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.

Wegovy (semaglutide) Injection
Patient Population Altered: December 23, 2022
Date of Original Approval: June 4, 2021
Wegovy (semaglutide) is a glucagon-like peptide-1 (GLP-1) receptor agonist indicated as an adjunct to diet and exercise for chronic weight management in adult patients who are overweight (BMI ≥27 kg/m^2) or obese (BMI ≥30 kg/m^2).

Actemra (tocilizumab) Injection
New Indication Approved: December 21, 2022
Date of Original Approval: January 8, 2010
Actemra (tocilizumab) is a humanized interleukin-6 (IL-6) receptor-inhibiting monoclonal antibody for the treatment of rheumatoid arthritis, giant cell arteritis, systemic sclerosis-associated interstitial lung disease, polyarticular juvenile idiopathic arthritis, systemic juvenile idiopathic arthritis, cytokine release syndrome, and COVID-19.

Tymlos (abaloparatide) Injection
New Indication Approved: December 19, 2022
Date of Original Approval: April 28, 2017
Tymlos (abaloparatide) is a synthetic peptide analog of hPTHrP (human parathyroid hormone-related protein) for the treatment of osteoporosis.

Vraylar (cariprazine) Capsules
New Indication Approved: December 16, 2022
Date of Original Approval: September 17, 2015
Vraylar (cariprazine) is an atypical antipsychotic for the treatment of schizophrenia, bipolar I disorder, and major depressive disorder.

Pemfexy (pemetrexed) Injection
New Indication Approved: December 14, 2022
Date of Original Approval: February 8, 2020
Pemfexy (pemetrexed for injection) is a branded alternative to Alimta for the treatment of nonsquamous non-small cell lung cancer and malignant pleural mesothelioma.

Asceniv (immune globulin intravenous, human – slra) Injection
Labeling Revision Approved: December 13, 2022
Date of Original Approval: April 1, 2019
Asceniv (immune globulin intravenous, human – slra) is a 10% immune globulin liquid for intravenous injection, indicated for the treatment of primary humoral immunodeficiency (PI).

Tecentriq (atezolizumab) Injection
New Indication Approved: December 9, 2022
Date of Original Approval: May 18, 2016
Tecentriq (atezolizumab) is a programmed death-ligand 1 (PD-L1) blocking antibody indicated for use in the treatment of non-small cell lung cancer (NSCLC), small cell lung cancer (SCLC), heptatocellular carcinoma, melanoma, and alveolar soft part sarcoma.

Brexafemme (ibrexafungerp) Tablets
New Indication Approved: November 30, 2022
Date of Original Approval: June 1, 2021
Brexafemme (ibrexafungerp) is a first-in-class, triterpenoid antifungal agent used to treat vulvovaginal candidiasis (VVC), and to reduce the incidence of recurrent VVC in adults and adolescent females who have started their menstruation.

Rylaze (asparaginase erwinia chrysanthemi (recombinant)-rywn) Injection
New Dosage Regimen: November 18, 2022
Date of Original Approval: June 30, 2021
Rylaze (asparaginase erwinia chrysanthemi (recombinant)-rywn) is an asparagine specific enzyme indicated as a component of a multi-agent chemotherapeutic regimen for the treatment of acute lymphoblastic leukemia (ALL) and lymphoblastic lymphoma (LBL).

Adcetris (brentuximab vedotin) Injection
Patient Population Altered: November 10, 2022
Date of Original Approval: August 19, 2011
Adcetris (brentuximab vedotin) is a CD30-directed antibody-drug conjugate (ADC) used for the

treatment of Hodgkin lymphoma, anaplastic large cell lymphoma, and mycosis fungoides.

Imfinzi (durvalumab) Injection
New Indication Approved: November 10, 2022
Date of Original Approval: May 1, 2017
Imfinzi (durvalumab) is a programmed death-ligand 1 (PD-L1) blocking antibody used for the treatment of non-small cell lung cancer, small cell lung cancer, and biliary tract cancer.

Liletta (levonorgestrel) Intrauterine Device
New Dosage Regimen: November 10, 2022
Date of Original Approval: February 26, 2015
Liletta (levonorgestrel) is a hormonal intrauterine device (IUD) for use by women to prevent pregnancy for up to eight years.

Libtayo (cemiplimab-rwlc) Injection
New Indication Approved: November 8, 2022
Date of Original Approval: September 28, 2018
Libtayo (cemiplimab-rwlc) is a programmed death receptor-1 (PD-1) blocking antibody for the treatment of cutaneous squamous cell carcinoma (CSCC), basal cell carcinoma (BCC), and non-small cell lung cancer (NSCLC).

Rotarix (rotavirus vaccine, live attenuated) Oral Suspension
New Formulation Approved: November 4, 2022
Date of Original Approval: April 3, 2008
Rotarix (rotavirus vaccine live) is an oral, two-dose, live attenuated vaccine for the prevention of rotavirus gastroenteritis in children.

Rinvoq (upadacitinib) Extended-Release Tablets
New Indication Approved: October 21, 2022
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, ankylosing spondylitis, and non-radiographic axial spondyloarthritis.

Vemlidy (tenofovir alafenamide) Tablets
Patient Population Altered: October 17, 2022
Date of Original Approval: November 10, 2016
Vemlidy (tenofovir alafenamide) is a hepatitis B virus (HBV) nucleoside analog reverse transcriptase inhibitor indicated for the treatment of chronic hepatitis B virus infection in adults and pediatric patients 12 years of age and older with compensated liver disease.

Menveo (meningococcal conjugate vaccine)
New Formulation Approved: October 14, 2022
Date of Original Approval: February 19, 2010
Menveo (Meningococcal (Groups A, C, Y and W-135) Oligosaccharide Diphtheria CRM197 Conjugate Vaccine) is a vaccine indicated for active immunization to prevent invasive meningococcal disease caused by Neisseria meningitidis serogroups A, C, Y and W-135.

Lyumjev (insulin lispro-aabc) Injection
Patient Population Altered: October 14, 2022
Date of Original Approval: June 15, 2020
Lyumjev (insulin lispro-aabc) is a rapid-acting human insulin analog indicated to improve glycemic control in adult and pediatric patients with diabetes mellitus.

Boostrix (tetanus, diphtheria, acellular pertussis vaccine (Tdap)) Injection
New Dosage Regimen: October 7, 2022
Date of Original Approval: May 3, 2005
Boostrix (Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine, Adsorbed; Tdap) is a combination vaccine that provides immunization against pertussis (whooping cough) in combination with tetanus and diphtheria.

Oxlumo (lumasiran) Injection
New Indication Approved: October 6, 2022
Date of Original Approval: November 23, 2020
Oxlumo (lumasiran) is a HAO1-directed small interfering ribonucleic acid (siRNA) indicated for the treatment of primary hyperoxaluria type 1 (PH1) to lower urinary and plasma oxalate levels in pediatric and adult patients.

Trogarzo (ibalizumab-uiyk) Injection
New Dosage Regimen: October 3, 2022
Date of Original Approval: March 6, 2018

Trogarzo (ibalizumab-uiyk) is a CD4-directed post-attachment HIV-1 inhibitor for the treatment of multidrug resistant human immunodeficiency virus-1 (HIV-1) infection.

Firdapse (amifampridine phosphate) Tablets
Patient Population Altered: September 29, 2022
Date of Original Approval: November 28, 2018
Firdapse (amifampridine phosphate) is a nonspecific, voltage-dependent, potassium (K+) channel blocker for the treatment of Lambert Eaton myasthenic syndrome (LEMS) in adults and pediatric patients six years of age and older.

Dupixent (dupilumab) Injection
New Indication Approved: September 28, 2022
Date of Original Approval: March 28, 2017
Dupixent (dupilumab) is an interleukin-4 receptor alpha antagonist used for the treatment of atopic dermatitis, asthma, chronic rhinosinusitis with nasal polyposis, eosinophilic esophagitis, and prurigo nodularis.

Retevmo (selpercatinib) Capsules
New Indication Approved: September 21, 2022
Date of Original Approval: May 8, 2020
Retevmo (selpercatinib) is a kinase inhibitor used for the treatment of certain cancers caused by abnormal RET genes.

Imfinzi (durvalumab) Injection
New Indication Approved: September 2, 2022
Date of Original Approval: May 1, 2017
Imfinzi (durvalumab) is a programmed death-ligand 1 (PD-L1) blocking antibody used for the treatment of non-small cell lung cancer, small cell lung cancer, and biliary tract cancer.

Orkambi (ivacaftor and lumacaftor) Tablets and Oral Granules
Patient Population Altered: September 2, 2022
Date of Original Approval: July 2, 2015
Orkambi (ivacaftor and lumacaftor) is a cystic fibrosis transmembrane conductance regulator (CFTR) potentiator and CFTR corrector combination for the treatment of cystic fibrosis in patients 1 year of age and older who have two copies of the F508del mutation (F508del/F508del) in their CFTR gene.

Pemazyre (pemigatinib) Tablets
New Indication Approved: August 25, 2022
Date of Original Approval: April 17, 2020
Pemazyre (pemigatinib) is a selective fibroblast growth factor receptor (FGFR) inhibitor for the treatment of adults with cholangiocarcinoma with FGFR2 rearrangement, and myeloid/lymphoid neoplasms with FGFR1 rearrangement.

Imbruvica (ibrutinib) Capsules, Tablets and Oral Suspension
Patient Population Altered: August 24, 2022
Date of Original Approval: November 13, 2013
Imbruvica (ibrutinib) is an oral Bruton's tyrosine kinase (BTK) inhibitor for the treatment of mantle cell lymphoma (MCL), chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL), Waldenström’s macroglobulinemia (WM), marginal zone lymphoma (MZL), and chronic graft versus host disease (cGVHD).

Hadlima (adalimumab-bwwd) Injection
New Formulation Approved: August 15, 2022
Date of Original Approval: July 23, 2019
Hadlima (adalimumab-bwwd) is a tumor necrosis factor (TNF) blocker biosimilar to Humira indicated for the treatment of rheumatoid arthritis (RA), juvenile idiopathic arthritis (JIA), psoriatic arthritis (PsA), ankylosing spondylitis (AS), Crohn’s disease (CD), ulcerative colitis (UC), and plaque psoriasis (Ps).

Mirena (levonorgestrel) Intrauterine System
New Dosage Regimen: August 12, 2022
Date of Original Approval: December 6, 2000
Mirena (levonorgestrel) is a progestin-containing intrauterine system indicated for intrauterine contraception for up to 8 years, and for the treatment of heavy menstrual bleeding for women who choose to use intrauterine contraception as their method of contraception for up to 5 years.

Xofluza (baloxavir marboxil) Tablets and Granules for Oral Suspension
Patient Population Altered: August 11, 2022
Date of Original Approval: October 24, 2018
Xofluza (baloxavir marboxil) is a polymerase acidic (PA) endonuclease inhibitor for the treatment and post-exposure prophylaxis of influenza in people 5 years of age and older.

Enhertu (fam-trastuzumab deruxtecan-nxki) Injection
New Indication Approved: August 11, 2022
Date of Original Approval: December 20, 2019
Enhertu (fam-trastuzumab deruxtecan-nxki) is a HER2-directed antibody and topoisomerase inhibitor conjugate used for the treatment of HER2-positive breast cancer, HER2-low breast cancer, HER2-mutant non-small cell lung cancer, and HER2-positive gastric or gastroesophageal junction adenocarcinoma.

Myfembree (relugolix, estradiol and norethindrone acetate) Tablets
New Indication Approved: August 5, 2022
Date of Original Approval: May 26, 2021
Myfembree (relugolix, estradiol and norethindrone acetate) is an oral gonadotropin-releasing hormone (GnRH) receptor antagonist, estrogen, and progestin combination indicated in premenopausal women for the management of heavy menstrual bleeding associated with uterine fibroids, and moderate to severe pain associated with endometriosis.

Enhertu (fam-trastuzumab deruxtecan-nxki) Injection
New Indication Approved: August 5, 2022
Date of Original Approval: December 20, 2019
Enhertu (fam-trastuzumab deruxtecan-nxki) is a HER2-directed antibody and topoisomerase inhibitor conjugate used for the treatment of HER2-positive breast cancer, HER2-low breast cancer, HER2-mutant non-small cell lung cancer, and HER2-positive gastric or gastroesophageal junction adenocarcinoma.

Nubeqa (darolutamide) Tablets
New Indication Approved: August 5, 2022
Date of Original Approval: July 30, 2019
Nubeqa (darolutamide) is an androgen receptor inhibitor (ARi) used in the treatment of prostate cancer.

Juvederm (dermal filler) Injectable Gel
New Formulation Approved: August 3, 2022
Date of Original Approval: June 2, 2006
Juvéderm hyaluronic acid dermal filler products are used for facial rejuvenation.

Calquence (acalabrutinib) Capsules and Tablets
New Dosage Form Approved: August 3, 2022
Date of Original Approval: October 31, 2017
Calquence (acalabrutinib) is a highly selective, potent, Bruton tyrosine kinase (BTK) inhibitor for the treatment of mantle cell lymphoma (MCL), and chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma.

Rebinyn (coagulation factor IX (recombinant), glycopegylated) Injection
New Indication Approved: July 29, 2022
Date of Original Approval: May 31, 2017
Rebinyn (coagulation factor IX (recombinant), glycoPEGylated) is an extended-half-life, recombinant DNA-derived coagulation factor IX concentrate used in the management of bleeding episodes in patients with hemophilia B.

Stelara (ustekinumab) Injection
Patient Population Altered: July 27, 2022
Date of Original Approval: September 25, 2009
Stelara (ustekinumab) is a human interleukin-12 and -23 antagonist indicated for the treatment of moderate to severe plaque psoriasis (Ps), active psoriatic arthritis (PsA), moderately to severely active Crohn's disease (CD), and moderately to severely active ulcerative colitis.

Benlysta (belimumab) Injection
Patient Population Altered: July 26, 2022
Date of Original Approval: March 10, 2011
Benlysta (belimumab) is B-lymphocyte stimulator (BLyS)-specific inhibitor for the treatment of active

systemic lupus erythematosus (SLE) and active lupus nephritis.

Opzelura (ruxolitinib) Cream
New Indication Approved: July 18, 2022
Date of Original Approval: September 21, 2021
Opzelura (ruxolitinib) cream is a topical Janus kinase (JAK) inhibitor used for the treatment of atopic dermatitis and nonsegmental vitiligo.

Xalkori (crizotinib) Capsules
New Indication Approved: July 14, 2022
Date of Original Approval: August 26, 2011
Xalkori (crizotinib) is an oral anaplastic lymphoma kinase (ALK) inhibitor for the treatment of ALK or ROS1-positive non-small cell lung cancer, ALK-positive anaplastic large cell lymphoma, and ALK-positive inflammatory myofibroblastic tumors.

Comirnaty (COVID-19 Vaccine, mRNA) Injection
Patient Population Altered: July 8, 2022
Date of Original Approval: August 23, 2021
Comirnaty is an mRNA vaccine indicated for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).

Krystexxa (pegloticase) Injection
Labeling Revision Approved: July 7, 2022
Date of Original Approval: September 14, 2010
Krystexxa (pegloticase) is a PEGylated uric acid specific enzyme indicated for the treatment of chronic gout in adult patients refractory to conventional therapy.

References: www.drugs.com/news

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