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 are mentioned below.

Cosentyx (secukinumab) Injection

Patient Population Altered: December 22, 2021
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, and non-radiographic axial spondyloarthritis.

Xarelto (rivaroxaban) Tablets and Oral Suspension

Patient Population Altered: December 20, 2021
Date of Original Approval: July 1, 2011

Xarelto (rivaroxaban) is a factor Xa inhibitor used for the treatment and prevention of blood clots that are related to certain conditions involving the heart and blood vessels.

Otezla (apremilast) Tablets

New Indication Approved: December 20, 2021
Date of Original Approval: March 21, 2014

Otezla (apremilast) is a phosphodiesterase 4 (PDE4) inhibitor indicated for the treatment of psoriatic arthritis, plaque psoriasis, and oral ulcers associated with Behçet's disease.

Oxbryta (voxelotor) Tablets

Patient Population Altered: December 17, 2021
Date of Original Approval: November 25, 2019

Oxbryta (voxelotor) is an oral, HbS (sickle hemoglobin) polymerization inhibitor for the treatment of patients with sickle cell disease (SCD).

Caplyta (lumateperone) Capsules

New Indication Approved: December 17, 2021
Date of Original Approval: December 20, 2019

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

Orencia (abatacept) Injection

New Indication Approved: December 15, 2021
Date of Original Approval: December 23, 2005

Orencia (abatacept) is a selective T cell costimulation modulator indicated for the treatment of rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis, and the prophylaxis of acute graft versus host disease (aGVHD).

Xeljanz (tofacitinib) Tablets and Oral Solution

New Indication Approved: December 14, 2021
Date of Original Approval: November 6, 2012

Xeljanz (tofacitinib) is an oral Janus kinase (JAK) inhibitor used for the treatment of rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, ulcerative colitis, and polyarticular course juvenile idiopathic arthritis.

Rinvoq (upadacitinib) Extended-Release Tablets

New Indication Approved: December 14, 2021
Date of Original Approval: August 16, 2019

Rinvoq (upadacitinib) is a Janus kinase (JAK) inhibitor for the treatment of rheumatoid arthritis and psoriatic arthritis.

Zynrelef (bupivacaine and meloxicam) Injection

New Indication Approved: December 8, 2021
Date of Original Approval: May 12, 2021

Zynrelef (bupivacaine and meloxicam) is an extended-release, fixed-dose combination of the local anesthetic bupivacaine and the nonsteroidal anti-inflammatory drug (NSAID) meloxicam indicated for the management of postoperative pain.

Keytruda (pembrolizumab) for Injection

New Indication Approved: November 17, 2021
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.

Dyanavel XR (amphetamine) Extended-Release Oral Suspension and Extended-Release Tablets

New Dosage Form Approved: November 4, 2021
Date of Original Approval: October 19, 2015

Dyanavel XR (amphetamine) is an extended-release central nervous system (CNS) stimulant for the treatment of Attention Deficit Hyperactivity Disorder (ADHD).

Dupixent (dupilumab) Injection

Patient Population Altered: October 20, 2021
Date of Original Approval: March 28, 2017

Dupixent (dupilumab) is an interleukin-4 receptor alpha antagonist used for the treatment of atopic dermatitis, asthma, and chronic rhinosinusitis with nasal polyposis (CRSwNP).

Cyltezo (adalimumab-adbm) Injection

Labeling Revision Approved: October 15, 2021
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 various inflammatory diseases including rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, Crohn's disease, ulcerative colitis, and plaque psoriasis.

Tecentriq (atezolizumab) Injection

New Indication Approved: October 15, 2021
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 urothelial carcinoma, non-small cell lung cancer (NSCLC), triple-negative breast cancer (TNBC), small cell lung cancer (SCLC), hepatocellular carcinoma and melanoma.

Verzenio (abemaciclib) Tablets

New Indication Approved: October 13, 2021
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.

Keytruda (pembrolizumab) for Injection

New Indication Approved: October 13, 2021
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.

Dextenza (dexamethasone) Ophthalmic Insert

New Indication Approved: October 7, 2021
Date of Original Approval: November 30, 2018

Dextenza (dexamethasone ophthalmic insert) is a corticosteroid intracanalicular insert for the treatment of post-surgical ocular inflammation and pain, and ocular itching associated with allergic conjunctivitis.

Biktarvy (bictegravir, emtricitabine and tenofovir alafenamide) Tablets

Patient Population Altered: October 7, 2021
Date of Original Approval: February 7, 2018

Biktarvy (bictegravir, emtricitabine and tenofovir alafenamide) is a combination of an integrase strand transfer inhibitor (bictegravir) and two HIV-1 nucleoside analog reverse transcriptase inhibitors (emtricitabine and tenofovir alafenamide) used for the treatment of HIV-1 infection.

Tecartus (brexucabtagene autoleucel) Suspension for Intravenous Infusion

New Indication Approved: October 1, 2021
Date of Original Approval: July 24, 2020

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Tecartus (brexucabtagene autoleucel) is a CD19-directed genetically modified autologous T cell immunotherapy for the treatment of mantle cell lymphoma (MCL) and B-cell precursor acute lymphoblastic leukemia (ALL).

Reference: www.drugs.com