New Indications & Dosage Forms for Existing Drugs

Casgevy (exagamglogene autotemcel) Suspension for Intravenous Infusion

New Indication Approved: January 16, 2024
Date of Original Approval: December 8, 2023

Casgevy (exagamglogene autotemcel) is a CRISPR/Cas9 genome-edited cell therapy for the treatment of sickle cell disease and transfusion-dependent beta-thalassemia.

Keytruda (pembrolizumab) for Injection

New Indication Approved: January 12, 2024
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, biliary tract cancer, Merkel cell carcinoma, renal cell carcinoma, endometrial carcinoma, tumor mutational burden-high (TMB-H) cancer, cutaneous squamous cell carcinoma and triple-negative breast cancer.

Udenyca (pegfilgrastim-cbqv) Injection

New Dosage Regimen: December 22, 2023
Date of Original Approval: November 2, 2018

Udenyca (pegfilgrastim-cbqv) is a PEGylated growth colony-stimulating factor biosimilar to Neulasta (pegfilgrastim) indicated to reduce the duration of febrile neutropenia in patients treated with chemotherapy and to increase survival in patients acutely exposed to myelosuppressive doses of radiation.

Brukinsa (zanubrutinib) Capsules

Labeling Revision Approved: December 21, 2023
Date of Original Approval: November 14, 2019

Brukinsa (zanubrutinib) is a Bruton's tyrosine kinase (BTK) inhibitor used for the treatment of mantle cell lymphoma (MCL), Waldenström's macroglobulinemia (WM), marginal zone lymphoma (MZL), and chronic lymphocytic leukemia or small lymphocytic lymphoma (SLL).

Yescarta (axicabtagene ciloleucel) Suspension for Intravenous Infusion

Labeling Revision Approved: December 21, 2023
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.

Tarpeyo (budesonide) Delayed Release Capsules

Labeling Revision Approved: December 20, 2023
Date of Original Approval: December 15, 2021

Tarpeyo (budesonide) is a targeted release formulation of the approved corticosteroid budesonide indicated to reduce the loss of kidney function in adults with primary immunoglobulin A nephropathy (IgAN) who are at risk for disease progression.

Padcev (enfortumab vedotin-ejfv) Lyophilized Powder for Injection

New Indication Approved: December 15, 2023
Date of Original Approval: December 18, 2019

Padcev (enfortumab vedotin-ejfv) is a Nectin-4 directed antibody-drug conjugate (ADC) for the treatment of urothelial cancer.

Zoryve (roflumilast) Cream and Foam

New Indication Approved: December 15, 2023
Date of Original Approval: July 29, 2022

Zoryve (roflumilast) is a topical phosphodiesterase 4 (PDE4) inhibitor indicated for the treatment of plaque psoriasis (cream formulation) and seborrheic dermatitis (foam formulation).

Adbry (tralokinumab-ldrm) Injection

Patient Population Altered: December 14, 2023
Date of Original Approval: December 27, 2021

Adbry (tralokinumab-ldrm) is an interleukin-13 antagonist used for the treatment of moderate-to-severe atopic dermatitis.

Welireg (belzutifan) Tablets

New Indication Approved: December 14, 2023
Date of Original Approval: August 13, 2021

Welireg (belzutifan) is a selective inhibitor of hypoxia-inducible factor 2 alpha (HIF-2α) for the treatment of von Hippel-Lindau (VHL) disease and advanced renal cell carcinoma.

Nexletol (bempedoic acid) Tablets

Labeling Revision Approved: December 13, 2023
Date of Original Approval: February 21, 2020

Nexletol (bempedoic acid) is an adenosine triphosphate-citrate lyase (ACL) inhibitor indicated as an adjunct to diet and statin therapy for the treatment of primary hyperlipidemia in adults with heterozygous familial hypercholesterolemia (HeFH) or atherosclerotic cardiovascular disease, who require additional lowering of LDL-C.

Trogarzo (ibalizumab-uiyk) Injection

New Dosage Regimen: December 12, 2023
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.

Cresemba (isavuconazonium) Capsules and Injection

Patient Population Altered: December 8, 2023
Date of Original Approval: March 6, 2015

Cresemba (isavuconazonium) is an azole antifungal indicated for the treatment of invasive aspergillosis and invasive mucormycosis.

Bivigam (immune globulin intravenous) Infusion

Patient Population Altered: December 8, 2023
Date of Original Approval: December 21, 2012

Bivigam is an immune globulin intravenous (human) indicated for the treatment of primary humoral immunodeficiency.

Jaypirca (pirtobrutinib) Tablets

New Indication Approved: December 1, 2023
Date of Original Approval: January 27, 2023

Jaypirca (pirtobrutinib) is a non-covalent (reversible) Bruton's tyrosine kinase (BTK) inhibitor for use in the treatment of mantle cell lymphoma (MCL), and chronic lymphocytic leukemia or small lymphocytic lymphoma (CLL/SLL).

Wilate (von Willebrand Factor/Coagulation Factor VIII Complex (Human)) Injection

New Indication Approved: December 1, 2023
Date of Original Approval: December 4, 2009

Wilate (von Willebrand Factor/Coagulation Factor VIII Complex (Human)) is used in the management of von Willebrand disease and hemophilia A.

Xtandi (enzalutamide) Capsules and Tablets

New Indication Approved: November 16, 2023
Date of Original Approval: August 31, 2012

Xtandi (enzalutamide) is an androgen receptor inhibitor used for the treatment of prostate cancer.

Tirosint-SOL (levothyroxine sodium) Oral Solution

New Dosage Regimen: November 16, 2023
Date of Original Approval: December 15, 2016

Tirosint-SOL is an oral liquid formulation of levothyroxine (T4) for the treatment of hypothyroidism and for pituitary thyrotropin (thyroid stimulating hormone, TSH) suppression.

Exparel (bupivacaine liposome) Injectable Suspension

New Indication Approved: November 9, 2023
Date of Original Approval: October 28, 2011

Exparel (bupivacaine liposome) is a long-acting amide local anesthetic used for postsurgical analgesia.

Voquezna Triple Pak (amoxicillin, clarithromycin, and vonoprazan) Co-Packaged Capsules and Tablets

New Formulation Approved: October 31, 2023
Date of Original Approval: May 3, 2022

Voquezna Triple Pak (amoxicillin, clarithromycin, and vonoprazan) is a co-packaged product containing amoxicillin (penicillin class antibacterial), clarithromycin (macrolide antimicrobial), and vonoprazan (potassium-competitive acid blocker (PCAB)) indicated for the treatment of Helicobacter pylori (H. pylori) infection in adults.

Cosentyx (secukinumab) Injection

New Indication Approved: October 31, 2023
Date of Original Approval: January 21, 2015

Cosentyx (secukinumab) is a selective interleukin-17A (IL-17A) inhibitor for the treatment of plaque psoriasis ankylosing spondylitis, psoriatic arthritis, non-radiographic axial spondyloarthritis, enthesitis-related arthritis, and hidradenitis suppurativa.

Keytruda (pembrolizumab) for Injection

New Indication Approved: October 31, 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, biliary tract cancer, Merkel cell carcinoma, renal cell carcinoma, endometrial carcinoma, tumor mutational burden-high (TMB-H) cancer, cutaneous squamous cell carcinoma and triple-negative breast cancer.

Vabysmo (faricimab-svoa) Intravitreal Injection

New Indication Approved: October 26, 2023
Date of Original Approval: January 28, 2022

Vabysmo (faricimab-svoa) is a vascular endothelial growth factor (VEGF) and angiopoietin-2 (Ang-2) inhibitor indicated for the treatment of neovascular (wet) age-related macular degeneration (AMD), diabetic macular edema (DME) and macular edema following retinal vein occlusion (RVO).

Tibsovo (ivosidenib) Tablets

New Indication Approved: October 24, 2023
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), IDH1-mutated cholangiocarcinoma and IDH1-mutated myelodysplastic syndromes.

Rozlytrek (entrectinib) Capsules and Oral Pellets

Patient Population Altered: October 20, 2023
Date of Original Approval: August 15, 2019

Rozlytrek (entrectinib) is a selective tyrosine kinase inhibitor for the treatment of patients with ROS1-positive, metastatic non-small cell lung cancer and neurotrophic tyrosine receptor kinase (NTRK) gene fusion-positive solid tumors.

Voxzogo (vosoritide) Lyophilized Powder for Injection

Patient Population Altered: October 20, 2023
Date of Original Approval: November 19, 2021

Voxzogo (vosoritide) is a C type natriuretic peptide (CNP) analog used to increase linear growth in pediatric patients with achondroplasia.

Opdivo (nivolumab) Injection

New Indication Approved: October 13, 2023
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.

Braftovi (encorafenib) Capsules

New Indication Approved: October 11, 2023
Date of Original Approval: June 27, 2018

Braftovi (encorafenib) is a kinase inhibitor used for the treatment of melanoma, colorectal cancer, and non-small cell lung cancer.

Cosentyx (secukinumab) Injection

New Formulation Approved: October 6, 2023
Date of Original Approval: January 21, 2015

Cosentyx (secukinumab) is a selective interleukin-17A (IL-17A) inhibitor for the treatment of plaque psoriasis, ankylosing spondylitis, psoriatic arthritis, non-radiographic axial spondyloarthritis, enthesitis-related arthritis and hidradenitis suppurativa.

Zoryve (roflumilast) Cream and Foam

Patient Population Altered: October 5, 2023
Date of Original Approval: July 29, 2022

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Zoryve (roflumilast) is a topical phosphodiesterase 4 (PDE4) inhibitor indicated for the treatment of plaque psoriasis (cream formulation) and seborrheic dermatitis (foam formulation).

Abrilada (adalimumab-afzb) Injection

Labeling Revision Approved: October 4, 2023
Date of Original Approval: November 15, 2019

Abrilada (adalimumab-afzb) is a tumor necrosis factor (TNF) blocker interchangeable biosimilar to Humira indicated for the treatment of rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, Crohn's disease, ulcerative colitis, plaque psoriasis, hidradenitis suppurativa and uveitis.

References: www.drugs.com