WASHINGTON STATE UNIVERSITY
College of Pharmacy and Pharmaceutical Sciences

Drug Information Center

Highlights of FDA Activities – 4/1/24 – 4/30/24

FDA Drug Safety Communications & Drug Information Updates:

Plastic Syringes Made in China – Safety Communication 4/10/24

The FDA updated the March safety communication regarding potential device failures and quality issues with plastic syringes made in China. Until further notice they advised immediately transitioning away from using plastic syringes manufactured by Jiangsu Caina Medical Co Ltd and Jiangsu Shenli Medical Co Ltd unless the use of these syringes is absolutely necessary until a transition can be completed. The FDA continues their evaluation of syringes made in China and advises to use syringes not manufactured in China when possible. At this time glass syringes, pre-filled syringes, and syringes used for oral or topical purposes are not included in these recommendations.

Counterfeit Botox 4/16/24

The FDA alerted health care professionals and consumers that counterfeit versions of Botox (botulinum toxin) have been found in multiple states and administered to consumers for cosmetic purposes, resulting in severe adverse events resulting in hospitalizations. Health care professionals are advised to check products for any signs of counterfeiting before use and to only purchase product from authorized sources. On 5/1 the FDA updated the safety communication to include images and descriptions of approved Botox products.

Pregnancy Problems Associated with Thiopurines 4/29/24

The FDA alerted health care professionals of the rare risk of intrahepatic cholestasis of pregnancy (ICP) associated with the use of thiopurines (azathioprine, 6-mercaptopurine, and 6-thioguanine). Thiopurines have a known risk of hepatotoxicity and are labeled warning of the risk of fetal harm; however, guidelines do indicate use may be appropriate to continue during pregnancy in management of some conditions. Pregnant patients should stop using thiopurines if they develop ICP. Thiopurine labeling is being updated to include postmarketing cases of ICP have been reported in patients treated with thiopurine agents during pregnancy, ICP symptoms and elevated bile acid levels improved following azathioprine discontinuation, and pregnancy patients should discontinue use of thiopurines if they develop ICP.

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

Atovaquone Oral Suspension USP 750 mg/5 mL, AvKARE LLC: Recall – Potential Contamination 4/1/24

AvKARE, LLC. recalled lot AW0221A of atovaquone oral suspension, USP 750 mg/5 mL (NDC 50268-086-12, expiration date 08/2025) to the consumer level due to potential *Bacillus cereus* contamination detected during stability testing by a third-party laboratory.

Honeywell Fendall 2000 Non-Sterile Eyewash Cartridges 4/5/24

Honeywell Safety Products recalled Fendall 2000 Non-Sterile Eyewash Cartridge (#32-0020500-0000) used with the Fendall 2000 Eyewash Station because the supplier has been found to be noncompliant with good manufacturing practice requirements.

Aruba Aloe Hand Sanitizer Gel Alcohol 80% and Alcoholada Gel, Aruba Aloe Balm NV: Recall - Methanol 4/5/24

Aruba Aloe Balm NV recalled 40 lots of Aruba Aloe Hand Sanitizer Gel Alcohol 80% and Aruba Aloe Alcoholada Gel because the products have been found to contain methanol. A full list of recalled lots can be found on the FDA site. Products were distributed between 5/1/21 and 10/27/23 and sold online only via the Aruba Aloe Balm NV website.

Convenience Kits, Medline Industries, LP: Recall – Contain Recalled Ingredients 4/8/24
Medline Industries, LP recalled Medline and Centurion branded convenience kits containing Nurse Assist 0.9% Sodium Chloride Irrigation USP and Sterile Water for Irrigation USP. The Nurse Assist products were recalled due to lack of sterility. A complete list of products can be found on the Medline Industries website.

Ivenix Infusion Pump LVP Software, Fresenius Kabi USA, LLC: Recall – Software Anomalies 4/17/24
Fresenius Kabi USA, LLC recalled the Ivenix Infusion System (IIS) LVP Software, an infusion pump software, due to multiple software anomalies that have the potential to result in serious patient harm. The recall will take the place of a software update.

Sapropterin Dihydrochloride Powder for Oral Solution, Dr. Reddy's: Recall – Sub-Potency 4/23/24
Dr. Reddy's Laboratories Ltd. recalled 6 lots of sapropterin dihydrochloride powder for oral solution 100 mg due to powder discoloration in some packets leading to decreased potency. The recalled product (NDCs 43598-097-30 and 43598-477-30), packaged in individual packets, 30 per carton, had the following lot numbers: T2200352, T2202812, T2204053, T2300975, T2300976, T2304356.

Stay-Safe Catheter Extension Sets and Luer Lock Adapter, Fresenius: Recall – Toxic Compound 4/25/24
Fresenius Medical Care recalled the Stay-Safe Catheter Extension Set and Stay-Safe/Luer Lock Adapter due to risk for patient exposure to higher than allowable levels of non-dioxin-like (NDL) polychlorinated biphenyl acid (PCBA) in dialysate solution as a result of leaching.

Nimbus and Nimbus II Infusion Pump Systems, InfuTronix LLC: Recall – Device Failures 4/25/24
InfuTronix LLC recalled Nimbus infusion pump systems due to multiple potential failures including battery failure, upstream occlusion, system errors, drug product leakage, high or low flow rate, or damaged housing. The devices will not be available or supported after 6/20/24.

VITEK 2 AST Kit, BioMerieux Inc: Recall – Incorrect Ceftriaxone Concentrations 4/30/24
BioMerieux Inc recalled VITEK 2 AST kits used to test susceptibility of bacteria to antibiotics. Two of the ceftriaxone wells contain more ceftriaxone than they should, possibly resulting in inaccurate susceptibility determination. A complete list of recalled kits can be found on the FDA site. The kits may still be used, but if the ceftriaxone results show that the minimal inhibitory concentration is in the range of 0.5, 1, 2, testing should be conducted using another testing method.

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***
ELV Control Herbal Supplement*	Weight loss	Yellow oleander
Eva Nutrition tejocote root*	Weight loss	Yellow oleander
ForeverMen capsules*	Sexual enhancement	Sildenafil and tadalafil
Niwali tejocote root*	Weight loss	Yellow oleander
NWL Nutra tejocote root*	Weight loss	Yellow oleander
Ossos-Sans tablets	Arthritis/pain	Diclofenac and methocarbamol
Science of Alpha tejocote root*	Weight loss	Yellow oleander
Schwinnng Capsules*	Sexual enhancement	Nortadalafil

*recalled

New Product Shortages	***Date Initially Posted***
Hydroxocobalamin injection	4/12/24

Brand Name or Sole Source Product Discontinuations/Withdrawals	***Date Posted***
Evolocumab injection (Repatha, Amgen), select formulations (NDC 55513-770-01 and 72511-770-01); other formulations remain available	4/12/24
Dofetilide Capsule (Tikosyn, Pfizer Inc): generics remain available	4/23/24
Fluticasone Propionate Powder, Metered (Flovent, GlaxoSmithKline): limited generic aerosol inhalers remain available, as do dry powder inhalers	4/30/24

New Drug Approvals:	***Description (See Attached Drug Summaries)***	***Date Approved***
Ceftobiprole medocaril sodium / Zevtera / Basilea Pharmaceutica International	Cephalosporin for the treatment of *Staphylococcus aureus* bacteremia, acute bacterial skin and skin structure infections, and community-acquired pneumonia	4/3/24
Pegulicianine / Lumisight / Lumicell, Inc.	Fluorescent imaging agent for use in adults with breast cancer to assist with the intraoperative detection of cancerous tissue within the resection cavity following removal of the primary specimen during lumpectomy surgery	4/17/24
Nogapendekin alfa inbakicept-pmln / Anktiva / Altor BioScience LLC)	Interleukin-15 receptor agonist for use with Bacillus-Calmette-Guerin (BCG) for adult patients with BCG-unresponsive non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ with or without papillary tumors.	4/22/24
Tovorafenib / Ojemda / Day One Biopharmaceuticals, Inc.	For patients 6 months and older with relapsed or refractory pediatric low-grade glioma harboring a BRAF fusion or rearrangement, or BRAF V600 mutation	4/23/24
Pivmecillinam / Pivya / Utility Therapeutics Ltd.	Penicillin antibacterial for treatment of female adults with uncomplicated urinary tract infections caused by susceptible isolates of Escherichia coli, Proteus mirabilis, and Staphylococcus saprophyticus	4/24/24
Fidanacogene elaparvovec-dzkt / Beqvez / Pfizer	Gene therapy for the treatment of adults with moderate to severe hemophilia B	4/25/24
Mavorixafor / Xolremdi / X4 Pharmaceuticals	Warts/hypogammaglobulinemia/infections/myelokathexis (WHIM) syndrome in patients 12 years and older.	4/30/24

New Indications:	***Description***	***Date Approved***
Idecabtagene vicleucel / Abecma / Celgene Corp.	Treatment of adults with relapsed or refractory multiple myeloma after two or more prior lines of therapy including an immunomodulator, a proteasome inhibitor, and an anti-CD38 monoclonal antibody	4/4/24
Iloperidone / Fanapt / Vanda Pharmaceuticals, Inc.	Acute treatment of manic or mixed episodes associated with bipolar I disorder in adults	4/2/24
Fam-trastuzumab deruxtecan-nxki / Enhertu / Daiichi Sankyo, Inc.	Treatment of adults with unresectable or metastatic HER2-positive (IHC 3+) solid tumors who have received prior systemic treatment and have no satisfactory alternative treatment options	4/5/24
Dolutegravir sodium; lamivudine / Dovato / ViiV Healthcare	Indication expanded to include use in HIV treatment in adolescents 12 years to less than 18 years and weighing at least 25 kg with no antiretroviral treatment history or to replace current antiretroviral regimen in those who are virologically suppressed on a stable antiretroviral regimen	4/5/24
Benralizumab / Fasenra / AstraZeneca Pharmaceuticals	Indication expanded to include use as add-on maintenance treatment of patients aged 6 to 11 years with severe asthma, and with an eosinophilic phenotype	4/5/24

New Indications: (continued)	***Description***	***Date Approved***
Alectinib / Alecensa / Genentech	For adjuvant treatment following tumor resection in patients with anaplastic lymphoma kinase (ALK)-positive non-small cell lung cancer	4/18/24
Lutetium Lu 177 dotatate / Lutathera / Advanced Accelerator Applications USA, Inc.	Indication expanded to include use in pediatric patients 12 years and older with somatostatin receptor positive gastroenteropancreatic neuroendocrine tumors	4/23/24
Lipid injectable emulsion / Clinolipid / Baxter Healthcare Corporation	Indication expanded to include use in pediatric patients, including term and preterm neonates, as a source of calories and essential fatty acids for parenteral nutrition	4/24/24
Apremilast / Otezla / Amgen	Indication expanded to include use in pediatric patients 6 to 17 years of age and weighing at least 20 kg with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy	4/25/24
Upadacitinib / Rinvoq / AbbVie	Indication expanded to include treatment of patients 2 years and older with active polyarticular juvenile idiopathic arthritis or active psoriatic arthritis who have had an inadequate response or intolerance to one or more TNF blockers	4/26/24
Methoxy plyethylene glycol-epoetin beta / Mircera / Vifor International	Indication expanded to include treatment of anemia associated with chronic kidney disease in pediatric patients 3 months to 17 years of age on dialysis and not on dialysis who are converting from another erythropoiesis-stimulating agent after their hemoglobin level stabilized; the approval also provides for a subcutaneous route of administration for pediatric patients rather than just the IV route	4/30/24

New Dosage Forms or Formulation:	***Description***	***Date Approved***
Hydroxyurea / Xromi / Nova Laboratories Limited	Oral solution: 100 mg/mL, strawberry-flavored; for use in pediatric patients 6 months to less than 2 years of age with sickle cell anemia	4/3/24
Selpercatinib / Retevmo / Eli Lilly	Tablets: 40 mg, 80 mg, 120 mg, 160 mg; new tablet dosage form with the same indications as the 40 mg and 80 mg capsules	4/10/24
Valbenazine / Ingrezza Sprinkle / Neurocrine	Capsule: 40 mg, 60 mg, 80 mg; may be opened and sprinkled over soft food or swallowed whole with water	4/30/24
Sacubitril; valsartan / Entresto Sprinkle / Novartis	Film coated oral pellets within capsules: 6 mg/6 mg and 15 mg/16 mg as an alternative to compounded oral suspension from tablets; for the treatment of symptomatic heart failure with systemic left ventricular systolic dysfunction in pediatric patients 1 year and older	4/12/24
Brimonidine / Lumify Preservative Free / Bausch and Lomb Inc	Ophthalmic solution: 0.025%; preservative-free over-the-counter product for relief of redness of the eyes	4/19/24
Naloxone HCl / Rezenopy / Summit Biosciences Inc	Nasal spray: 10 mg/0.11 mL; for emergency treatment of known or suspected opioid overdose	4/19/24
Apelisib / Vijoice / Novartis	Oral granules: 50 mg; for patients prescribed a 50 mg dose, as an alternative to whole tablets and oral suspension prepared from oral tablets	4/24/24

New Dosage Forms or Formulation:	***Description***	***Date Approved***
Diazepam / Libervant / Aquestive Therapeutics	Buccal film: 5 mg, 7.5 mg, 10 mg, 12.5 mg, 15 mg; for the acute treatment of intermittent, stereotypic episodes of frequent seizure activity that are distinct from a patient's usual seizure pattern in patients 2 to 5 years of age with epilepsy	4/26/24
Upadacitinib / Rinvoq LQ / AbbVie	Oral solution: 1 mg/mL dosed twice daily; treatment of patients 2 years and older with active polyarticular juvenile idiopathic arthritis or active psoriatic arthritis who have had an inadequate response or intolerance to one or more TNF blockers	4/26/24

Compiled by:

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Ceftobiprole / Zevtera / Basilea Pharmaceutica International	
Generic Name / Brand Name / Company	Ceftobiprole / Zevtera / Basilea Pharmaceutica International
Date of approval	4/3/24
Drug Class (Mechanism of Action if novel agent)	Fifth-generation broad spectrum bactericidal cephalosporin; inhibits bacterial cell wall synthesis. Activity against gram-positive and gram-negative bacteria, including methicillin-resistant and susceptible *S. aureus.*
Indication	*S. aureus* bacteremia (SAB) and acute bacterial skin and skin structure infections (ABSSSI) in adults, community-acquired pneumonia (CABP) in adults and pediatric patients 3 months of age and older
Comparative agent – Therapeutic interchange?	Depends on indication – ceftaroline, noncephalosporin antibiotics (daptomycin, vancomycin)
Dosage forms/strengths.	Injection: 667 mg as a lyophilized powder for reconstitution
Common Dose/sig	SAB: 667 mg IV every 6 hours on days 1-8 and every 8 hours from day 9 ABSSSI and CABP in adults: 667 mg IV every 8 hours CABP in pediatric patients: 20 mg/kg IV every 8 hours in patients 3 months to less than 12 years old; 13.3 mg/kg IV every 8 hours in patients 12-18 years old
DEA Schedule	N/A
Date of market availability	Mid-2024; has not identified commercialization partner in U.S.
Similar Medication Names (look-alike/sound alike)	Ceftaroline, Ceftibuten, Ceftolozane/Tazobactam, Zevalin
Clinical Use Evaluation	
Common Adverse Effects	SAB, ≥4%: anemia, nausea, hypokalemia, vomiting, increased hepatic enzyme and bilirubin, diarrhea, increased blood creatinine, hypertension, leukopenia, pyrexia ABSSSI, ≥2%: nausea, diarrhea, headache, injection site reaction, increased hepatic enzyme, rash, vomiting, dysgeusia CABP (adults), ≥2%: nausea, increased hepatic enzyme, vomiting, diarrhea, headache, rash, insomnia, abdominal pain, phlebitis, hypertension, dizziness CABP (pediatrics), ≥2%: vomiting, headache, increased hepatic enzyme, diarrhea, infusion site reaction, phlebitis, pyrexia
Severe Adverse Effects	Anaphylaxis, hypersensitivity, seizures, diarrhea
Severe Drug-Drug Interactions	Ceftobiprole administration is not recommended with OATP1B1 and OATP1B3 substrates. Ceftobiprole may cause false-positive results in urine protein, ketone, occult blood dipstick tests or the Coombs test.
Severe Drug-Food Interactions	None
Important Labs Values to assess prior to order entry or at point of clinical follow up.	Culture and susceptibility, WBC count; renal function for dose adjustments
Used in Pediatric Areas	Indicated in CABP in pediatric patients as young as 3 months of age; safety and efficacy have not been established in other indications
Renal or Hepatic Dosing	Effect of hepatic impairment on ceftobiprole is unknown. Reduce dosage in adults with CrCl less than 50 mL/min and in pediatric patients aged 2 years and older with eGFR less than 50 mL/min/1.73 m^2 and at least 15 mL/min/1.73 m^2; increase dosage in adults with CrCl greater than 150 mL/min
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindicated in patients with hypersensitivity to ceftobiprole or any component of the formulation or past medical history of hypersensitivity to cephalosporins.

	Warnings: Increase in mortality in subgroup of patients during clinical trials with ventilator-associated bacterial pneumonia treated with ceftobiprole; ceftobiprole is not approved for this use. Discontinue if hypersensitivity reaction occurs. Seizures have been reported; evaluate and consider discontinuation. Evaluate for *Clostridiodes difficile*-associated diarrhea if diarrhea occurs.
Special administration technique or considerations	Administered via intravenous infusion over 2 hours. Must be reconstituted in vial and further diluted with an appropriate diluent and proper aseptic technique before administration; compatible with 5% dextrose injection and 0.9% sodium chloride injection.
Prepared by	Emily Hitt, PharmD
Source	*Zevtera* (ceftobiprole) [package insert]. Allschwil, Switzerland: Basilea Pharmaceutica International Ltd; April 2024.

Pegulicianine / Lumisight / Lumicell, Inc.	
Generic Name / Brand Name / Company	Pegulicianine / Lumisight / Lumicell, Inc.
Date of approval	4/17/24
Drug Class (Mechanism of Action if novel agent)	Fluorescent imaging agent; for use with fluorescence imaging device
Indication	Fluorescent imaging in adults with breast cancer as an adjunct for the intraoperative detection of cancerous tissue within the resection cavity following removal of the primary specimen during lumpectomy surgery; must be used with the Lumicell Direct Visualization System or other fluorescence imaging device approved for this use
Comparative agent – Therapeutic interchange?	None
Dosage forms/strengths.	Injection: 39 mg as a lyophilized powder for reconstitution
Common Dose/sig	1 mg/kg IV administered 2 to 6 hours prior to imaging
DEA Schedule	N/A
Date of market availability	Available
Similar Medication Names (look alike/sound alike)	Lumizyme, Lumigan, Pegunigalsidase
Clinical Use Evaluation	
Common Adverse Effects	≥1%: hypersensitivity, chromaturia
Severe Adverse Effects	Hypersensitivity
Severe Drug-Drug Interactions	Avoid administration of dyes before imaging the lumpectomy cavity
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 have not been established in pediatric patients
Renal or Hepatic Dosing	No dosage adjustments are not required for renal or hepatic impairment
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindication: hypersensitivity reaction to pegulicianine Boxed warning: hypersensitivity, assess for history of hypersensitivity to pegulicianine, other contrast media or products containing polyethylene glycol; monitor for hypersensitivity reactions. Warnings: risk of misdiagnosis
Special administration technique or considerations	Administer by IV injection over 3 minutes. Consult labeling for product preparation instructions. Use only 0.45% sodium chloride injection USP for reconstitution. Flush the IV line before and after administration.
Prepared by	Terri Levien
Source	Lumisight (pegulicianine)[prescribing information]. Newton, MA: Lumicell, Inc.; April 2024.

Nogapendekin alfa inbakicept-pmln / Anktiva / Altor BioScience, LLC)	
Generic Name / Brand Name / Company	Nogapendekin alfa inbakicept-pmln / Anktiva / Altor BioScience, LLC)
Date of approval	4/22/24
Drug Class (Mechanism of Action if novel agent)	Interleukin-15 receptor agonist
Indication	For use with BCG for the treatment of adult patients with BCG-unresponsive nonmuscle invasive bladder cancer with carcinoma in situ (CIS) with or without papillary tumors
Comparative agent – Therapeutic interchange?	Gemcitabine plus docetaxel, nadofaragene firadenovec
Dosage forms/strengths.	400 mcg/0.4 mL solution for intravesical instillation after dilution
Common Dose/sig	Induction: 400 mcg intravesically with BCG once weekly x 6 weeks Maintenance: 400 mcg intravesically with BCG once weekly x 3 weeks at months 4, 7, 10, 13, and 19; additional doses may be administered if ongoing complete response at month 25 and later.
DEA Schedule	N/A
Date of market availability	Available
Similar Medication Names (look alike/sound alike)	Nadofaragene firadenovec
Clinical Use Evaluation	
Common Adverse Effects	>15%: increased creatinine, dysuria, hematuria, urinary frequency, micturition urgency, urinary tract infection, increased potassium, musculoskeletal pain, chills, pyrexia
Severe Adverse Effects	Hematuria, urinary tract infection, musculoskeletal pain, increased potassium
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 required
Used in Pediatric Areas	Safety and efficacy have not been established in pediatric patients
Renal or Hepatic Dosing	No dosage adjustments required
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications: none Warnings: delaying cystectomy risks development of metastatic cancer; if patients with CIS do not have a complete response after a second induction course consider cystectomy.
Special administration technique or considerations	Instilled intravesically after dilution into saline containing BCG suspension. Total time from vial puncture to completion of instillation should not exceed 2 hours. The instilled solution should be retained for 2 hours and then voided.
Prepared by	Terri Levien
Source	Anktiva (nogapendekin alfa inbakicept-pmln) [prescribing information]. Culver City, CA: Altor BioScience, LLC; April 2024.

Tovorafenib / Ojemda / Day One Biopharmaceuticals, Inc.	
Generic Name / Brand Name / Company	Tovorafenib / Ojemda / Day One Biopharmaceuticals, Inc.
Date of approval	4/23/24
Drug Class (Mechanism of Action if novel agent)	Type II RAF kinase inhibitor of mutant BRAF V600E, wild-type BRAF, and wild-type CRAF kinases
Indication	Treatment of patients 6 months and older with relapsed or refractory pediatric low-grade glioma harboring a BRAF fusion or rearrangement, or BRAF V600 mutation
Comparative agent – Therapeutic interchange?	None
Dosage forms/strengths.	Tablets: 100 mg; Oral suspension: 25 mg/mL
Common Dose/sig	Administered orally once weekly with dosage based on body surface area (see prescribing information); maximum recommended dose is 600 mg orally once weekly. Modify dose for severe adverse reactions.
DEA Schedule	N/A
Date of market availability	Available
Similar Medication Names (look alike/sound alike)	Tofacitinib, tofersen, topotecan, Ogestrel, Ozempic
Clinical Use Evaluation	
Common Adverse Effects	>30%: rash, hair color changes, fatigue, viral infection, vomiting, headache, hemorrhage, pyrexia, dry skin, constipation, nausea, dermatitis acneiform, upper respiratory tract infection
Severe Adverse Effects	Rash, fatigue, pyrexia, viral infection, vomiting, hemorrhage, dermatitis acneiform, pruritus, upper respiratory tract infection, paronychia, diarrhea, headache, plus the following laboratory abnormalities: decreased phosphate, hemoglobin, albumin, lymphocytes, leukocytes, potassium, sodium, and increased creatinine phosphokinase, ALT, AST
Severe Drug-Drug Interactions	Avoid use with strong or moderate CYP2C8 inhibitors, strong or moderate CYP2C8 inducers, CYP3A substrates where minimal concentration changes can cause reduced efficacy, and hormonal contraceptives
Severe Drug-Food Interactions	None known
Important Labs Values to assess prior to order entry or at point of clinical follow up.	Liver functions tests (ALT, AST, bilirubin) prior to and during treatment
Used in Pediatric Areas	Indicated in patients 6 months and older; a dosage for patients with BSA less than 0.3 m^2 has not been established
Renal or Hepatic Dosing	No dose adjustment in mild hepatic impairment or mild to moderate renal impairment; has not been studied in moderate or severe hepatic impairment or severe renal impairment.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Warnings: Major hemorrhagic events, skin toxicity including photosensitivity, hepatotoxicity, effects on growth, fetal harm, increased growth of NF1 associated tumors Confirm presence of BRAF fusion or rearrangement or BRAF V600 mutation prior to initiation of treatment.
Special administration technique or considerations	Administered with or without food. Use suspension for patients with BSA 0.3 to 0.89 m^2 and tablets or suspension for patients with BSA 0.9 m^2 or greater. Multiple suspension bottles may be reconstituted to supply one dosage, discard any suspension not administered within 15 minutes of preparation. If vomiting occurs immediately after taking a dose, repeat that dose.
Prepared by	Terri Levien
Source	Ojemda (tovorafenib) [prescribing information]. Brisbane, CA: Day One Biopharmaceuticals, Inc.; April 2024.

Pivmecillinam / Pivya / Utility Therapeutics Ltd.	
Generic Name / Brand Name / Company	Pivmecillinam / Pivya / Utility Therapeutics Ltd.
Date of approval	4/24/24
Drug Class (Mechanism of Action if novel agent)	Penicillin class antibacterial
Indication	Treatment of female patients 18 years of age and older with uncomplicated urinary tract infection caused by susceptible isolates of E. coli, P. mirabilis, and S. saprophyticus
Comparative agent – Therapeutic interchange?	Nitrofurantoin, trimethoprim-sulfamethoxazole, fosfomycin
Dosage forms/strengths.	Tablet: 185 mg
Common Dose/sig	185 mg orally 3 times a day for 3 to 7 days
DEA Schedule	N/A
Date of market availability	Unknown
Similar Medication Names (look alike/sound alike)	Pitavastatin
Clinical Use Evaluation	
Common Adverse Effects	≥2%: nausea, diarrhea
Severe Adverse Effects	Hypersensitivity reactions, severe cutaneous adverse reactions, C. difficile associated diarrhea.
Severe Drug-Drug Interactions	Avoid concomitant use with valproic acid, valproate, or other pivalate-generating drugs due to increased risk of carnitine depletion. May reduce methotrexate clearance; consider alternative antibiotic.
Severe Drug-Food Interactions	None known
Important Labs Values to assess prior to order entry or at point of clinical follow up.	Urine culture
Used in Pediatric Areas	Safety and efficacy have not been established in pediatric patients.
Renal or Hepatic Dosing	Routine dosage adjustments are not recommended.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications: serious hypersensitivity reaction to pivmecillinam, penicillins, or cephalosporins, primary or secondary carnitine deficiency resulting from an inherited disorder, acute porphyria. Warnings: hypersensitivity, severe cutaneous adverse reactions, carnitine depletion, C. difficile-associated diarrhea, interference with newborn screening test
Special administration technique or considerations	Administer with or without food.
Prepared by	Terri Levien
Source	Pivya (pivmecillinam) [prescribing information]. Florham Park, NJ: Utility Therapeutics Ltd; April 2024.

Fidanacogene elaparvovec-dzkt / Beqvez / Pfizer	
Generic Name / Brand Name / Company	Fidanacogene elaparvovec-dzkt / Beqvez / Pfizer
Date of approval	4/25/24
Drug Class (Mechanism of Action if novel agent)	Gene therapy encoding a high-activity factor IX variant; cell transduction and increase in circulating factor IX activity
Indication	Treatment of moderate to severe hemophilia B (congenital factor IX deficiency) in adults who currently use factor IX prophylaxis therapy or have current or historical life-threatening hemorrhage or have repeated, serious, spontaneous bleeding episodes, AND do not have neutralizing antibodies to adeno-associated virus serotype Rh74var (AAVRh74var) capsid
Comparative agent – Therapeutic interchange?	Etranacogene dezaparvovec (Hemgenix, CSL Behring)
Dosage forms/strengths.	Suspension for intravenous infusion after dilution, 1 x 10^{13} vg/mL
Common Dose/sig	5 x 10^{11} vector genomes per kg (vg/kg) body weight
DEA Schedule	N/A
Date of market availability	2nd quarter 2024
Similar Medication Names (look alike/sound alike)	Fidaxomicin, elapegademase
Clinical Use Evaluation	
Common Adverse Effects	≥5%: increase in transaminases
Severe Adverse Effects	Hepatotoxicity
Severe Drug-Drug Interactions	Hepatotoxic medications or substances
Severe Drug-Food Interactions	None
Important Labs Values to assess prior to order entry or at point of clinical follow up.	Pre-existing antibodies to AAVrh74 var, factor IX inhibitor presence, liver health before initiation; monitor transaminases and factor IX activity once or twice weekly for at least 4 months after administration, then weekly for weeks 17 to 18, at weeks 24, 32, 42, and 52, then quarterly in year 2 to the end of year 3, twice yearly in year4 to the end of year 6, and then annually
Used in Pediatric Areas	Safety and efficacy have not been established in pediatric patients
Renal or Hepatic Dosing	Has not been studied in patients with hepatic or renal impairment
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Warnings: hepatoxicity, infusion reactions, hepatocellular malignancy; consider corticosteroid treatment for transaminase elevation or a decline in factor IX activity. Do not administer to patients with pre-existing neutralizing antibodies to AAVRh74 var, positive test or history of factor IX inhibitor, HIV-1 or HIV-2 infection with either CD4+ cell count less than 200 mm3 or viral load of 20 copies/mL or greater, hypersensitivity to factor IX replacement product, current liver-related coagulopathy, hypoalbuminemia, jaundice, cirrhosis, portal hypertension, splenomegaly, hepatic encephalopathy, hepatic fibrosis, or active viral hepatitis.
Special administration technique or considerations	Administered as a one-time single-dose peripheral IV infusion after dilution in 0.9% sodium chloride with 0.25% human serum albumin with a final volume of 200 mL over approximately 60 minutes. Personal protective equipment (including gloves, safety goggles, laboratory coat and sleeves) should be worn while preparing or administering the agent. Monitor for infusion reactions throughout the infusion and for at least 3 hours after; the infusion may be reduced or stopped and restarted as needed to manage reactions.
Prepared by	Terri Levien
Source	Beqvez (fidanacogene elaparvovec-dzkt) [prescribing information]. New York, NY: Pfizer Labs; April 2024.

Mavorixafor / Xolremdi / X4 Pharmaceuticals	
Generic Name / Brand Name / Company	Mavorixafor / Xolremdi / X4 Pharmaceuticals
Date of approval	4/30/24
Drug Class (Mechanism of Action if novel agent)	CXC chemokine receptor 4 antagonist; inhibits response to CXCL12 in CXCR4 variants associated with WHIM syndrome, resulting in increased mobilization of neutrophils and lymphocytes from the bone marrow into the peripheral circulation
Indication	Use in patients 12 years and older with WHIM syndrome (warts, hypogammaglobulinemia, infections, and myelokathexis) to increase the number of circulating mature neutrophils and lymphocytes
Comparative agent – Therapeutic interchange?	None
Dosage forms/strengths.	Capsules: 100 mg
Common Dose/sig	Weight more than 50 kg: 400 mg orally once daily Weight 50 kg or less: 300 mg orally once daily
DEA Schedule	N/A
Date of market availability	Available through specialty pharmacy partner
Similar Medication Names (look alike/sound alike)	Xolair, mavacamten
Clinical Use Evaluation	
Common Adverse Effects	≥10%: thrombocytopenia, pityriasis, rash, rhinitis, epistaxis, vomiting, dizziness
Severe Adverse Effects	Thrombocytopenia
Severe Drug-Drug Interactions	Drugs highly dependent on CYP2D6 for clearance: contraindication Strong CYP3A4 inhibitors – reduce mavorixafor dose, P-gp inhibitors and moderate CYP3A4 inhibitors – monitor and reduce dose if needed, strong CYP3A4 inducers – avoid concomitant use, CYP3A4 or P-gp substrates – monitor for adverse reactions
Severe Drug-Food Interactions	Avoid grapefruit juice (CYP3A4 inhibitor). Administration of marvorixafor with food reduces absorption.
Important Labs Values to assess prior to order entry or at point of clinical follow up.	Pregnancy testing in females of reproductive potential; monitor absolute neutrophil count and absolute lymphocyte count
Used in Pediatric Areas	Indicated in patients 12 years and older; safety and efficacy not established in patients younger than 12 years of age
Renal or Hepatic Dosing	No dosage adjustment in mild to moderate renal impairment or mild hepatic impairment. Not recommended in patients with severe renal impairment, end-stage renal disease, or moderate to severe hepatic impairment.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindicated for use with drugs highly dependent on CYP2D6 for clearance. Warnings: fetal harm, QTc prolongation
Special administration technique or considerations	Administer on an empty stomach after an overnight fast and at least 30 minutes before food. Capsules should be swallowed whole.
Prepared by	Terri Levien
Source	Xolremdi (mavorixafor) [prescribing information]. Boston, MA: X4 Pharmaceuticals, Inc.; April 2024.