



## Highlights of FDA Activities – 12/1/24 – 12/31/24

### **FDA Drug Safety Communications & Drug Information Updates:**

#### **New Caution for Patients taking Ocaliva (obeticholic acid)**

12/12/24

Previously, it was shown that patients with cirrhotic liver disease were at higher risk of serious liver injury and liver transplant while taking Ocaliva for primary biliary cholangitis than patients without cirrhosis. The FDA has now identified that there are cases of serious liver injury in non-cirrhotic patients taking this drug that have resulted in liver transplant. Extreme caution should be taken with patients being treated with obeticholic acid. Liver function tests should be monitored frequently to detect worsening liver function early. Obeticholic treatment should be discontinued upon evidence of liver disease progression or if efficacy is not established.

#### **Boxed Warning Added to Veozah (fezolinetant) Labeling**

12/16/24

Following a strengthened warning and drug safety communication in September, the FDA has added a boxed warning regarding risk of liver injury to the Veozah labeling specifically stating hepatotoxicity has occurred with use of Veozah in the post-marketing setting in addition to the existing warnings of elevated liver function test values and required liver function testing. Recommendations have also been added for more frequent liver function tests, detailed as monthly testing for 3 months and then at months 6 and 9 of treatment. Patients should be advised to stop use immediately and contact their prescriber if signs and/or symptoms of liver injury appear.

#### **Policies Clarified for Compounders of Tirzepatide**

12/19/24

The FDA issued a new decision determining the tirzepatide injection shortage is resolved. The agency does not intend to take action against compounders for violations of the FD&C Act arising from conditions that depend on the tirzepatide injection product's inclusion on the FDA drug shortage list until 2/18/25 for state-licensed pharmacies compounding under section 503A or until 3/19/25 for outsourcing facilities compounding under section 503B. Action may still be taken for violations of other statutory or regulatory requirements, such as to address quality or safety issues. The FDA also noted that as of 12/19/24, dulaglutide injection, semaglutide injection, and liraglutide injection are in shortage.

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

#### **Monoject U-100 1 mL Insulin Syringe Luer Lock with Tip Cap Soft Packs: Recall – Incompatibility**

12/4/24

Cardinal Health recalled certain lots of Monoject U-100 1 mL Insulin Syringe Luer-Lock with Tip Cap Soft Pack (extended conical tip; product code 1188100777; lots 221201, 230201, and 230202) due to incompatibility with needleless IV connectors. The affected products should not be used to administer IV push insulin using a needleless connector.

#### **Ivenix Infusion Pumps, Fresenius Kabi USA: Early Alert – Valve Failures**

12/11/24

Fresenius Kabi USA has identified an issue with a subset of pneumatic valves installed in some Ivenix LVPs that have an increased chance of issuing a non-recoverable pump problem alarm. All devices with the affected valves should be removed from use and returned for repair. A complete list of affected units can be found on the FDA [website](#).

#### **Infusion Pump Batteries, ICU Medical: Recall – Reports of Counterfeit, Untested Batteries**

12/20/24

ICU Medical recalled some CSB batteries that are intended for use with Plum 360, Plum A+, and Plum A+3 Infusion Systems following reports of allegedly counterfeit batteries being used with infusion pumps. Batteries for use in these systems should not be used if they do not have an ICU Medical Test Label or CE Mark on the label.

**Adrenalin Chloride Solution (epinephrine nasal solution USP), Endo USA: Recall – Potential for Errors** 12/21/24  
Endo ISA recalled all lots of Adrenalin Chloride Solution (epinephrine nasal solution USP, 30 mg/30 mL) 30 mL vials because the product, which pre-dates the 1938 Federal Food, Drug & Cosmetic Act, has never submitted for FDA approval and is therefore an unapproved drug. In addition, the FDA has designated the product to be misbranded with a misleading label similar in appearance to the FDA-approved drug Adrenalin (epinephrine injection USP 1 mg/mL, 30 mL vials).

**Systane Lubricant Eye Drops Ultra PF, Alcon: Recall – Fungal Contamination** 12/23/24  
Alcon Laboratories recalled one lot of Systane Lubricant Eye Drops Ultra PF, Single Vials On-the-Go, 25 count (lot 10101) following a report of fungal contamination in a sealed single use vial.

**Prograf (tacrolimus) and Astagraf XL (tacrolimus extended-release), Astellas: Recall – Empty Capsules** 12/25/24  
Astellas Pharma US recalled one lot of Prograf (tacrolimus) 0.5 mg capsules (100 capsules per bottle, lot 0E3353D) and one lot of Astagraf XL (tacrolimus extended-release) 0.5 mg capsules (30 capsules per bottle, lot 0R3092A) because bottles may contain empty capsules.

**Fluid Delivery Set with Drip Chamber, Medline Custom Kits: Early Alert – Incorrectly Assembled** 12/30/24  
Medline has identified Fluid Delivery Sets with Drip Chamber within Medline Custom Kits that were incorrectly assembled with a white macro drip chamber instead of the required grey micro drip chamber. The macro drip chamber delivers three times more fluid per drop than the micro drip chamber. Medline advises that customers check for affected item numbers, and any products with incorrect white micro drip chambers be removed from use. Product from affected lots that have the grey micro drip chamber may be safely used. The complete list of item numbers and lot numbers can be found on the FDA [website](#).

**Solution Sets with Duo-Vent Spikes, Baxter Healthcare: Early Alert – Incorrectly Assembled** 12/31/24  
Baxter Healthcare Corporation has identified Solution Sets with Duo-Vent Spikes that were incorrectly assembled with inverted slide clamps. If loaded on an infusion pump, the medication may not be delivered and the patient's blood may backflow into the set and source container. The complete list of affected product and lot numbers can be found on the FDA [website](#). Products on the list should not be used.

### **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.

<b><u>Product</u></b>	<b><u>Promoted Use</u></b>	<b><u>Undeclared Ingredient(s) or Contaminants</u></b>
Fouzee SugarLin Herbal Formula*	Glucose/blood sugar support	Metformin, glyburide
Force Forever by GNMart Inc.*	Joint pain	Diclofenac, dexamethasone
VidaSlim Original Root, Root Plus, Root Capsules and VidaSlim Hot Body Brew*	Weight loss	Yellow oleander
Nhan Sam Tuyet Lien Truy Phong Hoan capsules*	Lumbago gout, arthrodynia, myasthenia, limb numbness, acclimation fever and rheumatism pain, osteocope, arthritis.	Furosemide, dexamethasone, chlorpheniramine

\*recalled

### **New Product Shortages**

No new shortages were announced by the FDA in December

<b><u>Brand Name or Sole Source Product Discontinuations/Withdrawals</u></b>	<b><u>Date Posted</u></b>
Edaravone injection (Radicava, Mitsubishi Tanabe Pharma America): generic edaravone injection and branded oral suspension (Radicava ORS) remain available	12/5/24
Cyclosporine oral solution (Gengraf, AbbVie): the oral solution 100 mg/mL has been discontinued; branded Neoral and one generic remain available	12/5/24
Lodoxamide tromethamine ophthalmic solution 0.1% (Alomide, Novartis): alternative mast cell stabilizers (nedocromil, cromolyn) and dual-acting antihistamine/mast cell stabilizers (azelastine, ketotifen, olopatadine) remain available	12/9/24
Bezlotoxumab (Zinplava, Merck): consider alternative therapies to prevent <i>Clostridioides difficile</i> recurrence	12/23/24

<b><u>Removed/Restricted Indications:</u></b>	<b><u>Description</u></b>	<b><u>Date Approved</u></b>
Bebtelovimab, Evusheld (tixagevimab co packaged with cilgavimab), sotrovimab, and REGEN-COV (casirivimab and imdevimab)	Emergency Use Authorizations (EUAs) withdrawn for these four monoclonal antibody products that had been authorized for emergency use in response to the COVID-19 public health emergency.	12/13/24

<b><u>New Drug Approvals:</u></b>	<b><u>Description (See Attached Drug Summaries)</u></b>	<b><u>Date Approved</u></b>
Zenocutuzumab-zbco/Bizengri/Merus US, Inc.	Bispecific HER2- and HER3-directed antibody for the treatment of advanced, unresectable, or metastatic non-small cell lung cancer (NSCLC) harboring a neuregulin 1 (NRG1) gene fusion with disease progression on or after systemic therapy, or advanced, unresectable, or metastatic pancreatic adenocarcinoma harboring a NRG1 gene fusion with disease progression on or after systemic therapy	12/4/24
Cosibelimab-ipdl/Unloxyt/Checkpoint Therapeutics, Inc.	Programmed death ligand-1 (PD-L1) blocking antibody for the treatment of adults with metastatic cutaneous squamous cell carcinoma (CSCC) or locally advanced CSCC who are not candidates for curative surgery or curative radiation	12/13/24
Crinecerfont/Crenessity / Neurocrine Biosciences, Inc.	Selective CRF1 receptor antagonist for adjunctive treatment to glucocorticoid replacement to control androgens in adult and pediatric patients 4 years of age and older with classic congenital adrenal hyperplasia (CAH)	12/13/24
Ensartinib/Ensacove/Xcovery	A kinase inhibitor for treatment of patients with ALK-positive locally advanced or metastatic non-small-cell lung cancer	12/18/24
Remestemcel-L-rknd/Ryoncil/Mesoblast Inc.	Allogeneic bone marrow-derived mesenchymal stromal cell therapy for the treatment of steroid-refractory acute graft-versus-host disease in pediatric patients 2 months of age and older	12/18/24
Olezarsen/Tryngolza/Ionis Pharmaceuticals, Inc.	<i>APOC-III</i> -directed antisense oligonucleotide indicated as an adjunct to diet to reduce triglycerides in adults with familial chylomicronemia syndrome (FCS)	12/19/24
Concizumab-mtci/Alhemo/Novo Nordisk	Tissue factor pathway inhibitor antagonist for routine prophylaxis to prevent bleeding in adults and pediatric patients 12 years and older with hemophilia A with FVIII inhibitors or hemophilia B with FIX inhibitors	12/20/24
Vanzacaftor, tezacaftor, and deuvacaftor/Alyftrek/Vertex Pharmaceuticals	A CFTR potentiator for the treatment of cystic fibrosis in patients 6 years and older who have at least one F508del mutation or another responsive mutation in the CFTR gene	12/20/24

<b><u>New Indications:</u></b>	<b><u>Description</u></b>	<b><u>Date Approved</u></b>
Durvalumab/Imfinzi/ AstraZeneca	For adults with limited-stage small cell lung cancer whose disease has not progressed following concurrent platinum-based chemotherapy and radiation therapy	12/4/24
Indocyanine green/IC-Green/ Renew Pharmaceuticals	Fluorescence imaging of vessels, blood flow and tissue perfusion before, during and after vascular, gastrointestinal, organ transplant, plastic, micro- and reconstructive surgeries in adults and pediatric patients aged 1 month and older, fluorescence imaging of extrahepatic biliary ducts in adults and pediatric patients aged 12 years and older, and fluorescence imaging of lymph nodes and lymphatic vessels during lymphatic mapping in adults with cervical and uterine cancer	12/5/24
Sugammadex/Bridion/Merck Sharp & Dohme LLC	Indication expanded to include reversal of neuromuscular blockade induced by rocuronium bromide and vecuronium bromide in patients birth to 2 years of age	12/12/24
Nemolizumab-ilot/Nemluvio/ Galderma Laboratories, LP	Treatment of adults and pediatric patients 12 years and older with moderate-to-severe atopic dermatitis in combination with topical corticosteroids and/or calcineurin inhibitors when the disease is not adequately controlled with topical prescription therapies	12/13/24
Diazepam/Valtoco/Neurelis Inc	Expanded indication for the nasal spray for the acute treatment of intermittent, stereotypic episodes of frequency seizure activity distinct from the patient's usual seizure pattern in patients 2 years and older with epilepsy	12/18/24
Vibegron/Gemtesa/Sumitomo Pharma America, Inc.	For the treatment of overactive bladder with symptoms of urge urinary incontinence, urgency, and urinary frequency in adult males on pharmacological therapy for benign prostatic hyperplasia	12/18/24
Canagliflozin; canagliflozin and metformin/Invokana, Invokamet, and Invokamet XR/Janssen	Indication expanded to include use as adjunct to diet and exercise to improve glycemic control in adults and pediatric patients 10 years and older with type 2 diabetes	12/18/24
Dapagliflozin and metformin/ Xigduo XR/AstraZeneca	Indication expanded to reflect current approvals for dapagliflozin in type 2 diabetes to reduce risk of cardiovascular death, hospitalization for heart failure, and urgent heart failure visit in patients with heart failure	12/20/24
Elexacaftor, tezacaftor, ivacaftor, plus ivacaftor/ Trikafta/Vertex	Indication expanded for use in the treatment of cystic fibrosis in patients 2 years and older with at least one F509del mutation of the CFTR gene or a mutation that is responsible based on clinical and/or in vitro data; 94 additional non-F509del CFTR mutations have been added to the label	12/20/24
Encorafenib/Braftovi/Pfizer	For use with cetuximab and mFOLFOX6 for patients with metastatic colorectal cancer with a BRAF V600E mutation	12/20/24
Setmelanotide/Imcivree/Rhythm Pharmaceuticals	Weight reduction indication expanded in patients with syndromic or monogenic obesity due to Bardet-Biedl syndrome or pre-opiomelanocortin, proprotein convertase subtilisin/kexin type 1, or leptin receptor deficiency expanded to include pediatric patients from 2 years to 6 years of age	12/20/24
Tirzepatide/Zepbound/Eli Lilly and Company	For the treatment of moderate to severe obstructive sleep apnea in adults with obesity	12/20/24
Fondaparinux sodium/Arixtra/ Mylan Institutional LLC	Indication expanded to include treatment of venous thromboembolism in pediatric patients aged 1 year or older and weighing at least 10 kg	12/23/24

<b><u>New Indications: (continued)</u></b>	<b><u>Description</u></b>	<b><u>Date Approved</u></b>
Tislelizumab-jsgr/Tevimbra/ Beigene	In combination with platinum and fluoropyrimidine-based chemotherapy in first-line treatment of unresectable or metastatic HER2-negative gastric or gastroesophageal junction adenocarcinoma whose tumors express PD-L1	12/26/24

<b><u>New Dosage Forms or Formulation:</u></b>	<b><u>Description</u></b>	<b><u>Date Approved</u></b>
Nivolumab and hyaluronidase-nvhy/Opdivo Qvantig/Bristol-Myers Squibb Company	Injection: 600 mg nivolumab and 10,000 units hyaluronidase per 5 mL in a single-dose vial; for subcutaneous administration	12/27/24

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<b>Zenocutuzumab-zbco/Bizengri/Merus US, Inc.</b>	
Generic Name / Brand Name / Company	Zenocutuzumab-zbco/Bizengri/Merus US, Inc.
Date of approval	12/4/24
Drug Class (Mechanism of Action if novel agent)	Bispecific HER2- and HER3-directed antibody
Indication	Treatment of advanced, unresectable, or metastatic NSCLC harboring a NRG1 gene fusion with disease progression on or after systemic therapy, or advanced, unresectable, or metastatic pancreatic adenocarcinoma harboring a NRG1 gene fusion with disease progression on or after systemic therapy
Comparative agent – Therapeutic interchange?	None
Dosage forms/strengths	Injection: 375 mg/18.75 mL (20 mg/mL) in a single dose vial
Common Dose/sig	750 mg as IV infusion every 2 weeks until disease progression or unacceptable toxicity
DEA Schedule	N/A
Date of market availability	Early 2025
Similar Medication Names	Zenzedi, zenatane, bimzelx, bimekizumab
<b>Clinical Use Evaluation</b>	
Common Adverse Effects	≥10%: diarrhea, nausea, musculoskeletal pain, dyspnea, cough, fatigue, edema, rash, infusion-related reactions, decreased appetite
Severe Adverse Effects	Infusion-related reactions, hypersensitivity and anaphylactic 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.	Verify pregnancy status of female patients before initiating therapy.
Used in Pediatric Areas	Safety and effectiveness in pediatric areas has not yet been established.

Renal or Hepatic Dosing	No routine adjustments required. No clinically significant differences in the pharmacokinetics were observed in patients with mild or moderate renal impairment, and mild hepatic impairment. Pharmacokinetics in patients with moderate to severe hepatic impairment and patients with severe renal impairment is unknown.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	<p>Contraindications: none</p> <p>Warnings:</p> <ul style="list-style-type: none"> <li>• Infusion-related reactions/Hypersensitivity/Anaphylactic reactions: Monitor during infusion and for at least one hour following completion of first infusion and as clinically indicated.</li> <li>• Interstitial Lung Disease/Pneumonitis: Monitor for new or worsening pulmonary symptoms indicative of ILD/pneumonitis (dyspnea, cough, fever). Immediately withhold treatment in patients with suspected ILD/pneumonitis and administer corticosteroids as clinically indicated. Permanently discontinue if ILD/pneumonitis <math>\geq</math> Grade 2 is confirmed.</li> <li>• Left ventricular dysfunction: evaluate LVEF before initiating and at regular intervals as clinically indicated. Discontinue if symptomatic congestive heart failure, or if LVEF of less than 45% or less than 50% with absolute decrease from baseline of 10% or greater is confirmed.</li> <li>• Embryo-Fetal Toxicity (Boxed Warning)</li> </ul>
Special administration technique or considerations	<p>Administer premedication prior to each infusion to reduce the risk of infusion-related reactions. Recommended premedication:</p> <ul style="list-style-type: none"> <li>• Corticosteroid – dexamethasone 10 mg (oral or IV)</li> <li>• Antipyretic – acetaminophen 1000 mg (oral or IV)</li> <li>• H1 Antihistamine – dexchlorpheniramine 5 mg or other anti-H1 equivalent (oral or IV)</li> </ul> <p>Administer intravenous solution over 4 hours via a peripheral or central line.</p>
Prepared by	Heather Kleven
Source	Bizengri (zenocutuzumab-zbco) [prescribing information]. Cambridge, MA: Merus US, Inc.; December 2024.

<b>Cosibelimab-ipdl/Unloxcyt/Checkpoint Therapeutics, Inc.</b>	
Generic Name / Brand Name / Company	Cosibelimab-ipdl/Unloxcyt/Checkpoint Therapeutics, Inc.
Date of approval	12/13/24
Drug Class (Mechanism of Action if novel agent)	PD-L1 blocking antibody
Indication	Treatment of adults with metastatic cutaneous squamous cell carcinoma (CSCC) or locally advanced CSCC who are not candidates for curative surgery or curative radiation
Comparative agent – Therapeutic interchange?	None
Dosage forms/strengths	Injection: 300 mg/5 mL (60 mg/mL) solution in single-dose vial
Common Dose/sig	1200 mg as an IV infusion every 3 weeks
DEA Schedule	N/A
Date of market availability	To be determined
Similar Medication Names	Cosentyx
<b>Clinical Use Evaluation</b>	
Common Adverse Effects	>10%: fatigue, musculoskeletal pain, rash, diarrhea, hypothyroidism, constipation, nausea, headache, pruritus, edema, localized infection, UTI
Severe Adverse Effects	Fatigue, musculoskeletal pain, rash, localized infection, immune-mediated 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.	Liver enzymes, creatinine, and thyroid function tests at baseline and periodically during treatment.
Used in Pediatric Areas	Safety and effectiveness have not been established in pediatric patients.
Renal or Hepatic Dosing	No routine dosage adjustments recommended. Renal or hepatic toxicity may require withholding of doses or discontinuation of therapy.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	No labeled contraindications. Warnings: Severe and fatal immune mediated reactions, including pneumonitis, hepatitis, endocrinopathies, nephritis, dermatologic reactions. Infusion-related reactions: monitor, consider premedication Complications of allogeneic hematopoietic stem cell transplantation Embryo-fetal toxicity
Special administration technique or considerations	Administer by IV infusion over 60 minutes through IV line containing 0.2- to 0.22-micron filter. No dosage modifications for adverse reactions; consult prescribing information for list of adverse reactions requiring withholding treatment or permanently discontinuation.
Prepared by	Terri Levien
Source	Unloxcyt (cosibelimab-ipdl) [prescribing information]. Waltham, MA: Checkpoint Therapeutics Inc; December 2024.

<b>Crinecerfont/Crenessity/Neurocrine Biosciences, Inc.</b>	
Generic Name / Brand Name / Company	Crinecerfont/Crenessity/Neurocrine Biosciences, Inc.
Date of approval	12/13/24
Drug Class (Mechanism of Action if novel agent)	Selective CRF1 receptor antagonist
Indication	Adjunctive treatment to glucocorticoid replacement to control androgens in adult and pediatric patients 4 years of age and older with classic congenital adrenal hyperplasia (CAH)
Comparative agent – Therapeutic interchange?	N/A
Dosage forms/strengths	Capsules: 25 mg, 50 mg, 100 mg; oral solution: 50 mg/mL in 30 mL bottle
Common Dose/sig	Adults and pediatric patients weighing $\geq 55$ kg: 100 mg orally, twice daily with a meal in the morning and evening Pediatric patients (aged 4 years and older): Weight-based dosing (25 mg if weight 10 kg to <20 kg; 50 mg if weight 20 kg to <55kg) orally, twice daily with a meal in the morning and evening
DEA Schedule	N/A
Date of market availability	Available
Similar Medication Names	N/A
<b>Clinical Use Evaluation</b>	
Common Adverse Effects	Adults ( $\geq 4\%$ ): fatigue, headache, dizziness, arthralgia, back pain, decreased appetite, myalgia; pediatric ( $\geq 4\%$ ): headache, abdominal pain, fatigue, nasal congestion, epistaxis
Severe Adverse Effects	Hypersensitivity reactions, acute adrenal insufficiency, adrenal crisis
Severe Drug-Drug Interactions	Strong and moderate CYP3A4 inducers: concomitant use decreases crinecerfont exposure, increased doses recommended.
Severe Drug-Food Interactions	None known
Important Labs Values to assess prior to order entry or at point of clinical follow up.	Androstenedione levels can be assessed beginning four weeks after therapy initiation to inform reduction in glucocorticoid dosage as clinically indicated.
Used in Pediatric Areas	Safety and effectiveness established in pediatric patients 4 years of age and older with classic CAH. Safety and effectiveness in pediatric patients less than 4 years of age has not been established.
Renal or Hepatic Dosing	Use is not recommended in patients with severe renal impairment or end-stage renal disease. No routine dosage adjustments recommended for renal or hepatic impairment; pharmacokinetics not affected in mild to moderate renal impairment or mild to severe hepatic impairment.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindicated in patients with hypersensitivity to crinecerfont or any excipients in Crenessity Warnings: Hypersensitivity reactions: if a clinically significant reaction occurs, initiate appropriate therapy and discontinue crinecerfont. Risk of acute adrenal insufficiency or adrenal crisis with inadequate concomitant glucocorticoid therapy. Continue glucocorticoids upon initiation of and during treatment with crinecerfont. Do not reduce glucocorticoid dose below the dose required for cortisol replacement.
Special administration technique or considerations	Each dose must be administered with a meal, without regard to fat or caloric content. Capsules are to be taken orally and swallowed whole with liquid. Discard any unused oral solution after 30 days of first opening the bottle.
Prepared by	Heather Kleven
Source	Crenessity (crinecerfont) [prescribing information]. San Diego, CA: Neurocrine Biosciences, Inc.; December 2024.

<b>Ensartinib/Ensacove/Xcovery</b>	
Generic Name / Brand Name / Company	Ensartinib/Ensacove/Xcovery
Date of approval	12/18/24
Drug Class (Mechanism of Action if novel agent)	Kinase inhibitor
Indication	Treatment of ALK-positive locally advanced or metastatic non-small-cell lung cancer in patients who have not previously received an ALK-inhibitor
Comparative agent – Therapeutic interchange?	Alectinib, brigatinib, ceritinib, crizotinib, lorlatinib
Dosage forms/strengths	Capsules: 25 mg, 100 mg
Common Dose/sig	225 mg orally once daily until disease progression or unacceptable toxicity
DEA Schedule	N/A
Date of market availability	Available
Similar Medication Names	Ensifentrine
<b>Clinical Use Evaluation</b>	
Common Adverse Effects	≥20%: rash, musculoskeletal pain, constipation, pruritus, cough, nausea, edema, vomiting, fatigue, pyrexia
Severe Adverse Effects	Rash, pruritus, musculoskeletal pain, nausea, edema, hemorrhage; Grade 3-4 laboratory abnormalities: increased uric acid, decreased lymphocytes, increased alanine aminotransferase, decreased phosphate, increased gamma glutamyl transferase, increased magnesium, increased amylase, decreased sodium, increased glucose, decreased hemoglobin, increased bilirubin, decreased potassium, and increased creatine phosphokinase
Severe Drug-Drug Interactions	Avoid concomitant use of strong or moderate CYP3A inhibitors, strong or moderate CYP3A inducers, or P-gp inhibitors.
Severe Drug-Food Interactions	None known
Important Labs Values to assess prior to order entry or at point of clinical follow up.	Confirm ALK rearrangement in tumor specimen; evaluate liver function tests and fasting blood glucose prior to initiating ensartinib; evaluate liver function tests (ALT, AST, total bilirubin) every 2 weeks during first cycle, then monthly and as clinically indicated. Monitor serum glucose, creatine phosphokinase, and uric acid periodically during treatment.
Used in Pediatric Areas	Safety and effectiveness are not established in pediatric patients.
Renal or Hepatic Dosing	Avoid use in severe hepatic impairment, monitor patients with moderate hepatic impairment for increased adverse reactions and adjust dose as clinically indicated. No dosage modification recommended in mild hepatic impairment or renal impairment.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindication: hypersensitivity to ensartinib, FD&C Yellow No 5 (tartrazine), or any product ingredients Warnings: Interstitial lung disease/pneumonitis – monitor, discontinue if occurs Hepatotoxicity, dermatologic reactions, bradycardia, hyperglycemia, hyperuricemia, or increased creatine phosphokinase – monitor; withhold, reduce dose, or discontinue based on severity Visual disturbances – withhold and evaluate Embryo-fetal toxicity
Special administration technique or considerations	Capsules should be swallowed whole; do not crush, chew, or open capsules. See labeling for dosage modifications for adverse reactions.
Prepared by	Terri Levien
Source	Ensacove (ensartinib) [prescribing information]. Miami, FL: Xcovery Holdings Inc; December 2024.

<b>Remestemcel-L-rknd/Ryoncil/Mesoblast Inc.</b>	
Generic Name / Brand Name / Company	Remestemcel-L-rknd/Ryoncil/Mesoblast Inc.
Date of approval	12/18/24
Drug Class (Mechanism of Action if novel agent)	Allogeneic bone marrow-derived mesenchymal stromal cell therapy
Indication	Treatment of steroid-refractory acute graft-versus-host disease in pediatric patients 2 months of age and older
Comparative agent – Therapeutic interchange?	None
Dosage forms/strengths	Cell suspension: 6.68 x 10 <sup>6</sup> MSC/mL in 3.8 mL in a 6 mL cryovial
Common Dose/sig	2 x 10 <sup>6</sup> MSC/kg body weight as IV infusion twice per week for 4 consecutive weeks. Assess response 28 days after the first dose to determine if repeat administration is advised.
DEA Schedule	N/A
Date of market availability	Available
Similar Medication Names	Remifentanyl
<b>Clinical Use Evaluation</b>	
Common Adverse Effects	≥20%: viral infectious disorders, bacterial infectious disorders, infection – pathogen unspecified, pyrexia, hemorrhage, edema, abdominal pain, hypertension
Severe Adverse Effects	Infections, pyrexia, hemorrhage, edema, abdominal pain, hypertension, vomiting, arrhythmia, diarrhea, hypotension, respiratory failure, GGT increased, thrombocytopenia, blood bilirubin increased
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.	As needed at day 28 to assess for need for repeat therapy
Used in Pediatric Areas	Safety and efficacy demonstrated in patients 2 months of age and older.
Renal or Hepatic Dosing	No dosage modifications
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindication: hypersensitivity to dimethyl sulfoxide or porcine and bovine proteins Warnings: Hypersensitivity Transmission of infectious agents Ectopic tissue formation
Special administration technique or considerations	Premedicate with corticosteroids and antihistamines 30 to 60 minutes prior to administration. Separate twice weekly doses by at least 3 days. Patient infusion must occur within 5 hours from the start time of first vial thaw. Extension dose preparation requirements; see product labeling. Administer using infusion pump and with a blood filter with a pore size of 40 to 260 microns. Infuse at no more than 6 mL/minute for patients weighing 35 kg or more, and over 60 minutes for patients weighing less than 35 kg. Flush lines after infusion.
Prepared by	Terri Levien
Source	Ryoncil (remestemcel-L-rknd) [prescribing information]. New York, NY: Mesoblast Inc; December 2024.

<b>Olezarsen/Tryngolza/Ionis Pharmaceuticals, Inc.</b>	
Generic Name / Brand Name / Company	Olezarsen/Tryngolza/Ionis Pharmaceuticals, Inc.
Date of approval	12/19/24
Drug Class (Mechanism of Action if novel agent)	<i>APOC-III</i> -directed antisense oligonucleotide (ASO) - ASO-GaINAc3 conjugate that binds to apoC-III protein. Reduction of apoC-III protein leads to increased clearance of plasma TG and VLDL.
Indication	Adjunct treatment with diet to reduce triglycerides in adults with familial chylomicronemia syndrome (FCS)
Comparative agent – Therapeutic interchange?	None
Dosage forms/strengths	Injection: 80 mg/0.8 mL single dose autoinjector
Common Dose/sig	80 mg administered subcutaneously once monthly
DEA Schedule	None
Date of market availability	Available
Similar Medication Names	Tranexamic acid, Trintellix, Trental, Otezla, olanzapine
<b>Clinical Use Evaluation</b>	
Common Adverse Effects	>5%: injection site reactions, decreased platelet count, arthralgia
Severe Adverse Effects	Hypersensitivity reactions: bronchospasm, diffuse erythema, facial swelling, urticaria, chills and myalgias (requiring medical treatment).
Severe Drug-Drug Interactions	None known
Severe Drug-Food Interactions	None known
Important Labs Values to assess prior to order entry or at point of clinical follow up.	None
Used in Pediatric Areas	Safety and effectiveness in pediatric patients have not been established
Renal or Hepatic Dosing	No dose adjustment is necessary in patients with mild to moderate renal impairment or mild hepatic impairment. No studies have been conducted in patients with severe renal impairment, end-stage renal disease, or moderate or severe hepatic impairment.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindicated in patients with a history of serious hypersensitivity to olezarsen or any of the excipients in Tryngolza. Hypersensitivity reactions have occurred. Patient should maintain a low-fat diet (no more than 20 g fat per day).
Special administration technique or considerations	Remove from the refrigerator 30 minutes prior to injection to allow to warm to room temperature. Inject subcutaneously into the abdomen or front of thigh; back of upper arm may also be used if healthcare provider or caregiver administers the injection.
Prepared by	Heather Kleven
Source	Tryngolza (olezarsen) [prescribing information]. Carlsbad, CA: Ionis Pharmaceuticals, Inc.; December 2024.

<b>Concizumab-mtci/Alhemo/Novo Nordisk</b>	
Generic Name / Brand Name / Company	Concizumab-mtci/Alhemo/Novo Nordisk
Date of approval	12/20/24
Drug Class (Mechanism of Action if novel agent)	Tissue factor pathway inhibitor antagonist
Indication	routine prophylaxis to prevent bleeding in adults and pediatric patients 12 years and older with hemophilia A with FVIII inhibitors or hemophilia B with FIX inhibitors
Comparative agent – Therapeutic interchange?	Marstacimab – also a tissue factor pathway inhibitor antagonist but indicated for hemophilia A or B without inhibitors
Dosage forms/strengths	Injection: 60 mg/1.5 mL (40 mg/mL), 150 mg/1.5 mL (100 mg/mL), and 300 mg/mL (100 mg/mL) in single-patient-use prefilled pen
Common Dose/sig	Day 1: loading dose of 1 mg/kg subcutaneously; starting day 2: 0.2 mg/kg once daily for 4 to 8 weeks, then base dose on concizumab-mtci plasma concentration
DEA Schedule	None
Date of market availability	Mid-February
Similar Medication Names	Caplacizumab, crovalimab
<b>Clinical Use Evaluation</b>	
Common Adverse Effects	≥5%: injection site reactions, urticaria
Severe Adverse Effects	hypersensitivity
Severe Drug-Drug Interactions	High and/or frequent use of bypassing agents with concizumab-mtci increases risk of thromboembolism
Severe Drug-Food Interactions	None known
Important Labs Values to assess prior to order entry or at point of clinical follow up.	Measure concizumab-mtci plasma concentration by ELISA at 4 weeks after initiation of treatment to guide dosing, and measure at clinical follow up to ensure steady-state is maintained
Used in Pediatric Areas	Safety and effectiveness demonstrated in patients 12 years and older.
Renal or Hepatic Dosing	No dosage adjustment.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindication: history of serious hypersensitivity to concizumab-mtci or any product ingredients Warnings: Thromboembolic events – monitor and discontinue if events occur Hypersensitivity reactions – discontinue if severe May increase laboratory values of Fibrin D dimer and Prothrombin Fragment 1+2 making them unreliable markers for clinical decision making Pause therapy at least 4 days prior to major surgery
Special administration technique or considerations	Administer by subcutaneous injection to the abdomen or thigh with daily rotation of injection sites. Recalculate the dose if the patient's body weight changes. For 2 to 6 missed doses, resume treatment with double dose followed by once daily at the maintenance dose level. If 7 or more missed doses, consider a new loading dose.
Prepared by	Terri Levien
Source	Alhemo (concizumab-mtci) [prescribing information]. Plainsboro, NJ: Novo Nordisk Inc; December 2024.

<b>Vanzacaftor, Tezacaftor, and Deutivacaftor/Alyftrek/Vertex Pharmaceuticals</b>	
Generic Name / Brand Name / Company	Vanzacaftor, tezacaftor, and deutivacaftor/Alyftrek/Vertex Pharmaceuticals
Date of approval	12/20/24
Drug Class (Mechanism of Action if novel agent)	CFTR potentiator
Indication	Treatment of cystic fibrosis in patients 6 years and older who have at least one F508del mutation or another responsive mutation in the CFTR gene
Comparative agent – Therapeutic interchange?	Depends on mutation: elexacaftor, tezacaftor and ivacaftor (Trikafta), lumacaftor and ivacaftor (Orkambi), or tezacaftor and ivacaftor (Symdeko)
Dosage forms/strengths	Tablets: vanzacaftor 4 mg, tezacaftor 20 mg, and deutivacaftor 50 mg, and vanzacaftor 10 mg, tezacaftor 50 mg, and deutivacaftor 125 mg
Common Dose/sig	12 years and older, or less than 12 years but weighing at least 40 kg: two tablets containing vanzacaftor 10 mg, tezacaftor 50 mg, and deutivacaftor 125 mg once daily 6 to <12 years and weighing <40 kg: three tablets containing vanzacaftor 4 mg, tezacaftor 20 mg, and deutivacaftor 50 mg once daily
DEA Schedule	None
Date of market availability	Available
Similar Medication Names	Alfentanil
<b>Clinical Use Evaluation</b>	
Common Adverse Effects	>5%: cough, nasopharyngitis, upper respiratory tract infection, headache, oropharyngeal pain, influenza, fatigue, increased ALT, rash, increased AST, sinus congestion
Severe Adverse Effects	Hypersensitivity, liver injury
Severe Drug-Drug Interactions	Avoid use with strong or moderate CYP3A inducers; reduce dosage/dosing frequency with concomitant strong or moderate CYP3A inhibitors. Monitor closely if used with BCRP substrates or CYP2C9 substrates.
Severe Drug-Food Interactions	Avoid grapefruit
Important Labs Values to assess prior to order entry or at point of clinical follow up.	Obtain liver function tests (ALT, AST, alkaline phosphatase, and bilirubin) prior to initiation, every month for the first 6 months, every 3 months during the next 12 months, and then at least annually thereafter
Used in Pediatric Areas	Safety and effectiveness established in patients 6 years and older
Renal or Hepatic Dosing	Avoid use in severe hepatic impairment. Only use in moderate hepatic impairment if the benefit outweighs the risk; if used, no dosage adjustment is recommended. No dosage adjustment is recommended in mild to moderate renal impairment; use only in severe renal impairment or end-stage renal disease if the benefits outweigh the risks.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications: none Boxed warning: drug-induced liver injury and liver failure Warnings: Hypersensitivity, including anaphylaxis Cataracts reported with similar drugs No data on use in patients who previously discontinued or interrupted treatment with drugs containing elexacaftor, tezacaftor, or ivacaftor due to adverse reactions
Special administration technique or considerations	Tablets should be swallowed whole with fat-containing food once daily at approximately the same time each day.
Prepared by	Terri Levien
Source	Alyftrek (vanzacaftor, tezacaftor, and deutivacaftor) [prescribing information]. Boston, MA: Vertex Pharmaceuticals Inc; December 2024.