Highlights of FDA Activities – 12/1/23 – 12/31/23

FDA Drug Safety Communications & Drug Information Updates:

Counterfeit Ozempic (Semaglutide) found in U.S. Drug Supply Chain. 12/21/23
The FDA warned consumers not to use counterfeit Ozempic Injections and advised pharmacies and health care practitioners and patients not to distribute, use, or sell product labeled with lot number NAR0074 and serial number 430834149057. Thousands of units of the product have been seized. The FDA and manufacturer of Ozempic (Novo Nordisk) are testing the seized products and have not released information about the drug's safety, identity, or quality yet. There are 5 reported adverse events from this lot, all of which are commonly known adverse effects to Ozempic: vomiting, diarrhea, abdominal pain, and constipation.

Labeling Updates for Promethazine Hydrochloride Injection Products 12/27/2023
FDA alerted health care professionals to labeling updates intended to further reduce the risk of severe chemical irritation/damage to tissues from intravenous administration of promethazine HCl injection. FDA is recommending that promethazine HCl is to be administered via deep intramuscular injection. If promethazine HCl must be administered IV, then follow the updated labeling to dilute the product for intravenous infusion.

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

Alaris Infusion Pumps, Becton Dickinson/Carefusion: Recall – Syringe Compatibility 12/1/23
Becton Dickinson/Carefusion recalled Alaris Syringe Module, Alaris PCU and PCA Module pumps due to compatibility issues with the Cardinal Health Monoject syringes (see November newsletter for syringe recall). These pumps are validated for use with 'Monoject' syringes, however, the changes dimension of the Cardinal Monoject syringes compared to the Covidien Monoject syringes resulted in a new Monoject syringe that has not been validated for use with these pumps. With the new syringes the pump may refuse to operate or incorrectly estimate the volume of liquid in the syringe resulting in over or under infusion. Thirteen reported injuries have been reported. The Cardinal syringes should not be used with the pumps and the list of compatible syringes and modules should be replaced with the new list provided by Becton Dickinson.

Sapphire Infusion Pumps, Eitan Medical: Recall – Failure to Detect Air in Line 12/1/23
Eitan Medical Ltd. recalled Sapphire Infusion Pumps running software version Rev 16.10 due to software issues that may result in failure to detect air in the line when running on battery power. A new software version will correct the problem. In the meantime, the pumps should be connected to continuous AC power and an air-eliminating filter should be added to the device.

Covidien and Cardinal Health Branded Urology and Operating Room Kits, Nurse Assist LLC: Recall – Lack of Sterility Assurance 12/5/23
Cardinal Health recalled Covidien and Cardinal Health brand urology and operating room kits and trays containing 0.9% sodium chloride irrigation USP and sterile water for irrigation USP supplied by Nurse Assist due to potential for lack of sterility assurance.

Vigabatrin Oral Solution, InvaGen Pharmaceuticals: Recall – Leaking Sachets 12/11/23
InvaGen Pharmaceuticals recalled one lot (NB301030, expiry 03/2025) of vigabatrin for oral solution USP 500 mg/sachet (NDC 6909-7964-53) due to seal integrity issues allowing powder to leak from the pouch.

Kits/Trays Containing Sterile Water Products, Busse Hospital Disposables: Recall—Potential Lack of Sterility 12/22/23

Busse Hospital Disposables recalled medical device kits and trays containing one Nurse Assist part 6240, Stericare 100 mL Sterile Saline Bottles. This is in response to Nurse Assist LLC's recall on 11/6/2023 due to lack of sterility assurance.

Americaine 20% Benzocaine Topical Anesthetic Spray, Insight Pharmaceuticals; Recall — Benzene 12/27/2023e

Insight Pharmaceuticals recalled one lot of Americaine 20% benzocaine topical anesthetic spray (lot 1A16420) due to a low level of benzene being present in the propellant when sprayed.

Bleomycin for Injection, USP 15 Units Single Dose ONCO-TAIN Glass Fliptop Vial, Hospira Inc.: Recall — Presence of Glass Particulate Matter 12/27/2023

Hospira Inc. recalled one lot of bleomycin for injection, USP 15 units single dose ONCO-TAIN glass fliptop vial (LOT BL12206A) due to a confirmed report of a glass particulate being present in a vial.

4.2% Sodium Bicarbonate Injection, 8.4% Sodium Bicarbonate Injection, and Atropine Sulfate Injection, Hospira Inc.: Recall — Presence of Glass Particulate Matter 12/27/2023

Hospira Inc. recalled 4.2% sodium bicarbonate injection (USP ABBOJECT glass syringe, 5 mEq/10 mL, lot GX1542), 8.4% sodium bicarbonate injection (USP Lifeshield ABBOJECT glass syringe, 50 mEq/50 mL, lot HA7295), and atropine sulfate injection (USP Lifeshield ABBOJECT glass syringe, 1 mg/10 mL, lot GY2496) due to glass particulate being present in product inspection.

Dietary Supplement Recalls & Public Notifications

Notifications were issued regarding undeclared active ingredients or contaminants in the following products. Patients are advised not to purchase or use these products.

Product	***Promoted Use***	***Undeclared Ingredient(s) or Contaminants***
Govvi WOW!	Weight loss	DMAA[1]
Himalayan Pain Relief Tea, WS Global*	Pain relief	Dexamethasone, diclofenac
Noto ginseng Formula Special Gout Granule*	Gout	Dexamethasone, diclofenac
Ram It	Sexual enhancement	Sildenafil
Schwinnng	Sexual enhancement	Nortadalafil (structurally similar to tadalafil)
Sustain	Sexual enhancement	Avanafil, tadalafil
TO THE MOON	Sexual enhancement	Sildenafil
T XTRA Strength Test Booster	Sexual enhancement, energy booster	Tadalafil
Wild Bull	Sexual enhancement	Nortadalafil

*Recalled

[1]DMAA, also known as 1,3-dimethylamylamine, 1,4-dimethylamylamine, or methylhexanamine, or "geranium extract" use can elevate blood pressure

Brand Name or Sole Source Product Discontinuations/Withdrawals	***Date Posted***
Atropine sulfate ophthalmic ointment 1% (Bausch & Lomb); ophthalmic solutions remain available	12/6/23
Testosterone gel, metered (Fortesta, Endo): generics remain available	12/7/23

New Drug Approvals:	***Description (See Attached Drug Summaries)***	***Date Approved***
Iptacopan / Fabhalta / Novartis Pharmaceuticals Corporation	Complement factor B inhibitor for the treatment of adults with paroxysmal nocturnal hemoglobinuria	12/5/23
Exagamglogene autotemcel / Casgevy / Vertex Pharmaceuticals	Cell based gene therapy using CRISPR/Cas9 gene editing for the treatment of sickle cell disease in patients 12 years and older with recurrent vaso-occlusive crises	12/8/23
Lovotibeglogene autotemcel / Lyfgenia / bluebird bio-Inc.	Cell based gene therapy using lentiviral vector for treatment of sickle cell disease in patients 12 years and older with a history of vaso-occlusive events	12/8/23
Eplontersen / Wainua / AstraZeneca Pharmaceuticals LP	Once monthly injection for treatment of polyneuropathy of hereditary transthyretin-medicated amyloidosis in adults.	12/21/23

New Indications:	***Description***	***Date Approved***
Pirtobrutinib / Jaypirca / Eli Lilly and Co.	Treatment of adult patients with chronic lymphocytic leukemia or small lymphocytic lymphoma who have received at least two prior lines of therapy, including a BTK inhibitor and a BCL-2 inhibitor	12/1/23
Von Willebrand Factor/Coagulation factor VIII complex (human) / wilate / Octapharma USA	Indication expanded to include routine prophylaxis in adults and children aged 6 and older with any type of von Willebrand disease	12/5/23
Isavuconazonium / Cresemba / Astellas Pharma US Inc.	Indication expanded to include treatment of invasive aspergillosis and invasive mucormycosis with the injectable in pediatric patients one year and older and with the capsules in pediatric patients 6 years and older	12/8/23
Immune globulin intravenous, human, 10% liquid / Bivigam / ADMA Biologics	Indication expanded to include use in pediatric patients 2 years and older with primary humoral immunodeficiency	12/12/23
Belzutifan / Welireg / Merck Sharp & Dohme LLC	Treatment of adult patients with advanced renal cell carcinoma following a programmed death receptor-1 or programmed death-ligand 1 inhibitor and a vascular endothelial growth factor tyrosine kinase inhibitor	12/14/23
Tralokinumab / Adbry / Regeneron Pharmaceuticals, Inc.	Indicated for treatment of moderate to severe atopic dermatitis in patients 12 years and older with disease not adequately controlled with topical therapy, or it is not advisable	12/14/23
Pembrolizumab / Keytruda / Merck Sharp & Dohme LLC	Expanded indication for use with enfortumab for locally advanced or metastatic urothelial cancer regardless of cisplatin eligibility	12/15/23
Enfortumab / Padcev / Astellas Pharma US, Inc	Expanded indication for use with pembrolizumab for patients with locally advanced or metastatic urothelial cancer	12/15/23

New Dosage Forms or Formulation:	***Description***	***Date Approved***
Dasatinib / Phyrago / Nanocopoeia	Tablets: 20 mg, 50 mg, 70 mg, 80 mg, 100 mg, 140 mg; for the treatment of Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia in chronic phase, chronic, accelerated, or myeloid or lymphoid blast phase Ph+ CML with resistance or intolerance to prior therapy, and Ph+ acute lymphoblastic leukemia with resistance or intolerance to prior therapy; this formulation is not approved for use in pediatric patients due to marketing exclusivity retained by Bristol-Myers Squibb Sprycel formulation of dasatinib	12/5/23
Bevacizumab-tnjn / Avzivi / Bio-Thera Solutions, Ltd.	Injection: 100 mg/4 mL, 400 mg/16 mL; biosimilar to Avastin	12/6/23
Travoprost / iDose TR / Glaukos Corp.	Intracameral ophthalmic implant: 75 mcg; for the reduction of intraocular pressure in patients with open-angle glaucoma or ocular hypertension	12/13/23
Roflumilast / Zoryve / Arcutis Biotherapeutics	Topical foam 0.3% for the treatment of seborrheic dermatitis in individuals aged 9 years and older.	12/15/23
Immune globulin intravenous, human-stwk / Alyglo / GC Biopharma	Liquid solution containing 10% IgG for IV infusion; for the treatment of primary humoral immunodeficiency in adults	12/15/23
Eflornithine / Iwilfin / US WorldMeds	Tablets: 192 mg; For reducing the risk of relapse in adult and pediatric patients with high-risk neuroblastoma who have demonstrated at least a partial response to prior multiagent, multimodality therapy, including anti-GD2 immunotherapy. (See summary below)	12/13/23
Pegfilgrastim-cbqv / Udenyca / Coherus BioSciences, Inc	6 mg/0.6 mL single-dose prefilled syringe co-packaged with an on-body injector for Udenyca Onbody; prefilled autoinjector applied to the upper arm and designed to deliver a dose 27 hours after application and no sooner than 24 hours after finishing chemotherapy	12/22/23

Compiled by:

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Iptacopan / Fabhalta / Novartis Pharmaceuticals Corporation	
Generic Name / Brand Name / Company	Iptacopan / Fabhalta / Novartis Pharmaceuticals Corporation
Date of approval	12/5/23
Drug Class (Mechanism of Action if novel agent)	Complement factor B inhibitor, regulates cleavage of C3
Indication	Treatment of adults with paroxysmal nocturnal hemoglobinuria
Comparative agent – Therapeutic interchange?	Eculizumab, ravulizumab
Dosage forms/strengths.	Capsules: 200 mg
Common Dose/sig	200 mg orally twice daily
DEA Schedule	None
Date of market availability	Currently available through REMS program
Similar Medication Names	Avacincaptad, Avacopan
Clinical Use Evaluation	
Common Adverse Effects	>10%: headache, nasopharyngitis, diarrhea, abdominal pain, bacterial infection, viral infection, nausea, rash
Severe Adverse Effects	Pyelonephritis, urinary tract infection, pneumonia
Severe Drug-Drug Interactions	CYP2C8 inducers: monitor for loss of iptacopan efficacy CYP2C8 inhibitors: coadministration not recommended
Severe Drug-Food Interactions	None known
Important Labs Values to assess prior to order entry or at point of clinical follow up.	Serum lipid parameters
Used in Pediatric Areas	Safety and efficacy not established in pediatric patients
Renal or Hepatic Dosing	Use is not recommended in severe renal or hepatic impairment. No dose adjustment required in mild or moderate renal or hepatic impairment.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications: serious hypersensitivity, initiation in patients with unresolved serious infection caused by encapsulated bacteria Boxed warnings: increased risk of serious and life-threatening infections caused by encapsulated bacteria; complete or update vaccinations according to ACIP recommendations prior to initiation; pharmacies and prescribers must enroll in the REMS Warnings: hyperlipidemia, hemolysis after discontinuation
Special administration technique or considerations	Administer with or without food. Swallow capsules whole. For patients switching from eculizumab, initiate iptacopan to later than 1 week after last eculizumab dose. For patients switching from ravulizumab, initiate iptacopan no later than 6 weeks after the last ravulizumab dose.
Prepared by	Terri Levien
Source	Fabhalta (iptacopan) [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; December 2023.

Exagamglogene Autotemcel / Casgevy / Vertex Pharmaceuticals	
Generic Name / Brand Name / Company	Exagamglogene autotemcel / Casgevy / Vertex Pharmaceuticals
Date of approval	12/8/23
Drug Class (Mechanism of Action if novel agent)	Autologous CRISPR-based gene editing therapy
Indication	Treatment of sickle cell disease in patients 12 and older with recurrent vaso-occlusive crises.
Comparative agent – Therapeutic interchange?	lovotibeglogene autotemcel / Lyfgenia
Dosage forms/strengths.	Frozen cell suspension for IV infusion
Common Dose/sig	Dose is based on weight. Minimum recommended dose is 3×10^6 CD34+ cells per kg of body weight, which may be composed of multiple vials.
DEA Schedule	None
Date of market availability	Available, administration is limited to certain medical facilities
Similar Medication Names	Casodex
Clinical Use Evaluation	
Common Adverse Effects	Mucositis, febrile neutropenia, and decreased appetite
Severe Adverse Effects	Mucositis, neutropenia, thrombocytopenia, leukopenia, anemia, and lymphopenia
Severe Drug-Drug Interactions	Granulocyte colony stimulating factor must not be used; hydroxyurea, voxelotor, and crizanlizumab should be discontinued at least 8 weeks prior to the start of mobilization and conditioning; iron chelators should be discontinued at least 7 days prior to start of myeloablative conditioning
Severe Drug-Food Interactions	None reported
Important Labs Values to assess prior to order entry or at point of clinical follow up.	Screen for HIV-1, HIV-2, HBV, HCV, and any other infectious agents according to local guidelines before collecting cells for manufacturing. Monitor hemoglobin and absolute neutrophil count (ANC)
Used in Pediatric Areas	12 years and older. Safety and efficacy in those less than 12 have not been established.
Renal or Hepatic Dosing	Has not been studied in hepatic or renal impairment
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	No contraindications Warnings: potential neutrophil engraftment failure, prolonged time to platelet engraftment, off-target genome editing risk, and risk of hypersensitivity reactions due to DMSO or dextran 40 in the cryopreserved solution.
Special administration technique or considerations	Full myeloablative conditioning must be administered 48 hours to 7 days before infusion. Prophylaxis for seizure should be considered prior to myeloablative conditioning. Acetaminophen and diphenhydramine should be administered as premedication. Confirm the total number of vials to be infused: administer each vial completely before proceeding to thaw and infuse the next vial. Administration is through a central venous catheter. Administer within 20 minutes of thawing. After each vial is administered flush the line with 0.9% sodium chloride.
Prepared by	Leanna LaVigne, 2024 PharmD Candidate
Source	Casgevy (exagamglogene autotemcel) [prescribing information]. Boston, MA: Vertex Pharmaceuticals Incorporated; December 2023.

Lovotibeglogene autotemcel / Lyfgenia / bluebird bio-Inc.	
Generic Name / Brand Name / Company	**Lovotibeglogene autotemcel / Lyfgenia / bluebird bio-Inc.**
Date of approval	12/8/23
Drug Class (Mechanism of Action if novel agent)	Autologous cell-based gene therapy
Indication	Treatment of sickle cell disease in those 12 and older with a history of vaso-occlusive events
Comparative agent – Therapeutic interchange?	exagamglogene autotemcel / Casgevy
Dosage forms/strengths.	Cell suspension for IV infusion containing a minimum of 3×10^6 CD34+ cells/kg of body weight, in one to four infusion bags.
Common Dose/sig	Minimum recommended dose of 3×10^6 CD34+ cells/kg
DEA Schedule	None
Date of market availability	Available at select treatment centers in early 2024
Similar Medication Names	Hemgenix, alegenix.
Clinical Use Evaluation	
Common Adverse Effects	Stomatitis, thrombocytopenia, neutropenia, febrile neutropenia, anemia, leukopenia
Severe Adverse Effects	Stomatitis, thrombocytopenia, neutropenia, febrile neutropenia, anemia, and leukopenia; hematologic malignancy
Severe Drug-Drug Interactions	Anti-retrovirals should be discontinued 1 month before mobilization; hydroxyurea should be discontinued 2 months prior to mobilization and 2 days before conditioning; iron chelation should be discontinued at least 7 days before mobilization and conditioning
Severe Drug-Food Interactions	Not reported.
Important Labs Values to assess prior to order entry or at point of clinical follow up.	ANC
Used in Pediatric Areas	Use established in 12 and older, younger has not been established for safety and efficacy
Renal or Hepatic Dosing	Has not been studied in hepatic or renal impairment
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	No contraindications Warnings: hematologic malignancy has occurred in treated patients requiring monitoring through CBC at least every 6 months for one year and as warranted; delayed platelet engraftment; neutrophil engraftment failure; and risk of hypersensitivity reactions from DMSO or dextran 40
Special administration technique or considerations	Administer within 4 hours of thawing, do not use an in-line blood filter or infusion pump. Administered intravenous over less than 30 minutes. Flush after with 0.9% sodium chloride to ensure all cells are infused into the patient.
Prepared by	Leanna LaVigne, 2024 PharmD Candidate.
Source	Lyfgenia (lovotibeglogene autotemcel) [prescribing information]. Somerville, MA: Bluebird bio, Inc; December 2023.

<table>
<tr><th colspan="2">Eflornithine / Iwilfin / US WorldMeds</th></tr>
<tr><td>Generic Name / Brand Name / Company</td><td>Eflornithine / Iwilfin / US WorldMeds</td></tr>
<tr><td>Date of approval</td><td>12/13/23</td></tr>
<tr><td>Drug Class (Mechanism of Action if novel agent)</td><td>Ornithine decarboxylase inhibitor</td></tr>
<tr><td>Indication</td><td>To reduce the risk of relapse in adults and pediatric patients with high-risk neuroblastoma who have demonstrated at least a partial response to prior multiagent, multimodality therapy, including Anti-GD2 immunotherapy</td></tr>
<tr><td>Comparative agent – Therapeutic interchange?</td><td>Dinutuximab (Anti-GD2 immunotherapy in combination with temozolomide and irinotecan for relapse/refractory)</td></tr>
<tr><td>Dosage forms/strengths.</td><td>Tablets: 192 mg</td></tr>
<tr><td>Common Dose/sig</td><td>Based off BSA:
<table>
<tr><th>Body Surface Area (m^2)</th><th>Dosage</th></tr>
<tr><td>> 1.5</td><td>768 mg (4 tablets) PO BID</td></tr>
<tr><td>0.75-1.5</td><td>576 mg (3 tablets) PO BID</td></tr>
<tr><td>0.5- < 0.75</td><td>384 mg (2 tablets) PO BID</td></tr>
<tr><td>0.25- < 0.5</td><td>192 mg (1 tablet) PO BID</td></tr>
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Dose reductions based off toxicity; Reducing by 1 tablet until tolerated, or to a minimum dose of 192 mg (1 tablet) PO daily</td></tr>
<tr><td>DEA Schedule</td><td>None</td></tr>
<tr><td>Date of market availability</td><td>Early 2024</td></tr>
<tr><td>Similar Medication Names</td><td>Wixela, Wegovy, Eplerenone.</td></tr>
<tr><td colspan="2">Clinical Use Evaluation</td></tr>
<tr><td>Common Adverse Effects</td><td>≥5%: hearing loss, otitis media, pyrexia, pneumonia, diarrhea</td></tr>
<tr><td>Severe Adverse Effects</td><td>Myelosuppression, hepatotoxicity, hearing loss, skin infections</td></tr>
<tr><td>Severe Drug-Drug Interactions</td><td>None known</td></tr>
<tr><td>Severe Drug-Food Interactions</td><td>Can be taken without regards to food</td></tr>
<tr><td>Important Labs Values to assess prior to order entry or at point of clinical follow up.</td><td>CMP, LFTs, CBC</td></tr>
<tr><td>Used in Pediatric Areas</td><td>Adequate evidence of safety and effectiveness for pediatrics from 1-17 years with a median age of 4 years old.</td></tr>
<tr><td>Renal or Hepatic Dosing</td><td>If ALT/AST ≥ 10 x ULN, withhold medication until recovery to < 10 x ULN. If recovered within 7 days, resume at same dose. If recovered after 7 days, resume at the next reduced dose level. Renal function dosing has not been studied</td></tr>
<tr><td>Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized</td><td>No contraindications
Warnings: monitor for myelosuppression, hepatotoxicity, and hearing loss</td></tr>
<tr><td>Special administration technique or considerations</td><td>Can be swallowed whole, chewed, or crushed, taken with or without food. Should be administered for 2 years, or until recurrence of disease or unacceptable toxicity.</td></tr>
<tr><td>Prepared by</td><td>Kyle Fay PharmD Candidate</td></tr>
<tr><td>Source</td><td>Iwilfin (eflornithine) [prescribing information]. Louisville, KY: US WorldMeds LLC; December 2023.</td></tr>
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Eplontersen / Wainua / AstraZeneca Pharmaceuticals LP	
Generic Name / Brand Name / Company	Eplonteren / Wainua / AstraZeneca Pharmaceuticals LP
Date of approval	12/21/2023
Drug Class (Mechanism of Action if novel agent)	Transthyretin-directed antisense oligonucleotide (ASO); causes degradation of mutant and wild-type transthyretin (TTR) mRNA, ultimately leading to reduction in serum TTR protein and TTE tissue deposits.
Indication	Polyneuropathy of hereditary transthyretin mediated amyloidosis in adults
Comparative agent – Therapeutic interchange?	Patisiran / Onpattro
Dosage forms/strengths.	Injection: 45 mg/0.8 mL single dose autoinjector
Common Dose/sig	Inject 45 mg (0.8 mL) SubQ once monthly
DEA Schedule	None
Date of market availability	Jan 2024
Similar Medication Names	Eplerenone, Wycillin,
Clinical Use Evaluation	
Common Adverse Effects	>5%: vitamin A decrease, blurry vision, vomiting, proteinuria, injection site reactions, cataracts
Severe Adverse Effects	Vitamin A deficiency, cataracts, atrioventricular heart block, complete AV block
Severe Drug-Drug Interactions	Drug-drug interaction studies have not been done; Invitro studies show no interaction with transporters, plasma protein binding, or CYP enzymes
Severe Drug-Food Interactions	None
Important Labs Values to assess prior to order entry or at point of clinical follow up.	Vitamin A level at point of clinical follow up (study subjects were normal at baseline, and 95% developed low vitamin A level during treatment)
Used in Pediatric Areas	Not studied/ safety and efficacy have not been established
Renal or Hepatic Dosing	No dosage adjustment is necessary in patients with mild-moderate renal impairment. It has not been studied in patients with severe renal impairment or ESRD. No dosage adjustment is necessary in patients with mild hepatic impairment. It has not been studied in moderate-severe hepatic impairment.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	No contraindications Reduces serum vitamin A levels (recommended supplementation with recommended daily allowance of vitamin A) If ocular symptoms suggestive of vitamin A deficiency occur, see ophthalmologist.
Special administration technique or considerations	Let autoinjector come to room temperature for 30 minutes before injecting (do not speed up warming process using other heat sources). If self-injecting, do not attempt injecting into the back of upper arm. Do not inject within 2 inches of belly button, into skin that is bruised, tender, red, or hard, or into scars or damaged skin. Place at a 90-degree angle against skin. 2 clicks may be heard once injecting, must hold for 10 seconds (or until the viewing window is covered by orange plunger rod.
Prepared by	Kyle Fay, PharmD Candidate
Source	Wainua (eplontersen) [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; 2023