College of Pharmacy and Pharmaceutical Sciences
WASHINGTON STATE UNIVERSITY

Drug Information Center

Highlights of FDA Activities – 8/1/21 – 8/31/21

FDA Drug Safety Communications & Drug Information Updates:

REGEN-COV monoclonal antibody therapy authorized for postexposure COVID-19 prophylaxis 8/12/21
FDA revised the emergency use authorization (EUA) for REGEN-COV (casirivimab and imdevimab, administered together) authorizing REGEN-COV for emergency use as postexposure prophylaxis for COVID-19 in adults and pediatric subjects (12 years of age and at least 40 kg) who are at high risk for progression to severe COVID-19. It remains authorized as treatment for mild-to-moderate COVID-19 in adults and pediatric patients 12 years of age and at least 40 kg with positive results of direct SARS-CoV-2 viral testing, and who are at risk for progression to severe COVID-19, including hospitalization or death. It is not a substitute for vaccination against COVID-19.

Moderna and Pfizer-BioNTech COVID-19 Vaccines - Emergency Use Authorization Update 8/12/21
FDA amended the EUAs for the Moderna and Pfizer-BioNTech COVID-19 vaccines to allow for an additional dose in certain immunocompromised individuals, specifically solid organ transplant recipients or those with conditions considered to have an equivalent level of immunocompromise.

Risks associated with intraocular use of compounded moxifloxacin 8/12/21
FDA reported they are aware of multiple literature reports that claim to support the use of intraocular moxifloxacin for the prophylaxis of endophthalmitis, and it is a common practice among ophthalmologists in association with cataract surgery. However, there are no FDA approved drugs for endophthalmitis prophylaxis. FDA has received reports of TASS (Toxic Anterior Segment Syndrome) following intraocular administration of compounded drugs using moxifloxacin as a bulk drug substance, as well as administration of repackaged and/or diluted FDA-approved moxifloxacin drugs. Health care professionals and compounders should be aware of the risks associated with intraocular moxifloxacin, particular those containing more than 0.3 mL of 0.5% moxifloxacin or inactive ingredients.

Eco-Med Ultrasound Gels and Lotions - Risk of Contamination with *Burkholderia cepacia* 8/18/21
The FDA informed all health care providers to immediately stop using and discard all ultrasound gels and lotions manufactured by Eco-Med Pharmaceutical, Inc. Eco-Med issued a voluntary recall on 8/4/21 of EcoGel 200 Ultrasound Gel due to risk of bacterial contamination, but the FDA has determined that all ultrasound gels and lotions manufactured by Eco-Med are at risk for bacterial contamination. The letter and list can be found on the FDA website.

FDA Approves First COVID-19 Vaccine 8/23/21
The FDA granted approval for the two-dose series of *Comirnaty* (COVID-19 Vaccine, mRNA) by Pfizer-BioNTech for active immunization to prevent COVID-19 caused by SARS-CoV-2 in patients ages 16 and older. The two-dose series of *Comirnaty* is still available to patients ages 12 through 15 under EUA. For patients 12 years and older who are immunocompromised, a third, or booster dose eight months after the second dose is also available under EUA.

Changes to Bamlanivimab and Etesevimab Emergency Use Authorization 8/27/21
FDA revised the EUA for bamlanivimab and etesevimab administered together to authorize use only in states, territories, and U.S. jurisdictions in which recent data shows the combined frequency of variants resistant to bamlanivimab and etesevimab administered together is ≤5%. More information, including the FDA list of states, territories, and U.S. jurisdictions in which bamlanivimab and etesevimab administered together are currently authorized can be found here.

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

Eco-Gel 200 by Eco-Med Pharmaceutical: Recall – Bacterial Contamination 8/4/21
Eco-Med Pharmaceuticals recalled eight lots of Eco Gel 200 (MediChoice M500812) ultrasound gel due to bacterial contamination with *Burkholderia cepacia* complex. The product is also distributed as MediChoice Ultrasound Gel by Owens and Minor and Mac Medical Supply. More information on lot numbers affected by the recall and product names affected by the quarantine can be found at the FDA website.

Atovaquone Oral Suspension, USP 750 mg/5 mL by KVK Tech: Recall – Temperature Abuse 8/6/21
KVK Tech is recalling two lots of atovaquone oral suspension 750 mg/5 mL (NDC 10702-223-21, lots 16653A and 16654A, expiration dates of December 2022) to the consumer level due to complaints of unusual grittiness, determined to be most probably caused by prolonged exposure to extremely cold weather during shipment. This may result in changes to the effectiveness, appearance, taste, and thickness of the liquid.

Sodium Bicarbonate in 5% Dextrose Injection 150 mEq/1000 mL, SterRx: Recall – Microbial Contamination 8/10/21
SterRx recalled three lots of sodium bicarbonate 5% dextrose injection 150 mEq/1000 mL (NDC 70324-325-01) to the hospital pharmacy level due to waterborne microbial contamination. Affected lots are BUP (exp 3/21/22), BUI (exp 3/16/22), and BTW (exp 3/8/22).

Dose IQ Safety Software used with Spectrum IQ Infusion System by Baxter Healthcare: Recall – Software Defect 8/12/21 & 8/24/21
Baxter Healthcare recalled the Dose IQ Safety Software version 9.0.x used with the Spectrum IQ Infusion System due to a software defect that may result in improper configuration of drug information in the software. This may cause serious adverse events including delayed therapy and under- or over-infusion of medication. Subsequently the recall was expanded to include all Spectrum IQ infusion pumps. A software upgrade is in development. More information about the initial recall can be found on the FDA website, as well as information about the subsequent notification.

Chantix (Varenicline) 0.5 mg and 1 mg Tablets by Pfizer: Recall - Presence of N-nitroso-varenicline 8/16/21
Pfizer is voluntarily recalling an additional four lots of Chantix 0.5 mg and 1 mg tablets to the consumer level due to presence of N-nitroso-varenicline above the acceptable level. Patients are not at immediate risk and should consult their provider or pharmacy to determine whether they have affected lots. Lot numbers can be found at the FDA website.

Monoject Saline Flush Prefilled Syringes by Cardinal Health: Recall – Risk of Air Reentering Syringe 8/23/21
Cardinal Health recalled all lots of three models of Monoject Saline Flush Prefilled Syringe due to risk of the syringe plunger pulling air into the syringe after air has been expelled; the company has received 37 reports of the plunger pulling back. This can cause air embolism, which can result in serious consequences including stroke or death. Affected product codes are 8881570121 (12 mL syringe, 10 mL saline fill), 8881570123 (12 mL syringe, 3 mL saline fill), and 8881570125 (12 mL syringe, 5 mL saline fill).

Alaris Infusion Pump Model 8100 Bezel by Bio-Medical Equipment Service: Recall – Separation 8/24/21
Bio-Medical Equipment Service Co. recalled the Alaris Infusion Pump Module Model 8100 (TIPA-8100-4410) due to risk of cracking or separation of the bezel components potentially leading to inaccurate fluid delivery. A complete list of recalled serial numbers can be found on the FDA website.

N95 Respirators by Shanghai Dasheng: Alert – Revocation of Respirator Approvals by NIOSH 8/25/21
FDA alerted health care personnel to stop using certain N95 respirators manufactured by Shanghai Dasheng. NIOSH has revoked all respiratory approvals previously issued to Shanghai Dasheng because the company did not implement, maintain, and control a quality management system. A completed list of affected respirators can be found on the FDA website.

Lidocaine HCl Topical Solution 4% by Teligent Pharma, Inc. Recall – Super Potency 8/27/21

Teligent Pharma, Inc. recalled lot #14218, Exp. 09/2022 of Lidocaine HCl Topical Solution 4%, 50 mL in a screw cap glass bottle to the user level. Testing has found it to be super potent based on an Out of Specification result obtained at the 19-month stability timepoint.

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***
365 Skinny High Intensity*	Weight Loss	Sibutramine[1]
365 Skinny Emergency Boutique*	Weight Loss	Sibutramine[1]
Hydro Pineapple Burn*	Weight Loss	Sibutramine[1]
Infant formulas by Able Group (HiPP Comfort Milk Formula, HiPP Dutch Stage 1 Combiotic Infant Milk Formula, HiPP HA Germany Hypoallergenic Stage PRE Combiotic Infant Milk Formula, HiPP German Stage 1 Combiotic Infant Milk Formula, Holle Bio Stage 1 Organic Infant Milk Formula, Holle Bio Stage PRE Organic Infant Milk Formula, Lebenswert Anfangsmilch Stage 1 Organic Infant Milk Formula, and HiPP UK Stage 1 Combiotic First Infant Milk Formula)*	Infant formula	Mislabeled, contain inadequate iron, and have not been submitted for FDA review
Themra Epimedyumlu Bitkisel Karisimli Macun	Sexual enhancement	sildenafil

*recalled

[1]Sibutramine has been associated with increased cardiovascular events; removed from market for safety reasons in 2010[FDA]

New Product Shortages	***Date Initially Posted***
Tocilizumab injection (Actemra, Genentech)	8/17/21

Brand Name or Sole Source Product Discontinuations/Withdrawals	***Date Posted***
Aluminum Hydroxide and Magnesium Carbonate (Gaviscon Regular Strength) oral liquid and chewable tablets (GlaxoSmithKline): 95 mg/15mL and 358 mg/15mL oral liquid in 6 oz bottle (NDC 0135-0094-42) and 12 oz bottle (NDC 0135-0094-41), 80 mg/1 and 14.2 mg/1 chewable tablets in 100 ct Bottle (NDC 0135-0096-26); generics remain available	8/6/21

New Drug Approvals:	***Description (See Attached Drug Summaries)***	***Date Approved***
Avalglucosidase alfa / Nexviazyme / Sanofi	Enzyme replacement therapy for treatment of late-onset Pompe disease in patients ages 1 year and older	8/6/21
Belzutifan / Welireg / Merck	Hypoxia-inducible factor inhibitor for treatment of adults with von Hippel-Lindau disease who require therapy for associated renal cell carcinoma, CNS hemangioblastomas, or pancreatic neuroendocrine tumors, not requiring immediate surgery	8/13/21
Tick-borne encephalitis vaccine / TicoVac / Pfizer	For active immunization to prevent tick-borne encephalitis in individuals 1 year of age or older	8/13/21
COVID-19 Vaccine, mRNA / Comirnaty / Pfizer-BioNTech	Two-dose series to prevent COVID-19 in individuals ages 16 and older	8/23/21

New Drug Approvals continued:	***Description (See Attached Drug Summaries)***	***Date Approved***
Difelikefalin / Korsuva / Cara Therapeutics	Kappa opioid receptor agonist for treatment of moderate-to-severe pruritis associated with chronic kidney disease in adults undergoing hemodialysis	8/23/21
Lonapegsomatropin / Skytrofa / Ascendis	Human growth hormone for treatment of pediatric patients 1 year and older who weigh at least 11.5 kg and have growth failure due to inadequate secretion of endogenous growth hormone	8/25/21

New Indications:	***Description***	***Date Approved***
Lenvatinib / Lenvima / Eisai Inc.	In combination with pembrolizumab, for the first line treatment of adult patients with advanced renal cell carcinoma.	8/10/21
Pembrolizumab / Keytruda / Merck & Co., Inc.	In combination with lenvatinib, for the first line treatment of adult patients with advanced renal cell carcinoma.	8/10/21
Calcium, magnesium, potassium, and sodium oxybates / Xywav / Jazz Pharmaceuticals	For treatment of adults with idiopathic hypersomnia.	8/12/21
Dostarlimab-gxly / Jemperli / GlaxoSmithKline	Treatment of adult patients with mismatch repair deficient recurrent or advanced solid tumors that have progressed on or following prior treatment and who have no satisfactory treatment alternatives	8/17/21
Empagliflozin / Jardiance / Boehringer Ingelheim Pharmaceuticals	To reduce the risk of cardiovascular death and hospitalization for heart failure in adults with heart failure and reduced ejection fraction	8/18/21
Nivolumab / Opdivo / Bristol-Myers Squibb Co.	Adjuvant treatment of patients with urothelial carcinoma who are at high risk of recurrence after undergoing radical resection.	8/19/21
Ivosidenib / Tibsovo / Servier Pharmaceuticals LLC	For adult patients with previously treated, locally advanced or metastatic cholangiocarcinoma with an isocitrate dehydrogenase-1 (IDH1) mutation as detected by an FDA-approved test.	8/25/21
Zanubrutinib / Brukinsa / BeiGene	Treatment of adult patients with Waldenström's macroglobulinemia	8/31/21

New Dosage Forms or Formulation:	***Description***	***Date Approved***
Glucagon / Gvoke Kit / Xeris Pharmaceuticals	Solution for injection: 1 mg/0.2 mL single-dose vial with syringe kit	08/23/21

Compiled by:

Terri Levien, Pharm.D.
Regan Smith, Pharm.D., PGY1 Drug Information Resident
Bahar Adamzadeh, Doctor of Pharmacy Candidate 2022
Katie Walley, Doctor of Pharmacy Candidate 2022
Roselyn Cachero, Doctor of Pharmacy Candidate 2022
Hunter Weitze, Doctor of Pharmacy Candidate 2022

Drug Information Center
College of Pharmacy and Pharmaceutical Sciences
Washington State University
412 E. Spokane Falls Blvd.
Spokane, WA 99202-2131
(509) 358-7662
Pharmacy.druginfo@wsu.edu

Avalglucosidase alfa-ngpt / Nexviazyme/ Sanofi Genzyme	
Generic Name / Brand Name / Company	Avalglucosidase alfa-ngpt / Nexviazyme / Sanofi Genzyme
Date of approval	8/6/21
Drug Class (Mechanism of Action if novel agent)	Enzyme replacement therapy
Indication	Late onset Pompe Disease (lysosomal acid alpha-glucosidase deficiency)
Comparative agent – Therapeutic interchange?	Alglucosidase alfa (Lumizyme)
Dosage forms/strengths. Common Dose/sig	For injection: 100 mg avalglucosidase alfa-ngpt as a lyophilized powder in a single dose vial for reconstitution ≥30 kg: 20 mg/kg of actual body weight every 2 weeks <30 kg: 40 mg/kg of actual body weight every 2 weeks
DEA Schedule	None
Date of market availability	Available
Similar Medication Names	Alglucosidase Alfa, Agalsidase Alfa, Agalsidase Beta, Alglucerase
Clinical Use Evaluation	
Common Adverse Effects	>5%: headache, fatigue, diarrhea, nausea, arthralgia, dizziness, myalgia, pruritus, vomiting, dyspnea, erythema, paresthesia, urticaria
Severe Adverse Effects	Hypersensitivity reactions including anaphylaxis and infusion-associated reactions, including respiratory distress, chest discomfort, and flushing
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	Indicated in pediatric patients 1 year of age and older
Renal or Hepatic Dosing	No renal or hepatic dosing recommendations available
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Appropriate medical support measures including cardiopulmonary resuscitation equipment should be readily available during administration. Severe hypersensitivity and infusion-related reactions have occurred. Patients susceptible to fluid volume overload should be closely monitored.
Special administration technique or considerations	Administer using an in-line, low protein binding, 0.2 micrometer filter. Flush line with 5% dextrose infusion after infusion. Consider pretreating with antihistamines, antipyretics, and/or corticosteroids. Discontinue infusion if severe hypersensitivity or infusion-related reaction; temporarily hold or slow rate if mild to moderate hypersensitivity or infusion-related reaction. Initial infusion rate: 1 mg/kg/hour, gradually increase rate every 30 minutes if no signs of infusion-associated reactions to 3 mg/kg/hour, 5 mg/kg/hour, and then 7 mg/kg/hour; then maintain the infusion rate at 7 mg/kg/hour until the infusion is complete. Appropriate infusion duration is 4 hours to 5 hours.
Prepared by	Roselyn Cachero, Doctor of Pharmacy Candidate 2022
Source	Nexviazyme (avalglucosidase alfa-ngpt) [prescribing information]. Cambridge, MA: Genzyme Corporation, August 2021

Belzutifan / Welireg / Merck	
Generic Name / Brand Name / Company	Belzutifan / Welireg / Merck
Date of approval	8/13/21
Drug Class (Mechanism of Action if novel agent)	Hypoxia-inducible factor 2 alfa (HIF-2α) inhibitor; HIF-2α is a transcription factor that is degraded by von Hippel-Lindau (VHL) protein. In VHL disease, lack of functional VHL protein results in accumulation of HIF-2α and

	expression of downstream genes that promote cellular proliferation, angiogenesis, and tumor growth.
Indication	Treatment of adults with VHL disease who require therapy for associated renal cell carcinoma, CNS hemangioblastomas, or pancreatic neuroendocrine tumors, not requiring immediate surgery.
Comparative agent – Therapeutic interchange?	None
Dosage forms/strengths. Common Dose/sig	Oral tablets: 40 mg 120 mg (three 40 mg tablets) by mouth once daily
DEA Schedule	None
Date of market availability	September 2021
Similar Medication Names	Coreg, Onureg
Clinical Use Evaluation	
Common Adverse Effects	≥20%: anemia, fatigue, increased creatinine, headache, dizziness, increased glucose, nausea, visual impairment, upper respiratory tract infection, dyspnea, increased ALT
Severe Adverse Effects	Anemia, hypoxia
Severe Drug-Drug Interactions	Coadministration of belzutifan with hormonal contraceptives may lead to contraceptive failure
Severe Drug-Food Interactions	None known
Important Labs Values to assess prior to order entry or at point of clinical follow up.	Hemoglobin at baseline and periodically during treatment; verify pregnancy status prior to initiation of therapy.
Used in Pediatric Areas	Safety and effectiveness have not been established in pediatric patients.
Renal or Hepatic Dosing	No dose modifications are recommended in patients with mild-to-moderate renal or hepatic impairment. Belzutifan has not been studied in patients with severe renal or hepatic impairment.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications: none in product labeling Warnings: Anemia: for hemoglobin <9 g/dL, hold belzutifan until >9 g/dL then resume at a reduced dose or permanently discontinue depending on severity of anemia; transfuse patients as clinically indicated. Severe hypoxia requiring discontinuation, supplemental oxygen, or hospitalization: monitor oxygen saturation at baseline and periodically during treatment; for oxygen saturation <88% or PaO2 <55 mmHg with exercise, consider holding belzutifan until pulse oximetry with exercise is >88%, then resume at the same dose or at a reduced dose. For oxygen saturation <88% or PaO2 <55 mmHg at rest, hold belzutifan until resolved and resume at reduced dose or discontinue. For life-threatening hypoxia or recurrent, symptomatic hypoxia, permanently discontinue belzutifan. Embryo-fetal toxicity: belzutifan can cause fetal harm when administered to pregnant women. Coadministration of belzutifan with hormonal contraceptives may lead to contraceptive failure. Verify the pregnancy status of females of reproductive potential prior to initiation belzutifan and advise patients to use effective non-hormonal contraception during treatment and for one week after the last dose of belzutifan.
Special administration technique or considerations	Belzutifan should be taken at the same time each day and may be taken with or without food. Advise patients to swallow tablets whole, and not chew, crush, or split belzutifan tablets prior to swallowing.
Prepared by	Regan Smith
Source	Welireg (belzutifan) [prescribing information]. Whitehouse Station, NJ: Merck & Co., Inc.; August 2021.

Tick-borne encephalitis vaccine / TicoVac / Pfizer	
Generic Name / Brand Name / Company	Tick-borne encephalitis vaccine / TicoVac / Pfizer
Date of approval	8/13/21
Drug Class (Mechanism of Action if novel agent)	Inactivated whole virus vaccine
Indication	Active immunization to prevent tick-borne encephalitis (TBE) in patients 1 year of age and older.
Comparative agent – Therapeutic interchange?	None; previously only available in endemic areas
Dosage forms/strengths. Common Dose/sig	Suspension for injection: 0.25 mL & 0.5 mL single-dose, prefilled syringes Patients 1 through 15 years old: series of three 0.25 mL doses administered IM; first dose on day 0, second dose 1 to 3 months after the first, and the third dose 5 to 12 months after the second. Patients ≥16 years old: series of three 0.5 mL doses administered IM; first dose on day 0, second dose 14 days to 3 months after the first, and the third dose 5 to 12 months after the second. A fourth (booster) dose may be administered ≥3 years after completion of the primary series if ongoing exposure or re-exposure to TBE virus is expected.
DEA Schedule	None
Date of market availability	TBD
Similar Medication Names	*Tenivac*, *Tikosyn*
Clinical Use Evaluation	
Common Adverse Effects	Age 1-15 years (>9%): tenderness, local pain, headache, fever, restlessness. Age ≥16 years (>5%): tenderness, local pain, fatigue, headache, muscle pain.
Severe Adverse Effects	None known
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	Established safety and efficacy in ages 1 year and older
Renal or Hepatic Dosing	No recommended dose modifications for renal or hepatic impairment.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications: severe allergic reaction (eg, anaphylaxis) to any component Warnings: Appropriate medical treatment and supervision must be available to manage possible anaphylactic reactions following administration. Some individuals with altered immunocompetence may have reduced immune response Contains albumin, a derivative of human blood. There is remote risk of transmission of viral diseases and variant Creutzfeldt-Jakob disease (vCJD), and theoretical risk of transmission of Creutzfeldt-Jakob disease (CJD). No cases of transmission of viral diseases, vCJD, or CJD have been identified for licensed albumin or albumin contained in other licensed products. Vaccination may not protect all individuals.
Special administration technique or considerations	Bring vaccine to room temperature and shake well prior to administration. Do not administer if particulate matter or discoloration remains after shaking (visual appearance should be of a homogenous off-white, opalescent suspension). Administer vaccine by intramuscular injection.
Prepared by	Regan Smith
Source	Ticovac (Tick-borne encephalitis vaccine) [prescribing information]. New York, NY: Pfizer Labs; August 2021.

Difelikefalin / Korsuva / Cara Therapeutics	
Generic Name / Brand Name / Company	Difelikefalin / Korsuva / Cara Therapeutics
Date of approval	8/23/21
Drug Class (Mechanism of Action if novel agent)	Kappa opioid receptor agonist
Indication	Treatment of moderate-to-severe pruritis associated with chronic kidney disease in adults undergoing hemodialysis
Comparative agent – Therapeutic interchange?	None
Dosage forms/strengths. Common Dose/sig	Injection: 65 mcg/1.3 mL (50 mcg/mL) single-dose vials 0.5 mcg/kg intravenous bolus injection into the venous line of dialysis circuit at the end of each hemodialysis treatment
DEA Schedule	None
Date of market availability	2022
Similar Medication Names	Diflucan, Rasuvo
Clinical Use Evaluation	
Common Adverse Effects	≥3%: diarrhea, dizziness, nausea, gait disturbances, hyperkalemia, headache, somnolence, mental status change
Severe Adverse Effects	Rare; serious mental status change (1.4%), serious fall (<1%)
Severe Drug-Drug Interactions	None known
Severe Drug-Food Interactions	None known
Important Labs Values to assess prior to order entry or at point of clinical follow up.	None
Used in Pediatric Areas	Safety and effectiveness have not been established in pediatric patients.
Renal or Hepatic Dosing	No dose modifications are recommended in patients with mild-to-moderate hepatic impairment. Difelikefalin use is not recommended in patients with severe hepatic impairment or in patients undergoing peritoneal dialysis.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications: none in product labeling Warnings: Dizziness, somnolence, mental status change, and gait disturbances including falls; CNS depressants, sedating antihistamines, and opioids should be used with caution during treatment with difelikefalin. Difelikefalin may impair mental or physical abilities. Advise patients not to drive or operate dangerous machinery until the effects of difelikefalin on the patient are known.
Special administration technique or considerations	Do not mix or dilute difelikefalin prior to administration. Dose of difelikefalin is determined by the patient's target dry body weight in kg. Difelikefalin is removed by hemodialysis and must be administered after blood is no longer circulating through the dialyzer. The dose must be administered within 60 minutes of syringe preparation.
Prepared by	Regan Smith
Source	Korsuva (difelikefalin) [prescribing information]. Stamford, CT: Cara Therapeutics, Inc.; August 2021.

Lonapegsomatropin-tcgd / Skytrofa / Ascendis	
Generic Name / Brand Name / Company	Lonapegsomatropin-tcgd / Skytrofa / Ascendis
Date of approval	8/25/21
Drug Class (Mechanism of Action if novel agent)	Growth hormone
Indication	Treatment of pediatric patients 1 year or older who have growth failure due to inadequate secretion of endogenous growth hormone GH and weigh at least 11.5 kg.
Comparative agent – Therapeutic interchange?	Somatropin (Genotropin)
Dosage forms/strengths. Common Dose/sig	For injection: lyophilized powder in a single-dose, dual-chamber, prefilled cartridges containing lonapegsomatropin-tcgd and diluent in 9 cartridges: 3 mg, 3.6 mg, 4.3 mg, 5.2 mg, 6.3 mg, 7.6 mg, 9.1 mg, 11 mg, and 13.3 mg. Dose: 0.24 mg/kg/wk body weight by subcutaneous injection once weekly
DEA Schedule	None
Date of market availability	September 2021
Similar Medication Names	Somatropin, Genotropin, Norditropin
Clinical Use Evaluation	
Common Adverse Effects	≥5%: viral infection, pyrexia, cough, nausea and vomiting, hemorrhage, diarrhea, abdominal pain, arthralgia, and arthritis.
Severe Adverse Effects	None known
Severe Drug-Drug Interactions	Glucocorticoid treatment, CYP450 metabolized drugs, insulin and/or other antihyperglycemic agents may require dosage adjustment. Oral estrogen may increase growth hormone requirements.
Severe Drug-Food Interactions	None known
Important Labs Values to assess prior to order entry or at point of clinical follow up.	Serum levels of parathyroid hormone, phosphate, and alkaline phosphatase may increase after somatropin treatment. If the labs are elevated, monitor as appropriate. Monitor serum glucose.
Used in Pediatric Areas	Efficacy established in pediatric patients at least 1 year old and weighing at least 1.5 kg
Renal or Hepatic Dosing	No specific renal or hepatic studies have been performed.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications: Acute critical illness, hypersensitivity to somatropin or any of the excipients, children with closed epiphyses, active malignancy, active proliferative or severe non-proliferative diabetic retinopathy, children with Prader-Willi syndrome who are severely obese or have severe respiratory impairment due to risk of sudden death. Warnings: Increased mortality in patients with acute critical illness; increased risk of neoplasms; glucose intolerance and diabetes mellitus may be unmasked requiring antihyperglycemic agent dose adjustments; intracranial hypertension; fluid retention may occur; hypoadrenalism, hypothyroidism may become evident or worsen; slipped capital femoral epiphysis in pediatric patients may develop; progression of preexisting scoliosis in pediatric patients may develop; pancreatitis.
Special administration technique or considerations	If refrigerated, the lonapegsomatropin-tcgd cartridge must be kept at room temperature for 15 minutes before use. Use cartridges within 4 hours of reconstitution, discard reconstituted cartridges after 4 hours when stored at room temperature up to 86°F. The mixed solution should be clear and colorless and may contain air bubbles occasionally, do not inject if solution is cloudy or contaminated. Inject lonapegsomatropin-tcgd subcutaneously into the abdomen, buttock, or thigh, rotating injection sites to reduce risk of lipoatrophy.
Prepared by	Hunter Weitze
Source	Skytrofa (lonapegsomatropin-tcgd) [prescribing information]. Hellerup, DK: Ascendis Pharma; August 2021.