New Indications & Dosage Forms for Existing Drugs

Drugs that have gained FDA approval for the treatment of additional diseases/conditions or new dosage forms/regimens.

Leqvio (inclisiran) Injection
New Indication Approved: July 7, 2023
Date of Original Approval: December 22, 2021
Leqvio (inclisiran) is a small interfering RNA (siRNA) directed to PCSK9 (proprotein convertase subtilisin kexin type 9) mRNA used to reduce low-density lipoprotein cholesterol (LDL-C).
US FDA Approves Expanded Indication for Novartis Leqvio (inclisiran) to Include Treatment of Adults with High LDL-C and Who Are At Increased Risk of Heart Disease

Leqembi (lecanemab-irmb) Injection
Labeling Revision Approved: July 6, 2023
Date of Original Approval: January 6, 2023
Leqembi (lecanemab) is an amyloid beta-directed antibody indicated for the treatment of Alzheimer's disease.
FDA Grants Traditional Approval for Leqembi (lecanemab-irmb) for the Treatment of Alzheimer's Disease

Liletta (levonorgestrel) Intrauterine Device
New Indication Approved: June 29, 2023
Date of Original Approval: February 26, 2015
Liletta (levonorgestrel) is a progestin-containing intrauterine system indicated for the prevention of pregnancy for up to 8 years, and the treatment of heavy menstrual bleeding for up to 5 years in patients who choose intrauterine contraception as their method of contraception.
FDA Approves Medicines360's Supplemental New Drug Application for Liletta (levonorgestrel-releasing intrauterine system) 52 mg as Treatment of Heavy Menstrual Bleeding

Talzenna (talazoparib) Capsules
New Indication Approved: June 20, 2023
Date of Original Approval: October 16, 2018
Talzenna (talazoparib) is a poly (ADP-ribose) polymerase (PARP) inhibitor used for the treatment of BRCA-mutated HER2-negative breast cancer and HRR gene-mutated metastatic castration-resistant prostate cancer.
Pfizer's Talzenna (talazoparib) in Combination with Xtandi (enzalutamide) Receives U.S. FDA Approval for HRR Gene-Mutated Metastatic Castration-Resistant Prostate Cancer

Blincyto (blinatumomab) Injection
Labeling Revision Approved: June 20, 2023
Date of Original Approval: December 3, 2014
Blincyto (blinatumomab) is a bispecific CD19-directed CD3 T-cell engager indicated for the treatment of B-cell precursor acute lymphoblastic leukemia (ALL).
FDA Grants Full Approval for Blincyto (blinatumomab) to Treat Minimal Residual Disease-Positive B-Cell Precursor Acute Lymphoblastic Leukemia

Jardiance (empagliflozin) Tablets
Patient Population Altered: June 20, 2023
Date of Original Approval: August 1, 2014
Jardiance (empagliflozin) is a sodium glucose co-transporter-2 (SGLT2) inhibitor used for the treatment of type 2 diabetes; and to reduce the risk of cardiovascular death in patients with heart failure, and type 2 diabetes patients with established cardiovascular disease.
FDA Approves Jardiance (empagliflozin) for the Treatment of Type 2 Diabetes in Children 10 Years and Older

Synjardy (empagliflozin and metformin) Tablets
Patient Population Altered: June 20, 2023
Date of Original Approval: August 26, 2015
Synjardy (empagliflozin and metformin hydrochloride) is a sodium glucose co-transporter-2 (SGLT2) inhibitor and biguanide combination for the treatment of type 2 diabetes.
FDA Approves New Class of Medicines to Treat Pediatric Type 2 Diabetes

Bylvay (odevixibat) Capsules
New Indication Approved: June 13, 2023
Date of Original Approval: July 20, 2021
Bylvay (odevixibat) is an ileal bile acid transport (IBAT) inhibitor for the treatment of progressive familial intrahepatic cholestasis and cholestatic pruritus due to Alagille syndrome.
FDA Approves Bylvay for Patients Living with Cholestatic Pruritus Due to Alagille Syndrome

Linzess (linaclotide) Capsules
Patient Population Altered: June 12, 2023
Date of Original Approval: August 30, 2012
Linzess (linaclotide) is a guanylate cyclase-C agonist used for the treatment of irritable bowel syndrome with constipation (IBS-C) and chronic idiopathic constipation (CIC) in adults, and functional

constipation (FC) in pediatric patients 6 to 17 years of age.
Ironwood Pharmaceuticals Announces FDA Approval of New Indication for Linzess (linaclotide) for the Treatment of Functional Constipation in Pediatric Patients Ages 6-17 Years-Old

Prevymis (letermovir) Tablets and Injection
New Indication Approved: June 5, 2023
Date of Original Approval: November 8, 2017
Prevymis (letermovir) is a CMV DNA terminase complex inhibitor used for the prophylaxis of cytomegalovirus (CMV) infection.
U.S. FDA Approves New Indication for Merck's Prevymis (letermovir) for Prevention of Cytomegalovirus (CMV) Disease in High-Risk Adult Kidney Transplant Recipients

Lynparza (olaparib) Tablets
New Indication Approved: May 31, 2023
Date of Original Approval: December 19, 2014
Lynparza (olaparib) is a poly ADP ribose polymerase (PARP) inhibitor for the treatment of ovarian cancer, breast cancer, pancreatic cancer, and prostate cancer.
FDA Approves Lynparza (olaparib) Plus Abiraterone and Prednisone or Prednisolone for Treatment of Adult Patients With BRCA-Mutated Metastatic Castration-Resistant Prostate Cancer (mCRPC)

Injectafer (ferric carboxymaltose) Injection
New Indication Approved: May 31, 2023
Date of Original Approval: July 25, 2013
Injectafer (ferric carboxymaltose) is an iron replacement product for the treatment of iron deficiency anemia.
Injectafer Approved in the U.S. for the Treatment of Iron Deficiency in Adult Patients with Heart Failure

Ayvakit (avapritinib) Tablets
New Indication Approved: May 19, 2023
Date of Original Approval: January 9, 2020
Ayvakit (avapritinib) is a tyrosine kinase inhibitor for use in the treatment of gastrointestinal stromal tumors, advanced systemic mastocytosis, and indolent systemic mastocytosis.
FDA Approves Ayvakit (avapritinib) as the First and Only Treatment for Indolent Systemic Mastocytosis

Rinvoq (upadacitinib) Extended-Release Tablets
New Indication Approved: May 18, 2023
Date of Original Approval: August 16, 2019
Rinvoq (upadacitinib) is a Janus kinase (JAK) inhibitor for the treatment of rheumatoid arthritis, psoriatic arthritis, atopic dermatitis, ulcerative colitis, Crohn's disease, ankylosing spondylitis, and non-radiographic axial spondyloarthritis.
U.S. FDA Approves Rinvoq (upadacitinib) as a Once-Daily Pill for Moderately to Severely Active Crohn's Disease in Adults

Cyltezo (adalimumab-adbm) Injection
New Dosage Form Approved: May 18, 2023
Date of Original Approval: August 25, 2017
Cyltezo (adalimumab-adbm) is an anti-TNF-α monoclonal antibody biosimilar to Humira, approved for the treatment of rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, Crohn's disease, ulcerative colitis, plaque psoriasis, and hidradenitis suppurativa.
US FDA Approves the Cyltezo Pen, a New Autoinjector Option, Ahead of July 1 Commercial Launch

Caldolor (ibuprofen) Intravenous Injection
Patient Population Altered: May 11, 2023
Date of Original Approval: June 11, 2009
Caldolor (ibuprofen) is an intravenous formulation of the approved nonsteroidal anti-inflammatory drug ibuprofen for use in the treatment of pain and fever.
Caldolor Now FDA Approved for Treatment of Fever & Pain in Infants

Rexulti (brexpiprazole) Tablets
New Indication Approved: May 10, 2023
Date of Original Approval: July 10, 2015
Rexulti (brexpiprazole) is an atypical antipsychotic for use in the treatment of major depressive disorder (MDD), schizophrenia, and agitation associated with dementia due to Alzheimer's disease.
Otsuka and Lundbeck Announce U.S. FDA Approval of Supplemental New Drug Application (sNDA) for Rexulti (brexpiprazole) for the Treatment of Agitation Associated with Dementia Due to Alzheimer's Disease

Farxiga (dapagliflozin) Tablets
New Indication Approved: May 8, 2023
Date of Original Approval: January 8, 2014
Farxiga (dapagliflozin) is a sodium-glucose cotransporter 2 (SGLT2) inhibitor for use in the treatment of type 2 diabetes mellitus, heart failure, and chronic kidney disease.
Farxiga Extended in the US to Reduce Risk of Cardiovascular Death and Hospitalisation for Heart Failure to a Broader Range of Patients

Sogroya (somapacitan-beco) Injection
Patient Population Altered: April 28, 2023
Date of Original Approval: August 28, 2020
Sogroya (somapacitan-beco) is a human growth hormone analog indicated for the replacement of endogenous growth hormone in adults with growth hormone deficiency.

FDA Approves Once-Weekly Sogroya for the Treatment of Children Living with Growth Hormone Deficiency

Prevnar 20 (pneumococcal 20-valent conjugate vaccine) Injection
Patient Population Altered: April 27, 2023
Date of Original Approval: June 8, 2021
Prevnar 20 (pneumococcal 20-valent conjugate vaccine) is a vaccine used for the prevention of invasive pneumococcal disease and otitis media.
U.S. FDA Approves Prevnar 20, Pfizer's 20-Valent Pneumococcal Conjugate Vaccine for Infants and Children

Trikafta (elexacaftor/tezacaftor/ivacaftor and ivacaftor) Tablets and Oral Granules
Patient Population Altered: April 26, 2023
Date of Original Approval: October 21, 2019
Trikafta (elexacaftor/tezacaftor/ivacaftor and ivacaftor) is a triple combination regimen for the treatment of cystic fibrosis (CF) in patients ages 2 years and older who have at least one F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene or a mutation in the CFTR gene that is responsive to Trikafta based on in vitro data.
Vertex Announces U.S. FDA Approval for Trikafta (elexacaftor/tezacaftor/ivacaftor and ivacaftor) in Children With Cystic Fibrosis Ages 2 Through 5 With Certain Mutations

Hizentra (immune globulin subcutaneous (human)) Liquid
New Formulation Approved: April 18, 2023
Date of Original Approval: March 4, 2010
Hizentra (immune globulin subcutaneous (human)) is an immune globulin indicated for the treatment of primary immunodeficiency, and for the maintenance treatment of chronic inflammatory demyelinating polyneuropathy.
CSL Behring Receives FDA Approval for Hizentra (Immune Globulin Subcutaneous [Human] 20% Liquid) 50mL Prefilled Syringe

Qulipta (atogepant) Tablets
New Indication Approved: April 17, 2023
Date of Original Approval: September 28, 2021
Qulipta (atogepant) is an oral, calcitonin gene-related peptide (CGRP) receptor antagonist approved to prevent episodic and chronic migraine.
U.S. FDA Approves Qulipta (atogepant) for Adults With Chronic Migraine

Tepezza (teprotumumab-trbw) Injection
Labeling Revision Approved: April 13, 2023
Date of Original Approval: January 21, 2020
Tepezza (teprotumumab-trbw) is a fully human monoclonal antibody (mAb) and a targeted inhibitor of the insulin-like growth factor 1 receptor (IGF-1R) for the treatment of active thyroid eye disease (TED).
Horizon Therapeutics plc Announces FDA Approval of an Update to the Indication Language for Tepezza (teprotumumab-trbw) to Specify its Use in Thyroid Eye Disease (TED) Patients Regardless of Disease Activity or Duration

Hyqvia (immune globulin and hyaluronidase) Solution for Subcutaneous Administration
Patient Population Altered: April 7, 2023
Date of Original Approval: September 12, 2014
Hyqvia (immune globulin and hyaluronidase) is an immune globulin with a recombinant human hyaluronidase indicated for the treatment of primary immunodeficiency (PI) in adults and pediatric patients two years of age and older.
Takeda Receives FDA Approval to Expand the Use of Hyqvia to Treat Primary Immunodeficiency in Children

Keytruda (pembrolizumab) for Injection
New Indication Approved: April 3, 2023
Date of Original Approval: September 4, 2014
Keytruda (pembrolizumab) is a human PD-1 (programmed death receptor-1)-blocking antibody indicated for the treatment of melanoma, non-small cell lung cancer, head and neck squamous cell carcinoma, classical Hodgkin lymphoma, primary mediastinal large B-cell lymphoma, urothelial carcinoma, microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) cancer, microsatellite instability-high or mismatch repair deficient colorectal cancer, gastric cancer, esophageal cancer, cervical cancer, hepatocellular carcinoma, Merkel cell carcinoma, renal cell carcinoma, endometrial carcinoma, tumor mutational burden-high (TMB-H) cancer, cutaneous squamous cell carcinoma, and triple-negative breast cancer.
FDA Approves Merck's Keytruda (pembrolizumab) in Combination With Padcev (enfortumab vedotin-ejfv) for First-Line Treatment of Certain Patients With Locally Advanced or Metastatic Urothelial Cancer

Narcan (naloxone) Nasal Spray
Labeling Revision Approved: March 29, 2023
Date of Original Approval: November 18, 2015
Narcan Nasal Spray (naloxone) is an intranasal opioid antagonist formulation indicated for the emergency treatment of known or suspected opioid overdose.

U.S. FDA Approves Over-the-Counter Designation for Emergent BioSolutions' Narcan Nasal Spray, a Historic Milestone for the Opioid Overdose Emergency Treatment

Keytruda (pembrolizumab) for Injection
Labeling Revision Approved: March 28, 2023
Date of Original Approval: September 4, 2014
Keytruda (pembrolizumab) is a human PD-1 (programmed death receptor-1)-blocking antibody indicated for the treatment of melanoma, non-small cell lung cancer, head and neck squamous cell carcinoma, classical Hodgkin lymphoma, primary mediastinal large B-cell lymphoma, urothelial carcinoma, microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) cancer, microsatellite instability-high or mismatch repair deficient colorectal cancer, gastric cancer, esophageal cancer, cervical cancer, hepatocellular carcinoma, Merkel cell carcinoma, renal cell carcinoma, endometrial carcinoma, tumor mutational burden-high (TMB-H) cancer, cutaneous squamous cell carcinoma, and triple-negative breast cancer.
FDA Converts to Full Approval Indication for Keytruda (pembrolizumab) for Certain Adult and Pediatric Patients With Advanced Microsatellite Instability-High (MSI-H) or Mismatch Repair Deficient (dMMR) Solid Tumors

Evkeeza (evinacumab-dgnb) Injection
Patient Population Altered: March 21, 2023
Date of Original Approval: February 11, 2021
Evkeeza (evinacumab-dgnb) is an angiopoietin-like 3 (ANGPTL3) inhibitor indicated as an adjunct to other low-density lipoprotein-cholesterol (LDL-C) lowering therapies for the treatment of adult and pediatric patients, aged 5 years and older, with homozygous familial hypercholesterolemia (HoFH).
FDA Approves First-in-class Evkeeza (evinacumab-dgnb) for Young Children with Ultra-Rare Form of High Cholesterol

Hyrimoz (adalimumab-adaz) Injection
New Formulation Approved: March 20, 2023
Date of Original Approval: October 30, 2018
Hyrimoz (adalimumab-adaz) is an anti-TNF-α monoclonal antibody biosimilar to Humira, approved for the treatment of rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, Crohn's disease, ulcerative colitis, plaque psoriasis, and hidradenitis suppurativa.
Sandoz Receives US FDA Approval for Biosimilar Hyrimoz (adalimumab-adaz) High-Concentration Formulation

Tafinlar (dabrafenib) Capsules and Tablets for Oral Suspension
New Indication Approved: March 16, 2023
Date of Original Approval: May 29, 2013
Tafinlar (dabrafenib) is a kinase inhibitor for the treatment of melanoma, non-small cell lung cancer, thyroid cancer, solid tumors, and low-grade glioma with BRAF V600 mutations.
Novartis Tafinlar + Mekinist Approved by FDA for Pediatric Patients with BRAF V600E Low-Grade Glioma

Illuccix (gallium Ga 68 gozetotide) Injection Kit
Patient Population Altered: March 15, 2023
Date of Original Approval: December 17, 2021
Illuccix (gallium Ga 68 gozetotide) is a radioactive diagnostic agent indicated for positron emission tomography (PET) of prostate-specific membrane antigen (PSMA) positive lesions in men with prostate cancer.
FDA Approves Expanded Indication for Telix's Illuccix to Include Patient Selection for PSMA-Directed Radioligand Therapy

Verzenio (abemaciclib) Tablets
New Indication Approved: March 3, 2023
Date of Original Approval: September 28, 2017
Verzenio (abemaciclib) is a selective ATP-competitive inhibitor of cyclin dependent kinases (CDK) 4 and 6 used for the treatment of patients with hormone receptor-positive, human epidermal growth factor receptor 2 negative (HR+ HER2-) metastatic breast cancer.
FDA Broadens Indication for Verzenio (abemaciclib) in HR+, HER2-, Node-Positive, High Risk Early Breast Cancer

Kevzara (sarilumab) Injection
New Indication Approved: February 28, 2023
Date of Original Approval: May 22, 2017
Kevzara (sarilumab) is an interleukin-6 (IL-6) receptor antagonist for the treatment of rheumatoid arthritis and polymyalgia rheumatica.
Kevzara (sarilumab) Approved by FDA as First and Only Biologic Indicated for Patients with Polymyalgia Rheumatica

Austedo XR (deutetrabenazine) Extended-Release Tablets
New Formulation Approved: February 17, 2023
Date of Original Approval: February 17, 2023
Austedo XR (deutetrabenazine) is a vesicular monoamine transporter 2 (VMAT2) inhibitor indicated in adults for the treatment of tardive dyskinesia, and chorea associated with Huntington's disease.

Teva Announces FDA Approval of Austedo XR (deutetrabenazine) Extended-Release Tablets, a New Once-Daily Formulation of Austedo

Jemperli (dostarlimab-gxly) Injection
Labeling Revision Approved: February 9, 2023
Date of Original Approval: April 22, 2021
Jemperli (dostarlimab-gxly) is a programmed death receptor-1 (PD-1)–blocking antibody for the treatment of mismatch repair deficient (dMMR) endometrial cancer, and dMMR solid tumors.
US FDA Grants Regular Approval for Jemperli for the Treatment of Patients with Recurrent or Advanced Mismatch Repair-Deficient Endometrial Cancer

Cibinqo (abrocitinib) Tablets
Patient Population Altered: February 9, 2023
Date of Original Approval: January 14, 2022
Cibinqo (abrocitinib) is a Janus kinase (JAK) 1 inhibitor for the treatment of moderate-to-severe atopic dermatitis.
FDA Approves Pfizer's Supplemental New Drug Application for Cibinqo (abrocitinib) to Include Adolescents with Moderate-to-Severe Atopic Dermatitis

Eylea (aflibercept) Injection
New Indication Approved: February 8, 2023
Date of Original Approval: November 18, 2011
Eylea (aflibercept) is a VEGF inhibitor indicated for the treatment of patients with neovascular (wet) age-related macular degeneration, macular edema following retinal vein occlusion, diabetic macular edema, diabetic retinopathy, and retinopathy of prematurity.
Eylea (aflibercept) Injection Approved as the First Pharmacologic Treatment for Preterm Infants with Retinopathy of Prematurity (ROP) by the FDA

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Trodelvy (sacituzumab govitecan-hziy) Injection
New Indication Approved: February 3, 2023
Date of Original Approval: April 22, 2020
Trodelvy (sacituzumab govitecan-hziy) is a Trop-2-directed antibody and topoisomerase inhibitor conjugate used for the treatment of breast cancer and urothelial cancer.
U.S. FDA Approves Trodelvy in Pre-treated HR+/HER2- Metastatic Breast Cancer

Takhzyro (lanadelumab-flyo) Injection
Patient Population Altered: February 3, 2023
Date of Original Approval: August 23, 2018
Takhzyro (lanadelumab-flyo) is a plasma kallikrein inhibitor (monoclonal antibody) for the prevention of angioedema attacks in patients with hereditary angioedema.
U.S. FDA Approves Takeda's Takhzyro (lanadelumab-flyo) to Prevent Hereditary Angioedema (HAE) Attacks in Children 2 Years of Age and Older

Tezspire (tezepelumab-ekko) Injection
New Dosage Regimen: February 1, 2023
Date of Original Approval: December 17, 2021
Tezspire (tezepelumab-ekko) is a thymic stromal lymphopoietin (TSLP) blocker, human monoclonal antibody (IgG2λ), indicated for the add-on maintenance treatment of adult and pediatric patients aged 12 years and older with severe asthma.
Tezspire Approved for Self-Administration in the U.S. With a New Pre-filled Pen

References: www.drugs.com/new-indications