Highlights of FDA Activities – 3/1/26 – 3/31/26

FDA Drug Safety Communications & Drug Information Updates:

Product	Description	Date Announced
National Drug Code (NDC) Format – 12-digit Format Starting March 7, 2033	The FDA adopted a new 12-digit format for the NDC to take effect on March 7, 2033. On that date the FDA will assign new 12-digit NDCs and convert all previously assigned 10-digit NDCs to the uniform 12-digit format. Through March 6, 2033 the FDA will continue to assign 10-digit NDCs. Manufacturers, distributors, repackagers, relabelers, pharmacies, health care providers, payors, and other supply chain partners are instructed to use this time to update their systems, processes, and infrastructure to handle the 12-digit format by March 7, 2033. There will be a 3-year transition period from March 7, 2033 through March 6, 2036 to allow complete label updates and deplete old labeling stock. Labeling may be updated before the implementation date with the new 12-digit NDC by adding leading zeroes to the labeler code, product code, and/or package code segments.	3/4/26
New Adverse Event Look-Up Tool – FDA Adverse Event Monitoring System (AEMS)	The FDA announced the launch of a new platform for analyzing adverse event reports: FDA Adverse Event Monitoring System (AEMS). Adverse events submitted to the FDA for drugs, biologics, vaccines, cosmetics, and animal food will all be processed and displayed in a single dashboard. The new system immediately replaced FDA Adverse Event Reporting System (FAERS), Vaccine Adverse Event Reporting System (VAERS), and Adverse Event Reporting System (AERS) and in May will also replace Manufacturer and User Facility Device Experiences (MAUDE), Human Foods Complaint System (HFCS), and Center for Tobacco Products Adverse Event Reporting System (CTPAE). For more information see the description on the FDA site or go to the public dashboard (AEMS).	3/11/26
Carbidopa/Levodopa Prescribing Information Update: New Warning – Vitamin B6 Deficiency	The FDA notified all application holders for all products containing carbidopa/levodopa that the FDA is requiring the addition of a warning to the prescribing information to state that these medications can cause vitamin B6 deficiency and vitamin B6 deficiency-associated seizures. Health care professionals are advised to assess vitamin B6 levels prior to initiating carbidopa/levodopa therapy and periodically during treatment and to supplement with vitamin B6 as necessary.	3/20/26

Product	Description	Date Announced
Avacopan (Tavenos, Amgen): Drug Safety Communication – Serious Liver Injury	The FDA alerted patients and health care professionals about serious postmarketing cases, including fatal cases, of drug-induced liver injury associated with the use of avacopan in patients with severe active anti-neutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis. Although hepatotoxicity is described in the prescribing information, new cases of vanishing bile duct syndrome and liver injury with fatal outcomes prompted the communication. In patients treated with avacopan liver panel testing should be conducted every 2 weeks in the first month of treatment, monthly for the next 5 months, and then as clinically indicated. Promptly discontinue avacopan if ALT or AST is greater than 3 times the upper limit of normal (ULN), alkaline phosphatase is greater than 2 times the ULN, or the patient presents with evidence of symptomatic cholestasis.	3/31/26

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

Product	Description	Date Announced
Omnipod 5 Pods, Insulet: Medical Device Correction – Leak in Internal Tubing	Insulet Corporation issued a device correction for select Omnipod 5 Pods due to small tears in the internal tubing that may result in leaks inside of the Pod which prevent full dose infusion. The list of impacted lots can be found at: https://www.omnipod.com/mdc-3-26/check-pod-lot. Replacement Pods are being provided by the manufacturer at no cost. If a Pod from an impacted lot is in current use, patients should discontinue use and replace it with a Pod from an unaffected lot. The manufacturer has received 18 reports of serious adverse events associated with high blood glucose levels. The continuous glucose monitoring (CGM) systems or CGM readings are not impacted.	3/13/26
Webcol Large Alcohol Prep Pad, Cardinal Health: Recall – Microbial Contamination	Cardinal Health recalled select lots of Webcol Large Alcohol Prep Pads (70% isopropyl alcohol; product code 5110) due to contamination with *Paenibacillus phoenicis*. The product was distributed between September 2025 and February 2026. A complete list of recalled lot numbers can be located via the FDA announcement.	3/20/26
Magnesium Sulfate in Water, USP 4 g/100 mL, Amneal Pharmaceuticals: Recall – Mixup with Tranexamic Acid Injection	Amneal Pharmaceuticals recalled one lot of Magnesium Sulfate in Water for Injection USP 4 g/100 mL IV bag (NDC 70121-1720-3; lot AH250161) to the hospital level. A pouch labeled Magnesium Sulfate in Water was found to contain an IV bag of Tranexamic Acid in 0.7% Sodium Chloride Injection, 10 mg/mL. The recalled product is packaged in 12 x 100 mL pouches to a carton and was distributed nationwide between 12/22/25 and 2/27/26.	3/24/26

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
Artri Ajo Rey	Joint pain	Dexamethasone, diclofenac, methocarbamol
Blue Bull Extreme*	Sexual enhancement	Sildenafil
Boner Bears Honey*	Sexual enhancement	Sildenafil, tadalafil
Gold Lion Aphrodisiac Chocolate Sachet*	Sexual enhancement	Sildenafil, tadalafil
Kian Pee Wan	Appetite stimulant	Cyproheptadine, dexamethasone
Naturista Reyes, Chupa Panza	Weight loss	Yellow oleander
Primal Herbs Volume*	Sexual enhancement	Sildenafil
Red Bull Extreme*	Sexual enhancement	Sildenafil
Vital Nutrients Aller-C*	Allergy relief	Egg, hazelnut, soy

**recalled*

New Product Shortages (per FDA or ASHP)

Product	Date Initially Posted
Acetylcysteine intravenous solution	3/11/26
Dextrose 25% injection	3/11/26
Hemgenix (per manufacturer)	3/17/26
Benzylpenicilloyl polylysine	3/19/26
Ketorolac injection	3/23/26
Hypromellose ophthalmic solution	3/25/26
Buprenorphine injection	3/30/26

ASHP Drug Shortages List contains up-to-date information on drug shortages

Brand Name or Sole Source Product Discontinuations/Withdrawals

Product	Date Posted
Peritoneal dialysis solution (DELFLEX® w/Dextrose, Solution, Fresenius Medical)	3/10/26
Ramelteon tablets (Rozerem, Takeda Pharmaceuticals) generics remain available	3/19/26
Tazemetostat tablets (Tazverik, Ipsen) – withdrawing from market due to secondary hematologic malignancies; patients should be transferred to alternative treatments	3/27/26

New Drug Approvals

Product	Description (See Attached Drug Summaries)	Date Approved
Icotrokinra/Icotyde/Janssen Biotech	Oral interleukin-23 receptor antagonist for the treatment of moderate-to-severe plaque psoriasis in adults and pediatric patients 12 years and older weighing at least 40 kg who are candidates for systemic therapy or phototherapy	3/17/26
Linerixibat/Lynavoy/GlaxoSmithKline	Oral ileal bile acid transporter (IBAT) inhibitor for adult patients with cholestatic pruritus associated with primary biliary cholangitis (PBC) who have no history of decompensated cirrhosis	3/17/26
Tividenofusp Alfa-eknm/Avlayah/ Denali Therapeutics	Weekly IV enzyme infusion to treat neurologic manifestations of Hunter syndrome when the medication is started in presymptomatic or symptomatic pediatric patients weighing at least 5 kg prior to advanced neurologic impairment	3/24/26
Relacorilant/Lifyorli/Corcept Therapeutics	Oral glucocorticoid receptor antagonist for use in combination with nab-paclitaxel for the treatment of adults with platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer who have received one to three prior systemic treatment regimens, at least one of which included bevacizumab	3/25/26
Insulin icodec-abae/Awiqli/Novo Nordisk	Once-weekly basal insulin for use as an adjunct to diet and exercise to improve glycemic control in adults living with type 2 diabetes	3/26/26
Marnetegragene autotemcel/Kresladi/ Rocket Pharmaceuticals	Gene therapy for the treatment of pediatric patients with severe leukocyte adhesion deficiency type I	3/26/26

New Indications

Product	New Indication	Date Approved
Lomitapide/Juxtapid/Chiesi	Indication expanded to include use in pediatric patients 2 years and older with homozygous familial hypercholesterolemia	3/3/26
Teclistamab/Tecvayi/Janssen Biotech	In combination with daratumumab hyaluronidase-fihj for adult patients with relapsed or refractor multiple myeloma who have received at least one prior line of therapy including a proteasome inhibitor and an immunomodulatory agent	3/5/26
Deucravacitinib/Sotyktu/Bristol Myers Squibb	Treatment of active psoriatic arthritis in adults	3/6/26
Leucovorin calcium/Wellcovorin/ GlaxoSmithKline	Treatment of cerebral folate deficiency in adult and pediatric patients with a confirmed variant in the folate receptor 1 gene (CFD-FOLR1)	3/10/26

Product	New Indication	Date Approved
Secukinumab/Cosentyx/Novartis	Indication expanded for subcutaneous injection to include treatment of moderate-to-severe hidradenitis suppurative in patients 12 years and older	3/12/26
Respiratory syncytial virus vaccine, adjuvanted/Arexvy/GlaxoSmithKline	Indication expanded to include adults 18 through 49 years who are at increased risk for lower respiratory tract disease caused by RSV	3/13/26
Setmelanotide/Imcivree/Rhythm Pharmaceuticals	To reduce excess body weight and maintain reduction long term in adults and pediatric patients 4 years and older with acquired hypothalamic obesity	3/19/26
Nivolumab/Opdivo/Bristol Myers Squibb	With doxorubicin, vinblastine, and dacarbazine for the treatment of adult and pediatric patients 12 years and older with previously untreated, stage 3 or 4 classical Hodgkin lymphoma	3/20/26
Epinephrine/Neffy/ARS Pharmaceuticals	Indication expanded to include use in all patients weighing at least 33 pounds (15 kg; also allows for use after freezing and in temperatures up to 122° F	3/26/27
Diclofenac epolamine/Licart/IBSA Pharma	Indication expanded to include pediatric patients 6 to less than 17 years for the topical treatment of acute pain due to minor strains, sprains, and contusions	3/27/26

New Dosage Forms or Formulation

Product	Description	Date Approved
Piflufolastat F 18/Pylarify TruVu/ Lantheus	Injection: 37 MBq/mL to 4,440 MBq/mL of piflufolastat F 18 at end of synthesis in a multiple-dose vial; enhanced stability formulation for PSMA PET imaging to detect suspected metastatic or recurrent prostate cancer in men eligible for definitive therapy or with rising PSA levels	3/6/26
Lidocaine hydrochloride and epinephrine/Flavalta/Septodont	Injection: lidocaine HCl 2% (20 mg/mL) and epinephrine 1:100,000 (0.1 mg/mL) in 1.7 mL single-dose cartridges; for production of local anesthesia for dental procedures by nerve block or infiltration techniques	3/19/26
Semaglutide/Wegovy HD/Novo Nordisk	Injection: 7.2 mg; to reduce excess body weight and maintain weight reduction long-term in adults with obesity or overweight with at least one weight-related condition	3/19/26
Atomomoxetine/Atoncy/Validus Pharmaceuticals	Oral solution: 4 mg/mL in 100 mL bottle, grape flavored; for the treatment of ADHD in adults and pediatric patients 6 years and older	3/20/26

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New Drug Approvals: Drug Summaries

Icotrokinra/Icotyde/Janssen Biotech

Date of approval	3/17/26
Drug Class/Mechanism of Action	Interleukin-23 receptor antagonist
Indication	Treatment of moderate-to-severe plaque psoriasis in adults and pediatric patients 12 years and older weighing at least 40 kg who are candidates for systemic therapy or phototherapy
Comparative agent	Skyrizi (risankizumab-rzaa)
Dosage forms/strengths	Tablets: 200 mg
Common Dose/sig	200 mg orally once daily
DEA Schedule	NA
Date of market availability	Available
Similar Medication Names	Invokana

Clinical Use Evaluation

Common Adverse Effects	Headache (4%), nausea (1%), cough (1%), fungal infection (1%), fatigue (1%)
Severe Adverse Effects	None reported
Severe Drug-Drug Interactions	None known
Severe Drug-Food Interactions	Absorption reduced when administered with a high-fat meal; should be taken on an empty stomach 30 minutes before eating
Important Lab Monitoring	Consider tuberculosis testing prior to initiation; no routine laboratory monitoring
Used in Pediatric Areas	Indicated in patients 12 years and older weighing at least 40 kg; safety and efficacy not established in patients younger than 12 years or weighing less than 40 kg
Renal or Hepatic Dosing	No dosage adjustments. Monitor for potential adverse reactions when used in patients with moderate or severe renal impairment (eGFR < 60 mL/min).
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	No labeled contraindications. Warnings: • Infection: avoid use during any clinically important active infection • Tuberculosis: consider evaluating for TB prior to initiation and monitor • Immunizations: avoid live vaccines during treatment; complete all age-appropriate vaccinations prior to initiating treatment
Special administration technique or considerations	Administer on an empty stomach with water upon waking and at least 30 minutes before eating food. Can be dispersed in water if difficulty swallowing; do not crush, split or chew.
Source	Icotyde (icotrokinra) [prescribing information]. Horsham, PA: Janssen Biotech Inc; March 2026.

Linerixibat/Lynavoy/GlaxoSmithKline

Date of approval	3/17/26
Drug Class/Mechanism of Action	Ileal bile acid transporter (IBAT) inhibitor
Indication	Treatment of cholestatic pruritus in adult patients with primary biliary cholangitis
Comparative agent	Iqirvo (elafibranor), Livdelzi (seladelpar)
Dosage forms/strengths	Tablets: 40 mg
Common Dose/sig	40 mg by mouth twice daily
DEA Schedule	N/A
Date of market availability	Pending
Similar Medication Names	Linzess, Genvoya

Clinical Use Evaluation

Common Adverse Effects (≥5%)	Diarrhea (62%), abdominal pain, nausea, increased ALT, hemorrhage, increased AST, headache, dyspepsia, gastroesophageal reflux disease, abdominal distention, dizziness, arthralgia
Severe Adverse Effects	Diarrhea
Severe Drug-Drug Interactions	Bile acid binding resins may inhibit and decrease the amount of available drug. Take 4 hours before or 4 hours after taking a bile acid binding resin.
Severe Drug-Food Interactions	None known
Important Lab Monitoring	Liver enzymes and fat soluble vitamin levels at baseline and periodically
Used in Pediatric Areas	Safety and efficacy have not been established in pediatric patients
Renal or Hepatic Dosing	Renal impairment: There are no dosage adjustments necessary for this population as renal excretion is minimal. Hepatic impairment: There are no dosage adjustments necessary for use in mild hepatic impairment (Child-Pugh A). There is no data on whether use in moderate to severe impairment (Child-Pugh B or C) requires dosage adjustment.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	No labeled contraindications. Warnings: liver test elevations, diarrhea, fat soluble vitamin deficiency and related effects (eg, bleeding, bone fractures)
Special administration technique or considerations	Should be taken at least 30 minutes before food or beverage (other than water).
Source	Lynavoy (linerixibat) [prescribing information]. Durham, NC: GlaxoSmithKline; March 2026.

Tividenofusp Alfa-eknm/Avlayah/ Denali Therapeutics

Date of approval	3/24/26
Drug Class/Mechanism of Action	Hydrolytic lysosomal glycoaminoglycan (GAG)-specific enzyme
Indication	Treatment of neurologic manifestations of Hunter syndrome when the medication is started in presymptomatic or symptomatic pediatric patients weighing at least 5 kg prior to advanced neurologic impairment
Comparative agent	None; idursulfase does not cross the blood-brain barrier
Dosage forms/strengths	Injection: 150 mg as a lyophilized powder in a single-dose vial
Common Dose/sig	Starting dose: 3 mg/kg IV once weekly x 4 weeks, then 7.5 mg/kg IV once weekly x 4 weeks; maintenance dose: 15 mg/kg IV infusion once weekly
DEA Schedule	NA
Date of market availability	Available
Similar Medication Names	Avalide, tivozanib

Clinical Use Evaluation

Common Adverse Effects (≥20%)	Infusion-related reaction, upper respiratory tract infection, ear infection, pyrexia, anemia, cough, vomiting, diarrhea, rash, COVID-19, rhinorrhea, nasal congestion, fall, headache, skin abrasion, urticaria
Severe Adverse Effects	Hypersensitivity reactions (including anaphylaxis), infusion-related reactions, anemia, membranous nephropathy
Severe Drug-Drug Interactions	No severe drug-drug interactions were found.
Severe Drug-Food Interactions	No severe drug-drug interactions were found.
Important Lab Monitoring	Hemoglobin at baseline, 3 months, and as clinically indicated; monitor serum creatinine and urinary protein to creatinine ratio
Used in Pediatric Areas	Safety and efficacy studies established use for pediatric patients >5 kg
Renal or Hepatic Dosing	No dosage adjustments for renal or hepatic impairment
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	No labeled contraindications. Boxed warning: hypersensitivity including anaphylaxis Warnings: infusion-associated reactions (mild to moderate reactions - hold medication or adjust the rate or dose and re-evaluate pre-treatment options; severe reactions - discontinue or hold and re-evaluate benefits), anemia, membranous nephropathy.
Special administration technique or considerations	Administer as an IV infusion over 4 hours via dedicated line with 0.2 micron in-line filter. Hold or reduce infusion rate at least 50% for mild to moderate hypersensitivity or infusion-related reactions. After infusion, flush line using 0.9% sodium chloride injection at same rate as medication infusion. If tolerated, it may be administered as home infusion by a healthcare provider. Consider pre-treatment with antihistamines, antipyretics, and/or corticosteroids. Not intended for use with other enzyme replacement therapies.
Source	Avlayah (tividenofusp alfa-eknm) [prescribing information]. San Francisco, CA: Denali Therapeutics Inc.; March 2026.

Relacorilant/Lifyorli/Corcept Therapeutics

Date of approval	3/25/26
Drug Class/Mechanism of Action	Selective glucocorticoid receptor antagonist; enhances chemotherapy sensitivity by inhibiting cortisol's suppression of apoptosis
Indication	For use in combination with nab-paclitaxel for the treatment of adults with platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer who have received one to three prior systemic treatment regimens, at least one of which included bevacizumab
Comparative agent	None
Dosage forms/strengths	Capsules: 25 mg, 100 mg
Common Dose/sig	150 mg orally once on the day before, day of, and day after each nab-paclitaxel infusion
DEA Schedule	NA
Date of market availability	Available
Similar Medication Names	None identified

Clinical Use Evaluation

Common Adverse Effects (>20%, with combination regimen)	Decreased hemoglobin, decreased neutrophils, fatigue, nausea, diarrhea, decreased platelets, rash, decreased appetite
Severe Adverse Effects	With combination regimen: neutropenia, febrile neutropenia, pneumonia, pleural effusion, fatigue, thrombocytopenia, peripheral neuropathy, cutaneous toxicity, mucositis, diarrhea, intestinal perforation
Severe Drug-Drug Interactions	Avoid use with strong CYP3A inducers, CYP3A substrates, or certain CYP2C8 substrates; monitor if used with
Severe Drug-Food Interactions	None known; food Increases absorption, administer with food
Important Lab Monitoring	Verify pregnancy status prior to initiating; CBC prior to each weekly treatment and as clinically indicated
Used in Pediatric Areas	Safety and efficacy not established in pediatric patients
Renal or Hepatic Dosing	No dosage adjustments; avoid use in moderate or severe hepatic impairment
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications: concurrent systemic glucocorticoid therapy for a lifesaving indication Warnings: neutropenia and severe infection, adrenal insufficiency, exacerbation of conditions treated with glucocorticoids, embryo-fetal toxicity
Special administration technique or considerations	Take with food. Swallow capsules whole; do not crush, chew, dissolve, or split capsules. Dosage reduction to 125 mg or discontinuation advised for specified adverse reactions.
Source	Lifyorli (relacorilant) [prescribing information]. Redwood City, CA: Corcept Therapeutics Incorporated; March 2026.

Insulin icodec-abae/Awiqli/Novo Nordisk

Date of approval	3/26/26
Drug Class/Mechanism of Action	Long-acting human insulin analog; basal insulin
Indication	Adjunct to diet and exercise to improve glycemic control in adults living with type 2 diabetes
Comparative agent	Basal insulins administered daily
Dosage forms/strengths	Injection: 700 units/mL in 1 mL, 1.5 mL, and 3 mL prefilled pens
Common Dose/sig	Individualize and titrate. In insulin naïve, recommended dose is 70 units weekly. When switching from daily basal insulin, the week 1 dose is 1.5 times the total daily dose multiplied by 7 and rounded to the nearest 10 units; the week 2 dose is the previous total daily insulin dose multiplied by 7 and rounded to the nearest 10 units. Administer subcutaneously once weekly on any day of the week on the same day each week.
DEA Schedule	N/A
Date of market availability	2nd quarter 2026
Similar Medication Names	Insulin degludec

Clinical Use Evaluation

Common Adverse Effects	Hypoglycemia, hypersensitivity reactions, injection site reactions, lipodystrophy, pruritus, rash, edema, weight gain
Severe Adverse Effects	Hypoglycemia, hypersensitivity reactions, hypokalemia
Severe Drug-Drug Interactions	Drugs that increase risk of hypoglycemia, decrease blood glucose lowering effect, or blunt signs and symptoms of hypoglycemia
Severe Drug-Food Interactions	N/A
Important Lab Monitoring	Blood glucose, potassium
Used in Pediatric Areas	Safety and efficacy have not been established in pediatric patients
Renal or Hepatic Dosing	Dose adjustments may be needed with changes in renal or hepatic function
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindicated during episodes of hypoglycemia or if hypersensitive. Warnings: hypoglycemia, hyperglycemia, hypersensitivity reactions, hypokalemia; fluid retention or heart failure with concomitant use of thiazolidinediones.
Special administration technique or considerations	Inject subcutaneously into the thigh, upper arm, or abdomen. Rotate sites to reduce risk of lipodystrophy and localized cutaneous amyloidosis. Do not administer intramuscularly, intravenously, or in an insulin pump. Due to long half-life, adjustments in dose cannot be made in response to acute illness or short-term changes in physical activity of diet.
Source	Awiqli (insulin icodec-abae) [prescribing information]. Plainsboro, NJ: Novo Nordisk Inc; March 2026.

Marnetegragene autotemcel/Kresladi/ Rocket Pharmaceuticals

Date of approval	3/26/26
Drug Class/Mechanism of Action	Autologous hematopoietic stem-cell gene therapy
Indication	Treatment of severe leukocyte adhesion deficiency-I due to biallelic variants in ITGB2 in pediatric patients without HLA-matched sibling donor
Comparative agent	None
Dosage forms/strengths	Cell suspension for IV infusion: 1-2 infusion bags (30 mL) containing 0.34 to 6.1 x 10^6 cells/mL suspended in cryopreservation solution
Common Dose/sig	Minimum dose: 2.8 x 10^6 CD34+ cells/kg
DEA Schedule	None
Date of market availability	By end of 2026
Similar Medication Names	None identified

Clinical Use Evaluation

Common Adverse Effects (>30%)	Mucositis, upper respiratory tract infection, viral infection, febrile neutropenia, skin lesion, nausea, vomiting, rash, dermatitis, pyrexia, device-related infection, skin infection; decreased hemoglobin, platelet count, neutrophil count, leukocyte count; increased AST, ALT
Severe Adverse Effects	Serious infection, mucositis, febrile neutropenia, gastroenteritis, skin lesion; decreased hemoglobin, platelets, neutrophils, leukocytes
Severe Drug-Drug Interactions	Avoid anti-retroviral medications for one month prior to mobilization and until all cycles of apheresis are completed; avoid vaccination from 6 weeks prior to myeloablative conditioning through hematologic recovery
Severe Drug-Food Interactions	None known
Important Lab Monitoring	Pregnancy test in females of childbearing potential. Liver function tests during first month. Neutrophil and platelet counts until engraftment. Complete blood count with differential at least annually.
Used in Pediatric Areas	Indicated in pediatric patients; studied in patients 9.8 months to 9.8 years
Renal or Hepatic Dosing	No dosage adjustments
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	No labeled contraindications. Monitor for hypersensitivity during infusion (contains DMSO), for infection, veno-occlusive disease, neutrophil engraftment failure, and delayed platelet engraftment after infusion, and hematologic malignancies for at least 15 years.
Special administration technique or considerations	Must undergo hematopoietic stem cell mobilization and apheresis for manufacturing. Must undergo myeloablative conditioning prior to administration. Confirm patient identity. Complete infusion within 30 minutes of start of thaw. Do not use in-line blood filter or infusion pump. Flush bag and tubing with normal saline. Allow 1-2 hours after administration of first bag before thawing and infusion the second bag.
Source	Kresladi (marnetegragene autotemcel) [prescribing information]. Cranbury,NJ: Rocket Pharmaceuticals, Inc; March 2026.