WASHINGTON STATE UNIVERSITY
College of Pharmacy and Pharmaceutical Sciences

Drug Information Center

Highlights of FDA Activities – 12/1/22 – 12/31/22

FDA Drug Safety Communications & Drug Information Updates:

COVID-19 Bivalent Vaccines Authorized for Children Down to 6 Months of Age 12/8/22
The FDA amended the Emergency Use Authorizations (EUAs) for the bivalent Moderna and Pfizer-BioNTech COVID-19 vaccines to include use in children down to 6 months of age. Children 6 months through 5 years who received the Moderna monovalent vaccine are eligible to receive a single booster of the updated bivalent Moderna vaccine after completing the primary series with the monovalent vaccine. Children 6 months through 4 years who have not begun the 3-dose primary series with the Pfizer-BioNTech vaccine will receive the bivalent Pfizer-BioNTech vaccine as the third dose following two doses with the monovalent vaccine. Those in this age group who have completed the 3-dose primary series with the monovalent Pfizer-BioNTech vaccine will not be eligible for a booster with the bivalent vaccine at this time.

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

DNA/RNA Preservation Kits, Dewei Medical Equipment Co.: Recall - Not Authorized by the FDA 12/8/22
Dewei Medical Equipment Co. DNA/RNA Preservation Kits used to detect SARS-CoV-2, influenza, avian influenza, hand, foot, and mouth disease, measles, norovirus, and rotavirus were recalled. The kits that were distributed in the USA are not approved, cleared, or authorized for use by the FDA and their use can result in false negative, false positive, or misinterpretation of results.

Detect Covid-19 Test, by Detect: Recall - Increased Chance for False Negative Results 12/14/22
Detect recalled three lots (HB264, HY263, HY264) of the Detect Covid-19 Test, because there is an increased chance that the tests may give false negative results. The manufacturer shipped 11,102 tests to customers from July 26, 2022 through August 26, 2022.

Allergenic Extract – Peanut (Arachis Hypogaea), ALK-Abello, Inc.: Recall – False Negative Results 12/20/22
ALK-Abello, Inc. recalled four lots (0004014634, 0004014635, 0004218744, 0004218745) of Allergenic Extract – Peanut (*Arachis hypogaea*) – For Diagnostic Use Only, due to postmarketing reports of false negative skin test results, including cases of life-threatening anaphylaxis from subsequent peanut exposure.

Quinapril Tablets, Lupin Pharmaceuticals: Recall - Potential Presence of N-Nitroso- Impurity 12/22/22
Lupin Pharmaceuticals recalled four lots (G102929, G100533, G100534, and G203071) of quinapril tablets due to the presence of a nitrosamine impurity, N-Nitroso-Quinapril. These lots were distributed between March 15, 2021 and September 1, 2022.

Vancomycin HCl Injection, USP 1.5 g /vial, Hospira: Recall – Visible Glass Particles 12/27/22
Hospira recalled one lot (33045BA) of vancomycin HCl injection USP 1.5 g single dose fliptop vial due to the presence of two glass particulates observed in a vial.

Daptomycin for Injection 350 mg and 500 mg/vial, Accord Healthcare: Recall – Product Mix-Up 12/27/22
Accord Healthcare recalled one lot of daptomycin for injection 500 mg and daptomycin for injection 350 mg/vial product contained in cartons imprinted with lot #R2200232, expiration 01/2025 following reports of vials labeled as the 500 mg strength found in cartons labeled as 350 mg.

Easy Care First Aid Burn Cream & First Aid Kits, GFA Production: Recall – Microbial Contamination 12/27/22
GFA Production (Xiamen) recalled one lot of Easy Care first aid AfterBurn cream 0.9 g single-use packets after FDA analysis revealed contamination with *Bacillus licheniformis* and *Bacillus sonorensis*. The packets were sold in boxes of 10 or packaged in first aid kits.

Dietary Supplement Recalls & Public Notifications

No notifications were issued in December regarding undeclared active ingredients or contaminants.

New Product Shortages	***Date Initially Posted***
Chlorothiazide Oral Suspension	12/20/22
Difluprednate Ophthalmic Emulsion	12/21/22

Brand Name or Sole Source Product Discontinuations/Withdrawals	***Date Posted***
Ranolazine extended-release tablets (Ranexa, Gilead); remains available from generic manufacturers	12/22/22

Removed/Restricted Indications:	***Description***	***Date Approved***
Atezolizumab / Tecentriq / Genentech	FDA removed the indication for treatment of adult patients with locally advanced or metastatic urothelial carcinoma.	12/2/22
Niraparib / Zejula / GlaxoSmithKline, LLC.	FDA restricted the indication for maintenance treatment of patients with recurrent ovarian cancer to those with a germline BRCA mutation only.	12/9/22
Pembrolizumab / Keytruda / Merck & Co, Inc.	FDA restricted the indication for an additional 400 mg dosage every 6 weeks to Classical Hodgkin Lymphoma and Primary Mediastinal Large B-Cell Lymphoma only.	12/16/22
Rucaparib / Rubraca / Clovis Oncology, Inc.	FDA limited the indication of maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy to those with a deleterious BRCA mutation (germline and/or somatic)	12/21/22

New Drug Approvals:	***Description (See Attached Drug Summaries)***	***Date Approved***
Olutasidenib / Rezlidhia / Rigel Pharmaceuticals	An IDH1 inhibitor indicated for the treatment of adult patients with relapsed or refractory acute myeloid leukemia (AML) with a susceptible IDH1 mutation as detected by an FDA-approved test.	12/1/22
Adagrasib / Krazati / Mirati Therapeutics, Inc.	A KRAS inhibitor indicated for the treatment of adult patients with KRAS G12C-mutated locally advanced or metastatic non-small cell lung cancer (NSCLC), as determined by an FDA approved test, who have received at least one prior systemic therapy.	12/12/22
Nadofaragene firadenovec-vncg / Adstiladrin / Ferring Pharmaceuticals	A non-replicating adenoviral vector-based gene therapy indicated for the treatment of adult patients with high-risk Bacillus Calmette Guérin (BCG)-unresponsive non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) with or without papillary tumors.	12/16/22
Lenacapavir / Sunlenca / Gilead Sciences, Inc.	A human immunodeficiency virus-1 (HIV-1) capsid inhibitor indicated for the treatment of HIV-1 infection in heavily treatment-experienced adults with multidrug resistant HIV-1 infection failing their current antiretroviral regimen due to resistance, intolerance, or safety considerations, in combination with other antiretroviral(s).	12/22/22

New Drug Approvals (cont.):	***Description (See Attached Drug Summaries)***	***Date Approved***
Mosunetuzumab-axgb / Lunsumio / Genentech	Bispecific CD-20 directed CD3 T-cell engager indicated for the treatment of adult patients with relapsed or refractory follicular lymphoma after two or more lines of systemic therapy	12/22/22
Xenon Xe 129 hyperpolarized / Xenoview / Polarean	Hyperpolarized contrast agent for use with MRI for evaluation of lung ventilation in adult and pediatric patients 12 years and older	12/23/22
Ublituximab / Briumvi / Tg Therapeutics	CD20-directed cytolytic antibody for the treatment of relapsing forms of multiple sclerosis in adults	12/28/22
Anacaulase-bcdb / NexoBrid / Vericel Corporation	Topical enzyme for eschar removal in adults with deep partial thickness and/or full thickness thermal burns	12/28/22

New Indications:	***Description***	***Date Approved***
Atezolizumab / Tecentriq / Genentech, Inc.	As a single agent for the treatment of adult and pediatric patients 2 years and older with unresectable or metastatic alveolar soft part sarcoma	12/9/22
Palbociclib / Ibrance / Pfizer, Inc.	Indication expanded to include pre-/perimenopausal women in the indication for the treatment of patients with HR-positive/HER2-negative advanced or metastatic breast cancer in combination with an aromatase inhibitor as initial endocrine-based therapy	12/13/22
Capecitabine / Xeloda / Genentech, Inc.	Several new indications and updates to current indications: • Adjuvant treatment of patients with Stage III colon cancer as a single agent or as a component of a combination chemotherapy regimen • Treatment of patients with advanced or metastatic breast cancer in combination with docetaxel after disease progression on prior anthracycline-containing chemotherapy • Treatment of adults with unresectable or metastatic gastric, esophageal, or gastroesophageal junction cancer as a component of a combination chemotherapy regimen • Treatment of patients with advanced or metastatic breast cancer as a single agent if an anthracycline- or taxane-containing chemotherapy is not indicated • Treatment of patients with unresectable or metastatic colorectal cancer as a single agent or as a component of a combination chemotherapy regimen • Adjuvant treatment of adults with pancreatic adenocarcinoma as a component of a combination chemotherapy regimen • Perioperative treatment of adults with locally advanced rectal cancer as a component of chemoradiotherapy • Treatment of adults with HER2-overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma who have not received prior treatment for metastatic disease as a component of a combination regimen	12/14/22
Pemetrexed / Pemfexy / Eagle Pharmaceuticals, Inc.	In combination with pembrolizumab and platinum chemotherapy for the initial treatment of patients with metastatic non-squamous non-small cell lung cancer, with no EGFR pr ALK genomic tumor aberrations	12/14/22

New Indications (cont.):	***Description***	***Date Approved***
Cariprazine / Vraylar / Allergan USA, Inc.	As adjunctive therapy to antidepressants for the treatment of major depressive disorder in adults	12/16/22
Pafolacianine / Cytalux / On Target Laboratories, Inc.	For intraoperative identification of malignant and non-malignant pulmonary lesion in adult patients with known or suspected cancer in the lung	12/16/22
Abaloparatide / Tymlos / Radius Health, Inc.	Treatment to increase bone density in men with osteoporosis at high risk for fracture or who have failed or are intolerant to other available osteoporosis therapy	12/19/22
Tocilizumab / Actemra / Genentech, Inc.	For the treatment of hospitalized adult patients with COVID-19 who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO); remains authorized for emergency use in pediatric patients through an Emergency Use Authorization	12/22/22
Ceftazidime and avibactam / Avycaz / Allergan	For the treatment of hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia (HABP/VABP) to include pediatric patients aged 3 months to less than 18 years.	12/20/22
Semaglutide / Wegovy / Novo Nordisk	Indication expanded to include chronic weight management in pediatric patients aged 12 years and older with an initial BMI at the 95th percentile or greater standardized for age and sex (obesity)	12/23/22

New Dosage Forms or Formulation:	***Description***	***Date Approved***
Adalimumab-aacf / Idacio / Fresenius Kabi, LLC	Biosimilar to Humira (adalimumab) with a projected launch of July 2023	12/13/22
Sodium phenylbutyrate / Olpruva / Acer Therapeutics Inc.	Oral suspension as pellets in packets for reconstitution (2, 3, 4, 5, 6, and 6.67 g); adjunctive therapy to standard of care for the chronic management of adult and pediatric patients weighing 20 kg or greater and with a body surface area of at least 1.2 m2, with urea cycle disorders involving deficiencies of carbamylphosphate synthetase, ornithine transcarbamylase, or argininocuccinic acid synthetase.	12/22/22

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Olutasidenib / Rezlidhia / Rigel Pharmaceuticals	
Generic Name / Brand Name / Company	Olutasidenib / Rezlidhia / Rigel Pharmaceuticals
Date of approval	12/1/22
Drug Class (Mechanism of Action if novel agent)	IDH1 Inhibitor
Indication	Treatment of adult patients with relapsed or refractory acute myeloid leukemia (AML) with a susceptible IDH1 mutation as detected by an FDA-approved test.
Comparative agent – Therapeutic interchange?	Ivosidenib (Tibsovo)
Dosage forms/strengths	Oral capsules: 150 mg
Common Dose/sig	Take 150 mg orally twice daily, until disease progression or unacceptable toxicity
DEA Schedule	N/A
Date of market availability	Available
Similar Medication Names	Ivosidenib, Rezamid
Clinical Use Evaluation	
Common Adverse Effects	>20%: aspartate aminotransferase increased, alanine aminotransferase increased, potassium decreased, sodium decreased, alkaline phosphatase increased, nausea, creatinine increased, fatigue/malaise, arthralgia, constipation, lymphocytes increased, bilirubin increased, leukocytosis, uric acid increased, dyspnea, pyrexia, rash, lipase increased, mucositis, diarrhea and transaminitis
Severe Adverse Effects	Differentiation syndrome and hepatotoxicity
Severe Drug-Drug Interactions	Avoid concomitant use of olutasidenib with strong or moderate CYP3A inducers and sensitive CYP3A substrates.
Severe Drug-Food Interactions	The mean Cmax increased by 191% and AUC increased by 83% following administration of a single 150 mg dose of olutasidenib with a high-fat meal in healthy subjects; take on an empty stomach
Important Labs Values to assess prior to order entry or at point of clinical follow up.	Assess blood counts, and blood chemistries including liver function tests prior to initiation at least once weekly for the first two months; once every other week for the third month; once in the fourth month, and once every other month for the duration of therapy.
Used in Pediatric Areas	Not established.
Renal or Hepatic Dosing	No dosage modification is recommended for patients with mild to moderate renal or hepatic impairment. The recommended dosage has not been established in patients with severe renal or hepatic impairment. Dose modifications are advised for drug-induced hepatotoxicity.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Black Box Warning: Differentiation Syndrome Warning: Hepatotoxicity
Special administration technique or considerations	Take on an empty stomach at least 1 hour before or 2 hours after a meal. Take at the same time each day. Swallow tablets whole. For patietns without disease progression or unacceptable toxicity, continue treatment for at least 6 months to allow time for response.
Prepared by	Samuel Nahulu
Source	*Rezlidhia* (olutasidenib) [prescribing information]. South San Francisco, CA: Rigel Pharmaceuticals, Inc.; December 2022.

Adagrasib / Krazati / Mirati Therapeutics, Inc.	
Generic Name / Brand Name / Company	Adagrasib / Krazati / Mirati Therapeutics, Inc.
Date of approval	12/12/22
Drug Class (Mechanism of Action if novel agent)	KRAS inhibitor
Indication	Treatment of adult patients with KRAS G12C-mutated locally advanced or metastatic non-small cell lung cancer (NSCLC), as determined by an FDA approved test, who have received at least one prior systemic therapy
Comparative agent – Therapeutic interchange?	Sotorasib
Dosage forms/strengths	Tablets: 200 mg
Common Dose/sig	600 mg taken orally twice daily
DEA Schedule	N/A
Date of market availability	Unknown
Similar Medication Names	None
Clinical Use Evaluation	
Common Adverse Effects	>25%: nausea, diarrhea, vomiting, fatigue, musculoskeletal pain, hepatotoxicity, renal impairment, edema, dyspnea, and decreased appetite
Severe Adverse Effects	Gastrointestinal adverse effects, QTc interval prolongation, hepatotoxicity, and interstitial lung disease/pneumonitis
Severe Drug-Drug Interactions	Strong CYP3A4 inducers, sensitive CYP3A4, CYP2C9, CYP2D6, or P-gp substrates, and drugs that prolong the QT interval
Severe Drug-Food Interactions	Not assessed
Important Labs Values to assess prior to order entry or at point of clinical follow up.	Monitor liver function tests prior to initiation, monthly for 3 months, and then as clinically indicated. Monitor ECG and electrolytes in patients at risk for arrhythmias, and in patients taking QT prolonging medications.
Used in Pediatric Areas	The safety and efficacy have not been established in pediatric patients
Renal or Hepatic Dosing	Dosage adjustments not required in mild to severe renal or hepatic impairment; adjustments required for drug-induced hepatotoxicity
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications - None Warnings and Precautions - Gastrointestinal adverse events - QTc interval prolongation - Hepatotoxicity - Interstitial lung disease/pneumonitis
Special administration technique or considerations	Can be administered with or without food. Swallow tablets whole. Take at the same time each day.
Prepared by	Brittney Kessel
Source	*Krazati* (adagrasib) [prescribing information]. San Diego, CA: Mirati Therapeutics, Inc.; December 2022.

Nadofaragene firadenovec-vncg / Adstiladrin / Ferring Pharmaceuticals	
Generic Name / Brand Name / Company	Nadofaragene firadenovec-vncg / Adstiladrin / Ferring Pharmaceuticals
Date of approval	12/16/22
Drug Class (Mechanism of Action if novel agent)	Recombinant adenovirus serotype 5 vector containing a transgene encoding the human interferon alfa-2b (IFNα2b). Results in cell transduction and transient local expression of the IFNα2b protein that is anticipated to have anti-tumor effects
Indication	Treatment of adult patients with high-risk Bacillus Calmette Guérin (BCG)-unresponsive non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) with or without papillary tumors.
Comparative agent – Therapeutic interchange?	None
Dosage forms/strengths.	Suspension for intravesical instillation: 3 x 10^{11} viral particles (vp)/mL in 20 mL vials, packaged in cartons of 4 vials
Common Dose/sig	75 mL instilled intravesically once every 3 months
DEA Schedule	N/A
Date of market availability	Second half of 2023
Similar Medication Names	Adcentris, Advil, Astelin, nadolol
Clinical Use Evaluation	
Common Adverse Effects	>10%: glucose increased, instillation site discharge, triglycerides increased, fatigue, bladder spasm, micturition, creatinine increased, hematuria, phosphate decreased, chills, pyrexia, and dysuria.
Severe Adverse Effects	Coronary artery disease and hematuria
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 efficacy have not been established in pediatric patients
Renal or Hepatic Dosing	No dosage adjustment required.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications - Hypersensitivity to interferon alfa or any component of the product Warnings and Precautions - Risk of muscle invasive or metastatic bladder cancer with delayed cystectomy - Risk of disseminated adenovirus infection
Special administration technique or considerations	Premedication with an anticholinergic is recommended before each instillation. The product should be left in the bladder for 1 hour following instillation. During dwell time, the patient should be repositioned every 15 minutes to maximize bladder surface exposure. Voided urine must be disinfected for 30 minutes with an equal volume of virucidal agent before flushing the toilet.
Prepared by	Brittney Kessel
Source	*Adstiladrin* (nadofaragene firadenovec-vncg) [prescribing information]. Kastrup, Denmark: Ferring Pharmaceuticals; December 2022.

Lenacapavir / Sunlenca / Gilead Sciences, Inc.	
Generic Name / Brand Name / Company	Lenacapavir / Sunlenca / Gilead Sciences, Inc.
Date of approval	12/22/22
Drug Class (Mechanism of Action if novel agent)	A HIV-1 capsid inhibitor – interferes with capsid-mediated cellular uptake, virus assembly and release, and capsid core formation.
Indication	Treatment of HIV-1 infection in heavily treatment-experienced adults with multidrug resistant HIV-1 infection failing their current antiretroviral regimen due to resistance, intolerance, or safety considerations, in combination with other antiretroviral(s).
Comparative agent – Therapeutic interchange?	None
Dosage forms/strengths.	Tablets: 300 mg Injection: 463.5 mg/1.5 mL (309 mg/mL) in single-dose vials
Common Dose/sig	There are two recommended dosing regimens: - Option 1: 927 mg SQ and 600 mg orally on day 1, 600 mg orally on day 2, and 927 mg SQ every 6 months (26 ± 2 weeks) thereafter - Option 2: 600 mg orally on days 1 and 2, 300 mg orally on day 8, 927 mg SQ on day 15 and every 6 months (26 ± 2 weeks) thereafter
DEA Schedule	N/A
Date of market availability	January 2023
Similar Medication Names	Glecaprevir, ledipasvir
Clinical Use Evaluation	
Common Adverse Effects	≥3%: nausea and injections site reactions
Severe Adverse Effects	Injection site reactions
Severe Drug-Drug Interactions	Strong or moderate CYP3A inducers and combined P-gp, UGT1A1, and strong CYP3A inhibitors
Severe Drug-Food Interactions	None known
Important Labs Values to assess prior to order entry or at point of clinical follow up.	CD4 cell counts, HIV viral load
Used in Pediatric Areas	Safety and efficacy have not been established in pediatric patients
Renal or Hepatic Dosing	No dosage adjustments are recommended in mild, moderate, or severe renal impairment nor in mild or moderate hepatic impairment
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications: - Concomitant use with strong CYP3A inducers Warnings & Precautions: - Immune reconstitution syndrome - Non-adherence leads to development of resistance - Injection site reactions
Special administration technique or considerations	The SQ injection is for administration into the abdomen by a healthcare professional. Tablets may be taken with or without food.
Prepared by	Brittney Kessel
Source	*Sunlenca* (lenacapavir) [prescribing information]. Foster City, CA: Gilead Sciences, Inc.; December 2022.

Mosunetuzumab-axgb / Lunsumio / Genentech	
Generic Name / Brand Name / Company	Mosunetuzumab-axgb / Lunsumio / Genentech
Date of approval	12/22/22
Drug Class (Mechanism of Action if novel agent)	Bispecific CD-20 directed CD3 T-cell engager
Indication	Treatment of adult patients with relapsed or refractory follicular lymphoma after two or more lines of systemic therapy
Comparative agent – Therapeutic interchange?	First-In-Class, Blinatumomab / Blincyto / Amgen
Dosage forms/strengths.	Injection: 1 mg/mL solution in a single-dose vial; 30 mg/30 mL solution in a single-dose vial.
Common Dose/sig	Cycle 1 Day 1, 8, and 15, administer 1 mg, 2 mg and 60 mg of mosunetuzumab-axgb respectively. Cycle 2 Day 1 administer 60 mg of mosunetuzumab-axgb. Cycle 3+ Day 1 administer 30 mg of mosunetuzumab-axgb.
DEA Schedule	N/A
Date of market availability	First quarter 2023
Similar Medication Names	Motavizumab, Monalizumab, Moxetumomab pasudotox
Clinical Use Evaluation	
Common Adverse Effects	≥ 20%: cytokine release syndrome, fatigue, rash, pyrexia, and headache.
Severe Adverse Effects	Severe adverse effects can include severe cytokine release syndrome, serious neurologic toxicity, serious or fatal infections, serious or severe cytopenia's, serious or severe tumor flares, and/or embryo-fetal toxicity.
Severe Drug-Drug Interactions	No clinical studies evaluating the drug interaction potential of mosunetuzumab-axgb have been conducted. Causes release of cytokines that may suppress activity of CYP450 enzymes, resulting in increased exposure of CYP450 substrates. Monitor for toxicity or concentrations of drugs that are CYP450 substrates where minimal concentration changes may lead to serious adverse reactions.
Severe Drug-Food Interactions	None known
Important Labs Values to assess prior to order entry or at point of clinical follow up.	Lymphocyte counts, serum phosphate levels, glucose levels, neutrophil counts, uric acid levels, white blood cell count, hemoglobin and platelets.
Used in Pediatric Areas	Safety and efficacy not established in pediatric patients.
Renal or Hepatic Dosing	No dosage adjustment required in mild to moderate renal impairment or mild hepatic impairment. The effects of severe renal impairment (CrCL 15 to 29 mL/min) or moderate to severe hepatic impairment (total bilirubin greater than 1.5 times ULN with any AST) on the pharmacokinetics of mosunetuzumab-axgb are unknown.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Cytokine release syndrome. Treatment with mosunetuzumab-axgb should be initiated with a step-up dosing schedule to reduce the risk of cytokine release syndrome. Mosunetuzumab-axgb should be withheld until cytokine release syndrome resolves or permanently discontinued based on severity.
Special administration technique or considerations	Premedicate to reduce the risk of cytokine release syndrome and infusion-related reactions. Administer as an intravenous infusion only. Do not use an in-line filter to administer. Do not mix with or administer mosunetuzumab-axgb through the same infusion line as other medicinal products. When diluting mosunetuzumab-axgb in the infusion bag, do not shake the bag; gently and slowly invert the bag.
Prepared by	Samuel Nahulu
Source	*Lunsumio* December 2022. *Lunsumio* (Mosunetuzumab-axgb) [prescribing information]. South San Francisco, CA: Genentech, Inc.; December 2022.

Ublituximab / Briumvi / Tg Therapeutics	
Generic Name / Brand Name / Company	Ublituximab / Briumvi / Tg Therapeutics
Date of approval	12/28/2022
Drug Class (Mechanism of Action if novel agent)	CD20-directed cytolytic antibody
Indication	Treatment of relapsing forms of multiple sclerosis in adults
Comparative agent – Therapeutic interchange?	Ocrelizumab, Ofatumumab
Dosage forms/strengths.	Injection: 150 mg/6 mL in a single-dose vial
Common Dose/sig	150 mg IV infusion as a single dose, initially. A second 450 mg IV infusion is administered 2 weeks later. Then, 450 mg IV infusion at 24 weeks following the first infusion, and every 24 weeks after that.
DEA Schedule	N/A
Date of market availability	Q1 2023
Similar Medication Names	Obiltoxaximab
Clinical Use Evaluation	
Common Adverse Effects	>10%: infection, infusion related reactions, extremity pain, insomnia, fatigue
Severe Adverse Effects	Infection, hepatitis B exacerbation, PML due to JCV infection (risk)
Severe Drug-Drug Interactions	Vaccination with live-attenuated or live vaccines is not recommended during treatment or until B-cell repletion following discontinuation; administrator all vaccines at least 4 weeks prior to initiation for live/live attenuated vaccines at 2 weeks prior for non-live vaccines.
Severe Drug-Food Interactions	N/A
Important Labs Values to assess prior to order entry or at point of clinical follow up.	Hepatitis B serology, serum IgG concentrations, pregnancy testing
Used in Pediatric Areas	Safety and efficacy have not been established.
Renal or Hepatic Dosing	No adjustment needed for mild impairment. Effect of moderate to severe renal or hepatic impairment is unknown
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications: Active hepatitis B infection, history of life-threatening infusion reaction to ublituximab Withhold ublituximab and perform an appropriate diagnostic evaluation at the first sign or symptom of PML
Special administration technique or considerations	Premedicate with a corticosteroid and an antihistamine before each dose. Infusion duration varies from 4 hours for the first infusion to 1 hour for later infusions. Monitor patients closely during and for at least 1 hour after the first 2 infusions; monitoring after subsequent infusions is at physician discretion unless an infusion reaction or hypersensitivity has been observed. Infusion reactions may occur up to 24 hours after the infusion.
Prepared by	Ryan Anderson
Source	Briumvi (ublituximab-xiiy) injection package insert. Morrisville, NC: TG Therapeutics, Inc.; December 2022.

Anacaulase-bcdb / NexoBrid / Vericel Corporation	
Generic Name / Brand Name / Company	Anacaulase-bcdb / NexoBrid / Vericel Corporation
Date of approval	12/28/22
Drug Class (Mechanism of Action if novel agent)	Topical enzyme: dissolves burn would eschar. The mechanism by which this happens has not been identified.
Indication	Eschar removal in adults with deep partial thickness and/or full thickness thermal burns
Comparative agent – Therapeutic interchange?	N/A
Dosage forms/strengths.	Topical gel: 8.8% - 2 g of lyophilized powder (containing 1.94 grams of anacaulase-bcdb) mixed in 20 g gel vehicle per 1% body surface area (BSA) - 5 g lyophilized powder (containing 4.85 grams of anacaulase-bcdb) mixed in 50 g gel vehicle per 2.5% BSA.
Common Dose/sig	Apply to clean, moist wound bed free of burned epidermis layer and blisters, and cover with an occlusive film dressing for 4 hours.
DEA Schedule	N/A
Date of market availability	Anticipated in the second quarter of 2023
Similar Medication Names	Anacin, Anacaine, Brimonidine, Bridion, Oxybryta, Trexbrom, Nexa Plus, Noxipak, Nexplanon, Lanacane, Cellulase, Clavulanate, Inclisiran, Ony-Clear, Onglyza, Inclisiran
Clinical Use Evaluation	
Common Adverse Effects	>10%: pruritus and pyrexia
Severe Adverse Effects	Hypersensitivity reactions
Severe Drug-Drug Interactions	None known
Severe Drug-Food Interactions	N/A
Important Labs Values to assess prior to order entry or at point of clinical follow up.	None
Used in Pediatric Areas	Safety and efficacy not established
Renal or Hepatic Dosing	No dosage adjustments
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications: - Hypersensitivity to anacaulase, bromelain, pineapples, or any component of the formulation - Known hypersensitivity to papayas or papain because of the risk of cross-sensitivity Warnings and Precautions: - Not recommended for use in wounds where medical devices (implants, pacemakers ect.) or vital structures (large vessels, ect.) maybe exposed. - Avoid use in patients with uncontrolled disorders of coagulation - Use with caution in patients on anticoagulant therapy or other drugs affection coagulation and in patients with low platelet counts and increase risk of bleed from other causes. - Monitor for signs and symptoms of abnormal bleeding.
Special administration technique or considerations	- Apply ointment to healthy skin in the surrounding are to prevent damage to non-eschar tissue.

	- Must be administered in a healthcare setting with proper analgesia and/or anesthesia. - Prepare next to patient bedside within 15 minutes of intended use. - Initial application on up to 15% body surface area (BSA). - May apply for a second treatment 24 hours later if needed. - Total use should not exceed 20% BSA.
Prepared by	Ciera Sitton
Source	NexoBrid (anacaulase-bcdb) topical gel [prescribing information]. Cambridge, MA: Vericel Corporation; December 2022.