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Key Inforbits:



- 2022 New Drug Approvals
- Summary of Approved Drugs
- Rare Disease Categories for New Drug Treatment

New Drugs Approved in 2022

Brand Name Generic Name (Manufacture) ¹	Approval Date ¹	Category ¹	FDA Indication ^{1,2}	Route ¹	Warnings/Precautions ^{1,2}	Orphan Drug ¹
<i>Quviviq</i> daridorexant (Idorsia Pharmaceuticals US Inc)	01/07/22	Orexin receptor antagonist	Insomnia	Oral; Tablet	<u>CI</u> : Narcolepsy. <u>W/P</u> : Impairs alertness and motor coordination including morning impairment, worsening of depression/suicidal ideation, compromised respiratory function	
<i>Cibinqo</i> abrocitinib (Pfizer Inc)	01/14/22	Janus kinase (JAK) inhibitor	Refractory, moderate-to-severe atopic dermatitis	Oral; Tablet	<u>CI</u> : Antiplatelet therapies (except Aspirin 81mg) during first 3 months of therapy. <u>W/P</u> : Lab abnormalities (platelets, lymphocytes, lipids), serious infections, mortality, malignancy, MACE Avoid use of live vaccines prior to, during, and immediately after treatment	
<i>Kimmtrak</i> tebentafusp (Immunocore)	01/25/22	Bispecific gp100 peptide-HLA-directed CD3 T-cell engager	Unresectable or metastatic uveal melanoma	IV	<u>CI</u> : None listed by the manufacturing's label <u>W/P</u> : Skin reactions, elevated liver enzymes, embryo-fetal toxicity	x
<i>Vabysmo</i> faricimab (Genentech, Inc)	01/28/22	Vascular endothelial growth factor and angiopoietin-2 inhibitor	Neovascular (wet) aged-related macular degeneration and diabetic macular edema	Intra-vitreous	<u>CI</u> : ocular or periocular infection, active intraocular inflammation, hypersensitivity. <u>W/P</u> : Acute increase of intraocular pressure Arterial thromboembolic events, endophthalmitis, and retinal detachments	
<i>Enjaymo</i> sutimlimab (Bioverativ USA Inc)	02/04/22	Classical complement inhibitor	Decrease need for RBC transfusion due to hemolysis in cold agglutinin disease	IV	<u>CI</u> : hypersensitivity to sutimlimab-jome or any active ingredient. <u>W/P</u> : Serious infection, infusion-related reactions, risk of autoimmune disease, and recurrent hemolysis after discontinuation	x

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<i>Pyrukynd</i> Mitapivat (Agios Pharmaceuticals, Inc.)	02/17/22	Pyruvate kinase activator	Hemolytic anemia in pyruvate kinase deficiency	Oral; Tablet	<u>CI</u> : None listed by the manufacturing's label <u>W/P</u> : Acute hemolysis	x
<i>Vonjo</i> Pacritinib (CTI BioPharma Corp)	02/28/22	Kinase inhibitor	Intermediate or high-risk primary or secondary myelofibrosis in adults with low platelets	Oral; Capsule	<u>CI</u> concomitant use of strong CYP3A4 inhibitors or inducers. <u>W/P</u> : Hemorrhage, diarrhea, thrombocytopenia, prolonged QT interval, MACE, thrombosis, secondary malignancies, and risk of infection	x
<i>Ztalmy</i> Ganaxolone (Marinus Pharmaceuticals, Inc)	03/18/22	Neuroactive steroid gamma- aminobutyric acid (GABA) A receptor positive modulator	Seizures in cyclin- dependent kinase- like 5 deficiency disorder	Oral; suspension	<u>CI</u> : None listed by the manufacturing's label <u>W/P</u> : Somnolence, sedation suicidal behavior/ideation, and withdrawal of antiepileptic drugs	x
<i>Opdualag</i> relatlimab and nivolumab (Bristol-Myers Squibb Company)	03/18/22	Combination of nivolumab (programmed death receptor-1 blocking antibody) and relatlimab (lymphocyte activation gene-3 blocking antibody)	Unresectable or metastatic melanoma	IV	<u>CI</u> : None listed by the manufacturing's label <u>W/P</u> : Immune-mediated adverse reactions, infusion related reactions, complications of allogenic HSCT, and embryo-fetal toxicity	x
<i>Pluvicto</i> lutetium Lu-177 vipivotide tetraxetan (Novartis AG)	03/23/22	Radioligand therapeutic agent	Prostate-specific membrane antigen-positive metastatic castration-resistant prostate cancer	IV	<u>CI</u> : None listed by the manufacturing's label <u>W/P</u> : Risk from radiation exposure, myelosuppression, renal toxicity, embryo- fetal toxicity, and infertility	
<i>Vivjoa</i> oteseconazole (Mycovia Pharmaceuticals, Inc.)	04/26/22	Azole antifungal	Vulvovaginal candidiasis (RVVC) in females with a history of RVVC who are not of reproductive potential	Oral; Capsule	<u>CI</u> : Females of reproductive potential, pregnant and lactating women, hypersensitivity. <u>W/P</u> : Embryo-fetal toxicity	

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<i>Camzyos</i> mavacamten (MyoKardia, Inc)	04/28/22	Cardiac myosin inhibitor	Classes of obstructive hypertrophic cardiomyopathy	Oral; Capsule	<u>CI</u> : Mod-strong CYP2C19 inhibitors/inducers or strong CYP3A4 inhibitors/inducers. <u>W/P</u> : Heart failure, drug interactions leading to heart failure or loss of effectiveness, embryo-fetal toxicity	x
<i>Voquezna triple pak</i> vonoprazan, amoxicillin, and clarithromycin (Phantom)	05/03/22	Contains vonoprazan (potassium-competitive acid blocker), amoxicillin (penicillin antibacterial), and clarithromycin (macrolide antimicrobial)	Treats <i>Helicobacter pylori</i> infection	Oral; Tablets, Capsules	<u>CI</u> : Hypersensitivity to any component of VOQUEZNA TRIPLE PAK: vonoprazan, amoxicillin (or other β- lactam drugs) or clarithromycin (or other macrolide drugs) <u>W/P</u> : Hypersensitivity reactions, Severe Cutaneous Adverse Reactions (SCAR), <i>Clostridioides difficile</i> -associated diarrhea (CDAC), QTC prolongation, hepatotoxicity, embryo-fetal toxicity, and exacerbation of myasthenia gravis	
<i>Mounjaro</i> tirzepatide (Eli Lilly and CO)	05/13/22	Glucose-dependent insulinotropic polypeptide (GIP) receptor and glucagon-like peptide-1 (GLP-1) receptor agonist	Improves blood sugar control in diabetes, in addition to diet and exercise	SubQ	<u>CI</u> : Hypersensitivity to tirzepatide or any ingredient in Mounjaro, personal or family history of medullary thyroid cancer, and patients with multiple endocrine neoplasia syndrome type 2 <u>W/P</u> : Pancreatitis, hypoglycemia risk when combined with certain diabetic agents, hypersensitivity reactions, acute kidney injury, severe gastrointestinal side effects, diabetic retinopathy, and cholelithiasis	
<i>Vtama</i> tapinarof (Dermavant Sciences Inc.)	05/23/22	Aryl hydrocarbon receptor agonist	Treats plaque psoriasis	Topical cream	<u>CI</u> : None listed by the manufacturing's label <u>W/P</u> : None listed by the manufacturing's US label	
<i>Amvuttra</i> vutrisiran (Alnylam Pharmaceuticals Inc.)	06/13/22	Transthyretin-directed small interfering RNA	Treats polyneuropathy of hereditary transthyretin-mediated amyloidosis	SubQ	<u>CI</u> : None listed by the manufacturing's label <u>W/P</u> : Reduced serum A levels	x
<i>Xenpozyme</i> olipudase alfa (Genzyme Corporation)	08/31/22	Hydrolytic lysosomal sphingomyelin-specific enzyme	Treats acid sphingomyelinase deficiency	IV	<u>CI</u> : None listed by the manufacturing's label <u>W/P</u> : Hypersensitivity reactions, infusion-associated reactions, elevated transaminase enzymes, and fetal malformations	x

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<i>Spevigo</i> spesolimab (Boehringer Ingelheim Pharmaceuticals Inc.)	09/01/22	Interleukin-36 receptor antagonist	Treats generalized pustular psoriasis flares	IV	<u>CI</u> : Hypersensitivity to spesolimab or any ingredient in Spevigo <u>W/P</u> : Increased risk of infections, tuberculosis, hypersensitivity and infusion- related reactions and avoid live vaccinations with this drug	x
<i>Daxxify</i> daxibotulinumtox ina (Revance Therapeutics Inc)	09/07/22	Acetylcholine release inhibitor and neuromuscular blocking agent	Treats moderate- severe glabellar lines associated with corrugator and/or procures muscle activity	IM	<u>CI</u> : Known hypersensitivity to any botulinum toxin preparation, DAXXIFY or any of the components in DAXXIFY and if infection occurs at injection site <u>W/P</u> : Cardiovascular adverse events, exacerbation of neuromuscular disorder, respiratory and swallowing difficulties, and use caution in compromised respiratory function or dysphagia	
<i>Sotyktu</i> deucravacitinib (Bristol-Myers Squibb Company)	09/09/22	Tyrosine kinase 2 inhibitor	Treats moderate- severe plaque psoriasis	Oral; Tablet	<u>CI</u> : Hypersensitivity to deucravacitinib or any ingredient in Sotyktu <u>W/P</u> : Hypersensitivity reactions, Increased risk of infections, tuberculosis, malignancy, rhabdomyolysis, avoid live vaccinations with this drug and increased triglycerides, and liver enzymes	
<i>Rolvedon</i> eflapegrastim (Spectrum Pharmaceuticals Inc)	09/09/22	Leukocyte growth factor	Used to decrease incidence of infection in patients with non- myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with clinically significant incidence of febrile neutropenia	SubQ	<u>CI</u> : Hypersensitivity to human granulocyte colony-stimulating factors such as eflapegrastim, pegfilgrastim or filgrastim products <u>W/P</u> : Thrombocytopenia, leukocytosis, glomerulonephritis, acute respiratory distress syndrome (ARDS), fatal splenic rupture, sickle cell crisis, myelodysplastic syndrome (MDS) and acute myeloid leukemia (AML)	
<i>Terlivaz</i> terlipressin (Mallinckrodt Hospital Products Inc)	09/14/22	Vasopressin receptor agonist	Improves kidney function in adults with hepatorenal syndrome with rapid reduction in kidney function	IV	<u>CI</u> : Patients experiencing hypoxia or worsening respiratory symptoms and patients with ongoing coronary, peripheral, or mesenteric ischemia <u>W/P</u> : Ischemic events, embryo-fetal toxicity, fatal respiratory failure and liver transplant failure	x

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<i>Elucirem</i> gadopichlenol (Liebel-Flarsheim Company LLC)	09/21/22	Gadolinium-based contrast agent	Detects and visualizes lesions, together with MRI, with abnormal vascularity in the central nervous system and the body	IV	<u>CI</u> : Hypersensitivity to Elucirem <u>W/P</u> : Hypersensitivity reactions, gadolinium retention and nephrogenic systemic fibrosis	
<i>Omlonti</i> omidenepeg isopropyl (Santen Incorporated)	09/22/22	Selective prostaglandin E2 (EP2) receptor agonist	Reduces elevated intraocular pressure in patients with open-angle glaucoma or ocular hypertension	Ophthal- mic solution	<u>CI</u> : None listed by the manufacturing's label <u>W/P</u> : Increased pigmentation, eyelash changes, ocular inflammation, and macular edema	
<i>Relyvrio</i> sodium phenylbutyrate; taurursodiol (Amylyx Pharmaceuticals, Inc)	09/29/22	Histone Deacetylase Inhibitor; Hydrophilic Bile acid	To treat amyotrophic lateral sclerosis (ALS)	Oral, Packet	<u>CI</u> : None listed by the manufacturing's label <u>W/P</u> : Biliary disorder, pancreatic or intestinal disease, renal impairment, use caution in patients sensitive to salt intake product contains 928 mg of sodium/2 packet	x
<i>Lytgobi</i> futibatib (Taiho Pharmaceutical Co)	09/30/22	Antineoplastic Agent, Fibroblast Growth Factor Receptor (FGFR) Inhibitor; Antineoplastic Agent, Tyrosine Kinase Inhibitor	To treat intrahepatic cholangiocarcinoma a harboring fibroblast growth factor receptor 2 (FGFR2) gene fusions or other rearrangements	Oral, tablet therapy pack	<u>CI</u> : None listed by the manufacturing's label <u>W/P</u> : Hyperphosphatemia, ocular toxicity, fibroblast growth factor receptor alteration	x
<i>Imjudo</i> tremelimumab (AstraZeneca Pharmaceuticals LP)	10/21/22	Antineoplastic Agent, Anti-CTLA4 Monoclonal Antibody; Antineoplastic Agent, Immune Checkpoint Inhibitor; Antineoplastic Agent, Monoclonal Antibody	To treat unresectable hepatocellular carcinoma	IV	<u>CI</u> : None listed by the manufacturing's label <u>W/P</u> : Adverse reactions (immune- mediated), dermatologic toxicity, endocrinopathies, GI toxicity, hepatotoxicity, infusion-related reaction, nephrotoxicity, ocular toxicity, pulmonary toxicity, other immune-mediated toxicities.	x

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<i>Tecvayli</i> teclistamab (Janssen Biotech, Inc)	10/25/22	Antineoplastic Agent, Anti- BCMA; Antineoplastic Agent, Anti-CD3; Antineoplastic Agent, Bispecific T Cell Engager; Antineoplastic Agent, Monoclonal Antibody	To treat relapsed or refractory multiple myeloma among adults who have received at least four specific lines of therapy	SubQ	<u>CI</u> : None listed by the manufacturing's label <u>W/P</u> : Cytokine release syndrome, cytopenias, hepatotoxicity, hypersensitivity reactions, infection, and neurologic toxicity	x
<i>Elahere</i> mirvetuximab soravtansine (ImmunoGen, Inc)	11/14/22	Antineoplastic agent, anti-folate receptor alpha; Antineoplastic agent, antibody drug conjugate, antineoplastic agent, antimicrotubular, antineoplastic agent, monoclonal antibody	To treat patient with recurrent ovarian cancer that is resistant to platinum therapy	IV	<u>CI</u> : None listed by the manufacturing's label <u>W/P</u> : Ocular adverse reactions, peripheral neuropathy, pulmonary toxicity	x
<i>Tzield</i> teplizumab (Provention Bio, Inc)	11/18/22	Anti-CD3 Antibody; Monoclonal Antibody	To delay the onset of stage 3 type 1 diabetes	IV	<u>CI</u> : None listed by the manufacturing's label <u>W/P</u> : Cytokine release syndrome, hematologic toxicity, hypersensitivity reactions, immunogenicity, infection	
<i>Rezlidhia</i> olutasidenib (Metrics Contract Services)	12/01/22	Antineoplastic Agent, IDH1 Inhibitor	To treat adults with relapsed or refractory acute myeloid leukemia with a susceptible isocitrate dehydrogenase-1 (IDH1) mutation	Oral, capsule	<u>CI</u> : None listed by the manufacturing's label <u>W/P</u> : Differentiation syndrome, hepatotoxicity	x

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<i>Krazati</i> adagrasib (Mirati Therapeutics, Inc)	12/12/22	Antineoplastic Agent, KRAS Inhibitor	To treat KRAS G12C-mutated locally advanced or metastatic non- small cell lung cancer in adults who have received at least one prior systemic therapy	Oral, tablet	<u>CI</u> : None listed by the manufacturing's label <u>W/P</u> : GI toxicity, hepatotoxicity, pulmonary toxicity, QTc interval prolongation,	x
<i>Sunlenca</i> lenacapavir (Gilead Sciences, Inc)	12/22/22	Antiretroviral, capsid inhibitor (Anti-HIV)	To treat adults with HIV whose infection cannot be successfully treated with other available treatment due to resistance, intolerance, or safety considerations	SubQ	<u>CI</u> : Concomitant administration with CYP3A inducers <u>W/P</u> : Immune reconstitution syndrome, Injection site reactions, nodules, and indurations may be persistent.	
<i>Lunsumio</i> mosunetuzumab (Genentech, Inc)	12/22/22	Antineoplastic agent, Anti CD3; antineoplastic agent, bispecific T cell engager; antineoplastic agent, monoclonal antibody	To treat adults with relapsed or refractory follicular lymphoma, a type of non-Hodgkin lymphoma	IV	<u>CI</u> : None listed by the manufacturing's label <u>W/P</u> : Neurologic toxicity, Infections, cytopenia's, tumor flare, embryo-Fetal toxicity	x
<i>Xenoview</i> Xe 129 hyperpolarized (Polarean, Inc)	12/23/22	Radiopharmaceuti cal	To evaluate pulmonary function and imaging	Oral Inhala- tion	<u>CI</u> : None listed by the manufacturing's label <u>W/P</u> : Risk of decreased image quality from supplemental oxygen, risk of transient hypoxia	
<i>Briumvi</i> ublituximab (TG Therapeutics, Inc)	12/28/22	Anti-CD20 Monoclonal Antibody; Monoclonal Antibody	To treat relapsing forms of multiple sclerosis	IV	<u>CI</u> : History of life-threatening infusion reaction to ublituximab; active hepatitis B virus (HBV) infection <u>W/P</u> : Infusion Reactions, infections, reduction in immunoglobulins, fetal risk	

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Nexobrid anacaulase (MediWound LTD)	12/28/22	Enzyme, topical debridement, topical skin product	To remove eschar in adults with deep partial thickness or full thickness thermal burns	Topical Powder or Gel	<u>Cl</u> : hypersensitive to anacaulase, bromelain, pineapples or any component of the formulation; known hypersensitivity to papayas or papain because of the risk of cross-sensitivity <u>W/P</u> : Hypersensitivity reactions, pain management, proteolytic injury to non- target tissues, coagulopathy	x

IV: intravenous IM: intramuscular SubQ: subcutaneous W/P: Warnings and Precaution Cl: Contraindication

Disease Categories with New Treatment Options in 2022³

- **Heart, Blood, Kidney, and Endocrine diseases:** type 1 diabetes, type 2 diabetes, anemia, types of kidney impairment, chronic weight management
- **Autoimmune, Inflammatory, and Lung Diseases:** inflammatory bowel disease, nutritional deficiencies, lupus nephritis, arthritis, eosinophilic esophagitis, and psoriasis
- **Infectious diseases:** COVID-19, HIV, smallpox, influenza, and *H. pylori*
- **Neurological and Psychiatric Disorders:** amyotrophic lateral sclerosis and spinal muscular atrophy
- **Cancers:** lung cancer, prostate cancer, breast cancer, rare overgrowth syndrome known as PROS, and melanoma
- **Other rare diseases:** Acid sphingomyelinase deficiency, generalized pustular psoriasis, obstructive hypertrophic cardiomyopathy, metastatic or unresectable uveal melanoma, and hepatorenal syndrome

Summary of Newly Approved Drugs:

Each year to further advance disease management in the United States, the U.S. Food and Drug Administration’s (FDA) Center for Drug Evaluation and Research (CDER) reviews and approves a variety of new drugs and biological products.¹ For the year of 2022, CDER approved 37 novel drugs. Over the previous two years, the average new drug approvals has been 50, 2022 show drop in new drug approvals. The new medications were approved with the potential for a positive impact and unique contribution to patient care.³

In 2022, 37 new drugs were approved for various targeted diseases and conditions that have never been addressed before in the United States.³ Amongst the approved drugs, 68% (25/37) were “approved in the United States before other countries”. The novel drug approval rate remained the same as last year at 54% (20 of 37 drugs) for rare diseases. In 2022 CDER noted 54% (20 of 37) of the novel drugs were first-in-class conditions including Mounjaro (tirzepatide), an injection that improves glycemic control by activating two hormone receptors along with diet and exercise.

In conclusion, CDER collaborated with the medical community, patient advocacy groups, and caregivers to enhance patient health with the 2022 new medications. CDER states that “CDER approved many safe and effective drug therapies in 2022, even as we contended with the COVID-19 pandemic. These approvals, spanning a wide range of diseases and conditions, will help many people live better and potentially longer lives.”³

References:

1. FDA: novel drug approvals for 2022 [Internet]. Silver Spring, MD: U.S. Food and Drug Administration; FDA's center for drug evaluation and research; 2022 Dec 29 [cited 2023 Jan 05]; [about 40 p]. Available from: <https://www.fda.gov/drugs/new-drugs-fda-cders-new-molecular-entities-and-new-therapeutic-biological-products/novel-drug-approvals-2022>
2. Lexicomp [AUHSOP Intranet]. Hudson, OH: Wolters Kluwer Health. [cited 2023 Jan 05]. Available from: <https://online.lexi.com/lco/action/home>
3. New Drug Therapy Approvals 2022. FDA's Center for Drug Evaluation and Research. Release 2023 Jan [cited 2023 Jan 11]. Available from: <https://www.fda.gov/media/164429/download>



The last “dose” ...

“The beautiful thing about learning is that no one can take it away from you.”

-B.B. King [American singer-songwriter, 1925-2015]

Health Professional with a Question? Drugs – Therapeutics – Pharmacy Practice?

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