Highlights of FDA Activities – 8/1/23 – 8/31/23

FDA Drug Safety Communications & Drug Information Updates:

Tests Manufactured by Universal Meditech, Inc.: Recall & FDA Warning Not to Use 8/11/23 & 8/31/23

The FDA advised not using the following tests manufactured by Universal Meditech, as the company has ceased operation and there are concerns the tests may not be safe and effective: One Step Pregnancy Test, DiagnosUS One Step Ovulation Test, HealthyWiser UriTest 10 Parameter Reagent Test Strips for Urinalysis, HealthyWiser UriTest UTI Test Strips, HealthyWiser KetoFast Ketone Test Strips, HealthyWiser pH-Aware pH Test Strips, To Life hCG Pregnancy Urine Test, Am I Pregnant Pregnancy Midstream Test, DeTec hCG Pregnancy Urine Test, PrestiBio Pregnancy Strips, PrestiBio Rapid Detection Pregnancy Test Midstream, PrestiBio Ovulation Strips, PrestiBio Urinalysis Test Strip 10 Parameters, PrestiBio Ketone Test Strips, PrestiBio Breast Milk Alcohol Test Strips. The tests may have been labeled and distributed by AC&C Distribution LLC, HealthyWiser, Home Health US Inc., Prestige Biotech Inc., and others. The manufacturer recalled undistributed tests from their distributors, but failed to recall tests that were already distributed until July 2023. The products were manufactured between March 2021 and November 2022.

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

Digoxin 0.125 mg and 0.25 mg, Marlex Pharmaceuticals Inc.: Recall – Label Mix-Up 8/31/23

Marlex Pharmaceuticals, Inc. recalled to the consumer level one lot of digoxin 0.125 mg tablets (NDC 10135-0747-01, lot# E3810, expiration 2/2025) and one lot of digoxin 0.25 mg (NDC 10135-0748-01, lot# E3811, expiration 2/2025) due to a mix up in labeling between the two lots.

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***
Big Guys Male Energy Supplement	Energy booster	Sildenafil
Dr. Berne's MSM Drops 5% and 15% Solution Eye Drops*	Eye drops	Bacterial (Bacillus, spp.), fungal (Exophiala, sp.)
Genergy	Energy booster for men	Tadalafil
GoHealthy Probiotics for Infants, Kids, Men and Women*	Probiotic	Potential for contamination with microbial growth
LightEyez MSM Eye Drops – Eye Repair	Eye drops	Bacterial (Pseudomonas, spp.; Mycobacterium, spp.; Mycolicibacterium, spp.; Methylorubrum, spp.)
Mens Maximum Energy Supplement	Energy booster	Sildenafil
Ozona Probiotics for Digestive Health*	Probiotic	Potential for contamination with microbial growth
Round 2	Strength, energy, & endurance booster	Tadalafil
Tapee Tea	Pain relief	Dexamethasone and piroxicam
Vegetal Vigra	Sexual enhancement	Sildenafil
WeFun*	Energy & performance booster	Sildenafil
X Max Triple Shot Energy Honey	Energy booster	Tadalafil

*recalled

Brand Name or Sole Source Product Discontinuations/Withdrawals	***Date Posted***
Pramipexole dihydrochloride extended-release tablets (Mirapex ER, Boehringer Ingelheim Pharmaceuticals, Inc.): remains available from generic manufacturers	8/1/23
Linezolid (Zyvox, Pfizer): remains available from generic manufacturers	8/3/23
Iobenguane I131 (Azedra, Progenics Pharmaceuticals); discontinued for lack of commercial demand	8/23/23
Piroxicam (Feldene, Pfizer): remains available from generic manufacturers	8/24/23
Hyaluronidase injection, ovine (Vitrase, Bausch & Lomb)	8/28/23

New Drug Approvals:	***Description (See Attached Drug Summaries)***	***Date Approved***
Avacincaptad pegol / Izervay / IVERIC bio, Inc.	Complement inhibitor for the treatment of geographic atrophic secondary to age-related macular degeneration	8/4/23
Zuranolone / Zurzuvae / Biogen Inc.	GABA-A receptor positive modulator for the treatment of postpartum depression	8/4/23
Talquetamab-Tgvs / Talvey / Janssen Biotech	Bispecific GPRC5D-directed CD3 T-cell engager indicated for the treatment of refractory multiple myeloma after at least four prior lines of therapy	8/9/23
Elranatamab-bcmm / Elrexfio / Pfizer	in the treatment of relapsed or refractory multiple myeloma after receiving at least four prior lines of treatment	8/14/23
Palovarotene / Sohonos / Ipsen Biopharmaceuticals	Retinoid indicated for reduction of heterotopic ossification in females 8 years and older and males 10 and older with fibrodysplasia ossificans progressiva	8/16/23
Pozelimab-bbfg / Veopoz / Regeneron	Complement inhibitor used in patients 1 year and older to treat CD55-deficient protein-losing enteropathy	8/18/23

New Indications:	***Description***	***Date Approved***
Tipiracil HCl, Trifluridine / Lonsurf / Taiho Oncology	With bevacizumab in the treatment of metastatic colorectal cancer previously treated with fluoropyrimidine-, oxaliplatin- and irinotecan- based chemotherapy, an anti-VEGF biological therapy, and if RAS wild-type, an anti-EGFR therapy	8/2/23
Rosuvastatin / Ezallor Sprinkle / Sun Pharmaceutical Industries	Adjunct to other LDL-C lowering therapies, or alone if such treatments are unavailable, to reduce LDL-C in patients 7 years and older with homozygous familial hypercholesterolemia; adjunct to diet to reduce LDL-C in adults and pediatric patients age 8 years and older with heterozygous familial hypercholesterolemia; adjunct to diet to reduce LDL-C in adults with primary hyperlipidemia; adjunct to diet to reduce LDL-C and slow the progression of atherosclerosis in adults; to reduce the risk of stroke, myocardial infarction, and arterial revascularization procedures in adults without established coronary heart disease who are at increased risk of cardiovascular disease based on age, hsCRP>2 mg/L, and at least one additional cardiovascular risk factor	8/4/23
DaxibotulinumtoxinA-LANM / Daxxify / Revance Therapeutics	Treatment of cervical dystonia in adults	8/11/23
Valbenazine / Ingrezza / Neurocrine Biosciences, Inc.	Treatment of chorea associated with Huntington's disease	8/18/23

New Indications Continued:	***Description***	***Date Approved***
Abrysvo / Respiratory Syncytial Virus Vaccine / Pfizer Inc	Vaccination of pregnant individuals at 32 through 36 weeks gestational age of pregnancy to prevent lower respiratory tract disease and severe lower respiratory tract disease caused by the respiratory syncytial virus in infants from birth through 6 months of age	8/21/23
Canakinumab / Ilaris / Novartis	Gout flares in adults in whom non-steroid anti-inflammatory drugs and colchicine are contraindicated, not tolerated, or do not provide an adequate response, and in whom repeated courses of corticosteroids are not appropriate	8/25/23
Luspatercept-aamt / Reblozyl / Celgene Corp	Anemia in ESA-naïve patients with very low to intermediate risk myelodysplastic syndromes who may require regular red blood cell transfusions	8/28/23
Dabrafenib mesylate / Tafinlar / Novartis	Indication expanded to include patients 1 year of age and older with unresectable or metastatic solid tumors with a BRAF V600E mutations who have no effective alternate treatment options	8/31/23
Trametinib / Mekinist / Novartis	Indication expanded to include patients 1 year of age and older with unresectable or metastatic solid tumors with a BRAF V600E mutations who have no effective alternate treatment options	8/31/23

New Dosage Forms or Formulation:	***Description***	***Date Approved***
Niraparib and Abiraterone acetate / Akeega / Janssen Biotech	Tablets: 50 mg niraparib/500 mg abiraterone acetate, 100 mg niraparib/500 mg abiraterone acetate; use with prednisone for treatment of deleterious/suspected deleterious BRCA-mutated metastatic castration-resistant prostate cancer	8/11/23
Melphalan / Hepzato / Delcath Systems	Injection: 50 mg lyophilized powder in single-dose vials for reconstitution; liver-directed treatment administered by intra-arterial infusion into the hepatic artery indicated for patients with uveal melanoma with unresectable hepatic metastasis affecting less than 50% of the liver and no extrahepatic disease, or extrahepatic disease limited to the bone, lymph nodes, subcutaneous tissues, or lung that is amenable to resection or radiation	8/14/23
Aflibercept / Eylea HD / Regeneron Pharmaceuticals	Injection: 8 mg (0.07 mL of 114.3 mg/mL solution) in a single-dose vial; for intravitreal injection in the treatment of patients with neovascular (wet) age-related macular generation, diabetic macular edema, or diabetic retinopathy	8/18/23
Fosaprepitant / Focinvez / Spes Pharmaceuticals	Injection: 150 mg/50 mL in a single-dose vial; indicated in patients 6 months and older, in combination with other antiemetic agents, for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of highly emetogenic cancer chemotherapy including high-dose cisplatin, and delayed nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy	8/22/23
Natalizumab-sztn / Tyruko / Sandoz Inc	Injection: 300 mg/15 mL in single-dose vial for dilution prior to infusion; biosimilar for natalizumab (Tysabri) indicated for treatment of multiple sclerosis and Crohn's disease	8/24/23

Compiled by:

Terri Levien, Pharm.D.
Emily Hitt, Pharm.D., PGY1 Drug Information Resident
Mason Melbuer, Doctor of Pharmacy Candidate 2024

Drug Information Center
College of Pharmacy and Pharmaceutical Sciences
Washington State University
412 E. Spokane Falls Blvd.
Spokane, WA 99202-2131
(509) 358-7662
Pharmacy.druginfo@wsu.edu

Avacincaptad pegol / Izervay / IVERIC bio, Inc.	
Generic Name / Brand Name / Company	Avacincaptad pegol / Izervay / IVERIC bio, Inc.
Date of approval	8/4/23
Drug Class (Mechanism of Action if novel agent)	Complement C5 inhibitor
Indication	Geographic atrophy secondary to age-related macular degeneration (AMD)
Comparative agent – Therapeutic interchange?	Pegcetacoplan (Syvovre)
Dosage forms/strengths.	Intravitreal solution: 20 mg/mL in single-dose vial
Common Dose/sig	2 mg (0.1 mL) administered by intravitreal injection to each affected eye once monthly for up to 12 months
DEA Schedule	None
Date of market availability	Available
Similar Medication Names	Avacopan, Zerviate
Clinical Use Evaluation	
Common Adverse Effects	Conjunctival hemorrhage (13%), increased intraocular pressure (IOP, 9%), blurred vision (8%), neovascular age-related macular degeneration (7%), eye pain (4%), vitreous floaters (2%), blepharitis (2%)
Severe Adverse Effects	Potential for ocular/periocular infection, intraocular inflammation, endophthalmitis and retinal detachment, neovascular AMD, increased IOP
Severe Drug-Drug Interactions	None known
Severe Drug-Food Interactions	None
Important Labs Values to assess prior to order entry or at point of clinical follow up.	None; monitor IOP
Used in Pediatric Areas	Safety and efficacy not established in pediatric patients
Renal or Hepatic Dosing	No dosage adjustments required in renal or hepatic impairment
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindicated in patients with ocular or periocular infections. Warnings: • Endophthalmitis and retinal detachment with intravitreal injections • Neovascular AMD • Increase in IOP: monitor for elevated IOP using tonometry prior to intravitreal injection; ocular hypotensive medication can be given to lower IOP. Monitor IOP immediately after injection.
Special administration technique or considerations	Each vial should be used for the treatment of a single eye. Use filter needle to draw up dose, then use 30-gauge x ½ inch injection needle to administer. Any excess volume drawn into syringe should be disposed.
Prepared by	Terri Levien, PharmD
Source	Izervay (avacincaptad pegol) [prescribing information]. Parsippany, NJ: IVERIC bio, Inc.; August 2023.

Zuranolone / Zurzuvae / Biogen Inc.	
Generic Name / Brand Name / Company	Zuranolone / Zurzuvae / Biogen Inc.
Date of approval	8/4/23
Drug Class (Mechanism of Action if novel agent)	Antidepressant; positive allosteric $GABA_A$ modulator
Indication	Postpartum depression
Comparative agent – Therapeutic interchange?	Brexanolone (Zulresso): injectable agent
Dosage forms/strengths.	Capsules: 20, 25, and 30 mg
Common Dose/sig	50 mg orally once daily in the evening for 14 days, may be reduced to 40 mg once daily if CNS depressant effects
DEA Schedule	Pending/under review
Date of market availability	4th quarter of 2023
Similar Medication Names	Brexanolone, Zurampic, Zurcal, Zurig, Zulresso
Clinical Use Evaluation	
Common Adverse Effects	≥5%: Drowsiness, dizziness, diarrhea, fatigue, nasopharyngitis, urinary tract infection
Severe Adverse Effects	CNS depressant effects, suicidal ideation and behavior
Severe Drug-Drug Interactions	CNS depressants and/or alcohol: use with caution; may increase the risk of impairment in psychomotor performance or severe somnolence. Reduce zuranolone dose if use with another CNS depressant is unavoidable. CYP3A4 inhibitors: increases the exposure of zuranolone. Reduce the dose of zuranolone when used in combination with strong CYP3A4 inhibitors. CYP3A4 Inducers: decreases the exposure of zuranolone and therefore, may reduce its efficacy. Avoid use of zuranolone with CYP3A4 inducers.
Severe Drug-Food Interactions	The concentration of zuranolone is increased when taken in combination with a fatty meal. Should be taken with fat-containing food.
Important Labs at order entry or follow-up	None
Used in Pediatric Areas	Safety and effectiveness have not been established in pediatric patients
Renal or Hepatic Dosing	No dosage adjustment required in mild/moderate hepatic impairment or mild renal impairment. Reduce dose to 30 mg once daily in moderate or severe renal impairment or severe hepatic impairment. No information in patients with eGFR < 15 mL/min/1.73 m^2 or patients requiring dialysis.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	No contraindications in labeling. Warnings: Patients should not drive a motor vehicle or engage in activities requiring complete mental alertness until 12 hours after administration for the duration of treatment. Patients may be unable to assess their own driving competence or degree of driving impairment. CNS depressant effects: causes somnolence and confusion; increased fall risk. Effects may be increased with alcohol, benzodiazepines, opioids, tricyclic antidepressants, or drugs that increase zuranolone levels. Risk of suicidal thoughts and behavior may be increased, notably in patients 24 years and younger; highest risk in patients with major depressive disorder. Fetal harm: advise females of reproductive potential to use effective contraception during treatment and for one week after final dose
Special administration technique or considerations	Administer with fat-containing food to increase absorption. Administer in the evening. May be used alone or as an adjunct to oral antidepressant therapy.
Prepared by	Emily Hitt, PharmD
Source	Zurzuvae (zuranolone) [prescribing information]. Cambridge, MA: Biogen Inc.; August 2023.

Talquetamab-tgvs / Talvey / Janssen Biotech	
Generic Name / Brand Name / Company	Talquetamab-tgvs / Talvey / Janssen Biotech
Date of approval	8/9/23
Drug Class (Mechanism of Action if novel agent)	GPRC5D-directed CD3 T-cell engager
Indication	Relapsed or refractory multiple myeloma in adult patients who have received at least 4 prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody.
Comparative agent – Therapeutic interchange?	Same indication: ciltacabtagene autoleucel, elranatamab-bcmm, idecabtagene vicleucel, teclistamab-cqyv
Dosage forms/strengths.	Injectable: 3 mg/1.5 mL and 40 mg/mL in single-dose vials
Common Dose/sig	Initiate with step-up dosing schedule: 0.01 mg/kg on day 1, 0.06 mg/kg on day 4, 0.4 mg on day 7, then 0.4 mg/kg subcutaneously once weekly. Alternative regimen adds 0.8 mg/kg step-up dose on day 10, then 0.8 mg/kg every 2 weeks. Dose is based on actual weight.
DEA Schedule	None
Date of market availability	Available through a REMS program
Similar Medication Names	Taltz, Talicia, Talzenna, Talazoparib
Clinical Use Evaluation	
Common Adverse Effects	≥20%: pyrexia, dysgeusia, cytokine release syndrome (CRS), dysgeusia, nail disorder, musculoskeletal pain, skin disorder, rash, fatigue, weight loss, dry mouth, xerosis, dysphagia, upper respiratory tract infection, diarrhea, hypotension, headache; common lab abnormalities (≥30%): decreased lymphocytes, neutrophils, white blood cells, hemoglobin
Severe Adverse Effects	Pyrexia, fatigue, pain, CRS, dysphagia, diarrhea, stomatitis, rash, infection, hypotension, encephalopathy, headache, dyspnea, hypoxia, cytopenias
Severe Drug-Drug Interactions	Causes cytokine release which may suppress activity of CYP enzymes, resulting in increased exposure of CYP substrates, which is more likely to occur after the first dose and up to 14 days and during and after CRS.
Severe Drug-Food Interactions	None known
Important Labs at order entry or follow-up	Complete blood counts (CBC), liver enzymes, bilirubin
Used in Pediatric Areas	Safety and effectiveness have not been established in pediatric patients
Renal or Hepatic Dosing	None
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	No contraindications in labeling. Warnings: CRS: initiate with step-up dosing, monitor closely, available through a REMS program due to CRS risk Oral toxicity and weight loss: monitor, withhold or discontinue Infections: monitor, withhold or discontinue Cytopenias: monitor CBC Hepatotoxicity: monitor liver enzymes and bilirubin, withhold or discontinue Skin toxicity: monitor, intervene early, withhold if necessary
Special administration technique or considerations	Patients should be hospitalized for 48 hours after doses on days 1, 4, and 7 (step-up dosing). Pretreatment medications (corticosteroid, antihistamine, antipyretic) are recommended. Doses >2 mL should be divided into multiple syringes. Do not inject into tattoos, scars, or areas where the skin is red, bruised, tender, or broken.
Prepared by	Mason Melbuer, PharmD Candidate 2024
Source	Talvey (talquetamab-tgvs) [prescribing information]. Horsham, PA: Janssen Biotech, Inc.; August 2023.

Elranatamab-bcmm / Elrexfio / Pfizer	
Generic Name / Brand Name / Company	Elranatamab-bcmm / Elrexfio / Pfizer
Date of approval	8/14/23
Drug Class (Mechanism of Action if novel agent)	B-cell maturation antigen (BCMA)-directed CD3 T-cell engager
Indication	Relapsed or refractory multiple myeloma in adult patients who have received at least 4 prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody.
Comparative agent – Therapeutic interchange?	Same indication: ciltacabtagene autoleucel, idecabtagene vicleucel, talquetamab-tgvs, teclistamab-cqyv
Dosage forms/strengths.	Injection: 76 mg/1.9 mL and 44 mg/1.1 mL in single-dose vials
Common Dose/sig	Step-up dosing to reduce the incidence and severity of cytokine release syndrome (CRS): 12 mg on Day 1, 32 mg on Day 4, 76 mg on Day 8, followed by 76 mg weekly through week 24 then 76 mg every 2 weeks
DEA Schedule	None
Date of market availability	Available through a REMS program
Similar Medication Names	Elotuzumab, Empliciti
Clinical Use Evaluation	
Common Adverse Effects	≥20%: CRS, fatigue, injection site reaction, diarrhea, upper respiratory tract infection, musculoskeletal pain, pneumonia, decreased appetite, rash, cough, nausea, and pyrexia; common lab abnormalities (≥30%): decreased lymphocytes, neutrophils, hemoglobin, white blood cells, and platelets
Severe Adverse Effects	Pneumonia, sepsis, acute kidney injury, encephalopathy, pyrexia, febrile neutropenia, acute respiratory distress syndrome, cardiorespiratory arrest, cardiogenic shock, cardiopulmonary failure, failure to thrive, pulmonary embolism
Severe Drug-Drug Interactions	Cytokine release may suppress activity of CYP enzymes, resulting in increased exposure of CYP substrates which is more likely to occur after the first dose and up to 14 days after the 32 mg dose on Day 4 as well as during and after CRS.
Severe Drug-Food Interactions	None known
Important Labs at order entry or follow up	CBC, liver enzymes, bilirubin
Used in Pediatric Areas	Safety and effectiveness have not been established in pediatric patients.
Renal or Hepatic Dosing	No dosage adjustments are necessary in mild/moderate renal and mild hepatic impairment. The effects of severe renal impairment or moderate/severe hepatic impairment are unknown.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	No contraindications in labeling. Warnings: CRS and neurologic toxicity: initiate with step-up dosing, monitor closely, available through a REMS program due to CRS and neurologic toxicity risk Infections: monitor, withhold or discontinue Neutropenia: monitor CBC, withhold based on severity Hepatotoxicity: monitor liver enzymes and bilirubin, withhold or discontinue
Special administration technique or considerations	Patients should be hospitalized for 48 hours after the first step-up dose and for 24 hours after the second step-up dose. Administer pre-treatment medications (acetaminophen, dexamethasone, diphenhydramine) 1 hour before the first 3 step-up doses. The abdomen is the preferred subcutaneous injection site.
Prepared by	Emily Hitt, PharmD
Source	Elrexfio (elranatamab-bcmm) [prescribing information]. New York, NY: Pfizer Labs; August 2023.

Palovarotene / Sohonos / Ipsen Biopharmaceuticals	
Generic Name / Brand Name / Company	Palovarotene / Sohonos / Ipsen Biopharmaceuticals
Date of approval	8/16/23
Drug Class	Retinoid acid receptor agonist
Indication	Reduction of volume of new heterotopic ossification in females 8 years and older and males 10 years and older with fibrodysplasia ossificans progressiva
Comparative agent	None
Dosage forms/strengths.	Capsules: 1 mg, 1.5 mg, 2.5 mg, 5 mg, 10 mg
Common Dose/sig	For adults and pediatric patients 14 years and older the recommended dosage is 5 mg once daily, with an increase at the time of flare-up symptoms. Weight-adjusted dosing is recommended for patients younger than 14 years
DEA Schedule	None
Date of market availability	Available
Similar Medication Names	Paliperidone, Palonosetron, Palbociclib
Clinical Use Evaluation	
Common Adverse Effects	≥10%: dry skin, lip dry, arthralgia, pruritis, pain in extremity, rash, alopecia, erythema, headache, back pain, skin exfoliation, nausea, musculoskeletal pain, myalgia, dry eye, hypersensitivity, peripheral edema, fatigue
Severe Adverse Effects	Premature epiphyseal closure, decreased bone density, depression, anxiety, suicidal thoughts, night blindness
Severe Drug-Drug Interactions	CYP3A4 inhibitors: avoid concomitant strong/moderate inhibitors and grapefruit, pomelo, or juices containing those fruits CYP3A4 inducers: avoid strong/moderate inducers Vitamin A: avoid higher than recommended daily allowance and/or other oral retinoids Tetracyclines: risk of intracranial hypertension; avoid concomitant use
Severe Drug-Food Interactions	Grapefruit, pomelo, or juices containing those fruits
Important Labs Values to assess prior to order entry or at point of clinical follow up.	Pregnancy test for females of reproductive potential prior to initiating, periodically during therapy, and one month after treatment discontinuation
Used in Pediatric Areas	Indicated in females >8 years old and males >10 years old
Renal or Hepatic Dosing	No dosage adjustment in mild or moderate renal impairment; not recommended in patients with severe renal impairment (CrCl<29 mL/minute). No dosage adjustment in mild hepatic impairment; use is not recommended in patients with moderate or severe hepatic impairment (Child-Pugh B or C).
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications: pregnancy (may cause fetal harm) or hypersensitivity Warnings: Bone toxicity/metabolic bone disorders may occur. Signs of reduced bone mass, spontaneous osteoporosis, or spontaneous fracture should be monitored. Premature epiphyseal closure may occur. Growth should be monitored, and all pediatric patients should undergo baseline assessment of skeletal maturity. Retinoid toxicities: monitor for worsening psychiatric events such as depression, anxiety, and suicidal thoughts/ideation; mucocutaneous adverse reactions, night blindness
Special administration technique or considerations	Take at the same day every day with food; capsules can be emptied onto 1 teaspoon of soft food. Advise patients not to donate blood during therapy and for 1 week following because the blood could be given to a pregnant patient and cause fetal harm.
Prepared by	Mason Melbuer, PharmD Candidate 2024
Source	Sohonos (palovarotene) [prescribing information]. Cambridge, MA: Ipsen Biopharmaceuticals, Inc.; August 2023.

Pozelimab-bbfg / Veopoz / Regeneron	
Generic Name / Brand Name / Company	Pozelimab-bbfg / Veopoz / Regeneron
Date of approval	8/18/23
Drug Class (Mechanism of Action if novel agent)	IgG4P monoclonal antibody for complement protein C5
Indication	CD55-deficient protein-losing enteropathy (Chaple disease)
Comparative agent	None
Dosage forms/strengths.	Injection: 400 mg/2 mL in a single-dose vial
Common Dose/sig	Loading dose 30 mg/kg IV infusion on day 1, maintenance dose 10 mg/kg subcutaneously once weekly starting on day 8
DEA Schedule	None
Date of market availability	3rd quarter 2023
Similar Medication Names	Veozah, Vepesid, Posaconazole
Clinical Use Evaluation	
Common Adverse Effects	upper respiratory tract infection, fracture, urticaria, alopecia
Severe Adverse Effects	Bone fracture, hematuria, increased liver enzymes, meningococcal infection
Severe Drug-Drug Interactions	Immunoglbulins may decrease levels of pozelimab-bbfg; avoid concomitant use or monitor for decreased response
Severe Drug-Food Interactions	None
Important Labs at order entry or follow up.	None
Used in Pediatric Areas	May be used in patients aged 1 year and older
Renal or Hepatic Dosing	No dosage adjustment necessary
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications: unresolved *Neisseria meningitidis* infection Warnings: Hypersensitivity and infusion reactions, including anaphylaxis. Monitor for signs of cardiovascular and respiratory compromise, if present, interrupt therapy and manage supportively. Pozelimab-bbfg may increase the risk of meningococcal infections. Patients should be updated on meningococcal vaccinations at least 2 weeks prior to the first dose. Consider discontinuation in patients undergoing meningococcal treatment. Increased risk of other bacterial infections, especially encapsulated bacteria. Vaccination for Streptococcus pneumoniae and Haemophilus influenzae is recommended. Discontinue therapy if infected until the infection resolves.
Special administration technique or considerations	Loading dose infused over a minimum of 1 hour. Observe patient for 30 minutes following infusion. Subcutaneous doses must be prepared and administered by a healthcare provider. For doses greater than 400 mg, prepare 2 separate injections. Observe patient for 30 minutes following first subcutaneous injection.
Prepared by	Mason Melbuer, PharmD Candidate 2024
Source	Veopoz (pozelimab-bbfg) [prescribing information]. Tarrytown, NY: Regeneron Pharmaceuticals, Inc.; August 2023.