New Indications & Dosage Forms for Existing Drugs

Tremfya (guselkumab) Injection
New Indication Approved: July 13, 2020
Date of Original Approval: July 13, 2017
Tremfya (guselkumab) is an interleukin-23 blocker indicated for the treatment of moderate-to-severe plaque psoriasis and psoriatic arthritis in adults.

Botox (onabotulinumtoxinA) Injection
New Indication Approved: July 8, 2020
Date of Original Approval: December 9, 1991
Botox (onabotulinumtoxinA) is an acetylcholine release inhibitor and a neuromuscular blocking agent indicated for the treatment of **overactive bladder**, **urinary incontinence**, **chronic migraine, spasticity, cervical dystonia, hyperhidrosis, blepharospasm**, **strabismus**.

Dysport (abobotulinumtoxinA) Injection
New Indication Approved: July 8, 2020
Date of Original Approval: April 29, 2009
Dysport (abobotulinumtoxinA) is an acetylcholine release inhibitor and neuromuscular blocking agent indicated for the treatment of cervical dystonia in adults, the temporary improvement in the appearance of moderate to severe glabellar lines associated with procerus and corrugator muscle activity in adults < 65 years of age also in the treatment of spasticity in patients 2 years of age and older.

Bavencio (avelumab) Injection
New Indication Approved: June 30, 2020
Date of Original Approval: March 23, 2017
Bavencio (avelumab) is a programmed death ligand-1 (PD-L1) blocking antibody indicated for the treatment of patients with metastatic Merkel cell carcinoma (MCC); patients with advanced or metastatic urothelial carcinoma; and in combination with axitinib for patients with advanced renal cell carcinoma.

Keytruda (pembrolizumab) for Injection
New Indication Approved: June 29, 2020
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, small cell lung cancer, head and neck squamous cell carcinoma, classical Hodgkin lymphoma, primary mediastinal large B-cell lymphoma, urothelial carcinoma, microsatellite instability-high cancer, gastric cancer, esophageal cancer, cervical cancer, hepatocellular carcinoma, Merkel cell carcinoma, renal cell carcinoma, endometrial carcinoma, tumor mutational burden-high (TMB-H) cancer, and cutaneous squamous cell carcinoma.

Xpovio (selinexor) Tablets
New Indication Approved: June 22, 2020
Date of Original Approval: July 3, 2019
Xpovio (selinexor) is a first in class Selective Inhibitor of Nuclear Export (SINE) XPO1 antagonist for the treatment of patients adult patients with multiple myeloma (RRMM) and relapsed or refractory diffuse large B-cell lymphoma (DLBCL).

Crysvita (burosumab-twza) Injection
New Indication Approved: June 18, 2020
Date of Original Approval: April 17, 2018
Crysvita (burosumab-twza) is a fibroblast growth factor 23 (FGF23) blocking antibody for the treatment of x-linked hypophosphatemia (XLH) and FGF23-related hypophosphatemia in tumor-induced osteomalacia (TIO).

Tazverik (tazemetostat) Tablets
New Indication Approved: June 18, 2020
Date of Original Approval: January 23, 2020
Tazverik (tazemetostat) is a methyltransferase inhibitor for the treatment of **epithelioid sarcoma** and **follicular lymphoma**

Dupixent (dupilumab) Injection
New Dosage Form Approved: June 18, 2020
Date of Original Approval: March 28, 2017
Dupixent (dupilumab) is an interleukin-4 receptor alpha antagonist indicated for the treatment of **atopic**

dermatitis, moderate-to-severe **asthma and** controlled **chronic rhinosinusitis with nasal polyposis**.

Cosentyx (secukinumab) Injection

New Indication Approved: June 16, 2020

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.

Keytruda (pembrolizumab) for Injection

New Indication Approved: June 16, 2020

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, small cell lung cancer, head and neck squamous cell carcinoma, classical Hodgkin lymphoma, primary mediastinal large B-cell lymphoma, urothelial carcinoma, microsatellite instability-high cancer, gastric cancer, esophageal cancer, cervical cancer, hepatocellular carcinoma, Merkel cell carcinoma, renal cell carcinoma, endometrial carcinoma, tumor mutational burden-high (TMB-H) cancer, and cutaneous squamous cell carcinoma.

Ilaris (canakinumab) Injection

New Indication Approved: June 16, 2020

Date of Original Approval: June 17, 2009

Ilaris (canakinumab) is a human anti-interleukin-1β monoclonal antibody for the treatment of Periodic Fever Syndromes (Cryopyrin-Associated Periodic Syndromes, Tumor Necrosis Factor Receptor Associated Periodic Syndrome, Hyperimmunoglobulin D Syndrome/Mevalonate Kinase Deficiency, Familial Mediterranean Fever), and active Still's disease, including Adult-Onset Still's Disease (AOSD) and Systemic Juvenile Idiopathic Arthritis (SJIA).

Tivicay (dolutegravir) Tablets

New Dosage Form Approved: June 12, 2020

Date of Original Approval: August 12, 2013

Tivicay (dolutegravir) is a human immunodeficiency virus type 1 (HIV-1) integrase strand transfer inhibitor (INSTI) indicated for use in combination with other antiretroviral (ARV) agents for the treatment of HIV-1.

Opdivo (nivolumab) Injection

New Indication Approved: June 10, 2020

Date of Original Approval: December 22, 2014

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

Recarbrio (imipenem, cilastatin, and relebactam) for Injection

New Indication Approved: June 4, 2020

Date of Original Approval: July 16, 2019

Recarbrio (imipenem, cilastatin, and relebactam) is a combination of **imipenem**, a penem antibacterial, **cilastatin**, a renal dehydropeptidase inhibitor, and **relebactam**, a betalactamase inhibitor, indicated for the treatment of complicated urinary tract infections (cUTI), complicated intra-abdominal infections (cIAI), and hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia (HABP/VABP) in adults.

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References: *www.drugs.com/newdrugs*