MC-Rx

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Insights on the Drugs Pipeline

Exploring the changes in the drugs market.

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MC-Rx is dedicated to improved drug therapy vigilance, continuity of care, patient safety and effective formulary management. This edition is developed by our clinical team, which is comprised of registered clinical pharmacists, to provide you with continuous evaluation and insights of the drugs market and its impact as it evolves.

Here you will find

- Drug pipeline
- FDA drug approvals
- New indications
- Patent expirations
- Generic approvals
- FDA safety updates/ withdrawals/ recalls
- Drug shortages/ discontinuations

COVID-19 Emergency Use Authorization (EUA) Update

R&D | FDA Approval | In Market Brand | Generic Available | Off Market

Date of first EUA issuance	Treatment	Authorized use	Clinical Studies
12/08/2021	Evusheld (tixagevimab co-packaged with cilgavimab)	For emergency use as pre-exposure prophylaxis for prevention of COVID-19 in adults and pediatric individuals (12 years of age and older weighing at least 40 kg): • Who are not currently infected with SARS-CoV-2 and who have not had a known recent exposure to an individual infected with SARS-CoV-2 **and** o Who have moderate to severe immune compromise due to a medical condition or receipt of immunosuppressive medications or treatments and may not mount an adequate immune response to COVID-19 vaccination **or** o For whom vaccination with any available COVID-19 vaccine, according to the approved or authorized schedule, is not recommended due to a history of severe adverse reaction (e.g., severe allergic reaction) to a COVID-19 vaccine(s) and/or COVID-19 vaccine component(s).	• The primary data supporting this EUA for Evusheld are from PROVENT, a randomized, double-blind, placebo-controlled clinical trial in adults greater than age 59 or with a prespecified chronic medical condition or at increased risk of SARS-CoV-2 infection for other reasons who had not received a COVID-19 vaccine and did not have a history of SARS-CoV-2 infection or test positive for SARS-CoV-2 infection at the start of the trial. • The main outcome measured in the trial was whether a trial participant had a first case of COVID-19 after receiving Evusheld or placebo and before day 183 of the trial. In this trial, 3,441 people received Evusheld and 1,731 received a placebo. • In the primary analysis, Evusheld recipients saw a 77% reduced risk of developing COVID-19 compared to those who received a placebo, a statistically significant difference. In additional analyses, the reduction in risk of developing COVID-19 was maintained for Evusheld recipients through six months. • The safety and effectiveness of Evusheld for use in the pre-exposure prevention of COVID-19 continue to be evaluated.

COVID-19 Vaccines Updates

R&D | FDA Approval | In Market Brand | Generic Available | Off Market

Date	Update
12/09/2021	**FDA Expands Eligibility for Pfizer-BioNTech COVID-19 Booster Dose to 16- and 17-Year-Olds:** The FDA amended the emergency use authorization (EUA) for the Pfizer-BioNTech COVID-19 Vaccine, authorizing the use of a single booster dose for administration to individuals 16 and 17 years of age at least six months after completion of primary vaccination with the Pfizer-BioNTech COVID-19 Vaccine. The EUA for a single booster dose of the Pfizer-BioNTech COVID-19 Vaccine for individuals 16 and 17 years of age is based on the FDA's previous analysis of immune response data that supported use of a booster dose in individuals 18 years of age and older. The FDA had analyzed the immune response data from approximately 200 participants, 18 through 55 years of age, who received a single booster dose approximately six months after their second dose. The antibody response against the SARS-CoV-2 virus one month after a booster dose of the vaccine, when compared to the response one month after the two-dose primary series in the same individuals, demonstrated a booster response. The FDA's assessment of the effectiveness of a booster dose for individuals 16 and 17 years of age is based on these data. Based on the available data for individuals 18 and older regarding effectiveness, the FDA has concluded that these data support extending the eligible booster age population to 16- and 17-year-olds.
11/19/2021	**FDA Expands Eligibility for COVID-19 Vaccine Boosters:** The FDA amended the emergency use authorizations (EUA) for both the Moderna and Pfizer-BioNTech COVID-19 vaccines authorizing use of a single booster dose for all individuals 18 years of age and older after completion of primary vaccination with any FDA-authorized or approved COVID-19 vaccine. Previously, a single booster dose of the Moderna and Pfizer-BioNTech COVID-19 vaccines was authorized for administration to individuals 65 years of age and older, individuals 18 through 64 years of age at high risk of severe COVID-19 and individuals 18 through 64 years of age with frequent institutional or occupational exposure to SARS-CoV-2. Now the FDA expands the use of booster doses of both vaccines to include all individuals 18 years of age and older at least six months after completion of the primary vaccination series of the Moderna COVID-19 Vaccine or Pfizer-BioNTech COVID-19 Vaccine or at least two months after completion of primary vaccination with the Janssen COVID-19 Vaccine.
10/29/2021	**FDA Authorizes COVID-19 Vaccine in Children 5 through 11:** The Pfizer-BioNTech COVID-19 Vaccine for children 5 through 11 years of age is administered as a two-dose primary series, 3 weeks apart, but is a lower dose (10 micrograms) than that used for individuals 12 years of age and older (30 micrograms). • Effectiveness: Immune responses of children 5 through 11 years of age were comparable to those of individuals 16 through 25 years of age. In addition, the vaccine was found to be 90.7% effective in preventing COVID-19 in children 5 through 11. • Safety: The vaccine's safety was studied in approximately 3,100 children age 5 through 11 who received the vaccine and no serious side effects have been detected in the ongoing study.

COVID-19 Vaccine Booster Shots - CDC Recommendations

R&D | FDA Approval | In Market Brand | Generic Available | Off Market

Vaccine that was administered:	Who can get a booster?	Who should get a booster?	When to get a booster?	Which booster can you get?
Pfizer-BioNTech	Teens 16-17 years old	Adults 18 years and older	At least 6 months after completing your primary COVID-19 vaccination series	Teens 16–17 years old can get a Pfizer-BioNTech COVID-19 vaccine booster Adults 18 years and older can get any of the COVID-19 vaccines authorized in the United States
Moderna	N/A	Adults 18 years and older	At least 6 months after completing your primary COVID-19 vaccination series	Any of the COVID-19 vaccines authorized in the United States
Johnson & Johnson's Janssen	N/A	Adults 18 years and older	At least 2 months after completing your primary COVID-19 vaccination	Any of the COVID-19 vaccines authorized in the United States

N/A: Not applicable

References:

- Emergency Use Authorization: https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#coviddrugs
- FDA COVID-19 Vaccine News and Updates: https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines
- COVID-19 Vaccine Booster Shots: https://www.cdc.gov/coronavirus/2019-ncov/vaccines/booster-shot.html

Specialty Pipeline

R&D | FDA Approval | In Market Brand | Generic Available | Off Market

There is a growing trend of specialty drugs in the market. Therapeutic areas where the specialty drug pipeline could yield new approvals in the coming years include treatments for dermatologic conditions, hemophilia, genetic disorders, among others.

Pipeline Drug	Current Status	Anticipated Approval	Indication
Abrocitinib (Pfizer)	NDA Filed	2021/2022	Janus kinase 1 (JAK1) inhibitor for the treatment of patients with moderate-to-severe atopic dermatitis (AD); oral *Breakthrough Therapy*
Adagrasib (Mirati Therapeutics)	Phase 2	2022	KRAS G12C specific inhibitor for the treatment of KRAS G12C- mutated locally advanced or metastatic non-small cell lung cancer (NSCLC); oral *Breakthrough Therapy*
Arimoclomol (Miplyffa - Orphazyme)	Complete Response	2022	Molecular chaperone activator that stimulates the normal cellular protein repair pathway for the treatment of NiemannPick Disease Type C (NPC); oral *Breakthrough Therapy* *Orphan Drug*
Bardoxolone methyl (Reata Pharmaceuticals)	NDA Filed	02/25/2022	Antioxidant inflammation inhibitor that acts on Nrf2 for the treatment of chronic kidney disease caused by Alport Syndrome; oral *Orphan Drug*
Betibeglogene autotemcel (Zynteglo – Bluebird Bio)	BLA Filed	05/21/2022	Gene therapy for the treatment of β-globin gene therapy for the treatment of transfusion-dependent β thalassemia; IV infusion *Breakthrough Therapy* *Orphan Drug*
Bimekizumab (UCB)	BLA Filed	11/15/2021	Monoclonal antibody that blocks the effects of IL-17A and IL-17F for the treatment of moderate-to-severe plaque psoriasis; SC injection

Specialty Pipeline

R&D | FDA Approval | In Market Brand | Generic Available | Off Market

Pipeline Drug	Current Status	Anticipated Approval	Indication
Ciltacabtagene autoleucel (JNJ4528 – Janssen)	BLA Filed	02/28/2022	B-cell maturation antigen (BCMA)-directed chimeric antigen receptor T cell (CAR-T) therapy in previously treated patients with multiple myeloma; IV infusion *Breakthrough Therapy* *Orphan Drug*
Deucravacitinib (Bristol Myers Squibb)	Phase 3	2022	Tyrosine kinase 2 (TYK2) inhibitor for use in patients with moderate to severe plaque psoriasis; oral therapy
Efgartigimod (Argenx)	BLA Filed	12/17/2021	FcRn-targeting antibody fragment designed to depleted pathogenic IgGs for the treatment of myasthenia gravis (MG); IV infusion *Orphan Drug*
Eladocagene exuparvovec (PTC Therapeutics)	Phase 3	2022	Recombinant, adeno-associated virus, containing the human cDNA encoding the AADC enzyme for the treatment of AADC deficiency; intracerebral infusion deficiency; intracerebral infusion *Orphan Drug*
Futibatinib (Taiho Oncology)	Phase 3	2022	Fibroblast growth factor (FGFR) 1-4 inhibitor for the treatment of patients with previously treated locally advanced or metastatic cholangiocarcinoma harboring FGFR2 gene rearrangements, including gene fusions; oral *Breakthrough Therapy* *Orphan Drug*
Inclisiran (Leqvio - Novartis)	NDA Filed	01/01/2022	Small interfering RNA (siRNA) therapy that lowers low-density lipoprotein cholesterol (LDL-C) for the treatment of adults with atherosclerotic cardiovascular disease (ASCVD) or heterozygous familial hypercholesterolemia (HeFH) who have elevated LDL-C while being on a maximum tolerated dose of a lipid-lowering therapy (LLT); subcutaneous injection (administration by a healthcare professional)

Specialty Pipeline

R&D | FDA Approval | In Market Brand | Generic Available | Off Market

Pipeline Drug	Current Status	Anticipated Approval	Indication
Obeticholic acid (Intercept Pharmaceuticals)	Complete Response	2022	Farnesoid X receptor (FXR) agonist for the treatment of nonalcoholic steatohepatitis (NASH); oral *Breakthrough Therapy* *Orphan Drug*
Pegunigalsidase alfa (Protalix BioTherapeutics)	Complete Response	2022	Plant cell-expressed, recombinant alpha-galactosidase-A enzyme for the treatment of Fabry disease; IV infusion (monthly) *Breakthrough Therapy* *Orphan Drug*
Sutimlimab (Sanofi)	Complete Response	2022	Humanized monoclonal antibody engineered to alter the function of the T lymphocytes that mediate the destruction of the insulin-producing beta cells of the islets of the pancreas to delay or prevent the onset of type 1 diabetes in at-risk individuals; IV *Breakthrough Therapy*
Tezepelumab (Amgen/ Astrazeneca)	BLA Filed	01/10/2022	Anti-thymic stromal lymphopoietin (anti-TSLP) monoclonal antibody for the treatment of severe, uncontrolled asthma; SC *Breakthrough Therapy*
Tralokinumab (Adtralza - LEO Pharma)	BLA Filed	01/02/2022	Anti-IL-13 for the treatment of moderate to severe atopic dermatitis (AD); SC
Valoctocogene roxaparvovec (Roctavian – BioMarin Pharmaceuticals)	Complete Response	2022	Adenovirus-associated virus vector-mediated the transfer of Human Factor VIII gene in patients with severe hemophilia A; IV Infusion *Breakthrough Therapy* *Orphan Drug*
Vosoritide (Voxzogo - BioMarin)	NDA Filed	11/20/2021	Analog of C-type Natriuretic Peptide (CNP) for the treatment of children with achondroplasia; SC *Orphan Drug*

Biosimilar Pipeline

R&D | FDA Approval | In Market Brand | Generic Available | Off Market

Below is a list of biosimilars that are currently under FDA review. Approval of a biosimilar does not imply availability and allocation in the market.

Additional patent, exclusivities, settlement agreements, etc. may result in a delay in launch of a biosimilar.

Pipeline Biosimilar	Manufacturer	Reference Biologic	Possible FDA Approval Date	Potential Launch Date
Bevacizumab	Biothera	Avastin (bevacizumab)	11/27/2021	TBD (Pending FDA Approval
Adalimumab	Coherus	Humira (adalimumab)	Dec. 2021	Settlement: 07/01/2023
Insulin aspart (Kixelle)	Viatris/Biocon	Novolog (insulin aspart)	2021 /2022	TBD (Pending FDA Approval)
Pegfilgrastim biosimilar	Fresenius Kabi	Neulasta (pegfilgrastim)	2021/2022	TBD (Pending FDA Approval)
Adalimumab biosimilar	Cipla/Alvotech	Humira (adalimumab)	2022	Ongoing Litigation: 4Q2022?
Bevacizumab biosimilar (Abevmy)	Viatris/Biocon	Avastin (bevacizumab)	2021/2022	TBD (Pending FDA Approval)
Bevacizumab biosimilar (Aybintio)	Samsung Bioepis/ Merck	Avastin (bevacizumab)	2021/2022	TBD (Pending FDA Approval)
Filgrastim biosimilar	Tanvex BioPharma	Neupogen (filgrastim)	2021/2022	TBD (Pending FDA Approval)
Filgrastim biosimilar	Adello Biologic	Neupogen (filgrastim)	2021/2022	TBD (Pending FDA Approval)
Pegfilgrastim	Adello Biologic	Neulasta (pegfilgrastim)	1/13/2022	TBD (Pending FDA Approval)
Pegfilgrastim (Lupifil-P)	Lupin	Neulasta (pegfilgrastim)	4/2/2022	TBD (Pending FDA Approval)
Bevacizumab (Almysys)	Amneal	Avastin (bevacizumab)	4/17/2022	TBD (Pending FDA Approval)
Ranibizumab	Bioeq/Coherus	Lucentis (ranibizumab)	8/5/2022	TBD (Pending FDA Approval)

New Drug Formulations

R&D | FDA Approval | In Market Brand | Generic Available | Off Market

Drug Name	Information
Ruxolitinib (Opzelura)	**Dose:** Cream: 1.5% Ruxolitinib **Indication:** short-term and non-continuous chronic treatment of mild to moderate atopic dermatitis in non-immunocompromised patients 12 years of age and older whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. **Comparable:** N/A **Guidelines:** American Academy of Dermatology: Guidelines of care for the management of atopic dermatitis (AD) (2014) - Topical corticosteroids are recommended for AD-affected individuals who have failed to respond to good skin care and regular use of emollients alone. Topical calcineurin inhibitors (TCI's) are recommended and effective for acute and chronic treatment, along with maintenance, in both adults and children with AD, and are particularly useful in selected clinical situations.
Sertraline Hydrochloride (Zercapli)	**Dose:** Capsules 150mg, 200mg **Indication:** 1) Major depressive disorder (MDD) in adults 2) Obsessive-compulsive disorder (OCD) in adults and pediatric patients 6 years and older. **Comparable:** Sertraline (Zoloft) **Guidelines:** Practice Guideline for the Treatment of Patients With Major Depressive Disorder Third Edition (May 2010) - An antidepressant medication is recommended as an initial treatment choice for patients with mild to moderate major depressive disorder and definitely should be provided for those with severe major depressive disorder unless electroconvulsive therapy is planned. Because the effectiveness of antidepressant medications is generally comparable between classes and within classes of medications, the initial selection of an antidepressant medication will largely be based on the anticipated side effects, the safety or tolerability of these side effects for the individual patient, pharmacological properties of the medication (e.g., half-life, actions on cytochrome P450 enzymes, other drug interactions), and additional factors such as medication response in prior episodes, cost, and patient preference.

New Drug Formulations

R&D | FDA Approval | In Market Brand | Generic Available | Off Market

Drug Name	Information
Varenicline solution (Tyrvaya)	**Dose:** Nasal spray delivering 0.03 mg of varenicline in each spray (0.05 mL) **Indication:** nasal spray is a cholinergic agonist indicated for the treatment of the signs and symptoms of dry eye disease. **Comparable:** Lifitegrast Ophthalmic Solution 5% (Xiidra) **Guidelines:** American Academy of Ophthalmology - Dry Eye Syndrome Preferred Practice Pattern (2018) - Pharmacological and procedural treatments are associated with improvements in patient symptoms and clinical signs, although chronic therapy and patient compliance are necessary in most instances. The first choice to manage dry eye syndrome is the use of ocular lubricants. If this option is inadequate, consider using the following prescribed medications: • Topical antibiotic or antibiotic/steroid combination applied to the lid margins for anterior blepharitis (if present) • Topical corticosteroid (limited-duration) • Topical secretagogues • Topical nonglucocorticoid immunomodulatory drugs (such as cyclosporine) • Topical LFA-1 antagonist drugs (such as lifitegrast) • Oral macrolide or tetracycline antibiotics
Ranibizumab (Susvimo)	**Dose:** Injection: 100 mg/mL solution in a single-dose vial **Indication:** for the treatment of patients with Neovascular (wet) Age-related Macular Degeneration (AMD) who have previously responded to at least two intravitreal injections of a VEGF inhibitor. **Comparable:** Bevacizumab (Avastin) **Guidelines:** American Academy of Ophthalmology: Age-Related Macular Degeneration Preferred Practice Pattern (2019) - Intravitreal injection therapy using anti-vascular endothelial growth factor (VEGF) agents (e.g., aflibercept, bevacizumab, and ranibizumab) is the most effective way to manage neovascular AMD and represents the first line of treatment.
Celecoxib and tramadol hydrochloride) Seglentis	**Dose:** Tablets: Celecoxib 56 mg and tramadol hydrochloride 44 mg **Indication:** for the management of acute pain in adults that is severe enough to require an opioid analgesic and for which alternative treatments are inadequate. **Comparables:** Tramadol (Ultram) and Celecoxib (Celebrex) **Guidelines:** Centers for Disease Control and Prevention Guideline for Prescribing Opioids for Chronic Pain (2016) - When opioids are used for acute pain, clinicians should prescribe the lowest effective dose of immediate-release opioids and should prescribe no greater quantity than needed for the expected duration of pain severe enough to require opioids. Three days or less will often be sufficient; more than seven days will rarely be needed.

New Drug Formulations

R&D | FDA Approval | In Market Brand | Generic Available | Off Market

Drug Name	Information
Amphetamine (Dyanavel XR)	**Dose:** Extended-release tablets: 5 mg (functionally scored), 10 mg, 15 mg, 20 mg **Indication:** for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in patients 6 years and older. **Comparable:** Amphetamines **Guidelines:** American Academy of Pediatrics (2019) Clinical Practice Guideline for the Diagnosis, Evaluation, and Treatment of Attention-Deficit/Hyperactivity Disorder in Children and Adolescents - For elementary and middle school–aged children (age 6 years to the 12th birthday) with ADHD, the primary care clinician should prescribe US Food and Drug Administration (FDA)–approved medications for ADHD, along with PTBM and/or behavioral classroom intervention (preferably both parent training in behavior management and behavioral classroom interventions).
Pilocarpine hydrochloride (Vuity)	**Dose:** Ophthalmic solution containing pilocarpine hydrochloride 1.25% **Indication:** for the treatment of presbyopia in adults. **Comparable:** Pilocarpine ophthalmic drops **Guidelines:** American Academy of Ophthalmologists (2020) – Presbyopia can be managed with the use of reading glasses. If the patient already uses glasses for other vision problems, bifocals, trifocals or progressive lenses might be needed. The use of contact lenses or corrective surgery are also considered treatment alternatives.
Triamcinolone acetonide (Xipere)	**Dose:** Injectable suspension: triamcinolone acetonide 40 mg/mL in a single-dose vial. **Indication:** for the treatment of macular edema associated with uveitis. **Comparable:** Xipere is the first approved treatment to use the suprachoroidal space as a delivery pathway for the treatment of macular edema associated with uveitis. **Guidelines:** American Academy of Ophthalmology: Treatment Options for Uveitic Macular Edema (2019) -The management of uveitic macular edema (UME) consists in treating the underlying disease first. Treatment will depend on the anatomical location, laterality of the disease and the severity. For unilateral disease, treatment consists of periocular or intravitreal corticosteroid injections, which are effective in controlling the inflammation associated with ME.

New Drug Formulations

R&D | FDA Approval | In Market Brand | Generic Available | Off Market

Drug Name	Information
Naloxone hydrochloride (Zimhi)	**Dose:** Injection: 5 mg/0.5 mL naloxone hydrochloride solution in a single-dose, prefilled syringe. **Indication:** for the emergency treatment of known or suspected opioid overdose, as manifested by respiratory and/or central nervous system depression. **Comparables:** Naloxone Injectable and nasal spray (Narcan, Kloxxado) **Guidelines:** Centers for Disease Control and Prevention Guideline for Prescribing Opioids for Chronic Pain (2016) - Before starting and periodically during continuation of opioid therapy, clinicians should evaluate risk factors for opioid-related harms. Clinicians should incorporate into the management plan strategies to mitigate risk, including considering offering naloxone when factors that increase risk for opioid overdose, such as history of overdose, history of substance use disorder, higher opioid dosages (≥50 MME/day), or concurrent benzodiazepine use, are present.

New Drug Indications

R&D | FDA Approval | In Market Brand | Generic Available | Off Market

Drug Name	Information
Cabozantinib (Cabometyx)	**Dose:** Tablets: 20 mg, 40 mg, and 60 mg **New Indication:** For adult and pediatric patients 12 years of age and older with locally advanced or metastatic differentiated thyroid cancer (DTC) that has progressed following prior VEGFR-targeted therapy and who are ineligible or refractory to radioactive iodine.
Ruxolitinib (Jakafi)	**Dose:** Tablets: 5 mg, 10 mg, 15 mg, 20 mg and 25 mg **New Indication:** For chronic graft-versus-host disease (cGVHD) after failure of one or two lines of systemic therapy in adult and pediatric patients 12 years and older.
Brexucabtagene autoleucel (Tecartus)	**Dose:** Single intravenous infusion of 1 x 106 CAR-positive viable T cells per kg body weight **New Indication:** For adult patients with relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL).
Nilotinib (Tasigna)	**Dose:** Capsules: 50 mg, 150 mg, and 200 mg **New Indication:** Pediatric patients greater than or equal to 1 year of age with Ph+ CML-CP and CML-AP resistant or intolerant to prior tyrosine-kinase inhibitor (TKI) therapy.
Cetuximab (Erbitux)	**Dose:** Injection: 100 mg/50 mL (2 mg/mL) or 200 mg/100 mL (2 mg/mL) in a single-dose vial. **New Indication:** In combination with encorafenib, for the treatment of adult patients with metastatic colorectal cancer (CRC) with a BRAF V600E mutation, as detected by an FDA-approved test, after prior therapy.
Evolocumab (Repatha)	**Dose:** Injection: 140 mg/mL solution single-dose prefilled syringe; Injection: 140 mg/mL solution single-dose prefilled SureClick® Autoinjector; Injection: 420 mg/3.5 mL solution single-dose Pushtronex® system (on-body infuser with prefilled cartridge) **New Indications:** 1) As an adjunct to diet and other LDL-C-lowering therapies in pediatric patients aged 10 years and older with HeFH, to reduce LDL-C. 2) As an adjunct to other LDL-C-lowering therapies in adults and pediatric patients aged 10 years and older with homozygous familial hypercholesterolemia (HoFH), to reduce LDL-C.
Bictegravir, emtricitabine, and tenofovir alafenamide (Biktarvy)	**Dose:** Tablet: 30 mg BIC, 120 mg FTC, and 15 mg TAF; Tablet: 30 mg of BIC, 120 mg of FTC, and 15 mg of TAF. **New Patient Population:** To expand the patient population for Biktarvy to include HIV-1 infected pediatric patients weighing at least 14 kg.

New Drug Indications

R&D | FDA Approval | In Market Brand | Generic Available | Off Market

Drug Name	Information
Abemaciclib (Verzenio)	**Dose:** Tablets: 50 mg, 100 mg, 150 mg, and 200 mg **New Indication:** in combination with endocrine therapy (tamoxifen or an aromatase inhibitor) for the adjuvant treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, node-positive, early breast cancer at high risk of recurrence and a Ki-67 score ≥20% as determined by an FDA approved test. *This is the first CDK 4/6 inhibitor approved for adjuvant treatment of breast cancer. * **New Patient Population:** in combination with an aromatase inhibitor as initial endocrine based therapy for the treatment of postmenopausal women, and men, with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer.
Dexamethasone (Dextenza)	**Dose:** Ophthalmic intracanalicular insert containing a 0.4 mg dose of dexamethasone **New Indication:** the treatment of ocular itching associated with allergic conjunctivitis.
Pembrolizumab (Keytruda)	**Dose:** Injection: 100 mg/4 mL (25 mg/mL) solution in a single-dose vial **New Indications:** 1) In combination with chemotherapy, with or without bevacizumab, for patients with persistent, recurrent or metastatic cervical cancer whose tumors express PD-L1 (CPS ≥1), as determined by an FDA-approved test. 2) For the adjuvant treatment of patients with RCC at intermediate-high or high risk of recurrence following nephrectomy, or following nephrectomy and resection of metastatic lesions. 3) For the adjuvant treatment of adult and pediatric (12 years and older) patients with Stage IIB, IIC, or III melanoma following complete resection
Atezolizumab (Tecentriq)	**Dose:** Injection: 840 mg/14 mL (60 mg/mL) and 1200 mg/20 mL (60 mg/mL) solution in a single-dose vial. **New Indication:** for adjuvant treatment following resection and platinum-based chemotherapy in patients with stage II to IIIA non-small cell lung cancer (NSCLC) whose tumors have PD-L1 expression on ≥ 1% of tumor cells, as determined by an FDA-approved test.
Dupilumab (Dupixent)	**Dose:** 300 mg/2 mL, 200 mg/1.14 mL, 100 mg/0.67 mL solution in a single-dose pre-filled pen. **New Indication:** as an add-on maintenance treatment of patients aged 6 years and older with moderate-to-severe asthma characterized by an eosinophilic phenotype or with oral corticosteroid dependent asthma.

New Drug Indications

R&D | FDA Approval | In Market Brand | Generic Available | Off Market

Drug Name	Information
Immune Globulin (Human)-hipp (Cutaquig)	**Dose:** Is a solution containing 16.5% IgG (165 mg/mL) for subcutaneous infusion. **New Indication:** is a 16.5% immune globulin solution for subcutaneous infusion indicated for treatment of primary humoral immunodeficiency (PI) in adults and pediatric patients 2 years of age and older.
Influenza Vaccine (Flucelvax)	**Dose:** Suspension for injection supplied in two presentations: a.0.5 mL single-dose pre-filled syringes. b.5 mL multi-dose vial containing 10 doses (each dose is 0.5 mL). **New Indication:** vaccine indicated for active immunization for the prevention of influenza disease caused by influenza virus subtypes A and types B contained in the vaccine. For use in persons 6 months of age and older.
Lacosamide (Vimpat)	**Dose:** 50 mg, 100 mg, 150 mg, 200 mg tablets, 200 mg/20 mL single-dose vial for intravenous use, 10 mg/mL oral solution. **New Indication:** Treatment of partial-onset seizures in patients 1 month of age and older.

In Market Brand

R&D → FDA Approval → In Market Brand → Generic Available → Off Market

Drug Name	Information
Mobocertinib (Exkivity)	**Dose:** Capsules: 40 mg **Indication:** For the treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 20 insertion mutations, as detected by an FDA-approved test, whose disease has progressed on or after platinum-based chemotherapy. **Comparable:** Amivantamab-vmjw (Rybrevant) **Guidelines:** NCCN Clinical Practice Guidelines in Oncology: Non-Small Cell Lung Cancer (Version 7.2021) – Recommend the use of Mobocertinib in NSCLC for patients with disease progression and EGFR exon 20 insertion mutation positive.
Ranibizumab-nuna (Byooviz)	**Dose:** Single-dose glass vial designed to provide 0.05 mL for intravitreal injections: 10 mg/mL solution. **Indication:** a vascular endothelial growth factor (VEGF) inhibitor, is indicated for the treatment of patients with: • Neovascular (Wet) Age-Related Macular Degeneration (AMD) • Macular Edema Following Retinal Vein Occlusion (RVO) • Myopic Choroidal Neovascularization (mCNV) **Comparable:** (Ranibizumab) Lucentis **Guidelines:** American Academy of Ophthalmology: Age-Related Macular Degeneration Preferred Practice Pattern (2019) - Intravitreal injection therapy using anti-vascular endothelial growth factor (VEGF) agents (e.g., aflibercept, bevacizumab, and ranibizumab) is the most effective way to manage neovascular AMD and represents the first line of treatment.
Tisotumab vedotin-tftv (Tivdak)	**Dose:** For Injection: 40 mg as a lyophilized cake or powder in a single-dose vial for reconstitution. **Indication:** For the treatment of adult patients with recurrent or metastatic cervical cancer with disease progression on or after chemotherapy. **Comparable:** Bevacizumab (Avastin) **Guidelines:** NCCN Clinical Practice Guidelines in Oncology: Cervical Cancer (Version 1.2022) – Recommend the use of Tisotumab vedotin-tftv as second line or subsequent therapy (Category 2A) in recurrent or metastatic disease.

In Market Brand

R&D | FDA Approval | In Market Brand | Generic Available | Off Market

Maralixibat (Livmarli)	**Dose:** Oral solution: 9.5 mg of maralixibat per mL. **Indication:** For the treatment of cholestatic pruritus in patients with Alagille syndrome (ALGS) 1 year of age and older. **Comparables:** Ursodiol, Rifampin, Cholestyramine, Colesevelam, Naltrexone **Guidelines:** National Organization for Rare Diseases: The treatment of Alagille syndrome is directed toward the specific symptoms that are apparent in each individual. Specific treatment may be indicated for individuals with cholestatic liver disease. The drug ursodeoxycholic acid is given to help improve bile flow, which can lead to a reduction in some symptoms such as itching (pruritus) or cholesterol deposits (xanthomas). However, pruritus associated with Alagille syndrome often is resistant to therapy. Additional drugs that have been used to treat pruritus include antihistamines, rifampin, cholestyramine, and naltrexone. Keeping the skin properly hydrated with moisturizers is also recommended.
Avacopan (Tavneos)	**Dose:** Capsules: 10 mg **Indication:** As an adjunctive treatment of adult patients with severe active anti-neutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis (granulomatosis with polyangiitis [GPA] and microscopic polyangiitis [MPA]) in combination with standard therapy including glucocorticoids. **Comparable:** Avacopan is the first FDA-approved orally administered inhibitor of the complement C5a receptor. **Guidelines:** American College of Rheumatology/Vasculitis Foundation Guideline for the Management of Antineutrophil Cytoplasmic Antibody–Associated Vasculitis (August 2021) - Recently, a clinical trial of Avacopan in patients with GPA and MPA was published. This guideline development effort did not include consideration of Avacopan, since the guidelines consider therapies that are approved by the FDA for use for any indication at the time of the last literature search. Therapies approved by the FDA after that date will be considered for inclusion in future updates to this guideline.
Tick-Borne Encephalitis Vaccine (Ticovac)	**Dose:** Suspension for injection supplied as a 0.25 mL or 0.5 mL single-dose in pre-filled syringes. **Indication:** for active immunization to prevent tick-borne encephalitis (TBE). Ticovac is approved for use in individuals 1 year of age and older. **Comparable:** Ticovac is the only FDA-approved vaccine to help protect U.S. adults and children against the TBE virus when visiting or living in TBE endemic areas. **Guidelines:** Centers for Disease Control and Prevention (August 2021) - The vaccine has both pediatric and adult formulations and is the only one currently licensed in the United States. An Advisory Committee on Immunization Practices (ACIP) Work Group was formed in 2020 to discuss the use of TBE vaccine in children and adults traveling to or residing in areas at risk and in laboratory workers. The Work Group is currently reviewing the epidemiology of TBE among travelers and laboratory workers, and data on the safety and effectiveness of the TBE vaccine. The Work Group is developing evidence-based recommendations for consideration by ACIP which will likely be approved in 2022.

In Market Brand

Asciminib (Scemblix)

Dose: Film-coated tablets: 20 mg and 40 mg

Indication: Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in chronic phase (CP), previously treated with two or more tyrosine kinase inhibitors (TKIs). This indication is approved under accelerated approval based on major molecular response (MMR).

Ph+ CML in CP with the T315I mutation.

Comparables: Ponatinib (Iclusig), Synribo

Guidelines: NCCN Clinical Practice Guidelines in Oncology: Chronic Myeloid Leukemia (Version 2.2022) – Recommend the use of Asciminib in the second line setting in patients that become disease resistant to primary treatment with Bosutinib, Dasatinib or Nilotinib. BCR-ABL1 mutation status must be taken into account prior to selecting an alternative tyrosine kinase inhibitor.

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First-Time Generic Approval

Generic Name	Applicant	Brand Name	Approval Date	Indication
Everolimus Tablets, 0.25 mg, 0.5 mg, 0.75 mg and 1 mg	Par Pharmaceutical, Inc.	Zortress (Everolimus) Tablets, 0.25 mg, 0.5 mg, 0.75 mg and 1 mg	10/18/2021	For the prophylaxis of organ rejection in adult patients
Lenalidomide Capsules , 2.5 mg, 5 mg, 10 mg, 15 mg, 20 mg and 25 mg	Dr. Reddy's Laboratories Limited	Revlimid (Lenalidomide) Capsules , 2.5 mg, 5 mg, 10 mg, 15 mg, 20 mg and 25 mg	10/14/2021	For the treatment for multiple myeloma
Carglumic Acid Tablets for Oral Suspension, 200 mg	Novitium Pharma LLC	Carbaglu (Carglumic Acid) Tablets for Oral Suspension, 200 mg	10/14/2021	For adjunctive therapy to standard of care for the treatment of acute hyperammonemia due to N-acetylglutamate synthase (NAGS) deficiency; maintenance therapy for the treatment of chronic hyperammonemia due to NAGS deficiency
Mivacurium Chloride Injection, 10 mg/5 mL (2 mg/mL) and 20 mg/10 mL (2 mg/mL) Single-dose Vials (Preservative Free)	Woodward Pharma Services, LLC	Mivacron (Mivacurium Chloride) Injection, 10 mg/5 mL (2 mg/mL) and 20 mg/10 mL (2 mg/mL) Single-dose Vials	10/12/2021	For inpatients and outpatients, as an adjunct to general anesthesia, to facilitate tracheal intubation and to provide skeletal muscle relaxation during surgery or mechanical ventilation
Romidepsin for Injection, 10 mg/vial, Single Dose Vial	Fresenius Kabi USA, LLC	Istodax (Romidepsin for Injection), 10 mg/vial	10/12/2021	For the treatment of cutaneous T-cell lymphoma (CTCL) in adult patients who have received at least one prior systemic therapy
Oxymetazoline Hydrochloride Cream, 1%	Taro Pharmaceuticals Inc.	Rhofade (Oxymetazoline Hydrochloride) Cream, 1%	10/4/2021	For the topical treatment of persistent facial erythema associated with rosacea in adults

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Recall

Date	Brand Name(s)	Product Description	Product Type	Recall Reason Description	Company Name
12/07/2021	Teligent Pharma, Inc.	Lidocaine HCl Topical Solution USP 4%, 50ml	Drugs	Super potent	Teligent Pharma, Inc.
12/07/2021	Edge Pharma, LLC	All drugs compounded at Edge Pharma, LLC	Drugs	Process issues that could lead to a lack of sterility assurance for products intended to be sterile and could impact the safety and quality of non-sterile products	Edge Pharma, LLC
12/03/2021	Gilead	Veklury® (remdesivir 100 mg for injection)	Drugs	Presence of glass particulates	Gilead Sciences Inc.
12/02/2021	Sandoz	Enoxaparin Sodium Injection	Drugs	Exposure to high temperatures may have impacted product effectiveness.	Sandoz, Inc.
11/22/2021	Sagent	Levetiracetam Injection	Drugs	Lack of sterility assurance	Sagent Pharmaceuticals, Inc.
11/19/2021	American Screening	Hand Sanitizer	Drugs	Hand sanitizer is packaged in 8 oz. containers that resemble water bottles posing a risk of consumption	American Screening
11/15/2021	SterRx, LLC	SterRx products intended to be sterile	Drugs	Lack of sterility assurance	SterRx, LLC
10/27/2021	Artnaturals	Scent Free Hand Sanitizer	Drugs	Due to Presence of Impurities	Artnaturals

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Date	Brand Name(s)	Product Description	Product Type	Recall Reason Description	Company Name
10/20/2021	CUBICIN	Daptomycin for injection 500mg	Drugs	Product contains particulate matter identified as glass	Merck
10/19/2021	Bryant Ranch Prepack	Methocarbamol 500mg	Drugs	Bottles labeled as Methocarbamol 500mg tablets were found to contain Methocarbamol 750mg tablets.	Bryant Ranch Prepack

Safety

No new drug safety communications.

Shortages (New)

Date	Drug Name (Shortage Reason)
12/03/2021	Bacteriostatic Water for Injection (Currently in Shortage)
12/02/2021	Sterile Water for Injection (Currently in Shortage)
12/01/2021	Megestrol Acetate Suspension (Discontinuation)
11/30/2021	Amphetamine Oral Suspension, Extended Release (Currently in Shortage)
11/30/2021	Betamethasone Valerate Topical Foam (Discontinuation)
11/30/2021	Clonidine Hydrochloride Extended Release Tablets (Discontinuation)
11/30/2021	Febuxostat Tablets (Discontinuation)
11/22/2021	Febuxostat Tablets (Discontinuation)

References

For the most up to date list of drug shortages visit:

- https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm
- https://www.ashp.org/Coronavirus
  - ASHP is providing free access to its AHFS Clinical Drug Information application, which also includes access to drug shortages information. AHFS Drug Information® - Open Access Effective March 16, 2020
    - Username: ahfs@ashp.org
    - Password: covid-19

Sources:

- https://www.ashp.org/COVID-19 t https://www.ashp.org/COVID-19 t
- https://www.cdc.gov/media/releases/2021/s-07082021.html t
- https://www.cdc.gov/mmwr/volumes/70/wr/mm7020e2.htm t
- https://www.fda.gov/drugs/drug-safety-and-availability/drug-recalls t
- https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts t
- https://www.fda.gov/drugs/new-drugs-fda-cders-new-molecular-entities-and-newtherapeutic-biological-products/novel-drug-approvals-2021 t
- https://www.fda.gov/drugs/drug-and-biologic-approval-and-ind-activity-reports/firstgeneric-drug-approvals
- https://www.fda.gov/drugs/drug-safety-and-availability/drug-safety-communications
- https://www.fda.gov/drugs/drug-and-biologic-approval-and-ind-activity-reports/first-generic-drug-approvals
- https://www.accessdata.fda.gov/scripts/drugshortages/

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