomab pasudotox-tdfk) [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; September 2018.

Fremanezumab-vfrm / Ajovy / Teva	
Generic Name / Brand Name / Company	Fremanezumab-vfrm / Ajovy / Teva
Date of approval	9/14/18
Drug Class (Mechanism of Action if novel agent)	Fully humanized IgG2Δa/kappa monoclonal antibody specific to calcitonin gene-related peptide ligand; calcitonin gene-related peptide antagonist
Indication	Preventive treatment for migraine in adults
Comparative agent – Therapeutic interchange?	Erenumab (Aimovig), galcanezumab (Emgality)
Dosage forms/strengths. Common Dose/sig	Injection: 225 mg/1.5 mL in single-dose prefilled syringe Dose: 225 mg subcutaneously monthly or 675 mg (three 225 mg injections) every 3 months
DEA Schedule	Not applicable
Date of market availability	Available
Similar Medication Names	Adefovir, Aimovig, galcanezumab, Jalyn
Clinical Use Evaluation	
Common Adverse Effects	>5%: Injection site reaction
Severe Adverse Effects	Hypersensitivity
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.	None
Used in Pediatric Areas	Safety and efficacy not established
Renal or Hepatic Dosing	Renal/hepatic impairment not expected to affect pharmacokinetics
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindicated in patients with serious hypersensitivity to the medication or the excipients
Special administration technique or considerations	Allow medication to sit at room temperature for at least 30 minutes before use. Patients can be instructed to self-administer.
Prepared by	Jordan Nelson
Source	Ajovy (fremanezumab-vfrm) [prescribing information]. North Wales, PA: Teva Pharmaceuticals USA, Inc.; September 2018.

Duvelisib / Copiktra / Verastem	
Generic Name / Brand Name / Company	Duvelisib / Copiktra / Verastem
Date of approval	9/24/18
Drug Class (Mechanism of Action if novel agent)	Dual inhibitor of phosphatidylinositol 3-kinases PI3K-δ and PI3K-γ MOA: causes induced growth inhibition and reduced viability in cell lines derived from malignant B-cells and in primary CLL tumor cell. It inhibits several key cell-signaling pathways, including B-cell receptor signaling and CXCR12-mediated chemotaxis of malignant B-cells and CXCL12-induced T cell migration and M-CSF and IL-4 driven M2 polarization of macrophages
Indication	Relapsed or refractory chronic lymphocytic leukemia or small lymphocytic lymphoma after at least two prior therapies, and relapse or refractory follicular lymphoma after at least two prior systemic therapies
Comparative agent – Therapeutic interchange?	Idelisib (Zydelig)
Dosage forms/strengths. Common Dose/sig	Capsule: 15 and 25 mg Dose: 25 mg twice daily
DEA Schedule	Not applicable
Date of market availability	Available
Similar Medication Names	Copanlisib
Clinical Use Evaluation	
Common Adverse Effects	>20%: diarrhea/colitis, neutropenia, rash, fatigue, pyrexia, cough, nausea, upper respiratory infection, pneumonia, musculoskeletal pain, anemia
Severe Adverse Effects	Infections (pneumonia, sepsis and lower respiratory infection), diarrhea, pneumonitis, cutaneous reactions, hepatotoxicity and neutropenia
Severe Drug-Drug Interactions	Strong CYP3A inducers: avoid co-administration Moderate or strong CYP3A inhibitors: monitor for duvelisib toxicity Sensitive CYP3A substrates: monitor for toxicities
Severe Drug-Food Interactions	None known
Important Labs Values to assess prior to order entry or at point of clinical follow up.	CBC, liver enzymes, electrolytes and creatinine
Used in Pediatric Areas	Safety and efficacy not established
Renal or Hepatic Dosing	No adjustment required for renal or hepatic impairment
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	No contraindications Warnings about Infections (pneumonia, sepsis and lower respiratory infection), serious cutaneous reactions, pneumonitis, diarrhea, hepatotoxicity and neutropenia
Special administration technique or considerations	- Do not crush or break capsule. - Provide *Pneumocystis jirovecii* (PJP) prophylaxis until the absolute CD4+ T cell count is greater than 200 cells/µL and withhold in patients with suspected PJP of any grade; discontinue if PJP is confirmed. - Consider prophylactic antivirals during duvelisib treatment to prevent cytomegalovirus (CMV) infection including CMV reactivation - Dose reduction table in package insert for hematologic adverse reactions and non-hematologic adverse reactions
Prepared by	Kayla Mielke
Source	Copiktra (duvelisib) [prescribing information]. Needham, MA: Verastem, Inc.; September 2018.

Dacomitinib / Vizimpro / Pfizer	
Generic Name / Brand Name / Company	Dacomitinib / Vizimpro / Pfizer
Date of approval	9/27/18
Drug Class (Mechanism of Action if novel agent)	Kinase inhibitor; Irreversible inhibitor of kinase activity of EGFR/Her1, HER2, and HER4 as well as certain EGFR active mutations
Indication	Treatment of metastatic non-small cell lung cancer with EGFR exon 19 deletion or exon 21 L858R substitution mutation
Comparative agent – Therapeutic interchange?	Gefitinib (Iressa)
Dosage forms/strengths. Common Dose/sig	Tablets: 15, 30, and 45 mg Dose: 45 mg once daily
DEA Schedule	Not applicable
Date of market availability	Mid-October 2018
Similar Medication Names	Dacogen
Clinical Use Evaluation	
Common Adverse Effects	>20%: diarrhea, rash, paronychia, stomatitis, decreased appetite, dry skin, decreased weight, alopecia, cough, pruritus
Severe Adverse Effects	Interstitial lung disease, pneumonitis, diarrhea, exfoliative skin reactions
Severe Drug-Drug Interactions	Proton pump inhibitors: avoid use with dacomitinib; administer dacomitinib at least 6 hours before or 10 hours after H2 blockers CYP2D6 substrates: avoid use if minimal increases in CYP2D6 substrate levels may lead to serious toxicity
Severe Drug-Food Interactions	None known
Important Labs Values to assess prior to order entry or at point of clinical follow up.	EGFR mutation
Used in Pediatric Areas	Safety and effectiveness not established
Renal or Hepatic Dosing	No adjustments for mild to moderate renal or hepatic impairment. Dose adjustments for severe renal or hepatic impairment not established
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	No labeled contraindications Warnings: interstitial lung disease, diarrhea, dermatologic adverse reactions
Special administration technique or considerations	Medication should be taken at approximately the same time each day. May be taken with or without food. Dose modifications or discontinuation are advised for severe toxicities.
Prepared by	Jordan Nelson
Source	Vizimpro (dacomitinib) [prescribing information]. New York, NY: Pfizer; September 2018.

Galcanezumab-gnlm / Emgality / Eli Lilly	
Generic Name / Brand Name / Company	Galcanezumab-gnlm / Emgality / Eli Lilly
Date of approval	9/27/18
Drug Class (Mechanism of Action if novel agent)	IgG4 monoclonal antibody that specifically targets and binds to calcitonin gene-related peptide; calcitonin gene-related peptide antagonist
Indication	Preventative treatment of migraines in adults
Comparative agent – Therapeutic interchange?	Erenumab (Aimovig), Fremanezumab (Ajovy)
Dosage forms/strengths. Common Dose/sig	Injection: 120 mg/ml single dose pen/syringe Dose: 240 mg subcutaneously once as a loading dose, followed by 120 mg subcutaneously every month
DEA Schedule	Not applicable
Date of market availability	Available
Similar Medication Names	Fremanezumab, galantamine
Clinical Use Evaluation	
Common Adverse Effects	>2%: injection site reactions
Severe Adverse Effects	Hypersensitivity reaction
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.	None
Used in Pediatric Areas	Safety and efficacy not established
Renal or Hepatic Dosing	Pharmacokinetics not expected to be affected by renal or hepatic impairment
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindicated in patients with hypersensitivity to the medication or any product excipients
Special administration technique or considerations	Allow medication to sit at room temperature for 30 minutes prior to administration. Administered subcutaneously; patients can self-administer
Prepared by	Jordan Nelson
Source	Emgality (galcanezumab-gnlm) [prescribing information]. Indianapolis, IN: Eli Lilly and Company; September 2018.

Amikacin liposome inhalation suspension / Arikayce / Insmed	
Generic Name / Brand Name / Company	Amikacin liposome inhalation suspension / Arikayce / Insmed
Date of approval	9/28/18
Drug Class (Mechanism of Action if novel agent)	Aminoglycoside antibiotic formulated in a liposomal suspension to allow delivery to the lung with reduced systemic exposure
Indication	Treatment of lung disease caused by Mycobacterium avium complex bacteria as part of a combination antibacterial regimen in adult patients with limited or no alternative treatment options
Comparative agent – Therapeutic interchange?	None
Dosage forms/strengths. Common Dose/sig	Liposome suspension for oral inhalation: 590 mg/8.4 ml sterile unit dose vials Dose: once daily oral inhalation of the contents of one 590 mg vial with the Lamira Nebulizer System
DEA Schedule	Not applicable
Date of market availability	October 2018
Similar Medications (Look-Alike Sound-Alike)	Amikacin, Aricept
CLINICAL USE EVALUATION	
Common Adverse Effects	>10%: dysphonia, cough, bronchospasm, hemoptysis, ototoxicity, upper airway irritation, musculoskeletal pain, fatigue/asthenia, exacerbation of underlying pulmonary disease, diarrhea, nausea
Severe Adverse Effects	hypersensitivity pneumonitis, hemoptysis, bronchospasm, exacerbation of underlying pulmonary disease, ototoxicity, nephrotoxicity, neuromuscular blockade, embryro-fetal toxicity
Severe Drug-Drug Interactions	Any drugs with neurotoxic, nephrotoxic, or ototoxic side effects should be avoided. Avoid use with ethacrynic acid, furosemide, urea, and mannitol.
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 test (in patients with confirmed/suspected impairment)
Used in Pediatric Areas	Safety and efficacy not established
Renal or Hepatic Dosing	No hepatic adjustments necessary. No renal adjustments indicated, however renal function should be monitored in patients with known or suspected impairment.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindicated if known aminoglycoside hypersensitivity Warnings: hypersensitivity pneumonitis, hemoptysis, bronchospasm, exacerbation of underling pulmonary disease, ototoxicity, nephrotoxicity, neuromuscular blockade or neuromuscular disorders such as myasthenia gravis
Special administration technique or considerations	Administer through the Lamira Nebulizer System; no other medications should be administered through the system other than liposomal amikacin. Pre-treatment with an inhaled bronchodilator recommended in patients with a history of hyperreactive airway disease.
Prepared by	Jordan Nelson
Source	Arikayce (amikacin liposome inhalation suspension) [prescribing information]. Bridgewater, NJ: Insmed; September 2018.

Cemiplimab-rwlc / Libtayo / Regeneron	
Generic Name / Brand Name / Company	Cemiplimab-rwlc / Libtayo / Regeneron
Date of approval	9/28/18
Drug Class (Mechanism of Action if novel agent)	IgG4 monoclonal antibody that binds to PD-1 and blocks its interaction with PD-L1 and PD-L2, releasing PD-1 pathway mediated inhibition of the immune response, including the anti-tumor immune response
Indication	Treatment of patients with metastatic cutaneous squamous cell carcinoma (CSCC) or locally advanced, unresectable CSCC
Comparative agent – Therapeutic interchange?	None
Dosage forms/strengths. Common Dose/sig	Injection: 350 mg vial Dose: 350 mg intravenously over 30 minutes every 3 weeks
DEA Schedule	Not applicable
Date of market availability	Available
Similar Medications (Look-Alike Sound-Alike)	None identified
CLINICAL USE EVALUATION	
Common Adverse Effects	>20%: fatigue, rash and diarrhea
Severe Adverse Effects	Cellulitis, sepsis, pneumonia, pneumonitis, colitis, hepatitis, infusion-related reactions, and urinary tract infection
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?)	Liver function tests, thyroid function tests
Used in Pediatric Areas	Safety and efficacy not established
Renal or Hepatic Dosing	No routine adjustment for renal or hepatic impairment; not studied in moderate or severe hepatic impairment. Dose withheld or discontinued if severe immune-mediated organ damage occurs.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Warning for severe and fatal immune-mediated adverse reactions including pneumonitis, colitis, hepatitis, endocrinopathies, nephritis, dermatologic reactions, neurologic reactions, cardiovascular reactions, ocular reactions, gastrointestinal reactions, musculoskeletal reactions, hematologic reactions, and immunologic reactions.
Special administration technique or considerations	Infuse over 30 minutes through an IV line containing a 0.2 micron to 5 micron filter
Prepared by	Kayla Mielke
Source	Libtayo (cemiplimab-rwlc) [prescribing information]. Tarrytown, NY: Regeneron Pharmaceuticals, Inc. September 2018.