College of Pharmacy and Pharmaceutical Sciences
WASHINGTON STATE UNIVERSITY

Drug Information Center

Highlights of FDA Activities – 8/1/2020 – 8/31/2020

FDA Drug Safety Communications & Drug Information Updates:

Extended "In-Use Time" Information – Drug Information Update 8/5/20

The FDA advised that use of the following agents beyond the in-use time in the FDA-approved labeling has not been studied but acknowledged institutions may consider such use due to shortages:

- bumetanide 0.25 mg/mL
- cisatracurium besylate EQ 2 mg base/mL, 10 mg base/mL
- epinephrine EQ 1 mg baseline/mL
- famotidine 10 mg/mL
- heparin sodium 1,000 units/mL, 5,000 units/mL, 10,000 units/mL
- hydromorphone 0.2 mg/mL, 1 mg/mL, 2 mg/mL, 4 mg/mL, 10 mg/mL
- midazolam HCl EQ 1 mg base/mL, 5 mg base/mL
- phenylephrine HCl 0.1 mg/mL, 10 mg/mL
- rocuronium bromide 10 mg/mL
- succinylcholine chloride 20 mg/mL

To minimize likelihood of physiochemical degradation or microbial proliferation when a provider is considering use beyond labeled in-use time for the above-listed products, the FDA advises use should be as short as possible, and for a maximum of 4 hours for refrigerated storage or 2 hours for room temperature. The extended use applies to either refrigerated or room temperature in-use storage and not both.

Hand Sanitizer Warning on Methanol Presence and Updated Guidance 8/7 & 8/24/20

The FDA warned that testing had revealed an increase in hand sanitizer products containing methanol but labeled as containing ethanol. They advised consumers to continue to avoid products on their list of recalled hand sanitizers. They also updated the hand sanitizer guidance to include product testing and adverse event reporting.

Hand Sanitizer Warnings Include 1-Propanol Contamination 8/12/20

The FDA warned that hand sanitizer products, including those manufactured by Harmonic Nature S de RL de MI in Mexico, that are labeled to contain ethanol or isopropyl alcohol (2-propanol/isopropanol) have tested positive for 1-propanol contamination. 1-propanol is not an acceptable hand sanitizer ingredient and can be toxic when ingested. The FDA maintains a site listing hand sanitizers that should not be used (www.fda.gov/unsafehandsanitizers).

Hydrochlorothiazide Risk of Non-Melanoma Skin Cancer – Drug Information Update 8/20/20

The FDA approved changes to the labeling for hydrochlorothiazide to inform health care professional and patients about a small increase in risk for non-melanoma skin cancer (basal cell or squamous cell skin cancers). A study found an increase mostly in squamous cell carcinoma; the increased risk in patients on hydrochlorothiazide was approximately one additional case per 16,000 patients per year. Patients are advised to protect their skin from the sun and undergo regular skin cancer screenings.

Convalescent Plasma Emergency Use Authorization for COVID-19 8/23/20

The FDA issued an emergency use authorization for the use of convalescent plasma for the treatment of COVID-19 in hospitalized patients.

Canagliflozin Boxed Warning Removed – Drug Safety Communication 8/26/20

The FDA removed the boxed warning regarding the risk of leg and foot amputations from the labeling for canagliflozin products (Invokana, Invokamet, Invokamet XR) following review of new data from three clinical trials. New data demonstrated heart and kidney function related benefits, which added expanded the FDA-approved indications, and demonstrated lower risk of amputation than previously described. Elevated risk still exists however, and careful patient selection and preventive foot care are still necessary.

Rifampin and Rifapentine Shortage Mitigation 8/26/20

Following detection of nitrosamine impurities in samples of rifampin and rifapentine, the FDA is allowing certain manufacturers to temporarily distribute rifampin containing 1-methyl-4-nitrosopiperazine (MNP) or rifapentine containing 1-cyclopentyl-4-nitrosopiperazine (CPNP) above acceptable limits to mitigate possible shortages of these medications. The FDA is reviewing products and tested levels on a case-by-case basis to determine which drugs may be released for distribution.

Hand Sanitizer Packaged in Food and Drug Containers 8/27/20

The FDA issued a warning regarding hand sanitizer products that have been packaged in containers that resemble food and drink containers, including beer cans, children's food pouches, water bottles, juice bottles, and vodka bottles. The FDA is also aware of hand sanitizer products containing food flavors including chocolate and raspberry. They have received reports of consumer confusion that could result in accidental ingestion of hand sanitizer products.

Veklury (remdesivir) Emergency Use Authorization Broadened 8/28/20

The FDA broadened the emergency use authorization for remdesivir to include treatment of all hospitalized adult and pediatric patients with suspected or laboratory-confirmed COVID-19 regardless of the severity of illness.

Major Medication/Drug-Related Product Recalls Announced Through MedWatch: Hand Sanitizer Recalls Listed Separately

DDAVP Nasal Spray 10 mcg/0.1 mL, Desmopressin Acetate Nasal Spray 10 mcg/0.1 mL, STIMATE Nasal Spray 1.5 mg/mL, Ferring US: Recall - Superpotency 8/5/20

Ferring Pharmaceuticals US recalled all lots of DDAVP Nasal Spray 10 mcg/0.1 mL, Desmopressin Acetate Nasal Spray 10 mcg/0.1 mL, and STIMATE Nasal Spray 1.5 mg/mL listed in the table below to the consumer level due to super potency noted on routine testing. The FDA site contains a list of all recalled DDVAP, Desmopressin and Stimate nasal sprays.

ChloraPrep™ 3 mL Applicator, BD: Recall in US Territories– Possible Fungal Contamination 8/10/20

BD has found that ChloraPrep™ 3mL applicators exposed to temperatures of 30° C (86 ° F) and 75% relative humidity for more than 6 months may become contaminated with *Aspergillus penicillioides*. While no adverse events, injuries or deaths have yet been linked to this product, the manufacturer recommends discarding all ChloraPrep™ 3 mL applicators of the following catalog numbers: 260400, 260415, 930400, 930415. The recall does not apply to any U.S. states, but does apply to the U.S. territories of American Samoa, Guam, Northern Mariana Islands, Puerto Rico, and the U.S. Virgin Islands, as well as several other countries.

Heparin Sodium Compounded Products, SCA Pharmaceuticals: Recall - Incorrect Preservative (Benzyl Alcohol) 8/18/20

SCA Pharmaceuticals, Windsor, CT recalled 10 lots of Heparin Sodium to the hospital/user level. The compounded Heparin Sodium bags contain the undeclared preservative benzyl alcohol. The labeled preservatives methylparaben and propylparaben are not present in the product. The FDA site includes a list of recalled lot numbers and NDCs.

Metformin Extended-Release, Bayshore Pharmaceuticals: Recall – NDMA Impurity 8/20/20
Bayshore Pharmaceuticals recalled one lot of 500 mg tablets in 1000 count bottles (lot 18641) and one lot of 750 mg tablets in 100 count bottles (lot 18657) due to detection of N-nitrosodimethylamine (NDMA) above the acceptable intake level. The tablets were manufactured by Beximco Pharmaceuticals Limited, Dhaka, Bangladesh for U.S. distribution by Bayshore. A complete list of recalled metformin products can be found on the FDA site.

Medfusion 3500 and 4000 Syringe Pumps, Smiths Medical: Recall – Medication Delivery Error Risk 8/25/20
Smiths Medical recalled specific software versions of the Medfusion 3500 and 4000 syringe pumps due to a software error that may lead to over-delivery or under-delivery of fluids or medication. A complete list of recalled pumps and firmware versions recalled can be found on the FDA site.

Amiodarone HCl injection, USP and Tranexamic Acid Injection, USP, Mylan: Recall – Label Mix-Up 8/31/20
Mylan recalled four lots of amiodarone HCl injection, USP 450 mg/9 mL (lots 191207, 191221) and tranexamic acid injection, USP 1000 mg/10 mL (lots 191223, 200120) packaged in cartons of 10 single-dose vials due to a mix-up resulting in the potential for cartons labeled as tranexamic acid to contain vials of amiodarone and cartons labeled as amiodarone to contain vials of tranexamic acid. The individual vials are correctly labeled.

Hand Sanitizer Recalls: The FDA website should be consulted for a current list of recalled hand sanitizers.

Jaloma Antiseptic Hand Sanitizer, Laboratorios Jalomas S.A de C.V.: Recall - Undeclared Methanol 8/1/20
LABORATORIOS JALOMA S.A. de C.V. recalled all lots and all bottle sizes of the Jaloma Antiseptic Hand Sanitizer, Ethyl Alcohol 62% With vitamin E to the consumer level following detection of undeclared methanol in FDA testing.

Command Brands Gel AntiBac Instant Hand Sanitizer, Roque Plast S.A. de C.V.: Recall - Methanol 8/4/20
Roque Plast S.A. de C.V. recalled lots 200371-12, 200371OH-05, 170420OH-06, 170420OH-8 of Command Brands Gel AntiBac Instant Hand Sanitizer to the consumer level following detection of methanol in FDA testing.

Gelbac T Antibacterial Handgel, Incredible Products Sa De Cv: Recall – Methanol 8/7/20
Incredible Products Sa de Cv recalled one lot of Gelbac T antibacterial handgel (1 liter (33.8 oz) plastic bottles and 125 mL (4.2 oz) plastic bottles, with lot code 001) following detection of methanol in FDA testing.

Bersih Hand Sanitizer Gel, Soluciones Cosméticas: Recall - Methanol 8/9/20
Soluciones Cosméticas recalled all lots of Berish Hand Sanitizer Gel Fragrance Free, sold in 16.9 oz bottles (UPC code 816822026667 or 7503007103178) due to potential methanol contamination.

SkinGuard24 Hand Sanitizer, SG24 LLC: Recall - Methanol 8/15/20
SG24 LLC recalled SkinGuard24 – All Day Hand Sanitizer Products due to concerns of methanol contamination. Products recalled include SkinGuard All Day hand Sanitizer Plastic Bottle with Foam Pump (8 oz and 24 oz), SkinGuard All Day Hand Sanitizer Spray Pocket Pen, and All Day Hand Sanitizer Individual Towlette packaged as Single Use. The corresponding UPCs relevant to the recall are: 7935733144725, 79357314703, 7935733147103, and 79357314709. The products were distributed throughout the United States.

Yacana Hand Sanitizer, Grupo Yacana México S.A.S. De C.V.: Recall - Methanol and Sub-Potent Ethanol 8/18/20
Grupo Yacana México S.A.S de C.V recalled all lots of Yacana Hand Sanitizer, 70% Alcohol, 250 ml to the consumer level due to the potential presence of methanol and subpotency for the ethanol content.

Hand Sanitizers, Albek de Mexico S.A. de C.V.: Recall - Methanol 8/4 & 8/18/20
Albek de Mexico S.A. de C.V. recalled all lots and all brands of hand sanitizer in US distribution to the consumer level. Recalled products include Nuuxan Instant Hand Sanitizer, Modesa Hand Sanitizer with Moisturizers and Aloe, Assured Hand Sanitizer Vitamin E and Aloe, Assured Hand Sanitizer Aloe Vera, and Next Hand Sanitizer.

Hand Sanitizer Recalls (continued):

Florence Morris Antiseptic Hand Sanitizer, Grupo Asimex De Mexico Sa De CV: Recall - Methanol and Sub-Potent Ethanol 8/20/20

Grupo Asimex de Mexico SA de CV recalled all lots of FLORANCE MORRIS Antiseptic Hand Sanitizer, 70% Alcohol, packaged in 8 fl oz bottles and 1 L bottles to the consumer level due to the potential presence of methanol and subpotency for the ethanol content.

V-Klean Hand Sanitizer Gel, Medically Minded Hand Sanitizer Gel, and Protz Real Protection Antibacterial Hand Sanitizer, Asiaticon SA de CV: Recall - Methanol and Subpotent Ethanol 8/25/20

Asiaticon SA de CV, Mexico, recalled all lots of V-Klean Hand Sanitizer Gel, Medically Minded Hand Sanitizer Gel and Protz Real Protection Antibacterial Hand Sanitizer sold in 13.5-, 16.9- and 33.8-ounce bottles to the consumer level due to the potential presence of methanol and subpotent ethanol levels.

Zanilast+gel, Nanomateriales, SA de CV: Recall – Presence of 1-Propanol 8/27/20

Nanomateriales, SA de CV recalled all lots of Zanliast+gel hand sanitizer gel in 1 L, 25 L, and 1-gallon plastic bottles due to the presence of 1-propanol.

Harmonic Nature Hand Sanitizer, Harmonic Nature S. De RLM: Recall – Presence of 1-Propanol 8/31/20

Harmonic Nature S De RLM recalled all 800 bottles of 250 mL Harmonic Nature hand sanitizer (UPC 7500462892210) due to the presence of 1-propanol.

Always Be Clean Hand Sanitizer, Just Hand Sanitizer, Open Book Extracts: Recall – Mislabeled to Contain Methanol 8/31/20

Open Book Extracts recalled all lots of Always Be Clean Hand Sanitizer and Just Hand Sanitizer

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	*Undeclared Ingredient(s) or Contaminants*
Organic Goldenseal Root Powder, Maison Terre/Starwest Botanicals*	Microbial contamination

*recalled

New Product Shortages	*Date Initially Posted*
Chlorothiazide (Diuril) Oral Suspension	8/12/20
Tobramycin Lyophilized Powder for Injection	8/24/20

Sole Source or Branded Product Discontinuations/Withdrawals	*Date Posted*
Olopatadine 0.7% ophthalmic solution (Pazeo, Novartis); joins olopatadine 0.1% and 0.2% in over-the-counter availability as Pataday Once Daily Relief Extra Strength	8/11/20

New Drug Approvals:	***Description (See Attached Drug Summaries)***	***Date Approved***
Belantamab mafodotin-blmf / Blenrep / GlaxoSmithKline	B-cell maturation antigen (BMCA)-directed antibody and microtubule inhibitor conjugate indicated for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least 4 prior therapies including an anti-CD38 monoclonal antibody, a proteasome inhibitor, and an immunomodulatory agent.	8/5/20
Nifurtimox / Lampit / Bayer HealthCare Pharmaceuticals Inc	Nitrofuran antiprotozoal, indicated in pediatric patients (birth to less than 18 years of age and weighing at least 2.5 kg) for the treatment of Chagas disease (American Trypanosomiasis), caused by *Trypanosoma cruzi*.	8/6/20
Oliceridine / Olinvyk / Trevena Inc.	Opioid agonist/Management of acute pain severe enough to require IV opioid analgesic, and after failure of alternatives	8/7/20
Risdiplam / Evrysdi / Genentech Inc.	Survival of motor neuron 2 (SMN2) splicing modifier indicated for the treatment of spinal muscular atrophy (SMA) in patients 2 months of age or older.	8/7/20
Viltolarsen / Viltepso / NS Pharma, Inc.	Antisense oligonucleotide indicated for the treatment of Duchenne muscular dystrophy (DMD) in patients who have a confirmed mutation of the DMD gene that is amenable to exon 53 skipping.	8/12/20
Satralizumab / Enspryng / Genentech INC	Interleukin-6 receptor antagonist indicated for the treatment of neuromyelitis optica spectrum disorder in adult patients who are anti-aqua-porin-4 antibody positive	8/14/20
Clascoterone / Winlevi / Cassiopea Inc.	Androgen receptor inhibitor for topical treatment of acne vulgaris in patients 12 years and older	8/26/20
Somapacitan-beco / Sogroya / Novo Nordisk	Human growth hormone analog administered weekly in treatment of adult growth hormone deficiency	8/28/20

New Indications:	***Description***	***Date Approved***
IncobotulinumtoxinA / Xeomin / Merz Pharmaceuticals	Treatment of upper limb spasticity in pediatric patients 2 to 17 years of age, excluding spasticity caused by cerebral palsy	8/18/20
Carfilzomib / Kyprolis / Amgen	Treatment of adult patients with relapsed or refractory multiple myeloma in combination with daratumumab and dexamethasone in patients who have received one to three prior lines of therapy	8/20/20
Daratumumab / Darzalex / Janssen Biotech	Treatment of adult patients with multiple myeloma in combination with carfilzomib and dexamethasone in patients who have received one to three prior lines of therapy	8/20/20
Levonorgesterl-releasing intrauterine system / Mirena / Bayer Healthcare	Indication expanded to extend contraceptive use from 5 years to up to 6 years	8/20/20
Halobetasol propionate / Ultravate / Sun Pharmaceuticals	Indication expanded to include use in patients 12 years and older for the treatment of plaque psoriasis	8/27/20

New Dosage Forms or Formulation:	***Description***	***Date Approved***
Enzalutamide / Xtandi / Astellas	Tablet: 40 mg, 80 mg; alternative to 40 mg capsule formulation	8/4/20
Cysteamine / Cystadrops / Recordata Rare Diseases Inc.	Ophthalmic solution 0.37%; cystine-depleting agent for treatment of corneal cystine crystal deposits in adults and children with cystinosis	8/19/20
Ofatumumab / Kesimpta / Novartis Pharmaceuticals Corp.	Prefilled pen and syringe for subcutaneous injection for the treatment of relapsing forms of multiple sclerosis	8/20/20

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Belantamab mafodotin-blmf / Blenrep / GlaxoSmithKline	
Generic Name / Brand Name / Company	Belantamab mafodotin-blmf / Blenrep / GlaxoSmithKline
Date of approval	8/5/20
Drug Class (Mechanism of Action if novel agent)	B-cell maturation antigen (BCMA)-antibody and microtubule inhibitor conjugate
Indication	Adult patients with relapsed or refractory multiple myeloma who have received at least 4 prior therapies including anti-CD38 monoclonal antibody, a proteasome inhibitor, and an immunomodulatory agent.
Comparative agent – Therapeutic interchange?	None
Dosage forms/strengths	Injection: 100 mg as a lyophilized powder in a single-dose vial for reconstitution and further dilution.
Common Dose/sig	2.5 mg/kg as an IV infusion over approximately 30 minutes once every 3 weeks.
DEA Schedule	None
Date of market availability	Available – through restricted REMS program
Similar Medication Names	Belatacept, belimumab, Blexten
Clinical Use Evaluation	
Common Adverse Effects	≥20%: keratopathy (corneal epithelium changes on eye exam), decreased visual acuity, nausea, blurred vision, pyrexia, infusion-related reactions, and fatigue.
Severe Adverse Effects	Severe vision loss and corneal ulcer, thrombocytopenia, infusion-related 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.	Complete blood cell counts at baseline and during treatment as clinically indicated. Pregnancy testing prior to initiating therapy for females of reproductive potential.
Used in Pediatric Areas	Safety and effectiveness have not been established in pediatric patients.
Renal or Hepatic Dosing	No dose adjustment is recommended for patients with mild or moderate renal impairment or mild hepatic impairment. The recommended dosage has not been established in patients with severe renal impairment, end-stage renal disease, or moderate to severe hepatic impairment.

Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Boxed warning: ocular toxicity. Causes changes in corneal epithelium resulting in vision changes, severe vision loss, and corneal ulcer. Conduct ophthalmic exams at baseline, prior to each dose, and promptly for worsening symptoms. Thrombocytopenia: monitor CBC. Consider withholding and/or reduce the dose based on severity. Infusion-related Reactions: monitor patients for infusion-related reactions. Interrupt and then reduce the rate or permanently discontinue based on the severity. Embryo-Fetal Toxicity: Can cause fetal harm. Advise females of reproductive potential of the potential risk to a fetus and to use effective contraception during treatment and for 4 months after last dose. Advise males with female partners of reproductive potential to use effective contraception during treatment and for 6 months after last dose. Lactation: Advise not to breastfeed.
Special administration technique or considerations	Belantamab mafodotin-blmf is a hazardous drug. Follow applicable special handling and disposal procedures. If refrigerated, allow the diluted infusion to equilibrate to room temperature prior to administration. Diluted infusion solution may be kept at room temperature for no more than 6 hours (including infusion time). Administer by IV infusion over approximately 30 minutes using an infusion set made of polyvinyl chloride (PVC) or polyolefin (PO). Filtration of the diluted solution is not required; if filtered, use 0.2-micron polyethersulfone (PES)-based filter.
Prepared by	Andrew Stephens
Source	Blenrep (Belantamab mafodotin) [prescribing information]. Research Triangle Park, NC: GlaxoSmithKline; August 2020

Nifurtimox / Lampit / Bayer HealthCare Pharmaceuticals Inc	
Generic Name / Brand Name / Company	Nifurtimox / Lampit / Bayer HealthCare Pharmaceuticals Inc
Date of approval	8/6/20
Drug Class (Mechanism of Action if novel agent)	Nitrofuran antiprotozoal
Indication	Indicated in pediatric patients, aged from birth to less than 18 years of age and weighing at least 2.5 kg for the treatment of Chagas disease caused by *Trypanosoma cruzi*
Comparative agent – Therapeutic interchange?	Benznidazole in children 2 to 12 years of age
Dosage forms/strengths	Tablets: 30 mg and 120 mg; functionally scored for oral use
Common Dose/sig	Administer orally, three times daily with food for 60 days. If weight is 40 kg or greater, total daily dose of nifurtimox is 8 to 10 mg/kg If weight is less than 40 kg, total daily dose of nifurtimox is 10 to 20 mg/kg Consult prescribing information for individual doses per weight
DEA Schedule	None
Date of market availability	Available
Similar Medication Names	Nitrofurantoin, Niferx, nifedipine, Lamisil, Lamictal
Clinical Use Evaluation	
Common Adverse Effects	≥5%: vomiting, abdominal pain, headache, decreased appetite, nausea, pyrexia and rash.
Severe Adverse Effects	Hypersensitivity
Severe Drug-Drug Interactions	Contraindicated in patients who consume alcohol during treatment
Severe Drug-Food Interactions	None known. Must be administered with food.

Important Labs Values to assess prior to order entry or at point of clinical follow up.	Pregnancy testing is recommended for females of reproductive potential prior to initiating treatment.
Used in Pediatric Areas	The safety and effectiveness have been established in pediatric patients from birth to less than 18 years of age weighing at least 2.5 kg.
Renal or Hepatic Dosing	Administer under close medical supervision. The effects of renal and hepatic impairment on the pharmacokinetics of nifurtimox is unknown.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications: known hypersensitivity to nifurtimox or tablet excipients; alcohol consumption. Embryo-fetal Toxicity: May cause fetal harm, pregnancy testing is recommended for females of reproductive potential. Advise females of reproductive potential of the potential risk to a fetus and to use effective contraception during treatment and for 6 months after last dose. Advise males to use condoms (during treatment and for 3 months after the last dose) with female partners of reproductive potential. Worsening Neurological and Psychiatric disease: Patients with a history of brain injury, seizures, psychiatric disease, serious behavioral alterations may experience worsening of their conditions when receiving nifurtimox. Hypersensitivity: Hypersensitivity reactions including hypotension, angioedema, dyspnea, pruritus, rash, or other severe skin reactions have been reported with the use of nifurtimox, discontinuation of treatment is recommended. Decreased appetite and Weight Loss: Check body weight every 14 days as dosage may need to be adjusted. Porphyria: Treatment with nitrofuran derivatives may precipitate acute attacks of porphyria. Administer under close medical supervision in patients with porphyria.
Special administration technique or considerations	Must be taken with food. Tablets should be hand split to reach recommended dose. Tablets can be made into slurry for patients who cannot swallow tablets.
Prepared by	Andrew Stephens
Source	Lampit (Nifurtimox) [prescribing information]. Whippany, NJ: Bayer HealthCare Pharmaceuticals Inc.; August 2020

Oliceridine / Olinvyk / Trevena Inc.	
Generic Name / Brand Name / Company	Oliceridine / Olinvyk / Trevena Inc.
Date of approval	8/7/20
Drug Class (Mechanism of Action if novel agent)	Opioid agonist (analgesic)
Indication	Adults with acute pain severe enough to require IV opioids, and for whom alternative treatments are inadequate.
Comparative agent – Therapeutic interchange?	1 mg oliceridine = approximately 5 mg morphine
Dosage forms/strengths	Injection: 1 mg/mL and 2 mg/2mL in single-dose vials, 30 mg/30 mL in single patient use vial for PCA use only.
Common Dose/sig	Initiate treatment with a 1.5 mg IV dose. For PCA, demand dose is 0.35 mg with a 6-minute lockout. A demand dose of 0.5 mg may be considered. Supplemental doses of 0.75 mg can be administered, beginning 1 hr after initial dose, and every hour thereafter as needed.
DEA Schedule	Pending
Date of market availability	Available when DEA issues the controlled substance schedule
Similar Medication Names	Omalizumab, tolterodine
Clinical Use Evaluation	

Common Adverse Effects	≥10%: nausea, vomiting, dizziness, headache, constipation, pruritis, and hypoxia
Severe Adverse Effects	Addiction, abuse, misuse; life-threatening respiratory depression; adrenal insufficiency; severe hypotension; seizures; withdrawal
Severe Drug-Drug Interactions	Concomitant administration of moderate-strong CYP2D6 inhibitors (Paroxetine, fluoxetine, quinidine, bupropion) may increase plasma concentration of oliceridine. Concomitant use of benzodiazepines, alcohol, and other CNS depressants with opioids increases risk of respiratory depression, hypotension, sedation, coma, and death. Concomitant administration of serotonergic drugs (SSRIs, SNRIs, TCAs, MAOIs) with opioids has in rare cases led to serotonin syndrome. Mixed agonist/antagonist and partial agonist opioid analgesics (butorphanol, nalbuphine, pentazocine, buprenorphine) may reduce analgesic effects of oliceridine and/or precipitate withdrawal symptoms. Muscle relaxants: oliceridine may enhance action of muscle relaxants and increase risk of respiratory depression. Diuretics: opioids can reduce efficacy of diuretics by inducing the release of anti-diuretic hormone. Anticholinergic drugs: may increase risk of urinary retention/severe constipation, which may lead to paralytic ileus.
Severe Drug-Food Interactions	None
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.
Renal or Hepatic Dosing	Renal impairment: no dose adjustment required. Mild-moderate hepatic impairment: no adjustment of initial dose—may require less-frequent dosing. Severe hepatic impairment: consider reducing initial dose; administer subsequent dosing only after a careful review of the patient's severity of pain and overall clinical status.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindicated in patients with severe respiratory depression, acute or severe bronchial asthma in unmonitored setting, known or suspected gastrointestinal obstruction, or known hypersensitivity to oliceridine. Warnings: opioid agonist cautions including risks of abuse and misuse, life threatening respiratory depression, neonatal opioids withdrawal syndrome, and risks from concomitant use with benzodiazepines or other CNS depressants. QT prolongation with daily doses exceeding 27 mg Life-threatening respiratory depression in patients with COPD, and in elderly, cachectic, or disabled patients. Adrenal insufficiency: if diagnosed, treat with corticosteroids and wean off opioid. Severe hypotension: monitor during initiation and titration. Do not use in patients with circulatory shock.
Special administration technique or considerations	For IV use only. Onset of analgesic effect expected within 2 to 5 minutes after initial dose. Do not administered single doses greater than 3 mg. Cumulative total daily dose should not exceed 27 mg.
Prepared by	Matthew Cavaletto
Source	Olinvyk (oliceridine) [prescribing information]. Chesterbrook, PA: Trevena, Inc.; August 2020.

Risdiplam / Evrysdi / Genentech, Inc.	
Generic Name / Brand Name / Company	Risdiplam / Evrysdi / Genentech, Inc.
Date of approval	8/7/20
Drug Class (Mechanism of Action if novel agent)	Survival of motor neuron 2 (SMN2) splicing modifier
Indication	Spinal muscular atrophy (SMA) in patients 2 months of age or older
Comparative agent – Therapeutic interchange?	Nusinersen, onasemnogene abeparvovec-xioi (gene therapy)
Dosage forms/strengths	Oral solution: 60 mg as powder for constitution to provide 0.75 mg/mL solution.
Common Dose/sig	2 months to less than 2 years of age: 0.2 mg/kg/day 2 years and older, weighing less than 20 kg: 0.25 mg/kg/day 2 years and older, weighing 20 kg or more: 5 mg/day Take orally once daily after a meal at approximately the same time every day.
DEA Schedule	None
Date of market availability	Available
Similar Medication Names	Risperdal, Risperidone, Evista, Evra
Clinical Use Evaluation	
Common Adverse Effects	>10%: fever, diarrhea, rash.
Severe Adverse Effects	None reported
Severe Drug-Drug Interactions	Avoid coadministration with MATE (multidrug and toxin extrusion protein transporter) substrates, as risdiplam may increase their plasma concentrations. Example: metformin.
Severe Drug-Food Interactions	None known
Important Labs Values to assess prior to order entry or at point of clinical follow up.	Pregnancy testing is recommending prior to initiating therapy in females of reproductive potential.
Used in Pediatric Areas	Safety and effectiveness in patients less than 2 months old have not been established.
Renal or Hepatic Dosing	Renal impairment not expected to alter exposures of risdiplam. Hepatic impairment: avoid use. Risdiplam is predominantly metabolized in the liver.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	No contraindications in product labeling. Pregnancy: may cause fetal harm and impaired fertility. Pregnant testing is advised in females of reproductive potential, and such females should use effective contraception during treatment and for at least 1 month after the last dose. Male fertility may be impaired by treatment; male patients may consider sperm preservation prior to treatment.
Special administration technique or considerations	Must be constituted by a pharmacist prior to dispensing. In breastfed infants: administer after breastfeeding. Cannot be mixed with formula or milk Drink water after taking risdiplam to ensure it has been completely swallowed. Risdiplam can be administered via nasogastric or gastrostomy tube. Flush with water after delivering.
Prepared by	Matthew Cavaletto
Source	Evrysdi (risdiplam) [prescribing information]. South San Francisco, CA: Genentech, Inc.; August 2020.

Viltolarsen / Viltepso / NS Pharma, Inc.	
Generic Name / Brand Name / Company	Viltolarsen / Viltepso / NS Pharma, Inc.
Date of approval	8/12/20
Drug Class (Mechanism of Action if novel agent)	Antisense oligonucleotide
Indication	Duchenne muscular dystrophy in patients with mutation of the DMD gene amenable to exon 53 skipping.
Comparative agent – Therapeutic interchange?	Golodirsen
Dosage forms/strengths	Injection: 250 mg/5 mL (50 mg/mL) in a single dose vial
Common Dose/sig	80 mg/kg of body weight IV once weekly
DEA Schedule	None
Date of market availability	Available
Similar Medication Names	Vilazodone, vilanterol, vildagliptin, Vilamit
Clinical Use Evaluation	
Common Adverse Effects	≥15%: upper respiratory infection, injection site reaction, cough, pyrexia
Severe Adverse Effects	None reported; potential for kidney toxicity
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.	Serum cystatin C, urine dipstick, and urine protein-to-creatinine ratio should be measured before starting therapy. Consider measurement of glomerular filtration rate prior to initiation of therapy. Monitor urine dipstick every month and serum cystatin C and urine protein-to-creatinine ratio every 3 months during therapy.
Used in Pediatric Areas	Viltolarsen is indicated for the treatment of DMD in patients who have a confirmed mutation of the DMD gene that is amenable to exon 53 skipping, including pediatric patients.
Renal or Hepatic Dosing	Viltolarsen has not been studied in patients with renal impairment but it is mostly excreted unchanged in the urine and renal impairment may increase its exposure. Because of the effect of reduced skeletal muscle mass on creatinine measurements in DMD patients, no specific dosage adjustment can be recommended for DMD patients with renal impairment based on estimated glomerular filtration rate. Patients with known renal function impairment should be closely monitored during treatment.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Kidney toxicity: Kidney toxicity was observed in animals who received viltolarsen. Although kidney toxicity was not observed in the clinical studies, the clinical experience is limited and kidney toxicity, including potentially fatal glomerulonephritis, has been observed after administration of some antisense oligonucleotides. Monitoring for kidney toxicity during treatment is recommended.
Special administration technique or considerations	Administer as an intravenous infusion over 60 minutes using a peripheral or central venous catheter. Filtration is not required. Flush the intravenous access line with 0.9% Sodium Chloride Injection, USP, after infusion. If the volume of viltolarsen required is less than 100 mL, dilution in 0.9% Sodium Chloride injection, USP, is required. Viltolarsen should be mixed with 0.9% Sodium Chloride Injection, USP, only.
Prepared by	Andrew Stephens
Source	Viltepso (Viltolarsen) [prescribing information]. Paramus, NJ.: NS Pharma, Inc.; August 2020.

Satralizumab mwge / Enspryng / Genentech, Inc	
Generic Name / Brand Name / Company	Satralizumab mwge / Enspryng / Genentech, Inc
Date of approval	8/14/20
Drug Class (Mechanism of Action if novel agent)	Interleukin-6 receptor antagonist
Indication	Treatment of neuromyelitis optica spectrum disorder (NMOSD) in adult patients who are anti-aquaporin-4 antibody positive
Comparative agent – Therapeutic interchange?	Eculizumab and inebilizumab are also indicated for treatment of NMOSD
Dosage forms/strengths	Injection: 120 mg/mL in a single-dose prefilled syringe
Common Dose/sig	Loading dose for first 3 administrations is 120 mg subcutaneously at weeks 0, 2, and 4, followed by a maintenance dose of 120 mg every 4 weeks
DEA Schedule	None
Date of market availability	Available
Similar Medication Names	Sativex, Enskyce, ensartinib
Clinical Use Evaluation	
Common Adverse Effects	≥15%: nasopharyngitis, headache, upper respiratory tract infection, gastritis, rash, arthralgia, extremity pain, fatigue and nausea.
Severe Adverse Effects	Infection, neutropenia
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.	Hepatitis B virus screening, tuberculosis screening, and liver transaminases and serum albumin prior to initiation of treatment. Monitor ALT and AST every 4 weeks for the first 3 months, followed by every 3 months for one year and then as clinically necessary. Monitor neutrophils 4 to 8 weeks after initiation and then regularly at clinically determined intervals.
Used in Pediatric Areas	Safety and effectiveness in pediatric patients have not been established
Renal or Hepatic Dosing	None
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications: known hypersensitivity to satralizumab or any of the inactive ingredients, active Hepatitis B infection, and active or untreated laten tuberculosis. Warnings: Infection: delay administration in patients with an active infection until the infection is resolved. Vaccination with live or live-attenuated vaccines is not recommended during treatment Hepatitis B virus reactivation. Tuberculosis. Elevated liver enzymes: monitor ALT and AST levels during treatment, interruption of treatment may be required. Decreased neutrophil counts: Monitor neutrophils during treatment Hypersensitivity reactions have occurred.
Special administration technique or considerations	Prior to use, remove the prefilled syringe from the refrigerator and allow to sit at room temperature outside of the carton for 30 minutes. After training patient or caregiver may administer. Administer by subcutaneous injection in the abdomen or thigh.
Prepared by	Andrew Stephens
Source	Enspryng (Satralizumab) [prescribing information]. South San Francisco, CA: Genentech, Inc.; August 2020.

Clascoterone / Winlevi / Cassiopea Inc.	
Generic Name / Brand Name / Company	Clascoterone / Winlevi / Cassiopea Inc.
Date of approval	8/26/20
Drug Class (Mechanism of Action if novel agent)	Androgen receptor inhibitor
Indication	Topical treatment of acne vulgaris is patients 12 years and older
Comparative agent – Therapeutic interchange?	Systemic agents (spironolactone, oral contraceptives)
Dosage forms/strengths	Cream: 1% in 60-gram tubes
Common Dose/sig	Apply a thin layer to affected area twice daily
DEA Schedule	None
Date of market availability	Early 2021
Similar Medication Names	Abiraterone, Sylevia
Clinical Use Evaluation	
Common Adverse Effects	7 to 12%: erythema, pruritus, scaling/dryness; >3%: edema, stinging, burning
Severe Adverse Effects	Hypothalamic-pituitary-adrenal (HPA) axis suppression
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 patients younger than 12 years
Renal or Hepatic Dosing	No adjustments necessary
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	No labeled contraindications. Warnings: local irritation and HPA axis suppression has occurred; withdraw therapy if HPA suppression occurs.
Special administration technique or considerations	Apply thin layer to dry clean skin. Avoid accidental transfer to eyes, mouth or other mucous membranes; rinse thoroughly with water if contact with mucous membranes occurs.
Prepared by	Terri Levien
Source	Winlevi (clascoterone) [prescribing information]. Milan, Italy: Cassiopea SpA; August 2020.

Somapacitan-beco / Sogroya / Novo Nordisk	
Generic Name / Brand Name / Company	Somapacitan-beco / Sogroya / Novo Nordisk
Date of approval	8/28/20
Drug Class (Mechanism of Action if novel agent)	Human growth hormone analog
Indication	Replacement of endogenous growth hormone in adults with growth hormone deficiency
Comparative agent – Therapeutic interchange?	Somatropin injection
Dosage forms/strengths	Injection: 10 mg/1.5 mL single-patient-se prefilled pen
Common Dose/sig	Initiate with 1.5 mg subcutaneously once weekly; dose may be increased by 0.5 to 1.5 mg every 2 to 4 weeks until desired response is achieved.
DEA Schedule	None
Date of market availability	Novo Nordisk is finalizing plans; date not announced
Similar Medication Names	Soliqua, somatropin
Clinical Use Evaluation	
Common Adverse Effects	>2%: back pain, arthralgia, dyspepsia, sleep disorder, dizziness, tonsillitis, peripheral edema, vomiting, adrenal insufficiency, hypertension, blood creatine phosphokinase increase, weight increase, anemia

Severe Adverse Effects	Intracranial hypertension, hypersensitivity
Severe Drug-Drug Interactions	Replacement glucocorticoid treatment: patients may require an increase in maintenance or stress doses Cytochrome P450-metabolized drugs: clearance of these drugs may be altered, monitor closely Oral estrogen: initiate with a somapacitan 2 mg dose Insulin and other hypoglycemic agents: may require dose adjustments
Severe Drug-Food Interactions	None known
Important Labs Values to assess prior to order entry or at point of clinical follow up.	Serum insulin-like growth factor (IGF-1) to guide dose; draw samples 3 to 4 days after the prior dose
Used in Pediatric Areas	Safety and effectiveness have not been established.
Renal or Hepatic Dosing	No dosage adjustment recommended in mild hepatic impairment. In moderate hepatic impairment initiate with a dose of 1 mg once weekly and use smaller dose increments when titrating the dose. Use is not recommended in patients with severe hepatic impairment. Routine dose adjustments are not necessary in renal impairment.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindicated in patients with acute critical illness after open-heart surgery, abdominal surgery or multiple accidental traumas, acute respiratory failure, active malignancy, hypersensitivity to the drug or any product excipients, and active proliferative or severe non-proliferative diabetic retinopathy. Warnings: Increased mortality in patients with acute critical illness. Increased risk of malignancy progression or new skin malignancy. Glucose intolerance and diabetes mellitus Severe hypersensitivity including anaphylactic reactions and angioedema Intracranial hypertension has occurred; perform fundoscopic examination before initiating treatment to elude preexisting papilledema Fluid retention – usually transient and dose dependent Hypoadrenalism Hypothyroidism Pancreatitis Lipohypertrophy or lipoatrophy
Special administration technique or considerations	Administer by subcutaneous injection to the abdomen or thigh; regularly rotate injection sites to avoid lipodystrophy. The maximum recommended dosage is 8 mg once weekly
Prepared by	Terri Levien
Source	Sogroya (somapacitan-beco) [prescribing information]. Plainsboro, NJ: Novo Nordisk Inc.; August 2020.