

New Indications & Dosage Forms for Existing Drugs

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.

Breyanzi (lisocabtagene maraleucel) Suspension for Intravenous Infusion

New Indication Approved: June 24, 2022

Date of Original Approval: February 5, 2021

Breyanzi (lisocabtagene maraleucel) is a CD-19 directed chimeric antigen receptor (CAR) T cell therapy for the treatment of adult patients with relapsed or refractory large B-cell lymphoma (LBCL).

Qsymia (phentermine and topiramate) Extended-Release Capsules

Patient Population Altered: June 24, 2022

Date of Original Approval: July 17, 2012

Qsymia (phentermine and topiramate) is a sympathomimetic amine anorectic and anticonvulsant combination for use in chronic weight management.

Tafinlar (dabrafenib) Capsules

New Indication Approved: June 22, 2022

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, and solid tumors with BRAF V600 mutations.

Imcivree (setmelanotide) Injection

New Indication Approved: June 16, 2022

Date of Original Approval: November 25, 2020

Imcivree (setmelanotide) is a melanocortin 4 (MC4) receptor agonist for chronic weight management of

obesity caused by proopiomelanocortin (POMC), proprotein convertase subtilisin/kexin type 1 (PCSK1), or leptin receptor (LEPR) deficiency; or Bardet-Biedl syndrome.

Skyrizi (risankizumab-rzaa) Injection

New Indication Approved: June 16, 2022

Date of Original Approval: April 23, 2019

Skyrizi (risankizumab-rzaa) is an interleukin-23 (IL-23) inhibitor for the treatment of plaque psoriasis, psoriatic arthritis, and Crohn's disease.

Dupixent (dupilumab) Injection

Patient Population Altered: June 7, 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 (CRSwNP), and eosinophilic esophagitis.

CellCept (mycophenolate mofetil) Tablets, Capsules, Oral Suspension, Injection

Patient Population Altered: June 6, 2022

Date of Original Approval: May 3, 1995

CellCept (mycophenolate mofetil) is an antimetabolite immunosuppressant indicated for the prophylaxis of organ rejection in adult and pediatric recipients 3 months of age and older of allogeneic kidney, heart or liver transplants, in combination with other immunosuppressants.

Riabni (rituximab-arrx) Injection

New Indication Approved: June 3, 2022

Date of Original Approval: December 17, 2020

Riabni (rituximab-arrx) is a CD20-directed cytolytic antibody biosimilar to Rituxan indicated for the treatment of adult patients with non-Hodgkin's Lymphoma (NHL), chronic lymphocytic leukemia (CLL), rheumatoid arthritis, and granulomatosis with polyangiitis (GPA) (Wegener's Granulomatosis) and microscopic polyangiitis (MPA).

Opdivo (nivolumab) Injection

New Indication Approved: May 27, 2022

Date of Original Approval: December 22, 2014

Opdivo (nivolumab) is a programmed death receptor-1 (PD-1) blocking antibody for the treatment of

melanoma, non-small cell lung cancer, malignant pleural mesothelioma, renal cell carcinoma, classical Hodgkin lymphoma, squamous cell carcinoma of the head and neck, urothelial carcinoma, MSI-H or dMMR metastatic colorectal cancer, hepatocellular carcinoma, esophageal cancer, gastric cancer, and gastroesophageal junction cancer.

Kymriah (tisagenlecleucel) Suspension for Intravenous Infusion

New Indication Approved: May 27, 2022

Date of Original Approval: August 30, 2017

Kymriah (tisagenlecleucel) is a chimeric antigen receptor T cell (CAR-T) therapy for the treatment of B-cell acute lymphoblastic leukemia (ALL), large B-cell lymphoma, and follicular lymphoma (FL).

Evrysdi (risdiplam) for Oral Solution

Patient Population Altered: May 27, 2022

Date of Original Approval: August 7, 2020

Evrysdi (risdiplam) is a survival of motor neuron 2 (SMN2) splicing modifier indicated for the treatment of spinal muscular atrophy (SMA) in pediatric and adult patients.

Beovu (brolucizumab-dblb) Injection

New Indication Approved: May 27, 2022

Date of Original Approval: October 7, 2019

Beovu (brolucizumab-dblb) is a human vascular endothelial growth factor (VEGF) inhibitor indicated for the treatment of neovascular (wet) age-related macular degeneration (AMD) and diabetic macular edema (DME).

Tibsovo (ivosidenib) Tablets

New Indication Approved: May 25, 2022

Date of Original Approval: July 20, 2018

Tibsovo (ivosidenib) is an isocitrate dehydrogenase-1 (IDH1) inhibitor used in the treatment of patients with IDH1-mutated acute myeloid leukemia (AML) and IDH1-mutated cholangiocarcinoma.

Tyvaso (treprostinil) Inhalation Solution

New Formulation Approved: May 23, 2022

Date of Original Approval: July 30, 2009

Tyvaso (treprostinil) is a prostacyclin mimetic used for the treatment of pulmonary arterial hypertension and pulmonary hypertension associated with interstitial lung disease.

Dupixent (dupilumab) Injection

New Indication Approved: May 20, 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 (CRSwNP), and eosinophilic esophagitis.

TPOXX (tecovirimat) Capsules and Injection

New Formulation Approved: May 18, 2022

Date of Original Approval: July 13, 2018

TPOXX (tecovirimat) is an orthopoxvirus-specific antiviral indicated for the treatment of human smallpox disease.

Enhertu (fam-trastuzumab deruxtecan-nxki) Injection

New Indication Approved: May 4, 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 and HER2-positive gastric or gastroesophageal junction adenocarcinoma.

Qelbree (viloxazine hydrochloride) Extended Release Capsules

Patient Population Altered: April 29, 2022

Date of Original Approval: April 2, 2021

Qelbree (viloxazine hydrochloride) is a serotonin norepinephrine modulating agent (SNMA) for the treatment of attention deficit hyperactivity disorder (ADHD) in adults and pediatric patients 6 years and older.

Rinvoq (upadacitinib) Extended-Release Tablets

New Indication Approved: April 29, 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, and ankylosing spondylitis.

Ultomiris (ravulizumab-cwvz) Injection

New Indication Approved: April 27, 2022

Date of Original Approval: December 21, 2018

Ultomiris (ravulizumab-cwvz) is a long-acting C5 complement inhibitor used for the treatment of

paroxysmal nocturnal hemoglobinuria, hemolytic uremic syndrome, and generalized myasthenia gravis.

Caplyta (lumateperone) Capsules

New Formulation Approved: April 26, 2022

Date of Original Approval: December 20, 2019

Caplyta (lumateperone) is an atypical antipsychotic for the treatment of schizophrenia and bipolar depression.

Veklury (remdesivir) Injection

Patient Population Altered: April 25, 2022

Date of Original Approval: October 22, 2020

Veklury (remdesivir) is a SARS-CoV-2 nucleotide analog RNA polymerase inhibitor indicated for the treatment of COVID-19.

Yescarta (axicabtagene ciloleucel) Suspension for Intravenous Infusion

New Indication Approved: April 1, 2022

Date of Original Approval: October 18, 2017

Yescarta (axicabtagene ciloleucel) is a CD19-directed genetically modified autologous T cell immunotherapy (CAR T-cell therapy) used for the treatment of large B-cell lymphoma and follicular lymphoma.

Triumeq (abacavir, dolutegravir and lamivudine) Tablets

New Dosage Form Approved: March 30, 2022

Date of Original Approval: August 22, 2014

Triumeq (abacavir, dolutegravir and lamivudine) is a fixed-dose combination containing the INSTI dolutegravir and the NRTIs abacavir and lamivudine for the treatment of HIV-1 infection.

Cabenuva (cabotegravir and rilpivirine) Extended-Release Injectable Suspension (Co-Packaged)

Patient Population Altered: March 29, 2022

Date of Original Approval: January 21, 2021

Cabenuva (cabotegravir and rilpivirine) is a long-acting, injectable regimen of the HIV-1 integrase strand transfer inhibitor (INSTI) cabotegravir, and the HIV-1 non-nucleoside reverse transcriptase inhibitor (NNRTI) rilpivirine indicated as a complete regimen for the treatment of HIV-1 infection in adults and adolescents 12 years of age and older.

Ozempic (semaglutide) Injection

New Dosage Regimen: March 28, 2022

Date of Original Approval: December 5, 2017

Ozempic (semaglutide) is a glucagon-like peptide-1 (GLP-1) analog for the treatment type 2 diabetes, and to reduce the risk of major cardiovascular events in patients with type 2 diabetes and known heart disease.

Fintepla (fenfluramine) Oral Solution

New Indication Approved: March 25, 2022

Date of Original Approval: June 25, 2020

Fintepla (fenfluramine) is an amphetamine derivative indicated for the treatment of seizures associated with Dravet syndrome and Lennox-Gastaut syndrome in patients 2 years of age and older.

Rinvoq (upadacitinib) Extended-Release Tablets

New Indication Approved: March 16, 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, and ankylosing spondylitis.

Lynparza (olaparib) Tablets

New Indication Approved: March 11, 2022

Date of Original Approval: December 19, 2014

Lynparza (olaparib) is a first-in-class oral poly ADP ribose polymerase (PARP) inhibitor indicated for the treatment of ovarian cancer, breast cancer, pancreatic cancer, and prostate cancer.

Opdivo (nivolumab) Injection

New Indication Approved: March 4, 2022

Date of Original Approval: December 22, 2014

Opdivo (nivolumab) is a programmed death receptor-1 (PD-1) blocking antibody for the treatment of melanoma, non-small cell lung cancer, malignant pleural mesothelioma, renal cell carcinoma, classical Hodgkin lymphoma, squamous cell carcinoma of the head and neck, urothelial carcinoma, MSI-H or dMMR metastatic colorectal cancer, hepatocellular carcinoma, esophageal cancer, gastric cancer, and gastroesophageal junction cancer.

Jardiance (empagliflozin) Tablets**New Indication Approved:** February 24, 2022**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.

Juvederm (dermal filler)**New Indication Approved:** February 8, 2022**Date of Original Approval:** June 2, 2006

Juvederm is a hyaluronic acid dermal filler indicated for the correction of facial wrinkles and folds.

Yescarta (axicabtagene ciloleucel) Suspension for Intravenous Infusion**Labeling Revision Approved:** January 31, 2022**Date of Original Approval:** October 18, 2017

Yescarta (axicabtagene ciloleucel) is a CD19-directed genetically modified autologous T cell immunotherapy (CAR T-cell therapy) used for the treatment of large B-cell lymphoma and follicular lymphoma.

Cabenuva (cabotegravir and rilpivirine) Extended-Release Injectable Suspension (Co-Packaged)**New Dosage Regimen:** January 31, 2022**Date of Original Approval:** January 21, 2021

Cabenuva (cabotegravir and rilpivirine) is a long-acting, injectable regimen of the HIV-1 integrase strand transfer inhibitor (INSTI) cabotegravir, and the HIV-1 non-nucleoside reverse transcriptase inhibitor (NNRTI) rilpivirine indicated as a complete regimen for the treatment of HIV-1 infection in adults and adolescents 12 years of age and older.

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Solosec (secnidazole) Oral Granules**Patient Population Altered:** January 26, 2022**Date of Original Approval:** September 15, 2017

Solosec (secnidazole) is a nitroimidazole antimicrobial for use as a single-dose oral therapy in the treatment of bacterial vaginosis (BV) and trichomoniasis.

Nucala (mepolizumab) Injection**New Dosage Regimen:** January 24, 2022**Date of Original Approval:** November 4, 2015

Nucala (mepolizumab) is an interleukin-5 antagonist monoclonal antibody (IgG1 kappa) used for the treatment of with severe eosinophilic asthma, chronic rhinosinusitis with nasal polyps (CRSwNP), eosinophilic granulomatosis with polyangiitis (Churg-Strauss syndrome), and hypereosinophilic syndrome (HES).

Veklury (remdesivir) Injection**New Indication Approved:** January 21, 2022**Date of Original Approval:** October 22, 2020

Veklury (remdesivir) is a SARS-CoV-2 nucleotide analog RNA polymerase inhibitor indicated for the treatment of COVID-19.

Skyrizi (risankizumab-rzaa) Injection**New Indication Approved:** January 21, 2022**Date of Original Approval:** April 23, 2019

Skyrizi (risankizumab-rzaa) is an interleukin-23 (IL-23) inhibitor for the treatment of plaque psoriasis, psoriatic arthritis, and Crohn's disease.

Reference: www.drugs.com