WASHINGTON STATE UNIVERSITY
College of Pharmacy and Pharmaceutical Sciences

Drug Information Center

Highlights of FDA Activities – 3/1/24 – 3/31/24

FDA Drug Safety Communications & Drug Information Updates:

First Over-the-Counter Continuous Glucose Monitor Approved 3/5/24

The Dexcom Stelo Glucose Biosensor System has been cleared to be marketed as the first over-the-counter continuous glucose monitor. This monitor is intended for adult patients 18 years or older who do not use insulin. The intended patient population which can utilize this monitor are patients who are managing their diabetes with oral medication and individuals who want to monitor blood sugar in response to diet and exercise. Of note, this glucose monitor does not alert the user if their blood glucose is low.

Paxlovid (nirmatrelvir and ritonavir) with Emergency Use Authorization Label No Longer Authorized 3/13/24

Paxlovid with EUA packaging is no longer authorized for emergency use, regardless of the labeled or extended expiration date. For both NDA-approved and EUA-authorized uses, only NDA-labeled or FDA approved Paxlovid may be dispensed. The EUA continues to authorize use in pediatric patients and prescribing by pharmacists. Through December 31, 2024, eligible patients (ie, Medicare beneficiaries, Medicaid beneficiaries, and uninsured individuals) will continue to qualify for free Paxlovid

Plastic Syringes Made in China – FDA Update and Recommendations 3/20/24

The FDA continues to investigate plastic syringes made in China with concerns that they may not provide consistent and adequate quality or performance. The FDA recommends US suppliers, consumers, and health care organizations immediately transition away from using plastic syringes manufactured by Jiangsu Caina Medical Co. Ltd and unauthorized plastic syringes manufactured by Jiangu Shenli Medical Production Co. Ltd (which includes all models other than the 5 mL Luer lock syringe). For other plastic syringes made in China the FDA continues to recommend use only until able to transition to alternatives, and to monitor for leaks, breakage, and other issues. The FDA also issued warning letters to Medline Industries and Sol-Millennium Medical Inc, two firms marketing and distributing plastic syringes made in China within the US.

Pemgarda (pemivibart) Monoclonal Antibody for COVID-19 Pre-Exposure Prophylaxis - EUA 3/22/24

The FDA issued an EUA for pemivibart, a monoclonal antibody for pre-exposure prophylaxis of COVID-19 in certain adults and adolescents (12 years and older and weighing at least 40 kg) who are not currently infected with SARS-CoV-2 and have not had a recent exposure to an individual infected with the virus, and who have moderate-to-severe immune compromise due to a medical condition, medication, or treatment and are unlikely to mount an adequate immune response to COVID-19 vaccination. The recommend dose is 4500 mg as an intravenous infusion; if ongoing protection is needed the dose can be repeated every 3 months.

Major Medication/Drug-Related Product Recalls Announced Through MedWatch

Medfusion Model 3500 Syringe Pump, Smiths Medical ASD Inc.: Recall - Software Issues 3/5/24

Smiths Medical ASD Inc. recalled the Medfusion model 3500 syringe pump due to issues with early versions of the software (before v.6). Issues included restarting infusion with incorrect parameters, issues with bolus or loading dose delivery, doses falling under the recommended rate, motor rate errors and more, which could result in incorrect amounts of medication being administered. The distribution of these pumps occurred from 8/9/22 to 8/15/23. Customers should ensure the most recent software has been installed.

ExactaMix Pro 1200 and Pro 2400, Baxter Healthcare: Recall – Software Error 3/6/24
Baxter Healthcare recalled the ExactaMix Pro 1200 and Pro 2400 with software versions 2.0.8 and 2.1.8 due to a software error. The software could potentially allow more ingredients than intended in the final solution as a result of the "Use Some Overfill" feature. Baxter sent a letter to all customers using this pump and software with guidance and they are working on a software update which is expected to be available in March of 2024.

Convenience Kits from Windstone Medical Packing Inc.: Recall – Sterility Concerns 3/11/24
In response to the recalls of 0.9% sodium chloride irrigation USP and sterile water for irrigation USP containing products from Nurse Assist, Windstone Medical Packing Inc. recalled their Local Lower Extremity Pack (AMS10833), In House Ocular Pack (AMS12947A and AMS12947), and Closure Kit (AMS13043). These items were distributed between 6/8/22 to 11/27/23.

Par Pharmaceutical Issues Voluntary Nationwide Recall of One Lot of Treprostinil Injection Due to Potential for Silicone Particulates in the Product Solution 3/12/24
Par Pharmaceuticals recalled a lot of treprostinil injection (20mg/20mL) due to the potential presence of silicon particulate in the product solution. Products were distributed in 20 mL multidose vials in individual packaged cartons with the NDC: 42023-0206-01. Lot 57014 with expiration date 4/2024. This was distributed between 6/16/22 to 10/17/22

Treprostinil Injection, Par Pharmaceutical: Recall – Potential for Silicone Particulate 3/13/24
Par Pharmaceutical recalled one lot of treprostinil injection 20 mg/20 mL (lot 57014) due to the potential presence of silicone particulates in the product solution. The affected lot was distributed from 6/16/22 through 10/17/22.

Feeding Tube Replacement Kits, Avanos Medical Inc.: Recall – Sterility Concerns 3/14/24
In response to the recalls of 0.9% sodium chloride irrigation USP and sterile water for irrigation USP containing products from Nurse Assist, Avanos Medical Inc. has recalled their MIC Gastric-Jejunal Feeding Tube Endoscopic/Radiologic Placement kit and MIC Gastric-Jejunal Feeding Tube with ENFit Connectors - Endoscopic/Radiologic Placement kit as they contain Nurse Assist supplied syringes pre-filled with sterile water. These products were distributed between 1/31/22 to 12/7/23.

Nimbus Ambulatory Infusion Pump System, InfuTronix LLC: Recall – Product Issues 3/21/24
InfuTronix LLC recalled the Nimbus Ambulatory Infusion Pump System including Nimbus II PainPro, Nimbus II Flex, Nimbus II Plus, Nimbus II EpiD, and Nimbus II EMS due to customer complaints identifying a number of different issues affecting battery power, alarms, inaccurate drug delivery, and leakage.

Medline Kits and Trays, Medline Industries: Recall – Sterility Concerns 3/25/24
In response to the recalls of 0.9% sodium chloride irrigation USP and sterile water for irrigation USP containing products from Nurse Assist, Medline Industries has recalled kits, trays, and packs containing Nurse Assist saline solution. The FDA is maintaining a complete list of products recalled subsequent to the Nurse Assist recall.

Methocarbamol Injection USP, 1000 mg/10 mL, Eugia US: Recall – White Particulate 3/28/24
Eugia US recalled one lot of methocarbamol injection USP 1000 mg/10 mL (lot 3MC23011) in 10 mL vials due to a customer complaint for the presence of white particles floating inside of the vial.

Vancomycin HCl Oral Solution USP 250 mg/5 mL, Amneal Pharmaceuticals: Recall – Super Potency 3/28/24
Amneal Pharmaceuticals LLC recalled 4 lots of vancomycin hydrochloride oral solution USP, 250 mg/5 mL (lots 22613003A, 22613004A, 22613005A, and 22613005B) packaged in 80 mL, 150 mL, or 300 mL pack sizes to the consumer level, as some bottles may have been overfilled resulting in an over potent dosing regimen.

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***
Pyramid Wholesale products*	Sexual enhancement	Sildenafil and/or tadalafil
Topical pain relief products from TKTX Company, SeeNext Venture Ltd, Tatoo Numbing Cream Co., Sky Bank Media LLC doing business as Painless Tattoo Co., Dermal Source Inc., and Indelicare doing business as INKEEZE	Pain relief	Concentrations of lidocaine higher than permitted for over-the-counter topical pain relief products

*recalled

New Product Shortages First Reported in March

None

Brand Name or Sole Source Product Discontinuations/Withdrawals	***Date Posted***
Praziquantel tablets 600 mg (Biltricide, Bayer healthcare); generic tablets remain available	3/5/24
Somatropin injection (Nutropin AQ, Genentech): all Nutropin AQ formulations have been discontinued, numerous alternative branded somatropin formulations remain available	3/22/24
Linezolid tablets 600 mg (Zyvox, Pfizer): generic tablets remain available	3/28/24
Fluconazole tablets 200 mg (Diflucan, Pfizer): generic tablets remain available	3/28/24

New Drug Approvals:	***Description (See Attached Drug Summaries)***	***Date Approved***
Tislelizumab-jsgr / Tevimbra / BeiGene USA	A programmed death receptor-1 (PD-1) blocking antibody for the treatment of unresectable or metastatic esophageal squamous cell carcinoma after prior systemic chemotherapy that did not include a PD-(L)1 inhibitor	3/13/24
Resmetirom / Rezdiffra / Madrigal Pharmaceuticals	A thyroid hormone receptor-beta agonist for use in conjunction with diet and exercise for the treatment of adults with noncirrhotic nonalcoholic steatohepatitis (NASH) with moderate to advanced liver fibrosis	3/14/24
Atidarsagene autotemcel / Lenmeldy / Orchard Therapeutics	Gene therapy for the treatment of children with pre-symptomatic late infantile, pre-symptomatic early juvenile, or early symptomatic early juvenile metachromatic leukodystrophy. Therapy is individualized, requiring a single dose of the patient's genetically modified hematopoietic stem cells following high-dose chemotherapy	3/18/24
Aprocitentan / Tryvio / Idorsia Pharmaceuticals US	Endothelin receptor antagonist for the treatment of hypertension in combination with other antihypertensive drugs, to lower blood pressure in adults who are not adequately controlled on other drugs	3/19/24
Givinostat / Duvyzat / ITF Therapeutics	Histone deacetylase inhibitor for the treatment of Duchenne muscular dystrophy in patients 6 years and older	3/21/24
Sotatercept-csrk / Winrevair / Merck Sharp & Dohme LLC	Activin signaling inhibitor for the treatment of pulmonary arterial hypertension (WHO Group 1)	3/26/24

New Drug Approvals (continued):	***Description (See Attached Drug Summaries)***	***Date Approved***
Vadadustat / Vafseo / Akebia Therapeutics	Hypoxia-inducible factor prolyl hydroxylase inhibitor for the treatment of anemia due to chronic kidney disease in adults receiving hemodialysis for at least 3 months	3/27/24
Danicopan / Voydeya / Alexion Pharmaceuticals	Complement Factor D inhibitor as add-on therapy to ravulizumab or eculizumab for the treatment of extravascular hemolysis in adults with paroxysmal nocturnal hemoglobinuria	3/29/24

New Indications:	***Description***	***Date Approved***
Amivantamab-vmjw / Rybrevant / Janssen	In combination with carboplatin and pemetrexed for first line treatment of locally advanced or metastatic non-small cell lung cancer with EGFR exon 20 mutations	3/1/24
Baloxavir Marboxil / Xofluza / Genetech	Indication expanded to include treatment of pediatric patients 5 to less than 12 years of age with acute uncomplicated influenza who are at high risk of developing influenza-related complications	3/1/24
Inotuzumab ozogamicin / Besponsa / Pfizer	Indication expanded to include treatment of pediatric patients 1 year and older for the treatment of CD22-positive B-cell precursor acute lymphoblastic leukemia	3/6/24
Nivolumab / Opdivo / Bristol-Myers Squibb	In combination with cisplatin and gemcitabine for first-line treatment of unresectable or metastatic urothelial carcinoma	3/6/24
Zanubrutinib / Brukinsa / BeiGene USA	In combination with obinutuzumab for treatment of relapsed or refractory follicular lymphoma, after two or more lines of systemic therapy	3/7/24
Semaglutide / Wegovy / Novo Nordisk	To reduce the risk of cardiovascular death, heart attack, and stroke in adult patients with cardiovascular disease and obesity or overweight	3/8/24
Alirocumab / Praluent / Regeneron Pharmaceuticals	Indication expanded to include use as an adjunct to diet and other LDL-C lowering therapies in pediatric patients 8 years and older with heterozygous familial hypercholesterolemia	3/8/24
Marilixibat / Livmarli / Mirum Pharmaceuticals	Indication expanded to include the treatment of cholestatic pruritus in patients 5 years of age and older with progressive familial intrahepatic cholestasis	3/13/24
Lisocabtagene maraleucel / Breyanzi / Bristol-Myers Squibb	Treatment of relapsed/refractory chronic lymphocytic leukemia or small lymphocytic lymphoma in patients who have received at least two prior lines of therapy including a Bruton's tyrosine kinase inhibitor and a B-cell lymphoma-2 inhibitor	3/14/24
Fluticasone propionate / Xhance / OptiNose US	Treatment of chronic rhinosinusitis without nasal polyps in adults	3/15/24
Rilpivirine / Edurant / Janssen	Indication expanded to include the treatment of HIV-1 in treatment naïve pediatric patients who are 2 to less than 12 years of age and weigh at least 25 kg to less than 35 kg	3/15/24
Spesolimab-sbzo / Spevigo / Boehringer Ingelheim Pharmaceuticals Inc	Indication expanded to include the treatment of generalized pustular psoriasis in pediatric patients 12 years and older and weighing at least 40 kg	3/18/24
Ponatinib / Inclusig / Takeda Pharmaceuticals USA	In combination with chemotherapy for the treatment of newly diagnosed Philadelphia chromosome-positive acute lymphoblastic leukemia in adults	3/19/24

New Indications (continued):	***Description***	***Date Approved***
Bempedoic acid / Nexletol / Esperion Therapeutics	To reduce the risk of myocardial infarction and coronary revascularization in adults who are unable to take recommended statin therapy and have established cardiovascular disease or a high risk for a CVD event but without established CVD	3/22/24
Bempedoic acid and ezetimibe / Nexlizet / Esperion Therapeutics	To reduce the risk of myocardial infarction and coronary revascularization in adults who are unable to take recommended statin therapy and have established cardiovascular disease or a high risk for a CVD event but without established CVD	3/22/24
Ravulizuamb-cwvz / Ultomris / Alexion	Treatment of adult patients with neuromyelitis optica spectrum disorder who are anti-aquaporin-4 antibody positive	3/22/24
Tenoforvir alafenamide / Vemlidy / Gilead	Indication expanded for the treatment of chronic hepatitis B virus infection in pediatric patients 6 to less than 12 years of age and weighing at least 25 kg	3/27/24

New Dosage Forms or Formulation:	***Description***	***Date Approved***
Clobetasol Propionate Ophthalmic Suspension / Formosa	Ophthalmic suspension: 0.05%; for treatment of postoperative inflammation and pain following ocular surgery	3/4/24
Tocilizumab-aazg / Tyenne / Fresenius Kabi USA	Injection: 80 mg/4 mL, 200 mg/10 mL, 400 mg/20 mL for dilution and IV infusion and 162 mg/0.9 mL in prefilled syringe or autoinjector for subcutaneous administration; biosimilar to tocilizumab (Actemra)	3/5/24
Denosumab-bbdz / Jubbonti / Sandoz	Injection solution in a prefilled syringe: 60 mg/1 mL; interchangeable biosimilar to denosumab (Prolia, Amgen)	3/5/24
Denosumab-bbez / Wyost / Sandoz	Injection solution in a Single-dose vial: 120 mg/1.7 mL; interchangeable biosimilar to denosumab (Xgeva, Amgen)	
Rilpivirine / Edurant / Janssen Prods	Tablet for oral suspension: 2.5 mg; for use in combination with other antiretroviral agents for the treatment of HIV-1 infection in treatment-naïve pediatric patients who are 2 years and older and weight at least 14 kg to less than 25 kg	3/15/24
Macitentan and tadalafil / Opsynvi / Actelion Pharmaceuticals	Tablets: macitentan 10 mg and tadalafil 20 mg; for the chronic treatment of adults with pulmonary arterial hypertension	3/22/24
Risperidone / Risvan / PharmaLex	Injectable suspension: 75 mg and 100 mg; intramuscular injection every 4 weeks for the treatment of schizophrenia in adults	3/29/24

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Tislelizumab-jsgr / Tevimbra / BeiGene USA	
Generic Name / Brand Name / Company	Tislelizumab-jsgr / Tevimbra / BeiGene USA
Date of approval	3/13/24
Drug Class (Mechanism of Action if novel agent)	Programmed death receptor-1 (PD-1) blocking antibody
Indication	Treatment of adult patients with unresectable or metastatic esophageal squamous cell carcinoma after prior systemic chemotherapy that did not include a PD-(L)1 inhibitor
Comparative agent – Therapeutic interchange?	Nivolumab, pembrolizumab
Dosage forms/strengths	Injection: 100 mg/10 mL solution in single-dose vial
Common Dose/sig	200 mg as an intravenous infusion once every 3 weeks
DEA Schedule	N/A
Date of market availability	2nd half of 2024
Similar Medication Names	Tisotumab vedotin
Clinical Use Evaluation	
Common Adverse Effects	>20%: increased glucose (46%), decreased hemoglobin (45%), decreased lymphocytes (43%), decreased sodium (34%), decreased albumin (33%), increased alkaline phosphatase, anemia, fatigue, increased AST, musculoskeletal pain, decreased weight, increased ALT, cough
Severe Adverse Effects	Immune-mediate adverse reactions: pneumonitis, colitis, hepatitis, endocrinopathies, nephritis, exfoliative dermatologic conditions, myocarditis, infusion-related reactions
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.	Pregnancy test before initiation of therapy; liver enzymes, creatinine, and thyroid function at baseline and periodically during therapy
Used in Pediatric Areas	Safety and efficacy have not been established in pediatric patients
Renal or Hepatic Dosing	No dosage adjustments advised
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	No labeled contraindications Warnings: severe and fatal immune-mediated adverse reactions, infusion-related reactions, embryo-fetal toxicity
Special administration technique or considerations	Preparation of a dosage requires two vials, transferred into an IV bag containing 0.9% sodium chloride injection USP. Administer through a sterile, nonpyrogenic, low-protein binding 0.2 micron or 0.22 micron in-line or add-on filter; flush line at end of infusion. Administer first infusion over 60 minutes; if tolerated, subsequent infusions may be administered over 30 minutes. No dose reductions for adverse reactions; if severe immune-mediate reactions dosing should be withheld.
Prepared by	Terri Levien
Source	Tevimbra (tislelizumab-jsgr) [prescribing information]. San Mateo, CA: BeiGene USA, Inc.; March 2024.

Remetirom / Rezdiffra / Madrigal Pharmaceuticals	
Generic Name / Brand Name / Company	Remetirom / Rezdiffra / Madrigal Pharmaceuticals
Date of approval	3/14/24
Drug Class (Mechanism of Action if novel agent)	Thyroid hormone receptor-beta (THR-beta) agonist
Indication	In conjunction with diet and exercise in the treatment of noncirrhotic nonalcoholic steatohepatitis (NASH) with moderate to advanced liver fibrosis
Comparative agent – Therapeutic interchange?	None
Dosage forms/strengths	Tablets: 60 mg, 80 mg, 100 mg
Common Dose/sig	80 mg orally once daily for patients weighing less than 100 kg; 100 mg orally once daily for patients weighing 100 kg or greater
DEA Schedule	N/A
Date of market availability	April 2024
Similar Medication Names	Remdesivir, Rozerem, Remsed, Remifentanil, Remicade, Remeron, Rezzayo
Clinical Use Evaluation	
Common Adverse Effects	≥5%: diarrhea (23-33%), nausea (15-18%), pruritus (6-10%), vomiting (7-8%), constipation (5-8%), abdominal pain (5-7%)
Severe Adverse Effects	Hepatoxicity, cholelithiasis, acute cholecystitis
Severe Drug-Drug Interactions	Strong CYP2C8 inhibitors: avoid concomitant use Moderate CYP2C8 inhibitors: reduce resmetirom dose OATP1B1 or OATP1B3 inhibitors: avoid concomitant use Statins: increased exposure of atorvastatin, pravastatin, rosuvastatin, simvastatin necessitates statin dosage adjustment
Severe Drug-Food Interactions	None known
Important Labs Values to assess prior to order entry or at point of clinical follow up.	Liver function test and signs/symptoms of hepatotoxicity. Monitor for coadministration of CYP2C8 substrates.
Used in Pediatric Areas	Safety and effectiveness have not been established in pediatric patients
Renal or Hepatic Dosing	No dosage adjustment in mild to moderate renal impairment; has not been studied in severe renal impairment. No dosage adjustment in mild hepatic impairment; may be increased risk of adverse reactions in moderate or severe hepatic impairment.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	No contraindications are noted in the package insert. Warnings: hepatoxicity, gallbladder-related adverse reactions. Avoid use in patients with decompensated cirrhosis.
Special administration technique or considerations	Administer with or without food.
Prepared by	Andrew Staten
Source	Rezdiffra (resmetirom) [prescribing information]. West Conshohocken, PA: Madrigal Pharmaceuticals, Inc; March 2024

Aprocitentan / Tryvio / Idorsia Pharmaceuticals US	
Generic Name / Brand Name / Company	Aprocitentan / Tryvio / Idorsia Pharmaceuticals US
Date of approval	3/19/24
Drug Class (Mechanism of Action if novel agent)	Endothelin receptor antagonist
Indication	Treatment of hypertension in combination with other antihypertensive drugs, to lower blood pressure in adult patients who are not adequately controlled on other drugs
Comparative agent – Therapeutic interchange?	Other endothelin receptor antagonists (bosentan, ambrisentan, macitentan) are only indicated for pulmonary arterial hypertension
Dosage forms/strengths.	Tablets: 12.5 mg
Common Dose	12.5 mg orally once daily
DEA Schedule	N/A
Date of market availability	2nd half of 2024; will only be available through a REMS
Similar Medication Names	Aprepitant
Clinical Use Evaluation	
Common Adverse Effects	Edema/fluid retention (9%), anemia (4%)
Severe Adverse Effects	Hypersensitivity, edema
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.	Pregnancy test monthly during treatment and one month after discontinuation. Hemoglobin, serum aminotransferase and total bilirubin prior to initiation and periodically during treatment.
Used in Pediatric Areas	Safety and efficacy have not been established in pediatric patients
Renal or Hepatic Dosing	No dosage adjustment in mild to severe renal impairment or mild hepatic impairment. Use is not recommended in patients with kidney failure (eGFR <15 mL/min) or on dialysis, or in patients with moderate to severe hepatic impairment (Child-Pugh class B and C).
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications: Pregnancy and hypersensitivity Black box warning: Embryo-fetal toxicity Additional warnings: hepatotoxicity, fluid retention, decreased hemoglobin; initiation is not recommended in patients with severe anemia
Special administration technique or considerations	Swallow tablets whole; may be taken with or without food. If a dose is missed, skip that dose and take the next dose as scheduled. Do not take two doses on the same day.
Prepared by	Andrew Staten
Source	Tryvio (aprocitenten) [prescribing information]. Radnor, PA: Idorsia Pharmaceuticals US Inc.; March 2024.

Givinostat / Duvyzat / ITF Therapeutics	
Generic Name / Brand Name / Company	Givinostat / Duvyzat / ITF Therapeutics
Date of approval	3/21/24
Drug Class (Mechanism of Action if novel agent)	Histone deacetylase inhibitor
Indication	Treatment of Duchenne muscular dystrophy in patients 6 years and older
Comparative agent – Therapeutic interchange?	None
Dosage forms/strengths	Oral suspension: 8.86 mg/mL
Common Dose	Weight based dose administered orally twice daily; 10 kg to < 20 kg: 22.2 mg; 20 kg to 40 kg: 31 mg; 40 kg to <60 kg: 44.3 mg; ≥60 kg: 52.2 mg
DEA Schedule	N/A
Date of market availability	3rd quarter of 2024
Similar Medication Names	Givosiran, duvelisib, Dyazide
Clinical Use Evaluation	
Common Adverse Effects	Diarrhea (37%), abdominal pain (34%), thrombocytopenia (33%), nausea/vomiting (32%), hypertriglyceridemia (23%), pyrexia (13%)
Severe Adverse Effects	Myelosuppression, nausea, vomiting, diarrhea
Severe Drug-Drug Interactions	CYP3A4 sensitive substrates or OCT2 transporter sensitive substrates: closely monitor Other drugs that prolong QTc interval: avoid or monitor ECG
Severe Drug-Food Interactions	None known
Important Labs Values to assess prior to order entry or at point of clinical follow up.	Complete blood counts and triglycerides prior to initiation; complete blood counts every 2 weeks for the first 2 months then monthly for 3 months and every 3 months thereafter; triglycerides at 1 month, 3 months, 6 months and every 6 months thereafter
Used in Pediatric Areas	Indicated in children aged 6 years and older
Renal or Hepatic Dosing	No dosage adjustments recommended however exposure is expected to be increased in hepatic impairment
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications: none in labeling. Do not initiate if platelet count less than 150 x 10^9/L. Warnings: hematologic changes, increased triglycerides, diarrhea, QTc prolongation Dosage modifications for decreased platelet counts, diarrhea, increased triglycerides, or QTc prolongation.
Special administration technique or considerations	Shake for 30 seconds before use by inverting bottle 180°. Administer using the provided graduated oral syringe. Administer with food.
Prepared by	Terri Levien
Source	Dyvyzat (givinostat) [prescribing information]. Concord, MA: ITF Therapeutics, LLC.; March 2024.

Sotatercept-csrk / Winrevair / Merck Sharp & Dohme LLC	
Generic Name / Brand Name / Company	Sotatercept-csrk / Winrevair / Merck Sharp & Dohme LLC
Date of approval	3/26/24
Drug Class (Mechanism of Action if novel agent)	Activin signaling inhibitor, modulates vascular proliferation
Indication	Treatment of pulmonary arterial hypertension (WHO Group 1) in adults to increase exercise capacity, improve WHO functional class, and reduce the risk of clinical worsening events
Comparative agent – Therapeutic interchange?	None; alternative therapies in other pharmacologic classes
Dosage forms/strengths	Injection: 45 mg and 60 mg lyophilized in single-dose vial
Common Dose	Starting dose: 0.3 mg/kg by subcutaneous injection; recommended target dose is 0.7 mg/kg subcutaneously every 3 weeks
DEA Schedule	N/A
Date of market availability	End of April
Similar Medication Names	Sotorasib, Sotradecol, Sotalol, Winlevi
Clinical Use Evaluation	
Common Adverse Effects	Headache (25%), epistaxis (22%), rash (20%), telangiectasia (17%), diarrhea (15%), dizziness (15%), erythema (14%)
Severe Adverse Effects	Thrombocytopenia, bleeding
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.	Hemoglobin and platelet count before each dose for the first 5 doses, or longer if values are unstable, then periodically
Used in Pediatric Areas	Safety and efficacy have not been established in pediatric patients
Renal or Hepatic Dosing	No dosage adjustment routinely recommended
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications: none in labeling Warnings: erythrocytosis, thrombocytopenia, bleeding, embryo-fetal toxicity, impaired fertility
Special administration technique or considerations	Reconstitute with Sterile Water for Injection included in kit. Administer via subcutaneous injection at a site on the abdomen, upper thigh, or upper arm; abdomen or upper thigh only if injection by patient or caregiver.
Prepared by	Terri Levien
Source	Winrevair (sotatercept-csrk) [prescribing information]. Rahway, NJ: Merck Sharp & Dohme LLC.; March 2024.

Vadadustat / Vafseo / Akebia Therapeutics	
Generic Name / Brand Name / Company	Vadadustat / Vafseo / Akebia Therapeutics
Date of approval	3/27/24
Drug Class (Mechanism of Action if novel agent)	Hypoxia-inducible factor prolyl hydroxylase (HIF PH) inhibitor
Indication	Treatment of anemia due to chronic kidney disease in adults who have been receiving hemodialysis for at least 3 months
Comparative agent – Therapeutic interchange?	Daprodustat
Dosage forms/strengths	Tablets: 150 mg, 300 mg, 450 mg
Common Dose	Starting dose 300 mg orally once daily; maintenance dose may range from 150 mg to 600 mg orally once daily.
DEA Schedule	N/A
Date of market availability	January 2025
Similar Medication Names	Vascepa
Clinical Use Evaluation	
Common Adverse Effects	Hypertension (14%), diarrhea (13%)
Severe Adverse Effects	Hepatotoxicity, hypertensive crisis, seizures, gastric or esophageal erosions, gastrointestinal bleeding
Severe Drug-Drug Interactions	Iron supplements and iron-containing phosphate binders: administer vadadustat at least 1 hour before iron containing products Non-iron-containing phosphate binders: administer vadadustat at least 1 hour before or 2 hours after Statins: monitor for statin-related adverse reactions
Severe Drug-Food Interactions	None known
Important Labs Values to assess prior to order entry or at point of clinical follow up.	Monitor hemoglobin and iron status. Monitor ALT, AST, and bilirubin prior to initiation, monthly for 6 months, and as clinically indicated
Used in Pediatric Areas	Safety and efficacy have not been established in pediatric patients
Renal or Hepatic Dosing	Indicated in chronic kidney disease with dialysis. Use not recommended in patients with cirrhosis or active, acute liver disease.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications: hypersensitivity, uncontrolled hypertension Boxed warning: increased risk of death, myocardial infarction, stroke, venous thromboembolism, and thrombosis of vascular access Warnings: hepatotoxicity, hypertension, seizures, gastrointestinal erosion, malignancy growth; use is not recommended in patients with anemia due to chronic kidney disease not on dialysis.
Special administration technique or considerations	Swallow tablets whole. Can be taken with or without food.
Prepared by	Terri Levien
Source	Vafseo (vadadustat) [prescribing information]. Cambridge, MA: Akebia Therapeutics, Inc.; March 2024.

Danicopan / Voydeya / AstraZeneca	
Generic Name / Brand Name / Company	Danicopan / Voydeya / Alexion Pharmaceuticals
Date of approval	3/29/24
Drug Class (Mechanism of Action if novel agent)	Complement factor D inhibitor, prevents amplification of the complement system response
Indication	Add-on therapy to ravulizumab or eculizumab for the treatment of extravascular hemolysis in adults with paroxysmal nocturnal hemoglobinuria
Comparative agent – Therapeutic interchange?	None
Dosage forms/strengths	Tablets: 50 mg and 100 mg
Common Dose	Starting dose: 150 mg orally three times daily; may be increased to 200 mg three times daily.
DEA Schedule	N/A
Date of market availability	Unknown; will be available through a REMS program
Similar Medication Names	Voquezna
Clinical Use Evaluation	
Common Adverse Effects	Headache (11%), vomiting (7%), pyrexia (7%), alanine aminotransferase increased (5%), hypertension (5%), pain in extremity (5%)
Severe Adverse Effects	Infection, hepatic enzyme increases, hyperlipidemia
Severe Drug-Drug Interactions	BCRP substrates: monitor for adverse events and consider dose reductions for BCRP substrate drugs; rosuvastatin dose should not exceed 10 mg P-gp substrates: dose adjustments for P-gp substrates may be needed
Severe Drug-Food Interactions	
Important Labs Values to assess prior to order entry or at point of clinical follow up.	Liver enzymes before initiation and periodically during treatment. Serum lipids periodically during treatment. Hemoglobin to assess response.
Used in Pediatric Areas	Safety and efficacy have not been evaluated in pediatric patients
Renal or Hepatic Dosing	No dose adjustment in renal impairment or mild to moderate hepatic impairment; avoid use in patients with severe hepatic impairment.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications: initiation in patients with serious infection caused by encapsulated bacteria Boxed warning: serious infections caused by encapsulated bacteria Warnings: hepatic enzyme increases, hyperlipidemia, close monitoring for hemolysis following discontinuation of therapy
Special administration technique or considerations	Vaccinate patients against encapsulated bacteria including *Neisseria meningitidis* and *Streptococcus pneumonia* prior to initiation of treatment. Taken with or without food. Missed doses should be taken as soon as remembered, unless it is within 3 hours prior to the next dose, in which case the missed dose should be skipped, and dosing resumed at the regularly scheduled time.
Prepared by	Terri Levien
Source	Voydeya (danicopan) [prescribing information]. Boston, MA: Alexion Pharmaceuticals, Inc.; March 2024.