



Highlights of FDA Activities – 8/1/24 – 8/31/24

FDA Drug Safety Communications & Drug Information Updates:

Infant Aluminum Toxicity Risk with Unapproved Hospira Potassium Phosphates Product 8/21/24

The FDA reissued a warning from February 2023 regarding the risk of aluminum toxicity associated with the use of an unapproved Hospira potassium phosphates product in pediatric patients, particularly when used in parenteral nutrition. The FDA advises health care professional to avoid use of the product in parenteral nutrition for pediatric patients and to use FDA-approved potassium phosphates products that have acceptable aluminum levels for use in pediatric patients.

Approval and Authorization of Updated mRNA COVID-19 Vaccines 8/22/24

The FDA has granted emergency use authorization for the new 2024-2025 formula COVID-19 vaccines. The vaccines include a monovalent component that corresponds to the Omicron variant KP.2 strain of SARS-CoV-2. This formula closely targets the current circulating variants. The updated mRNA COVID-19 vaccines include Comirnaty and Spikevax (for use in individuals 12 years old or greater), and the Moderna COVID-19 Vaccine and Pfizer-BioNTech COVID-19 Vaccine (for emergency use in individuals 6 months through 11 years old).

FDA Releases Information About Risk of COVID-19 Due to SARS-CoV-2 Viral Variants with Substantially Reduced Susceptibility to Pempgarda (pemivibart) 8/26/24

The FDA has revised the Emergency Use Authorization for Pempgarda to limit its use when the combined national frequency of variants with substantially reduced susceptibility to Pempgarda is $\leq 90\%$. Currently, Pempgarda remains authorized for emergency use for pre-exposure prevention of COVID-19 as stated in the Letter of Authorization.

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

Heparin Sodium 0.9% Sodium Chloride Injection, Baxter International Inc.: Recall – Elevated Endotoxin Levels 8/6/24

Baxter International Inc. is voluntarily recalling one lot of Heparin Sodium in 0.9% Sodium Chloride Injection to the consumer level due to the potential for elevated endotoxin levels related to the bacterial endotoxin test specific to lot number N008235. [Details Here.](#)

CADD-Solis Ambulatory Infusion Pump, Smiths Medical: Correction – Updates Needed 8/6/24

Smiths Medical issued a correction for CADD-Solis and CADD-Solis VIP Ambulatory infusion pump software due to multiple issues related to outdated software. This recall involves correcting certain devices and does not involve removing them from use. [Details Here.](#)

0.9% Sodium Chloride for Injection, B. Braun Medical Inc.: Recall – Potential for Particulate Matter and Leakage 8/8/24

B. Braun Medical Inc. is voluntarily recalling two lots of 0.9% sodium chloride for Injection USP 1000 mL in E3 containers to the consumer level due to the potential for particulate matter and fluid leakage of the respective containers. Lot numbers affected: J2L763, J2L764.

Plum 360, A+ and A+3 Infusion System, ICU Medical: Correction – Instructions for Use 8/20/24

ICU Medical updated use instructions for the Plum 360, Plum A+, and Plus A+3 Infusion Systems due to a manufacturing defect of the batteries that can result in diminished battery life. Replacement batteries are available.

Apple iOS t:connect Mobile App Used With t:slim X2 Insulin Pump with Control-IQ Technology, Tandem Diabetes Care, Inc.: Correction – Software

8/30/24

Tandem Diabetes Care, Inc. recalled version 2.7 of the Apple iOS t:connect Mobile App Used With t:slim X2 Insulin Pump with Control-IQ Technology due to a software issue that could result in insulin pump battery depletion. An updated version 2.8.2 of the software has been released to correct the issue.

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.

<u>Product</u>	<u>Promoted Use</u>	<u>Undeclared Ingredient(s) or Contaminants</u>
Boom Max capsules*	Male Performance and Energy	Sildenafil
Endurance Pro capsules by Veata*	Male Performance and Energy	Sildenafil
OPMS Black liquid Kratom ¹	Stimulant	Kratom alkaloids, mitragynine and 7-hydroxymitragynine
Unapproved Inhalants ²	Alertness and energy	Ammonia ³

*Recalled

¹FDA received an adverse event report of a person who died after using this product and other serious adverse events after consuming the product. FDA warns consumers not to use kratom because of the risk of serious adverse events, including liver toxicity, seizures, and substance use disorder.

²These products include Ward Smelling Salts, Ammonia Sport Inc., Skull Smash LLC, Spirochaete Research Labs, Innovative Formulations LLC, Native Salts LLC, and Nose Slap LLC

³Inhaling ammonia can quickly lead to coughing, airway constriction, and eye, nose and throat irritation

New Product Shortages

Date Initially Posted

Indocyanine Green Injection

8/23/24

Brand Name or Sole Source Product Discontinuations/Withdrawals

Date Posted

Glucotrol (glipizide) XL (Pfizer): Extended release 5 mg tablet (NDC) 0049-0174-02 – supply expected to exhaust mid-September 2024; glipizide generic tablets remain available.

8/5/24

Namenda (memantine) XR (Allergan, Inc.): Extended release 7 mg + 14 mg + 21 mg + 28 mg capsules – memantine extended-release capsules remain available.

8/7/24

Sandimmune (cyclosporine) oral solution (Novartis): 100 mg/1 mL (NDC) 0078-0110-22 – the product is no longer available.

8/20/24

Pandel (Hydrocortisone probutate) Cream (ANI Pharmaceuticals): 1 mg/1 g (NDC) 62559-325-26 – the product is no longer available.

8/21/24

Clobex (clobetasol propionate) Spray (Actavis): 0.005 g/1 mL (NDC) 0591-4039-46 and 0591-4039-74 – Discontinued by manufacturer. Clobetasol propionate spray remains available from other manufacturers.

8/28/24

<u>New Drug Approvals:</u>	<u>Description (See Attached Drug Summaries)</u>	<u>Date Approved</u>
Afamitresgene autoleucl / Tecelra / Adaptimmune, LLC.	A melanoma-associated antigen A4 (MAGE-A4)-directed genetically modified autologous T cell immunotherapy, for adults with unresectable or metastatic synovial sarcoma who have received prior chemotherapy, are HLA-A*02:01P, -A*02:02P, -A*02:03P, or -A*02:06P positive and whose tumor expresses the MAGE-A4 antigen	8/1/24
Vorasidenib / Voranigo / Servier Pharmaceuticals, LLC.	An isocitrate dehydrogenase-1 (IDH1) and isocitrate dehydrogenase-2 (IDH2) inhibitor, for adult and pediatric patients 12 years and older with Grade 2 astrocytoma or oligodendroglioma with a susceptible IDH1 or IDH2 mutation, following surgery	8/6/24
Palopegteriparatide / Yorvipath / Ascendis Pharma Endocrinology, Inc.	A parathyroid hormone analog (PTH(1-34)) indicated for the treatment of hypoparathyroidism in adults	8/9/24
Nemolizumab-ilto / Nemluvio / Galderma Laboratories, L.P.	An interleukin-31 receptor antagonist indicated for the treatment of adults with prurigo nodularis	8/12/24
Seladelpar / Livdelzi / Gilead Sciences, Inc.	A peroxisome proliferator-activated receptor (PPAR)-delta agonist indicated for the treatment of primary biliary cholangitis (PBC) in combination with ursodeoxycholic acid (UCDA) in adults who have an inadequate response to UDCA, or as monotherapy in patients unable to tolerate UCDA	8/14/24
Axatilimab-csfr / Niktimvo / Incyte Corporation	A colony stimulating factor-1 receptor (CSF-1R)-blocking antibody, for the treatment of chronic graft-versus-host disease (cGVHD) after failure of at least two prior lines of systemic therapy in adult and pediatric patients weighing at least 40 kg	8/14/24
Lazertinib / Lazcluze / Janssen Biotech, Inc.	A kinase inhibitor indicated in combination with amivantamab for the first-line treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R substitution mutations	8/19/24
<u>New Indications:</u>	<u>Description</u>	<u>Date Approved</u>
Dostarlimab-gxly / Jemperli / Glaxosmithkline	Use with carboplatin and paclitaxel, followed by use as a single-agent, for adult patients with primary advanced or recurrent endometrial cancer; limit to use in mismatch repair deficient or microsatellite-instability high disease removed	8/1/24
Iptacopan / Fabhalta / Novartis	For the reduction of proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk of rapid disease progression	8/7/24
Furosemide Injection / Furoscix / ScPharmaceuticals, Inc.	Indication changed to the treatment of congestion due to fluid overload in adults with chronic heart failure (CHF) – previously was indicated in adults with NYHA Class II/III CHF	8/9/24
Pantoprazole Injection / Protonix I.V. / Pfizer Inc.	Treatment of gastroesophageal reflux disease (GERD) and a history of erosive esophagitis (EE) for up to 7 days in pediatric patients 3 months and older.	8/12/24

New Indications: (continued...)

<u>Description</u>	<u>Date Approved</u>	
Durvalumab / Imfinzi / Astrazeneca	With platinum-containing chemotherapy as neoadjuvant treatment, followed by single-agent durvalumab as adjuvant treatment after surgery for adults with resectable non-small cell lung cancer and no known epidural growth factor receptor mutations or anaplastic lymphoma kinase rearrangements.	8/15/24
Anacaulase-bcdb / Nexobrid / Mediowound, LTD	For use in eschar removal in adults and pediatric patients with deep partial thickness and/or full thickness thermal burns	8/15/24
Amivantamab-Vmjw / Rybrevant / Janssen Biotech	Use in combination with lazertinib for first-line treatment of adult patients with locally advanced or metastatic NSCLC with EGFR exon 19 deletions or exon 21 L858R substitution mutations	8/19/24
Letemovir / Prevymis / Merck & Co., Inc.	Prophylaxis of cytomegalovirus (CMV) infection and disease in adult and pediatric patients 6 months of age and older and weighing at least 6 kg who are CMV-seropositive recipients [R+] of an allogenic hematopoietic stem cell transplant (HSCT) and prophylaxis of CMV disease in adults and pediatric patients 12 years of age and older and weighing at least 40 kg who are kidney transplant recipients at high risk (Donor CMV seropositive/Recipient CMV seronegative [D+/R-].	8/30/24

New Dosage Forms or Formulation:

<u>Description</u>	<u>Date Approved</u>	
Nalmefene / Zurnai / Purdue Pharma LP	Single-dose auto-injector: 1.5 mg/0.5 mL; treatment of known or suspected opioid overdose	8/7/24
Carbidopa and levodopa / Crexont / Amneal Specialty	Extended-release capsules: carbidopa and levodopa 35 mg/140 mg, 52.5 mg/ 210 mg, 70 mg/280 mg, 87.5 mg/350 mg; for the treatment of Parkinson's disease, post-encephalitic parkinsonism, and parkinsonism that may follow carbon monoxide or manganese intoxication	8/7/24
Denileukin diftitox-cxdl / Lymphir / Citius Pharmaceuticals, Inc.	Injectable, 300 mcg; updated formulation of Ontak which was previously discontinued due to production issues	8/7/24
Epinephrine / Neffy / ARS Pharmaceuticals	Nasal spray, 2 mg/0.1 mL; emergency treatment of Type 1 allergic reactions in adults and pediatric patients weighing at least 30 kg	8/9/24
Letemovir / Prevymis / Merck & Co., Inc.	Oral pellets, 20 mg or 120 mg per packet; for use orally or via nasogastric (NG) or gastric (G) tube	

Compiled by:

Terri Levien, Pharm.D.
Emily Hitt, Pharm.D., PGY2 Academic Fellow
Connor Hoffman, Doctor of Pharmacy Candidate 2025
Talia Moore, Doctor of Pharmacy Candidate 2025

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

Afamitresgene autoleucel / Tecelra / Adaptimmune, LLC.	
Generic Name / Brand Name / Company	Afamitresgene autoleucel / Tecelra / Adaptimmune, LLC.
Date of approval	8/1/24
Drug Class (Mechanism of Action if novel agent)	Cellular immunotherapy – genetically modified autologous T cell immunotherapy that consists of CD4 and CD8 positive T cells transduced with a self-inactivating lentiviral vector to express greater affinity on T-cell receptor (TCR) specific for human MAGE-A4 on cells surfaces. The TCR recognizes an HLA-A*02 restricted MAGE-A4 peptide. Activation of afamitresgene autoleucel results in T cell proliferation, cytokine secretion and killing of MAGE-A4/HLA-A*02 expressing synovial sarcoma cells.
Indication	For the treatment of adults with unresectable or metastatic synovial sarcoma who have received prior chemotherapy, are HLA-A*02:01, -A*02:02P, -A*02:03P, or -A*02:06P positive and whose tumor expresses the MAGE-A4 antigen
Comparative agent – Therapeutic interchange?	N/A
Dosage forms/strengths	Solution for intravenous infusion: 2.68 x 10 ⁹ to 10 x 10 ⁹ MAGE-A4 cell receptor (TCR) positive T cells
Common Dose/sig	One time dose IV infusion of 2.68 x 10 ⁹ to 10 x 10 ⁹ MAGE-A4 T cell receptor (TCR) positive T cells.
DEA Schedule	N/A
Date of market availability	Available
Similar Medication Names	axicabtagene ciloleucel, betibeglogene autotemcel, brexucabtagene autoleucel, ciltacabtagene autoleucel, elivaldogene autotemcel, exagamglogene autotemcel, idecabtagene vicleucel, lifileucel, sipuleucel-T, tisagenlecleucel, Tecentriq
Clinical Use Evaluation	
Common Adverse Effects	≥20%: cytokine release syndrome, nausea, vomiting, fatigue, infections, pyrexia, constipation, dyspnea, abdominal pain, non-cardiac chest pain, decreased appetite, tachycardia, back pain, hypotension, diarrhea, and edema
Severe Adverse Effects	≥5%: cytokine release syndrome and pleural effusion
Severe Drug-Drug Interactions	Avoid use of prophylactic systemic corticosteroids, as they may interfere with afamitresgene autoleucel activity
Severe Drug-Food Interactions	None known
Important Labs Values to assess prior to order entry or at point of clinical follow up.	Blood counts after infusion
Used in Pediatric Areas	Safety and effectiveness have not been established in pediatric patients
Renal or Hepatic Dosing	Hepatic and renal impairment studies were not conducted
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindication: do not use in adults who are heterozygous or homozygous for HLA-A*02:05P. Warnings and Precautions: Cytokine release syndrome (CRS) has been observed – during and following administration, monitor patients for signs and symptoms of CRS. Immune effector cell-associated neurotoxicity syndrome (ICANS) has been observed – During and following administration, monitor patients for signs and symptoms of ICANS. Prolonged severe cytopenia can occur – monitor blood counts Infections – can occur following administration. Monitor for signs and symptoms of infection before and after administration. Do not administer to patients with active infections and/or inflammatory disorders. Secondary malignancies or recurrence of cancer can occur.

	Hypersensitivity reactions can occur during administration. Potential for HIV nucleic acid test false-positive results may occur.
Special administration technique or considerations	Administer a lymphodepleting chemotherapy regimen of fludarabine 30 mg/m ² /day intravenously for 4 days starting on the seventh day before infusion (Day-7 to Day -4) and cyclophosphamide 600 mg/m ² /day intravenously for 3 days starting the seventh day before infusion (Day -7 to Day -5). Do not thaw until ready to use. Coordinate timing of thaw and infusion; administer within one hour after thawing. Premedicate with an H1-antihistamine and acetaminophen approximately 30-60 minutes prior to infusion. When administering, do not use a leukodepleting filter. Prime the tubing of the infusion set with 0.9% NaCl solution prior to infusion. Rinse infusion bag with approximately 50 mL 0.9% NaCl solution to ensure all product is delivered. Closely monitor for CRS during and following administration; patients must be monitored for at least 7 days at the healthcare facility.
Prepared by	Talia Moore
Source	Teclera (afamitresgene autoleucel) [prescribing information]. Philadelphia, PA: Adaptimmune, LLC; August 2024.

Vorasidenib / Voranigo / Servier Pharmaceuticals LLC	
Generic Name / Brand Name / Company	Vorasidenib / Voranigo / Servier Pharmaceuticals LLC
Date of approval	8/6/24
Drug Class (Mechanism of Action if novel agent)	Antineoplastic Agent, IDH1 and IDH2 Inhibitor
Indication	Treatment of adult and pediatric patients 12 years and older with Grade 2 astrocytoma or oligodendroglioma with a susceptible IDH1 or IDH2 mutation following surgery including biopsy, sub-total resection, or gross total resection
Comparative agent – Therapeutic interchange?	N/A
Dosage forms/strengths	Tablets: 10 mg and 40 mg
Common Dose/sig	Adults and pediatric patients weighing ≥40 kg: 40 mg orally once daily Pediatric patients weighing <40 kg: 20 mg orally once daily Dosage modifications are recommended for hepatotoxicity and Grade 3 and 4 adverse reactions
DEA Schedule	N/A
Date of market availability	Available
Similar Medication Names	Enasidenib, ivosidenib, olutasidenib, vandetanib, vemurafenib, vismodegib, vorapaxar, vorinostat
Clinical Use Evaluation	
Common Adverse Effects	≥15%: fatigue, headache, COVID-19, musculoskeletal pain, diarrhea, nausea
Severe Adverse Effects	Seizures; Grade 3 or 4 (≥2%) laboratory abnormalities: increased ALT, AST, and GGT, decreased neutrophils
Severe Drug-Drug Interactions	Strong and moderate CYP1A2 inhibitors: concomitant use may increase vorasidenib plasma concentrations Moderate CYP1A2 Inducers: concomitant use with CYP1A2 inducers and smoking tobacco may decrease vorasidenib plasma concentrations CYP3A Substrates: Concomitant use may decrease plasma concentrations of CYP3A substrates Hormonal contraception: concomitant use may decrease concentrations of hormonal contraceptives

Severe Drug-Food Interactions	None known
Important Labs Values to assess prior to order entry or at point of clinical follow up.	Prior to initiation blood chemistry and liver laboratory tests; every 2 weeks during the first 2 months of treatment, then monthly for the first 2 years of treatment: liver laboratory tests (AST, ALT, GGT, total bilirubin, and alkaline phosphatase)
Used in Pediatric Areas	Safety and effectiveness have not been established in patients younger than 12 years of age for any indication
Renal or Hepatic Dosing	No dosage adjustments if creatinine clearance >40 mL/min or mild to moderate hepatic impairment. Not studied in creatinine clearance ≤40 mL/min, renal impairment requiring dialysis, or severe hepatic impairment (Child-Pugh Class C); monitor for adverse reactions and modify the dose for adverse reactions as recommended.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Can cause hepatotoxicity, which can lead to hepatic failure, hepatic necrosis, and autoimmune hepatitis. Frequent liver laboratory tests must be monitored, and dose modifications, withhold, or discontinuation may be necessary. Can cause fetal harm when administered in pregnant women. Advise females of reproductive potential to use effective non hormonal contraception during treatment and for 3 months after the last dose. Advise male patients with female partners of reproductive potential to use effective contraception during treatment and for 3 months after the last dose.
Special administration technique or considerations	Swallow tablets whole with a glass of water, do not split, crush, or chew tablets. Take a dose at the same time every day. If a dose is missed within 6 hours of taking it, take the dose as soon as possible. If a dose is missed by more than 6 hours, take next dose at regular scheduled time. If patient vomits a dose, advise to take the next dose at the usual time.
Prepared by	Talia Moore
Source	Voranigo (vorasidenib) [prescribing information]. Boston, MA: Servier Pharmaceuticals LLC; August 2024.

Palopegteriparatide / Yorvipath / Ascendis Pharma Endocrinology, Inc.	
Generic Name / Brand Name / Company	Palopegteriparatide / Yorvipath / Ascendis Pharma Endocrinology, Inc.
Date of approval	8/9/24
Drug Class (Mechanism of Action if novel agent)	Parathyroid hormone analog
Indication	Treatment of hypoparathyroidism in adults
Comparative agent – Therapeutic interchange?	Parathyroid hormone
Dosage forms/strengths	Pen-injector containing 14 doses, supplied in 2-pen pack with 30 needles 168 mcg/0.56 mL pen, labeled doses of 6, 9, or 12 mcg 294 mcg/0.98 mL pen, labeled doses of 15, 18, or 21 mcg 420 mcg/1.4 mL pen, labeled doses of 24, 27, or 30 mcg
Common Dose/sig	Once daily subcutaneous dosage is individualized. Starting dose: 18 mcg once daily Titration: titrated in 3 mcg increments or decrements Maximum dose: 30 mcg once daily
DEA Schedule	N/A
Date of market availability	1 st quarter of 2025
Similar Medication Names	Palonosetron, Teriparatide

Clinical Use Evaluation	
Common Adverse Effects	>30%: Injection site reactions; >20%: Vasodilatory signs/symptoms (orthostatic hypotension, dizziness, palpitations, postural orthostatic tachycardia syndrome, presyncope, syncope, and vertigo), headache 7-10%: Diarrhea, back pain, hypercalcemia, oropharyngeal pain
Severe Adverse Effects	Hypercalcemia, hypocalcemia, orthostatic hypotension, potential risk of osteosarcoma
Severe Drug-Drug Interactions	Digoxin: concomitant use with digoxin may predispose patients to digitalis toxicity if hypercalcemia develops. Digoxin efficacy may be reduced if hypocalcemia is present. Monitor serum calcium and digoxin levels. Drugs that affect serum calcium may alter therapeutic response; measure serum calcium more frequently when used with these drugs.
Severe Drug-Food Interactions	None known
Important Labs Values to assess prior to order entry or at point of clinical follow up.	Prior: within two weeks before the first dose, confirm serum 2(OH) vitamin D is within normal range and albumin-corrected serum calcium is ≥ 7.8 mg/dL; Follow-up: measure serum calcium within 7-10 days after the first dose and any dose change.
Used in Pediatric Areas	Safety and effectiveness have not been established in pediatric patients
Renal or Hepatic Dosing	No dose adjustment is required in renal impairment; no dedicated hepatic impairment study has been conducted.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications: in patients with severe hypersensitivity to the medication or any of its excipients. Use only one injection to achieve the once daily recommended dosage. Using two injections to achieve the recommended once daily dosage increases the risk of unintended changes in serum calcium levels. Serious hypercalcemia and hypocalcemia have occurred; monitor. Monitor for orthostatic hypotension. May increase potential risk of osteosarcoma (a malignant bone tumor).
Special administration technique or considerations	Must be refrigerated until first use. Administer subcutaneously to the abdomen or front of the thigh. Rotate the injection site daily. Should be administered initially when the patient can sit or lie down because of the potential of orthostatic hypotension. Adjust doses of calcitriol and calcium supplements based on albumin-corrected serum calcium.
Prepared by	Talia Moore
Source	Yorvipath (Palopegteriparatide) [prescribing information]. Princeton, NJ: Ascendis Pharma Endocrinology; August 2024.

Nemolizumab-ilto / Nemluvio / Galderma Laboratories, L.P.	
Generic Name / Brand Name / Company	Nemolizumab-ilto / Nemluvio / Galderma Laboratories, L.P.
Date of approval	8/12/24
Drug Class (Mechanism of Action if novel agent)	Interleukin-31 Receptor Antagonist; Monoclonal Antibody
Indication	For the treatment of adults with prurigo nodularis
Comparative agent – Therapeutic interchange?	Dupilumab, an IL-4 and IL-13 antagonist
Dosage forms/strengths	For injection: single-dose prefilled dual chamber pen containing 30 mg of nemolizumab-ilto lyophilized powder and diluent, water for injection
Common Dose/sig	Adult patients weighing < 90 kg: initial dose of 60 mg (two 30 mg injections) subcutaneously, followed by 30 mg given every 4 weeks. Adult patients weighing ≥ 90 kg: initial dose of 60 mg (two 30 mg injections) subcutaneously, followed by 60 mg given every 4 weeks.
DEA Schedule	N/A
Date of market availability	Available at specialty pharmacies
Similar Medication Names	Nembutal
Clinical Use Evaluation	
Common Adverse Effects	≥1%: Headaches, atopic dermatitis, eczema, eczema nummular
Severe Adverse Effects	Allergic reaction
Severe Drug-Drug Interactions	Cytochrome P450 Substrates: monitor effects or concentration of substrate when initiating or discontinuing nemolizumab-ilto
Severe Drug-Food Interactions	None known
Important Labs Values to assess prior to order entry or at point of clinical follow up.	None stated
Used in Pediatric Areas	Safety and effectiveness have not been established in pediatric patients
Renal or Hepatic Dosing	No dosage adjustments required. No clinically significant difference in pharmacokinetics in mild to moderate renal or hepatic impairment. Effect of severe renal or hepatic impairment is unknown.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Avoid use of live vaccines during treatment Hypersensitivity – administer appropriate therapy and discontinue.
Special administration technique or considerations	Complete all age-appropriate vaccinations prior to treatment. Requires reconstitution. Administer subcutaneously into front upper thighs or abdomen; injection in upper arm should only be performed by caregiver or healthcare professional. Dispose of pen, without recapping, and cap in sharps disposal container.
Prepared by	Connor Hoffman
Source	Nemluvio (nemolizumab-ilto) [prescribing information]. Dallas, TX: Galderma Laboratories, L.P.; August 2024.

Seladelpar / Livdelzi / Gilead Sciences, Inc.	
Generic Name / Brand Name / Company	Seladelpar / Livdelzi / Gilead Sciences, Inc.
Date of approval	8/14/24
Drug Class (Mechanism of Action if novel agent)	Selective PPAR-delta agonist
Indication	For the treatment of primary biliary cholangitis (PBC) in combination with ursodeoxycholic acid (UCDA) in adults who have an inadequate response to UDCA, or as monotherapy in patients unable to tolerate UDCA. Limitations of use: Not recommended in patients who have or develop decompensated cirrhosis.
Comparative agent – Therapeutic interchange?	Elafibranor
Dosage forms/strengths	Capsules: 10 mg
Common Dose/sig	10 mg orally once daily
DEA Schedule	N/A
Date of market availability	2025
Similar Medication Names	Selexipag, Livtency, Livmarli
Clinical Use Evaluation	
Common Adverse Effects	≥5%: headache, abdominal pain, nausea, abdominal distension, and dizziness; <5%: dyspepsia, rash, alopecia, anemia, and cough
Severe Adverse Effects	Fractures
Severe Drug-Drug Interactions	OAT3 Inhibitors: Avoid concomitant use. Strong CYP2C9 Inhibitors: Avoid concomitant use. Rifampin: Monitor biochemical response (e.g., ALP and bilirubin) when patients initiate rifampin Dual Moderate CYP2C9 and Moderate to Strong CYP3A4 Inhibitors: Monitor closely for adverse effects. CYP2C9 Poor Metabolizers using Moderate to Strong CYP3A4 Inhibitors: Monitor more frequently for adverse effects. BCRP Inhibitors: Monitor closely for adverse effects. Bile Acid Sequestrants: Administer at least 4 hours before or 4 hours after taking a bile acid sequestrant, or at as great an interval as possible.
Severe Drug-Food Interactions	None known
Important Labs Values to assess prior to order entry or at point of clinical follow up.	Monitor liver laboratory tests prior to initiation and during therapy.
Used in Pediatric Areas	Safety and effectiveness have not been established in pediatric patients
Renal or Hepatic Dosing	No change in renal impairment; not studied in end stage renal disease. Not recommended in patients who have or develop decompensated cirrhosis; consider discontinuation if progress to moderate to severe hepatic impairment.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Fractures - Consider the risk of fracture and monitor bone health Liver test abnormalities - monitor Biliary Obstruction - Avoid use in patients with complete biliary obstruction Not recommended in patients who have or who develop decompensated cirrhosis (e.g., ascites, variceal bleeding, hepatic encephalopathy).
Special administration technique or considerations	Administer with or without food. Give 4 hours before or after 4 hours after bile acid sequestrants.
Prepared by	Connor Hoffman
Source	Livdelzi (seladelpar) [prescribing information]. Foster City, CA: Gilead Sciences, Inc.; August 2024.

Axatilimab-csfr/ Niktimvo / Incyte Corp.	
Generic Name / Brand Name / Company	Axatilimab-csfr/ Niktimvo / Incyte Corp.
Date of approval	8/14/24
Drug Class (Mechanism of Action if novel agent)	CSF-1R inhibitor
Indication	Treatment of chronic graft-versus-host disease after failure of at least 2 prior lines of systemic therapy in adults and pediatric patients weighing at least 40 kg
Comparative agent – Therapeutic interchange?	N/A
Dosage forms/strengths	Injection: 50 mg/mL solution in a single-dose vial
Common Dose/sig	0.3 mg/kg (maximum 35 mg) every 2 weeks
DEA Schedule	N/A
Date of market availability	1 st quarter Of 2025
Similar Medication Names	Axazolid
Clinical Use Evaluation	
Common Adverse Effects	>15%: increased AST, infection unspecified, increased ALT, decreased phosphate, decreased hemoglobin, viral infection, increased GGT, musculoskeletal pain, increased lipase, fatigue, increased amylase, increased calcium, increased CPK, increased ALP, nausea, headaches, diarrhea, cough, bacterial infection, pyrexia, dyspnea
Severe Adverse Effects	Infusion-related reactions, infection, musculoskeletal pain, fatigue, pyrexia, edema, nausea, diarrhea, headache, dyspnea, hypersensitivity, decreased appetite, hemorrhage; decreased hemoglobin, increased AST, ALT, GGT, lipase, or calcium
Severe Drug-Drug Interactions	CSF-1 and Interleukin (IL)-34 concentration increase by 20 times the approved dose if given together. A dose dependent reduction in non-classical monocytes has been witnessed.
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 prior to initiation; Monitor ALT, AST, ALP, CPK, amylase, and lipase prior to initiation, every 2 weeks for the first month, and every 1 to 2 months thereafter until abnormalities are resolved
Used in Pediatric Areas	Patients must weigh over 40 kg; safety and effectiveness have not been established in patients under 40 kg. Monitor bone growth.
Renal or Hepatic Dosing	No difference for mild to moderate renal impairment and for mild to moderate hepatic impairment. Effects on severe renal and hepatic impairment are unknown.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Embryo-Fetal Toxicity- advise females of reproductive potential to use effective contraception during treatment and for 30 days after last dose. Infusion-Related Reactions- stop or slow the infusion if symptoms occur.
Special administration technique or considerations	Administer diluted solution by intravenous infusion over 30 minutes through a dedicated infusion line that includes a sterile, low-protein binding 0.2-micron in-line or add-on polyethersulfone (PES) filter. After administration, flush the infusion line with 0.9% Sodium Chloride Injection. Adjust dose or infusion rate, withhold therapy, or discontinue for severe adverse effects.
Prepared by	Connor Hoffman
Source	Niktimvo (axatilimab-csfr) [prescribing information]. Incyte Corporation; August 2024.

Lazertinib / Lazcluze / Janssen Biotech, Inc.	
Generic Name / Brand Name / Company	Lazertinib / Lazcluze / Janssen Biotech, Inc.
Date of approval	8/19/24
Drug Class (Mechanism of Action if novel agent)	Antineoplastic Agent, EGFR Inhibitor, Tyrosine Kinase Inhibitor
Indication	In combination with amivantamab, is indicated for the first-line treatment of adult patients with locally advanced or metastatic NSCLC with EGFR exon 19 deletions or exon 21 L858R substitution mutations
Comparative agent – Therapeutic interchange?	Amivantamab, dacomitinib, erlotinib, gefitinib, osimertinib
Dosage forms/strengths	Tablets: 80 mg and 240 mg
Common Dose/sig	240 mg tablet orally once daily
DEA Schedule	N/A
Date of market availability	Available
Similar Medication Names	Lapatinib, larotrectinib, lenvatinib, lorlatinib
Clinical Use Evaluation	
Common Adverse Effects	≥20%: rash, nail toxicity, infusion-related reaction (amivantamab), musculoskeletal pain, edema, stomatitis, venous thromboembolism (VTE), paresthesia, fatigue, diarrhea, constipation, COVID-19, hemorrhage, dry skin, decreased appetite, pruritus, nausea, and ocular toxicity
Severe Adverse Effects	Common Grade 3 or 4 adverse reactions (>2%): rash, nail toxicity, infusion-related reactions, musculoskeletal pain, stomatitis, diarrhea, edema, fatigue, VTE; most common Grade 3 or 4 lab abnormalities (>2%): decreased albumin, sodium, potassium, hemoglobin, increased ALT, AST, GGT, and magnesium
Severe Drug-Drug Interactions	Strong and moderate CYP3A4 inducers: avoid use Certain BCRP substrates: monitor for adverse reactions associated with BCRP substrates
Severe Drug-Food Interactions	None known
Important Labs Values	Verify pregnancy status in females of reproductive potential.
Used in Pediatric Areas	Safety and effectiveness have not been established in pediatric patients
Renal or Hepatic Dosing	No dosage adjustments required in mild or moderate renal or hepatic impairment; has not been studied in severe renal impairment, end-stage renal disease, or severe hepatic impairment.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	VTE events can occur including deep venous thrombosis (DVT), and pulmonary embolism (PE). Administer anticoagulant prophylaxis to prevent VTE events for the first 4 months of treatment. Interstitial lung disease (ILD) and pneumonitis can occur. Dermatitis acneiform, pruritus, and dry skin can occur – consider prophylactic measures to reduce risk. Ocular toxicity including keratitis can occur. Can cause fetal harm if administered to a pregnant woman. Advise females of reproductive potential to use effective contraception during treatment and for 3 weeks after the last dose. Advise male patients with female partners of reproductive potential to use effective contraception during treatment and for 3 weeks after the last dose.
Special administration technique or considerations	Take once daily administered in combination with amivantamab with or without food. Administer any time prior to amivantamab when given on the same day. Swallow tablets whole. Do not crush, split, or chew.
Prepared by	Talia Moore
Source	Lazcluze (lazertinib) [prescribing information]. Horsham, PA: Janssen Biotech, Inc.; August 2024.