MC-Rx

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Insights on the Drug 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

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

A growing number of studies are available reviewing the safety and efficacy of new treatment and preventative regimens for COVID-19. There was a review of treatment options for mild COVID-19 symptoms (Sulodexide) and moderate to severe symptoms (Favipiravir, Tocilizumab, Progesterone, Canakinumab, etc.).

Title	Link	Summary	FDA Status	IDSA Guidelines
Safety and efficacy of Favipiravir in moderate to severe SARS-CoV-2 pneumonia.	https://pubmed.ncbi.nlm.nih.gov/33735712/	This study was designed to examine the safety and efficacy of a treatment protocol containing Favipiravir to treat SARS-CoV-2. Three hundred eighty patients were randomly allocated into Favipiravir (193) and Lopinavir/Ritonavir (187) groups in 13 centers. However, Favipiravir to the treatment protocol did NOT reduce the number of ICU admissions or intubations, or In-hospital mortality compared to Lopinavir/ Ritonavir regimen. It also did NOT shorten time to clinical recovery and length of hospital stay.	TBD	TBD
Sulodexide in the Treatment of Patients with Early Stages of COVID-19: A Randomized Controlled Trial	https://pubmed.ncbi.nlm.nih.gov/33677827/	This study was aimed to assess the effect of sulodexide when used within three days of coronavirus disease 2019 (COVID-19) clinical onset. Participants received sulodexide (oral 1,000 LRU/d) or placebo for 21 days, with the primary endpoint was the need for hospital care. A total of 243 patients were included in the per-protocol analysis, and only 17.7% of the patients in the sulodexide group required hospitalization, compared with 29.4% in the placebo group. Treatment of COVID-19 patients with sulodexide improved their clinical outcomes when provided within three days of clinical onset. Although the results should be confirmed, sulodexide could be valuable in an outpatient setting.	TBD	TBD

Clinical Pipeline

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

Title	Link	Summary	FDA Status	IDSA Guidelines
Intravenous methylprednisolone with or without tocilizumab in patients with severe COVID-19 pneumonia requiring oxygen support: A prospective comparison	https://pubmed.ncbi.nlm.nih.gov/34153729/	This study was aimed to determine whether a 7-day course of methylprednisolone (MP) administered with and without tocilizumab improves outcomes in patients with severe COVID-19 pneumonia requiring oxygen therapy. Patients hospitalized with severe COVID-19 were randomized 1:1 to receive intravenous MP (40 mg twice daily for seven days) with or without a single dose of intravenous tocilizumab (400 mg). In patients with severe COVID-19 pneumonia on oxygen support, administration of MP daily for seven days had reduced mortality at 45 days. It was associated with significantly lower ICU admission and ventilation rates compared with usual. Adding tocilizumab to MP did NOT improve any of the studied outcomes significantly.	EUA to treat COVID-19	Among hospitalized adults with severe progressive* or critical** COVID-19 who have elevated markers of systemic inflammation, the IDSA guideline panel suggests tocilizumab in addition to standard of care (i.e., steroids) rather than the standard of care alone. (Conditional recommendation, low certainty of evidence)
Progesterone in Addition to Standard of Care vs. Standard of Care Alone in the Treatment of Men Hospitalized With Moderate to Severe COVID-19: A Randomized, Controlled Pilot Trial	https://pubmed.ncbi.nlm.nih.gov/33621601/	This study assessed whether adding progesterone to the standard of care (SOC) would improve clinical outcomes of hospitalized men with moderate to severe COVID-19. Patients were randomly assigned to receive SOC plus progesterone (100 mg subcutaneously twice daily for up to 5 days) or SOC alone. There was a 1.5-point overall improvement in median clinical status score on a seven-point ordinal scale from baseline to day 7 in patients in the progesterone group compared with control subjects. Progesterone may represent a safe and effective approach for treatment in hypoxemic men with moderate to severe COVID-19.	TBD	TBD

Clinical Pipeline

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

Title	Link	Summary	FDA Status	IDSA Guidelines
Effect of Canakinumab vs. Placebo on Survival Without Invasive Mechanical Ventilation in Patients Hospitalized With Severe COVID-19: A Randomized Clinical Trial	https://pubmed.ncbi.nlm.nih.gov/34283183/	This study was designed to evaluate the efficacy of canakinumab versus placebo in patients hospitalized with severe COVID-19. However, among patients hospitalized with severe COVID-19, treatment with canakinumab, compared with placebo, did NOT significantly increase the likelihood of survival without IMV at day 29.	TBD	TBD

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COVID-19 Vaccines Update

Title	Link	Summary
Coronavirus (COVID-19) Update: FDA Authorizes Additional Vaccine Dose for Certain Immunocompromised Individuals	https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-additional-vaccine-dose-certain-immunocompromised	This new FDA guidance authorizes the use of an additional dose in certain immunocompromised individuals, specifically solid organ transplant recipients or those who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise. It should be noted that the Pfizer-BioNTech COVID-19 Vaccine is currently authorized for emergency use in individuals ages 12 and older, and the Moderna COVID-19 Vaccine is permitted for emergency use in individuals ages 18 and older.
New CDC Data: COVID-19 Vaccination Safe for Pregnant People	https://www.cdc.gov/media/releases/2021/s0811-vaccine-safe-pregnant.html	CDC has released new data on the safety of the COVID-19 vaccines in pregnant people and is recommending all people 12 years of age and older get vaccinated against COVID-19. A recent CDC analysis of current data from the v-safe pregnancy registry assessed vaccination early in pregnancy and did not find an increased risk of miscarriage among nearly 2,500 pregnant women who received an mRNA COVID-19 vaccine before 20 weeks of pregnancy. Miscarriage typically occurs in about 11-16% of pregnancies, and this study found miscarriage rates after receiving a COVID-19 vaccine were around 13%, similar to the expected rate of miscarriage in the general population.

Specialty Pipeline

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

There is a growing trend of specialty drugs in the market. It is predicted that 2021 will be when specialty drugs account for at least half of pharmacy drug spend. The therapeutic class of oncology is the leading category of specialty drugs. Other therapeutic areas where the specialty drug pipeline could yield new approvals in the coming years include treatments for immune-related, inflammatory conditions (especially TNF-inhibitors and biosimilars), Alzheimer's, hemophilia, genetic disorders, among others.

Pipeline Drug	Current Status	Anticipated Approval	Indication
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
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
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

Traditional Pipeline

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

Pipeline Drug	Current Status	Anticipated Approval	Indication
Ansofaxine (Luye Pharma)	NDA Filed	2021	A serotonin-norepinephrine-dopamine triple reuptake inhibitor for the treatment of major depressive disorder; Oral therapy
Atogepant (Allergan)	NDA Filed	3Q 2021	CGRP receptor antagonist for preventive treatment of migraines, without aura, in adults who meet the criteria for episodic migraine; oral
Budesonide Oral Suspension (Eohilia - Takeda)	NDA Filed	3Q 2021	Topically active, oral viscous formulation of budesonide for improving esophageal eosinophil counts and endoscopic findings in adults with a new diagnosis of eosinophilic esophagitis (EoE); topical/oral Priority Review/Breakthrough Therapy/Orphan Drug
Bupropion/ Dextromethorphan (Axs-05 - Axsome)	NDA Filed	8/22/2021	Fixed-dose combination of dextromethorphan (NMDA receptor antagonist) and bupropion (norepinephrine and dopamine reuptake inhibitor) for the treatment of major depressive disorder; oral therapy." Breakthrough Therapy/Priority Review
Daridorexant (Idorsia)	NDA Filed	1/8/2022	Dual orexin receptor antagonist (DORA) for the treatment of insomnia; oral therapy
Dihydroergotamine Mesylate (Trudhesa - Impel Neuropharma)	NDA Filed	9/6/2021	Dihydroergotamine mesylate for the acute treatment of "migraine headaches with or without aura in adult patients; intranasal."
Donepezil Transdermal System (Adlarity - Corium)	NDA Filed	2021	Once-weekly transdermal patch formulation of donepezil (a "cholinesterase inhibitor) for treatment of dementia of the Alzheimer's type; patch."
Eflornithine/Sulindac (Cancer Prevention Pharmaceuticals)	NDA Filed	Mid 2021	Combination of the ornithine decarboxylase inhibitor and the non-steroidal anti-inflammatory drug for the pharmaco-preventive treatment of adults with familial adenomatous polyposis (FAP); oral Orphan Drug

Traditional Pipeline

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

Pipeline Drug	Current Status	Anticipated Approval	Indication
Gefapixant (Mk-7264 - Merck)	NDA Filed	12/21/2021	Selective P2X3 receptor antagonist for the treatment of chronic refractory cough (RCC) or unexplained chronic cough (UCC) in adults; oral
Mavacamten (Bristol Myers Squibb)	NDA Filed	1/28/2022	Cardiac myosin modulator for the treatment of patients with obstructive hypertrophic cardiomyopathy (oHCM); oral Breakthrough Therapy/Orphan Drug
Nalmefene (Purdue)	NDA Filed	12/10/2021	Opioid antagonist for the treatment of opioid overdose; IM
Naloxone Injection (Zimhi - Adamis)	NDA Filed	11/12/2021	Higher dose of naloxone, an opioid antagonist, formulated in a “prefilled syringe for an injection to treat an opioid overdose; IM injection.” Priority Review
Pilocarpine 1.25% (Presbysol - Allergan)	NDA Filed	10/25/2021	Optimized formulation of pilocarpine, a cholinergic muscarinic “receptor agonist, for the treatment of presbyopia; ophthalmic solution.”
Sodium Thiosulfate (Pedmark - Fennec)	NDA Filed	11/27/2021	Formulation of sodium thiosulfate to prevent cisplatin-related “ototoxicity in pediatric patients with standard-risk hepatoblastoma; intravenous therapy.” Priority Review/Breakthrough Therapy
Tadalafil / Finasteride (Tadfin - Veru)	NDA Filed	12/23/2021	Combination of tadalafil (5mg) and finasteride (5mg) for treating benign prostatic hyperplasia (BPH); oral therapy.
Testosterone Undecanoate (Kyzatrex - Marius Pharmaceuticals)	NDA Filed	10/31/2021	Oral soft gelatin capsule formulation of the testosterone “replacement therapy for the treatment of primary and secondary hypogonadism in adult men; oral.”

New Drug Formulations

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

Drug Name	Information
Sofosbuvir and velpatasvir (Epclusa)	Dose: (a) Tablets: 400 mg of sofosbuvir and 100 mg of velpatasvir; 200 mg of sofosbuvir and 50 mg of velpatasvir. (b) **Pellets**: 200 mg of sofosbuvir and 50 mg of velpatasvir; 150 mg of sofosbuvir and 37.5 mg of velpatasvir. Indication: For the treatment of adults and pediatric patients three years of age and older with chronic HCV genotype 1, 2, 3, 4, 5, or 6 infections (1) without cirrhosis or with compensated cirrhosis • with decompensated cirrhosis for use in combination with ribavirin. Comparable: Elbasvir-grazoprevir (Zepatier), Glecaprevir-pibrentasvir (Mavyret), Ledipasvir-Sofosbuvir (Harvoni) Guidelines: https://www.hcvguidelines.org/
Glecaprevir and pibrentasvir (Mavyret)	Dose: (a) Tablets: 100 mg glecaprevir and 40 mg pibrentasvir. (b) **Pellets**: 50 mg glecaprevir and 20 mg pibrentasvir. Indication: (a) For the treatment of adult and pediatric patients three years and older with chronic HCV genotype (GT) 1, 2, 3, 4, 5, or 6 infections without cirrhosis or with compensated cirrhosis (Child-Pugh A). (b) For the treatment of adult and pediatric patients three years and older with HCV genotype one infection, who previously have been treated with a regimen containing an HCV NS5A inhibitor or an NS3/4A protease inhibitor, but not both. Comparable: Elbasvir-grazoprevir (Zepatier), Ledipasvir-sofosbuvir (Harvoni), Sofosbuvir and velpatasvir (Epclusa) Guidelines: https://www.hcvguidelines.org/

New Drug Indications

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

Drug Name	Information
Elexacaftor/ tezacaftor/ivacaftor and ivacaftor (Trikafta)	Dose: Tablets: (a) Fixed-dose combination containing elexacaftor 50 mg, tezacaftor 25 mg and ivacaftor 37.5 mg co-packaged with ivacaftor 75 mg. (b) Fixed-dose combination containing elexacaftor 100 mg, tezacaftor 50 mg, and ivacaftor 75 mg co-packaged with ivacaftor 150 mg. Indication: For the treatment of cystic fibrosis (CF) in patients aged six years and older who have at least one F508del mutation in the CFTR gene or a mutation in the CFTR gene that is responsive based on in vitro data. Comparable: Lumacaftor/Ivacaftor (Orkambi), Tezacaftor-Ivacaftor (Symdeko), Ivacaftor (Kalydeco) Guidelines: https://pubmed.ncbi.nlm.nih.gov/33459002/
Diclofenac Potassium (Zipsor)	Dose: Zipsor (diclofenac potassium) capsule: 25 mg Indication: For relief of mild to moderate acute pain in adult and pediatric patients 12 years of age and older. Guidelines: https://painmed.org/clinical-guidelines/ https://www.acpjournals.org/doi/full/10.7326/M19-3602 Comparable: Diclofenac Potassium (Cataflam)
Ipilimumab (Yervoy)	Dose: Injection: 50 mg/10 mL (5 mg/mL) and 200 mg/40 mL (5 mg/mL) in a single-dose vial. Indication: Treatment of adult patients with unresectable or metastatic melanoma, in combination with nivolumab. Comparable: Nivolumab (Opdivo), Pembrolizumab (Keytruda), Atezolizumab (Tecentriq) Guidelines: https://www.nccn.org/professionals/physician_gls/pdf/cutaneous_melanoma_blocks.pdf
Ozanimod (Zeposia)	Dose: Capsules: 0.23 mg, 0.46 mg, 0.92 mg Indication: Moderately to severely active ulcerative colitis (UC) in adults. Comparable: Tofacitinib (Xeljanz, Xeljanz XR) Guidelines: https://www.gastrojournal.org/article/S0016-5085(20)30018-4/fulltext
Rimegepant (Nurtec ODT)	Dose: Nurtec ODT orally disintegrating tablets: 75 mg Indication: Preventive treatment of episodic migraine in adults. Previously approved for acute treatment of migraine Comparable: Erenumab (Aimovig), Fremanezumab (Ajovi), Galcanezumab (Emgality), Eptinezumab (Vyepti) Guidelines: https://n.neurology.org/content/78/17/1337

New Drug Indications

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

Drug Name	Information
Posaconazole (Noxafil)	Dose: (a) Noxafil injection: 300 mg per vial (18 mg per mL) in a single-dose vial. (b) Noxafil delayed-release tablet 100 mg (c) Noxafil oral suspension 40 mg per mL (d) Noxafil PowderMix for delayed-release oral suspension 300 mg Indication: For the prophylaxis of invasive Aspergillus and Candida infections in patients who are at high risk of developing these infections due to being severely immunocompromised, such as hematopoietic stem cell transplant (HSCT) recipients with graftversus-host disease (GVHD) or those with hematologic malignancies with prolonged neutropenia from chemotherapy as follows: a) Noxafil injection: adults and pediatric patients two years of age and older or Noxafil delayed release tablets: adults and pediatric patients two years of age and older who weigh greater than 40 kg (b) Noxafil oral suspension: adults and pediatric patients 13 years of age and older or Noxafil PowderMix for delayed-release oral suspension: pediatric patients two years of age and older (who weigh 40 kg or less) (c) Noxafil oral suspension is indicated for the treatment of oropharyngeal candidiasis (OPC), including OPC refractory (rOPC) to itraconazole and/or fluconazole in adult and pediatric patients aged 13 years and older. Comparable: Fluconazole (Diflucan) Guidelines: https://www.idsociety.org/practice-guideline/aspergillosis/ https://www.idsociety.org/practice-guideline/candidiasis/
Avapritinib (Ayvakit)	Dose: Tablets: 25 mg, 50 mg, 100 mg, 200 mg and 300 mg. Indication: for the treatment of adult patients with AdvSM. AdvSM includes patients with aggressive systemic mastocytosis (ASM), systemic mastocytosis with an associated hematological neoplasm (SMAHN), and mast cell leukemia (MCL). Comparables: Midostaurin (Rydapt) Guidelines: https://www.nccn.org/professionals/physician_gls/pdf/mastocytosis_blocks.pdf
Fesoterodine fumarate (Toviaz)	Dose: Extended-release tablets: 4 mg and 8 mg Indication: Neurogenic detrusor overactivity (NDO) in pediatric patients six years of age and older and weighing greater than 25 kg. Comparables: Mirabegron (Myrbertriq), Vesicare LS Guidelines: https://pubmed.ncbi.nlm.nih.gov/27914999/

New Drug Indications

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

Drug Name	Information
Pembrolizumab (Keytruda)	Dose: Injection: 100 mg/4 mL (25 mg/mL) solution in a single-dose vial. Indication: 1) To treat patients with locally advanced cutaneous squamous cell carcinoma (cSCC) that is not curable by surgery or radiation. Comparables: Cemiplimab-rwlc (Libtayo) Guidelines: Squamous cell carcinoma: https://www.nccn.org/professionals/physician_gls/pdf/squamous_blocks.pdf
Secnidazole (Solosec)	Dose: Oral granules: 2 g secnidazole, in a unit-of-use child-resistant foil packet. Indication: Treatment of trichomoniasis in adults. Comparables: Metronidazole (Flagyl) Guidelines: https://www.cdc.gov/std/tg2015/default.htm
Daratumumab and hyaluronidase-fihj (Darzalex Faspro)	Dose: Injection: 1,800 mg daratumumab and 30,000 units hyaluronidase per 15 mL (120 mg and 2,000 units/mL) solution in a single-dose vial. Indication: for the treatment of adult patients with multiple myeloma in combination with pomalidomide and dexamethasone in patients who have received at least one prior therapy, including lenalidomide and a proteasome inhibitor. Comparables: Isatuximab-irfc (SARCLISA) Guidelines: https://www.nccn.org/professionals/physician_gls/pdf/myeloma_blocks.pdf
Enfortumab vedotin-ejfv (Padcev)	Dose: For Injection: 20 mg and 30 mg of enfortumab vedotin-ejfv as a lyophilized powder in a single-dose vial for reconstitution. Indication: for the treatment of adult patients with locally advanced or metastatic urothelial cancer who: are ineligible for cisplatin-containing chemotherapy and have previously received one or more prior lines of therapy. Comparables: Sacituzumab govitecan-hziy (Trodelvy) Guidelines: https://www.nccn.org/professionals/physician_gls/pdf/bladder_blocks.pdf
Fluticasone propionate (Armonair Respiclick & Armonair Digihaler)	Dose: Inhalation powder: 30 mcg, 55 mcg, 113 mcg, or 232 mcg of fluticasone propionate per actuation. Indication: for the maintenance treatment of asthma as prophylactic therapy in adult and pediatric patients four years of age and older. Comparables: Fluticasone (Arnuity Ellipta), (Fluticasone) Flovent Diskus, (Fluticasone) Flovent HFA Guidelines: https://ginasthma.org/wp-content/uploads/2020/04/GINA-2020-fullreport_-final-_wms.pdf

In Market Brand

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

Drug Name	Information
Amivantamab-Vmjw (Rybrevant)	Dose: Injection: 350 mg/7 mL (50 mg/mL) solution in a single-dose vial 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. Only alternative for (EGFR) exon 20 insertion mutations. Guidelines: https://www.nccn.org/professionals/physician_gls/pdf/nscl_blocks.pdf
Sotorasib (Lumakras)	Dose: Tablets: 120 mg Indication: for treating adult patients with KRAS G12C-mutated locally advanced or as determined by an FDA-approved test, metastatic non-small cell lung cancer (NSCLC) who have received at least one prior systemic therapy. Only alternative for KRAS G12C-mutated. Guidelines: https://www.nccn.org/professionals/physician_gls/pdf/nscl_blocks.pdf
Infigratinib (Truseltiq)	Dose: Capsules: 25 mg and 100 mg Indication: for the treatment of adults with previously treated, unresectable locally advanced or metastatic cholangiocarcinoma with a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangements as detected by an FDA-approved test. Comparables: Pemigatinib (Pemazyre) Guidelines: https://www.nccn.org/professionals/physician_gls/pdf/hepatobiliary_blocks.pdf
Olanzapine-Samidorphan (Lybalvi)	Dose: Tablets (olanzapine/samidorphan): 5 mg/10 mg, 10 mg/10 mg, 15 mg/10 mg and 20 mg/10 mg. Indication: For the treatment of schizophrenia in adults and bipolar I disorder in adults: (a) Acute treatment of manic or mixed episodes as monotherapy and as an adjunct to lithium or valproate. (b) Maintenance monotherapy treatment. ***New treatment combination of atypical antipsychotic and opioid antagonist*** Comparable: Olanzapine (Zyprexa) Guidelines: https://psychiatryonline.org/guidelines
Aducanumab-Avwa (Aduhelm)	Dose: Injection: (a) 170 mg/1.7 mL (100 mg/mL) solution in a single-dose vial (b) 300 mg/3 mL (100 mg/mL) solution in a single-dose vial. Indication: For the treatment of Alzheimer's disease. Treatment with ADUHELM should be initiated in patients with mild cognitive impairment or mild dementia stage of disease, the population in which treatment was initiated in clinical trials. There are no safety or effectiveness data on initiating treatment at earlier or later stages of the disease than were studied. Comparable: ***Novel treatment option*** Guidelines: https://www.aafp.org/afp/2017/0615/p771.html

In Market Brand

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Drug Name	Information
Semaglutide (Wegovi)	Dose: Injection: pre-filled, single-dose pen that delivers doses of 0.25 mg, 0.5 mg, 1 mg, 1.7 mg or 2.4 mg Indication: As an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adult patients with an initial body mass index (BMI) of (a) 30 kg/m2 or greater (obesity) (b) 27 kg/m2 or greater (overweight) in the presence of at least one weight-related comorbid condition (e.g., hypertension, type 2 diabetes mellitus, or dyslipidemia). Comparable: Liraglutide (Saxenda) Guidelines: https://www.ahajournals.org/doi/pdf/10.1161/01.cir.0000437739.71477.ee
Relugolix, Estradiol, and Norethindrone Acetate (Myfembree)	Dose: Tablets: fixed-dose combination containing relugolix 40 mg, estradiol 1 mg and norethindrone acetate 0.5 mg. Indication: For the management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) in premenopausal women. Comparable: Elagolix/Estradiol, and Norethindrone Acetate (Oriahnn) Guidelines: https://www.acog.org/clinical/search#q=heavy%20uterine%20bleeding%20in%20premenoPausal%20women&sort=relevancy
Brexafungerp (Brexafemme)	Dose: Tablets: 150 mg Indication: For the treatment of adult and post-menarchal pediatric females with vulvovaginal candidiasis (VVC). Comparable: Fluconazole 150mg tablets (Alternative)
Brincidofovir (Tembexa)	Dose: Tablets: 100 mg (3), Oral Suspension: 10 mg/mL Indication: For the treatment of human smallpox disease in adult and pediatric patients, including neonates. Comparable: (Tecovirimat) Tpoxx
Asparaginase erwinia chrysanthemi (recombinant) rywn (Rylaze)	Dose: Injection: 10 mg/0.5 mL solution in a single-dose vial. Indication: for the treatment of acute lymphoblastic leukemia (ALL) and lymphoblastic lymphoma (LBL) in adult and pediatric patients one month or older who have developed hypersensitivity to E. coli-derived asparaginase. Comparable: Asparaginase Erwinia chrysan-themi (Erwinaze) Guidelines: https://www.nccn.org/professionals/physician_gls/pdf/all_blocks.pdf

In Market Brand

Drug Name	Information
Finerenone (Kerendia)	Dose: Tablets: 10 mg and 20 mg Indication: Indicated to reduce the risk of sustained eGFR decline, end-stage kidney disease, cardiovascular death, non-fatal myocardial infarction, and hospitalization for heart failure in adult patients with chronic kidney disease (CKD) associated with type 2 diabetes (T2D). Comparable: Dapagliflozin (Farxiga), Canagliflozin (Invokana), Spironolactone (Aldactone), Eplerenone (Inspra) Guidelines: https://care.diabetesjournals.org/content/diacare/44/Supplement_1/S125.full.pdf
Belumosudil (Rezurock)	Dose: Tablet: 200 mg. Indication: For treating adult and pediatric patients 12 years and older with chronic graft-versus-host disease (chronic GVHD) after the failure of at least two prior lines of systemic therapy. Comparable: Ruxolitinib (Jakafi), Ibrutinib (Imbruvica) Guidelines: https://www.nccn.org/professionals/physician_gls/pdf/hct.pdf

New Generics

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

Generic Name	ANDA Applicant	Brand Name	ANDA Approval Date	ANDA Indications
Varenicline Tablets, 0.5 mg and 1 mg	Par Pharmaceutical, Inc.	Chantix (Varenicline) Tablets, 0.5 mg and 1 mg	8/11/2021	For use as an aid to smoking cessation treatment
Eslicarbazepine Acetate Tablets, 200 mg, 400 mg, 600 mg, 800 mg	Dr. Reddy's Laboratories Inc.	Aptiom (Eslicarbazepine Acetate) Tablets, 200 mg, 400 mg, 600 mg, 800 mg	6/29/2021	For the adjunctive treatment of partial-onset seizures
Arformoterol Tartrate Inhalation Solution, 15 mcg/2 mL, Unit-Dose Vials	Axar Pharmaceuticals, Inc.	Brovana (Arformoterol Tartrate) Inhalation Solution, 15 mcg/2 mL, Unit- Dose Vials	6/22/2021	For the long-term, twice-daily administration in the maintenance treatment of bronchoconstriction in patients with chronic obstructive pulmonary disease, including chronic bronchitis and emphysema
Arformoterol Tartrate Inhalation Solution, 15 mcg/2 mL, Unit-Dose Vials	Glenmark Pharmaceuticals Limited	Brovana (Arformoterol Tartrate) Inhalation Solution, 15 mcg/2 mL, Unit- Dose Vials	6/22/2021	For the long-term, twice-daily administration in the maintenance treatment of bronchoconstriction in patients with chronic obstructive pulmonary disease, including chronic bronchitis and emphysema
Formoterol Fumarate Inhalation Solution, 20 mcg/2 mL Single-Dose Vial	Cipla USA, Inc.	Perforomist (Formoterol Fumarate) Inhalation Solution, 20 mcg/2 mL Single-Dose Vial	6/22/2021	For the maintenance treatment of bronchoconstriction in patients with COPD, including chronic bronchitis and emphysema

New Generics

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Generic Name	ANDA Applicant	Brand Name	ANDA Approval Date	ANDA Indications
Formoterol Fumarate Inhalation Solution, 20 mcg/2 mL Single-Dose Vial	Teva Pharmaceuticals USA, Inc.	Perforomist (Formoterol Fumarate) Inhalation Solution, 20 mcg/2 mL Single-Dose Vial	6/22/2021	For the maintenance treatment of bronchoconstriction in patients with COPD, including chronic bronchitis and emphysema
Etravirine Tablets, 25 mg, 100 mg, and 200 mg	Amneal EU, Limited	Intelence (Etravirine) Tablets, 25 mg, 100 mg, and 200 mg	6/14/2021	For the treatment of HIV-1 infection in treatment-experienced patients six years of age and older
Carfilzomib for injection, 10 mg, 30 mg, and 60 mg Single-Dose Vials	Breckenridge Pharmaceutical, Inc.	Kyprolis (Carfilzomib) for injection, 10 mg, 30 mg, and 60 mg Single-Dose Vials	6/11/2021	For the treatment of adult patients with relapsed or refractory multiple myeloma who have received one to three lines of therapy in combination with dexamethasone
Lopinavir and Ritonavir Tablets USP, 100 mg/25 mg, 200 mg/50 mg	Hetero Labs Limited	Kaletra (Lopinavir and Ritonavir) Tablets, 100 mg/25 mg and 200 mg/50 mg	6/4/2021	For the treatment of HIV-1 infection in adults and pediatric patients (14 days and older)
Tofacitinib Tablets, 10 mg	Ajanta Pharma Limited	Xeljanz (Tofacitinib) Tablets, 10 mg	6/1/2021	For the treatment of adult patients with moderately to severely active rheumatoid arthritis, active psoriatic arthritis, moderately to severely active ulcerative colitis, and active polyarticular course, juvenile idiopathic arthritis

Off Market (Safety and Recall Information)

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

Recall

Date	Brand Name(s)	Product Description	Product Type	Recall Reason Description	Company Name
08/11/2021	Max Health	Hydro Pineapple Burn	Dietary Supplements, Drugs	undeclared sibutramine	Ebay Seller-John Nguyen
08/10/2021	SterRx, LLC	Sodium Bicarbonate in 5% Dextrose Injection 150mEq per 1,000 mL	Drugs	Due to waterborne microbial contamination	SterRx, LLC
07/19/2021	CHANTIX	Smoking cessation treatment	Drugs	N-Nitroso Varenicline content above ADI level	Pfizer

Safety

Date	Title
7/20/2021	FDA requests the removal of strongest warning against using cholesterol-lowering statins during pregnancy; still advises most pregnant patients should stop taking statins
7/28/2021	FDA alerts patients and health care professionals about clinical trial results showing an increased risk of death associated with Pepaxto (melphalan flufenamide)
7/14/2021	FDA notifies Amgen of misbranding of its biological product, Neulasta, due to false or misleading promotional communications about the product's benefit

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

Shortages (New)

Date	Drug Name (Shortage Reason)
8/10/2021	Piroxicam Capsules (Discontinuation)
8/9/2021	Captopril Tablets (Discontinuation)
8/9/2021	Captopril/Hydrochlorothiazide Tablets (Discontinuation)
8/6/2021	Aluminum Hydroxide and Magnesium Carbonate (Gaviscon Regular Strength) (Discontinuation)
8/6/2021	Busulfan Injection (Discontinuation)
8/4/2021	Fosphenytoin Sodium Injection (Discontinuation)
8/3/2021	Fluocinonide Topical Solution (Discontinuation)
8/3/2021	Morphine Sulfate Injection (Currently in Shortage)

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