

April 27th, 2022

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Dear provider of healthcare-related services,

To keep you up to date with the FDA approvals, here is a summary of the new indications and first-time generics approved by the FDA for January to March 2022. For more information regarding FDA approvals, you may visit the FDA website (<https://www.fda.gov>). Please note that the information provided in this educational material is not intended to substitute the revision of literature that contains the full details about these approvals.

I. New Indications Approved by the FDA from January 2022 to March 2022

Drug Name / Manufacturer	Therapeutic Class	Previous FDA-approved Indication(s)	New FDA-approved Indication(s)
January 2022			
Rinvoq™ (upadacitinib) extended-release tablets / AbbVie	Analgesics – anti-inflammatory	Rheumatoid arthritis, psoriatic arthritis	Refractory, moderate to severe atopic dermatitis
Skyrizi™ (Risankizumab-rzaa) injection / AbbVie	Dermatologicals	Plaque psoriasis	Active psoriatic arthritis
Veklury™ (remdesivir) injection / Gilead Sciences, Inc.	Antivirals	Hospitalized patients with coronavirus disease 2019 (COVID-19)	Non-hospitalized patients with mild-to-moderate COVID-19 and at high risk for progression to severe COVID-19
Solosec™ (secnidazole) oral granules / Lupin Pharmaceuticals Inc.	Amebicides	Bacterial vaginosis in female adults, trichomoniasis in adult patients	Bacterial vaginosis in female patients 12 years of age and older, trichomoniasis in patients 12 years of age and older
Vonvendi™ (von Willebrand factor [recombinant]) injection / Takeda Pharmaceutical Company Limited	Hematological agents	On-demand treatment and control of bleeding episodes and perioperative management of bleeding in adults diagnosed with von Willebrand disease	Routine prophylaxis to reduce the frequency of bleeding episodes in patients with severe Type 3 von Willebrand disease receiving on-demand therapy



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Drug Name / Manufacturer	Therapeutic Class	Previous FDA-approved Indication(s)	New FDA-approved Indication(s)
February 2022			
Juvéderm Volbella™ XC (dermal filler) injectable gel / Allergan Aesthetics, an AbbVie company	Cosmetic agents	Lip augmentation, correction of perioral lines	Improve the appearance of undereye hollows in adults over the age of 21
Jardiance™ (empagliflozin) tablets / Boehringer Ingelheim and Eli Lilly Co.	Antidiabetics	Type 2 diabetes mellitus, heart failure with reduced left ventricular ejection fraction (LVEF)	To reduce the risk of cardiovascular death and hospitalization for heart failure in adults with heart failure
March 2022			
Opdivo™ (nivolumab) injection / Bristol Myers Squibb	Antineoplastics and adjunctive therapies	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, colorectal cancer, hepatocellular carcinoma, esophageal cancer, gastric cancer, gastroesophageal junction cancer and esophageal adenocarcinoma	Adult patients with resectable (tumors ≥4cm or node positive) non-small cell lung cancer in the neoadjuvant setting, in combination with platinum-doublet chemotherapy
Lynparza™ (olaparib) tablets / AstraZeneca	Antineoplastics and adjunctive therapies	Ovarian cancer, breast cancer, pancreatic cancer, prostate cancer,	Adjuvant treatment of patients with germline BRCA-mutated (gBRCAm) HER2-negative high-risk early breast cancer who have already been treated with chemotherapy either before or after surgery
Rinvoq™ (upadacitinib) extended-release tablets / AbbVie	Analgesics – anti-inflammatory	Rheumatoid arthritis, psoriatic arthritis, atopic dermatitis	Moderately to severely active ulcerative colitis
Keytruda™ (pembrolizumab) injection / Merck	Antineoplastics and adjunctive therapies	Melanoma, non-small cell lung cancer, head and neck squamous cell	Advanced endometrial carcinoma that is microsatellite instability-



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Drug Name / Manufacturer	Therapeutic Class	Previous FDA-approved Indication(s)	New FDA-approved Indication(s)
		cancer, classical Hodgkin lymphoma, primary mediastinal large B-cell lymphoma, urothelial carcinoma, microsatellite instability-high or mismatch repair deficient 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 mutation burden-high cancer, cutaneous squamous cell carcinoma, triple-negative breast cancer	high (MSI-H) or mismatch repair deficient, who have disease progression following prior systemic therapy in any setting and are not candidates for curative surgery or radiation
Fintepla™ (fenfluramine) oral solution / UCB	Anticonvulsants	Seizures associated with Dravet syndrome	Seizures associated with Lennox-Gastaut syndrome

References:

New Indications & Dosage Forms for Existing Drugs. (2022). <https://www.drugs.com/new-indications.html>

Drugs@FDA: FDA-Approved Drugs. (2022). <https://www.accessdata.fda.gov/scripts/cder/daf/>



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II. New First-Time Generics Approved by the FDA from January 2022 to March 2022

Drug Name / Manufacturer	Generic For:	Therapeutic Class	Indication(s)
January 2022			
Pirfenidone capsules 267mg / Amneal Pharmaceuticals LLC	Esbriet™	Respiratory Agents	Idiopathic pulmonary fibrosis
Sofosbuvir tablets 400mg / Teva Pharmaceutical USA, Inc.	Sovaldi™	Antivirals	Hepatitis C
Brimonidine tartrate ophthalmic solution 0.15% / Apotex Inc.	Alphagan P™	Ophthalmic agents	Glaucoma
February 2022			
Cyclosporine ophthalmic emulsion 0.05% / Mylan Pharmaceuticals, Inc.	Restasis™	Ophthalmic agents	Dry eye disease
Maraviroc tablets 150mg and 300mg /	Selzentry™	Antivirals	HIV infection
Nalmefene hydrochloride injection 2mg base/2mL / Purdue Pharma LP	Revex™	Antidotes and specific antagonists	Opioid overdose
Dapagliflozin tablets 5mg and 10mg / Zydus Pharmaceuticals USA, Inc.	Farxiga™	Antidiabetics	Type 2 diabetes mellitus, heart failure chronic kidney disease
Apomorphine hydrochloride injection 30mg/3mL / Sage Chemicals, Inc.	Apokyn™	Antiparkinson and related therapy agents	Parkinson's disease
March 2022			
Methylphenidate extended-release transdermal film 10mg, 15mg, 20mg and 30mg / Mylan Pharmaceuticals Inc.	Daytrana™	ADHD/anti-narcolepsy/anti-obesity/anorexiant	Attention deficit hyperactivity disorder
Budesonide and formoterol fumarate dihydrate metered inhalation aerosol 0.08mg/0.0045mg per inhalation and 0.16mg/0.0045mg per inhalation / Mylan Pharmaceuticals Inc.	Symbicort™	Antiasthmatic and bronchodilator agents	Asthma, chronic obstructive pulmonary disease
Lacosamide tablets 50mg, 100mg, 150mg and 200mg / Alembic Pharmaceuticals	Vimpat™	Anticonvulsants	Seizures



Drug Name / Manufacturer	Generic For:	Therapeutic Class	Indication(s)
Ltd.; Amneal Pharmaceuticals LLC; Glenmark Pharmaceuticals Inc.; Hetero Labs Limited; Indoco Remedies Limited; MSN Laboratories Private Limited; ScieGen Pharmaceuticals Inc.; Sun Pharmaceutical Industries, Inc.			
Ioflupane I-123 injection for intravenous use 185MBq (5mCi) in 2.5mL / Curium US LLC	DaTscan™	Diagnostic products	Computed tomography

References:

Latest Generic Drug Approvals. (2022). <https://www.drugs.com/generic-approvals.html>

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Kind regards,

Clinical Department



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