MC-Rx

Powered by ProCare Rx

Better Health. Withing Reach. Every Day.

Insights on the Drugs Pipeline

Exploring the changes in the drugs market.

June 2022

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

Therapy Topic (e.g. COVID-19 Treatment and Vaccine Updates)

Treatment	Authorized Use	Date of First EUA Issuance	Most Recent FDA Update	Changes
Bamlanivimab and Etesevimab	Bamlanivimab and etesevimab administered together for the treatment of mild-to-moderate COVID-19 in adults and pediatric patients with positive results of direct SARS-CoV-2 viral testing, and who are at high risk for progression to severe COVID-19, including hospitalization or death. **Due to the high frequency of the Omicron variant, bamlanivimab and etesevimab are not currently authorized in any U.S. region. Therefore, these drugs may not be administered for treatment or post-exposure prevention of COVID-19 under the Emergency Use Authorization until further notice by the Agency.**	2/9/2021	5/4/2022	FDA Authorizes Shelf-Life Extension for Bamlanivimab From 18 to 24 Months
Baricitinib (Olumiant)	For emergency use by healthcare providers for the treatment COVID-19 in hospitalized pediatric patients 2 to less than 18 years of age requiring supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO).	11/19/2020	5/10/2022	Olumiant was approved for the treatment of COVID-19 in hospitalized adults requiring supplemental oxygen, non-invasive or invasive mechanical ventilation, or ECMO.

This information is up-to-date as of May 17th, 2022.

COVID-19 Emergency Use Authorization (EUA) Update

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

Treatment	Authorized Use	Date of First EUA Issuance	Most Recent FDA Update	Changes
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 ...	12/8/2021	5/17/2022	Revised the EUA as appropriate to protect the public health or safety ..., the FDA is reissuing the February 24, 2022 letter in its entirety, to revise the section 5.2 (Warnings and Precautions) of the authorized Fact Sheet for Healthcare Providers, including new information on hypersensitivity reactions and the risk of cross-hypersensitivity with COVID-19 vaccines and related clinical recommendations.
Lagevrio (molnupiravir)	Lagevrio is authorized for the treatment of mild-to-moderate coronavirus disease 2019 (COVID-19) in adults with positive results of direct SARS-CoV-2 viral testing who are at high risk for progressing to severe COVID-19, including hospitalization or death, and for whom alternative COVID-19 treatment options approved or authorized by FDA are not accessible or clinically appropriate.	12/23/2021	3/23/2022	Revised the EUA as appropriate to protect the public health or safety ..., the FDA is reissuing the February 11, 2022 letter in its entirety AND to add references to molnupiravir's trade name, "LAGEVRIO"
Paxlovid (nirmatrelvir tablets and ritonavir tablets)	Paxlovid is authorized for the treatment of mild-to-moderate COVID-19 in adults and pediatric patients (12 years of age and older weighing at least 40 kg) with positive results of direct SARS-CoV-2 viral testing, and who are at high risk for progression to severe COVID-19, including hospitalization or death.	12/22/2021	4/14/2022	Addition of Velkury as an FDA-approved available alternative therapy to PAXLOVID to the Fact Sheets for Health Care Providers and Patients

This information is up-to-date as of May 17th, 2022.

COVID-19 Emergency Use Authorization (EUA) Update

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

Treatment	Authorized Use	Date of First EUA Issuance	Most Recent FDA Update	Changes
REGEN-COV (Casirivimab and Imdevimab)	Casirivimab and imdevimab to be administered together for the treatment of mild to moderate COVID-19 in adults and pediatric patients (12 years of age and older weighing at least 40 kg) with positive results of direct SARS-CoV-2 viral testing, and who are at high risk for progression to severe COVID-19, including hospitalization or death. **Due to the high frequency of the Omicron variant, REGEN-COV is not currently authorized in any U.S. region. Therefore, REGEN-COV may not be administered for treatment or post-exposure prevention of COVID-19 under the Emergency Use Authorization until further notice by the Agency.**	11/21/2020	1/24/2022	Due to the high frequency of the Omicron variant, REGEN-COV is not currently authorized for use in any U.S. region because of markedly reduced activity against the omicron variant
Sotrovimab	For the treatment of mild-to-moderate COVID-19 in adults and pediatric patients (12 years of age and older weighing at least 40 kg) with positive results of direct SARS-CoV-2 viral testing, and who are at high risk for progression to severe COVID-19, including hospitalization or death. **Due to the high frequency of the Omicron BA.2 sub-variant, sotrovimab is not currently authorized in any U.S. region. Therefore, sotrovimab may not be administered for treatment of COVID-19 under the Emergency Use Authorization until further notice by the Agency.**	5/26/2021	5/12/2022	FDA Authorizes Shelf-Life Extension for Sotrovimab From 12 to 18 Months

This information is up-to-date as of May 17th, 2022.

COVID-19 Vaccines Updates

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

Vaccine	Authorized Use	Date of First EUA Issuance	Most Recent FDA Update	Changes
Janssen COVID-19 Vaccine	For the prevention of Coronavirus Disease 2019 (COVID-19) for individuals 18 years of age and older for whom other FDA-authorized or approved COVID-19 vaccines are not accessible or clinically appropriate, and in individuals 18 years of age and older who elect to receive the Janssen COVID-19 Vaccine because they would otherwise not receive a COVID-19 vaccine	2/27/2021	5/5/2022	Revision limiting the authorized use to individuals 18 years of age and older for whom other FDA-authorized or approved COVID-19 vaccines are not accessible or clinically appropriate, and individuals 18 years of age and older who elect to receive the Janssen COVID19 Vaccine because they would otherwise not receive a COVID-19 vaccine, due to a FDA conducted analysis of TTS cases.
Pfizer-BioNTech COVID-19 Vaccine	For the prevention of 2019 coronavirus disease (COVID-19) in people 5 and older	12/11/2020	5/17/2022	Authorization of a single booster dose administered at least 5 months after completing a primary series of the Pfizer-BioNTech COVID-19 Vaccine in individuals 5 through 11 years of age

This information is up-to-date as of May 17th, 2022.

COVID-19 Vaccine Booster Shots - CDC Recommendations

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

Vaccine that was administered:	Who should get a booster?	When to get a booster?	Which booster can you get?
Janssen	Adults 18 years and older	At least 2 months after completing your primary COVID-19 vaccination	Pfizer-BioNTech or Moderna (mRNA COVID-19 vaccines) are preferred
Moderna	Adults 18 years and older	At least 5 months after older completing your primary COVID-19 vaccination series	Pfizer-BioNTech or Moderna (mRNA COVID-19 vaccines) are preferred
Pfizer-BioNTech	Everyone ages 12 years and older can get 1 booster after completing their COVID-19 vaccine primary series. **CDC guidelines should reflect the EUA update on 05/17/2022**	At least 5 months after completing your primary COVID-19 vaccination	Teens 12-17 years old can get a Pfizer-BioNTech COVID-19 vaccine booster series Adults 18 years and older: Pfizer-BioNTech or Moderna (mRNA COVID-19 vaccines) are preferred in most situations

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

This information is up-to-date as of May 17th, 2022.

Specialty Pipeline

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

Top 25

Pipeline Drug Name	Generic Name	Brand Company	Route	Mechanism of Action	Indication	Stage	Expected Date	Tags
Abrilada	Adalimumab	Pfizer	Subcutaneous	TNF-alpha inhibitor	Ulcerative colitis; Ankylosing spondylitis*; Plaque psoriasis; Crohn's disease; Psoriatic arthritis; Juvenile idiopathic arthritis; Rheumatoid arthritis; Rheumatoid arthritis	Pending	4Q 2022	Specialty Biologics & Biosimilars Pharmacy Benefit
Actemra	Tocilizumab	Genentech; Roche	Intravenous	Interleukin 6 receptor (IL-6R) antagonist	Coronavirus disease 2019 (COVID-19)	Pending	2H 2022	Hospital Out-Patient Hospital In-Patient Specialty Biologics & Biosimilars REMS Medical Benefit Pharmacy Benefit Priority Review
ALN-TTRSC02	Vutrisiran	Alnylam Pharmaceuticals; Arbutus Biopharma	Subcutaneous	Small interfering RNA (siRNA)	Familial amyloid polyneuropathy; Transthyretin amyloid cardiomyopathy (ATTR-CM)	Pending	7/2022	Rare Disease Specialty Pharmacy Benefit Fast Track
ARQ-151	Roflumilast	Arcutis Biotherapeutics	Topical	Phosphodiesterase-4 (PDE4) Inhibitor	Plaque psoriasis; Atopic dermatitis	Pending	7/2022	Specialty Pharmacy Benefit
AVT02	Adalimumab	Alvogen; Alvotech; Teva	Subcutaneous	TNF-alpha inhibitor	Plaque psoriasis	Pending	12/2022	Specialty Biologics & Biosimilars Pharmacy Benefit

This information is up-to-date as of May 17th, 2022.

Specialty Pipeline

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

Pipeline Drug Name	Generic Name	Brand Company	Route	Mechanism of Action	Indication	Stage	Expected Date	Tags
Brukinsa	Zanubrutinib	BeiGene	Oral	Bruton's tyrosine kinase inhibitor	Chronic lymphocytic leukemia; Coronavirus disease 2019 (COVID-19); Follicular lymphoma	Pending	10/2022	Specialty Pharmacy Benefit
Dupixent	Dupilumab	Genzyme; Regeneron; Sanofi	Subcutaneous	Interleukin 13 receptor (IL-13R) antagonist; Interleukin 4 receptor (IL-4R) antagonist	Atopic dermatitis*; Eosinophilic esophagitis; Chronic idiopathic urticaria (CIU); Pruritus; Cold urticaria; Chronic rhinosinusitis; Allergic bronchopulmonary aspergillosis; Bullous pemphigoid; Prurigo Nodularis; Chronic obstructive pulmonary disease (COPD)	Pending	6/2022	Specialty Biologics & Biosimilars Pharmacy Benefit Priority Review Breakthrough Therapy
Evrysdi	Risdiplam	Genentech; PTC Therapeutics; Roche	Oral	Splicing modulator	Spinal muscular atrophy*; Spinal muscular atrophy*	Pending	5/2022	Rare Disease Specialty Pharmacy Benefit Priority Review
Hadlima	Adalimumab	Organon; Samsung Bioepis	Injectable	TNF-alpha inhibitor	Juvenile idiopathic arthritis; Ulcerative colitis; Rheumatoid arthritis; Psoriatic arthritis; Ankylosing spondylitis*; Crohn's disease; Plaque psoriasis; Ulcerative colitis; Crohn's disease; Plaque psoriasis; Ankylosing spondylitis*; Rheumatoid arthritis; Juvenile idiopathic arthritis; Psoriatic arthritis	Pending	8/2022	Hospital Out-Patient Specialty Biologics & Biosimilars Medical Benefit Pharmacy Benefit

This information is up-to-date as of May 17th, 2022.

Specialty Pipeline

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

Pipeline Drug Name	Generic Name	Brand Company	Route	Mechanism of Action	Indication	Stage	Expected Date	Tags
Imcivree	Setmelanotide Acetate	Rhythm Pharmaceuticals	Subcutaneous	Peptide melanocortin receptor agonist	Obesity*; Obesity*	Pending	6/2022	Specialty Pharmacy Benefit Priority Review
Myfembree	Estradiol; Norethindrone Acetate; Relugolix	Myovant Sciences; Pfizer; Roivant; Takeda	Oral	Estrogens; Gonadotropin-releasing hormone (GnRH) antagonist; Progestins	Endometriosis; Pregnancy prevention	Pending	8/2022	Specialty Pharmacy Benefit
Myrcludex B	Bulevirtide	Gilead; MYR Pharmaceuticals	Subcutaneous	Antiviral	Hepatitis D	Pending	3Q 2022	Rare Disease Specialty Biologics & Biosimilars Pharmacy Benefit Breakthrough Therapy Accelerated Approval Priority Review
Nuplazid	Pimavanserin Tartrate	Acadia Pharmaceuticals	Oral	Atypical antipsychotic	Psychosis associated with Alzheimer's disease; Frontotemporal degeneration; Lewy body dementia; Dementia; Vascular dementia; Alzheimer's disease; Schizophrenia; Major depressive disorder*; Dementia-related psychosis	Pending	8/2022	Specialty Pharmacy Benefit Breakthrough Therapy
OBE2109	Linzagolix	Kissei Pharmaceuticals; ObsEva	Oral	Gonadotropin-releasing hormone (GnRH) antagonist	Uterine fibroids; Endometriosis	Pending	9/2022	Specialty Pharmacy Benefit

This information is up-to-date as of May 17th, 2022.

Specialty Pipeline

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

Pipeline Drug Name	Generic Name	Brand Company	Route	Mechanism of Action	Indication	Stage	Expected Date	Tags
Opzelura	Ruxolitinib Phosphate	Incyte	Topical	Janus kinase (JAK) inhibitor	Vitiligo; Atopic dermatitis	Pending	7/2022	Specialty Pharmacy Benefit Priority Review
Poziotinib	Poziotinib	Hanmi Pharmaceutical; Spectrum Therapeutics	Oral	Receptor tyrosine kinase inhibitor	Non-small cell lung cancer (NSCLC)*; Brain cancer; HER2-positive breast cancer*; Solid tumors; Colorectal cancer	Pending	11/2022	Specialty Pharmacy Benefit Fast Track
Rinvoq	Upadacitinib	AbbVie	Oral	Janus kinase (JAK) inhibitor	Axial spondyloarthritis; Crohn's disease; Vasculitis; Ulcerative colitis; Giant cell arteritis (Temporal arteritis); Vitiligo; Hidradenitis suppurativa; Systemic lupus erythematosus	Pending	11/2022	Rare Disease Specialty Pharmacy Benefit
Skyrizi	Risankizumab-rzaa	AbbVie; Boehringer Ingelheim	Subcutaneous	Interleukin 23 (IL-23) antagonist	Plaque psoriasis; Psoriatic arthritis; Crohn's disease; Plaque psoriasis; Psoriasis; Ulcerative colitis; Ankylosing Spondylitis; Asthma; Atopic dermatitis	Pending	4Q 2022	Hospital Out-Patient Specialty Biologics & Biosimilars Medical Benefit Pharmacy Benefit
Skyrizi	Risankizumab-rzaa	AbbVie; Boehringer Ingelheim	Intravenous	Interleukin 23 (IL-23) antagonist	Crohn's disease; Ulcerative colitis	Pending	4Q 2022	Hospital Out-Patient Specialty Biologics & Biosimilars Medical Benefit Pharmacy Benefit
SPN-830	Apomorphine	Supernus Pharmaceuticals; US WorldMeds	Subcutaneous	Dopamine receptor agonist	Parkinson's disease*	Pending	10/2022	Specialty Pharmacy Benefit

This information is up-to-date as of May 17th, 2022.

Specialty Pipeline

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

Pipeline Drug Name	Generic Name	Brand Company	Route	Mechanism of Action	Indication	Stage	Expected Date	Tags
SPR994	Tebipenem Pivoxil Hydrobromide	Meiji Seika; Spero Therapeutics	Oral	Carbapenems	Complicated UTI caused by certain organisms; Acute pyelonephritis	Pending	6/2022	Hospital In-Patient Specialty Medical Benefit Fast Track Priority Review
Stelara	Ustekinumab	Janssen	Subcutaneous	Interleukin 12 (IL-12) antagonist; Interleukin 23 (IL-23) antagonist	Psoriatic arthritis*; Axial spondyloarthritis; Ulcerative colitis; Crohn's disease; Systemic lupus erythematosus	Pending	8/2022	Hospital Out-Patient Specialty Biologics & Biosimilars REMS Medical Benefit Pharmacy Benefit
TAS-120	Futibatinib	Taiho Pharma	Oral	Fibroblast growth factor receptor (FGFR) inhibitor	Biliary tract cancer	Pending	9/2022	Rare Disease Specialty LDD (Pipeline/ Anticipated) Pharmacy Benefit Breakthrough Therapy Priority Review
Tyvaso	Treprostinil	MannKind Corporation; United Therapeutics	Inhaled	Prostaglandin vasodilator	Pulmonary arterial hypertension; Lung disease-associated pulmonary hypertension; Idiopathic pulmonary fibrosis	Pending	5/2022	Rare Disease Specialty Pharmacy Benefit Priority Review
Ultomiris SC	Ravulizumab; Hyaluronidase	Alexion Pharmaceuticals; AstraZeneca; Halozyme Therapeutics	Subcutaneous	Complement inhibitors	Treatment of paroxysmal nocturnal hemoglobinuria (PNH)*; Atypical hemolytic uremic syndrome (aHUS)*	Pending	2H 2022	Rare Disease Specialty Biologics & Biosimilars Pharmacy Benefit

This information is up-to-date as of May 17th, 2022.

Biosimilar Pipeline

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

Top 25

Pipeline Drug Name	Generic Name	Brand Company	Route	Mechanism of Action	Indication	Stage	Expected Date	Tags
Hadlima	Adalimumab	Organon; Samsung Bioepis	Injectable	TNF-alpha inhibitor	Juvenile idiopathic arthritis; Ulcerative colitis; Rheumatoid arthritis; Psoriatic arthritis; Ankylosing spondylitis*; Crohn's disease; Plaque psoriasis; Ulcerative colitis; Crohn's disease; Plaque psoriasis; Ankylosing spondylitis*; Rheumatoid arthritis; Juvenile idiopathic arthritis; Psoriatic arthritis	Pending	08/2022	Hospital Out-Patient Specialty Biologics & Biosimilars Medical Benefit Pharmacy Benefit
TX05	Trastuzumab	Tanvex	Injectable	Anti-HER2 antibody	HER2-positive breast cancer	Pending	08/2022	Hospital Out-Patient Biologics & Biosimilars Medical Benefit
Cimerli	Ranibizumab	bioeq; Coherus BioSciences; Formycon; Polpharma; Santo Holding; Swiss Pharma International AG	Intravitreal	Vascular endothelial growth factor (VEGF) inhibitor	Wet age-related macular degeneration	Pending	08/2022	Hospital Out-Patient Biologics & Biosimilars Medical Benefit
Abrilada	Adalimumab	Pfizer	Subcutaneous	TNF-alpha inhibitor	Ulcerative colitis; Ankylosing spondylitis*; Plaque psoriasis; Crohn's disease; Psoriatic arthritis; Juvenile idiopathic arthritis; Rheumatoid arthritis; Rheumatoid arthritis	Pending	4Q 2022	Specialty Biologics & Biosimilars Pharmacy Benefit

This information is up-to-date as of May 17th, 2022.

Biosimilar Pipeline

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

Pipeline Drug Name	Generic Name	Brand Company	Route	Mechanism of Action	Indication	Stage	Expected Date	Tags
CT-P16	Bevacizumab	Celltrion	Intravenous	Vascular endothelial growth factor (VEGF) inhibitor	Non-small cell lung cancer (NSCLC)*	Pending	4Q 2022	Hospital Out-Patient Biologics & Biosimilars Medical Benefit
EG12014	Trastuzumab	EirGenix; Sandoz	Intravenous	Anti-HER2 antibody	HER2-positive breast cancer; Gastroesophageal cancer*; Gastric cancer	Pending	4Q 2022	Hospital Out-Patient Biologics & Biosimilars Medical Benefit
Idacio	Adalimumab	Fresenius	Subcutaneous	TNF-alpha inhibitor	Rheumatoid arthritis*; Plaque psoriasis	Pending	4Q 2022	Biologics & Biosimilars Pharmacy Benefit
AVT02	Adalimumab	Alvogen; Alvotech; Teva	Subcutaneous	TNF-alpha inhibitor	Plaque psoriasis	Pending	12/2022	Specialty Biologics & Biosimilars Pharmacy Benefit
Xlucane	Ranibizumab	Bausch + Lomb; Bausch Health; Stada; Xbrane	Intravitreal	Vascular endothelial growth factor (VEGF) inhibitor	Wet age-related macular degeneration	Pending	1Q 2023	Hospital Out-Patient Biologics & Biosimilars Medical Benefit
BAT1706	Bevacizumab	Bio-Thera Solutions; Sandoz	Intravenous	Vascular endothelial growth factor (VEGF) inhibitor	Metastatic kidney cancer; Colorectal cancer; Cervical cancer*; Glioblastoma multiforme; Non-small cell lung cancer (NSCLC)*	Pending	TBD	Hospital Out-Patient Biologics & Biosimilars Medical Benefit
Bmab-100	Bevacizumab	Biocon; Mylan; Viatris	Intravenous	Vascular endothelial growth factor (VEGF) inhibitor	Non-small cell lung cancer (NSCLC); Glioblastoma multiforme; Colorectal cancer; Metastatic kidney cancer; Cervical cancer*	Pending	TBD	Hospital Out-Patient Biologics & Biosimilars Medical Benefit

This information is up-to-date as of May 17th, 2022.

Biosimilar Pipeline

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

Pipeline Drug Name	Generic Name	Brand Company	Route	Mechanism of Action	Indication	Stage	Expected Date	Tags
FKB238	Bevacizumab	AstraZeneca; Centus Biotherapeutics; Fujifilm Kyowa Kirin	Intravenous	Vascular endothelial growth factor (VEGF) inhibitor	Non-small cell lung cancer (NSCLC)	Pending	TBD	Hospital Out-Patient Biologics & Biosimilars Medical Benefit
Grastofil	Filgrastim	Accord; Apotex; Intas	Intravenous; Subcutaneous	Colony stimulating factor	Cancer patients receiving bone marrow transplant; Cancer patients receiving myelosuppressive chemotherapy*; Severe chronic neutropenia; Acute myeloid leukemia patients receiving induction or consolidation chemotherapy; Patients undergoing peripheral blood progenitor cell collection and therapy	Pending	TBD	Rare Disease Hospital Out-Patient Specialty Biologics & Biosimilars Medical Benefit Pharmacy Benefit
Lapelga	Pegfilgrastim	Accord; Apotex; Intas	Subcutaneous	Colony stimulating factor	Cancer patients receiving myelosuppressive chemotherapy*	Pending	TBD	Rare Disease Hospital Out-Patient Biologics & Biosimilars Medical Benefit Pharmacy Benefit
Lupifil-P	Pegfilgrastim	Lupin	Subcutaneous	Colony stimulating factor	Cancer patients receiving myelosuppressive chemotherapy*	Pending	TBD	Rare Disease Hospital Out-Patient Biologics & Biosimilars Medical Benefit Pharmacy Benefit

This information is up-to-date as of May 17th, 2022.

Biosimilar Pipeline

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

Pipeline Drug Name	Generic Name	Brand Company	Route	Mechanism of Action	Indication	Stage	Expected Date	Tags
MSB11455	Pegfilgrastim	Dr. Reddy's; Fresenius	Subcutaneous	Colony stimulating factor	Cancer patients receiving myelosuppressive chemotherapy*	Pending	TBD	Rare Disease Hospital Out-Patient Biologics & Biosimilars Medical Benefit Pharmacy Benefit
MYL-1701P	Aflibercept	Janssen; Momenta; Mylan; Viatris	Intravitreal	Vascular endothelial growth factor (VEGF) inhibitor	Diabetic macular edema	Pending	TBD	Hospital Out-Patient Biologics & Biosimilars Medical Benefit
SB8	Bevacizumab	Organon; Samsung Bioepis	Intravenous	Vascular endothelial growth factor (VEGF) inhibitor	Non-small cell lung cancer (NSCLC)	Pending	TBD	Hospital Out-Patient Biologics & Biosimilars Medical Benefit
TPI-120	Pegfilgrastim	Adello Biologics; AE Companies; Amneal; Kashiv Biosciences	Subcutaneous	Colony stimulating factor	Cancer patients receiving myelosuppressive chemotherapy*	Pending	TBD	Hospital Out-Patient Biologics & Biosimilars Medical Benefit Pharmacy Benefit
TX01	Filgrastim	Tanvex	Injectable	Colony stimulating factor	Severe chronic neutropenia	Pending	TBD	Hospital Out-Patient Specialty Biologics & Biosimilars Medical Benefit Pharmacy Benefit
Yuflyma	Adalimumab	Celltrion	Subcutaneous	TNF-alpha inhibitor	Rheumatoid arthritis	Pending	TBD	Specialty Biologics & Biosimilars Pharmacy Benefit
MYL-1601D	Insulin Aspart	Biocon; Mylan; Viatris	Injectable	Insulin/insulin analog	Improve glycemic control in type 1 diabetes	Pending	01/2022	Biologics & Biosimilars Pharmacy Benefit

This information is up-to-date as of May 17th, 2022.

Biosimilar Pipeline

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

Pipeline Drug Name	Generic Name	Brand Company	Route	Mechanism of Action	Indication	Stage	Expected Date	Tags
SAIT101	Rituximab	Archigen; AstraZeneca; Samsung Biologics	Intravenous	Anti-CD20 antibody	Rheumatoid arthritis; Follicular lymphoma	Pending	TBD	Hospital Out-Patient Biologics & Biosimilars Medical Benefit
NI-071	Infliximab	Aprogen; Nichi-Iko; Sagent Pharmaceuticals	Injectable	TNF-alpha inhibitor	Rheumatoid arthritis*	Pending	TBD	Hospital Out-Patient Biologics & Biosimilars Medical Benefit

New Drug Entities

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

COVID-19 Vaccine, mRNA (Spikevax)	Dose: Suspension for injection. A single dose is 0.5 mL. Indication: For active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 18 years of age and older. Comparables: Comirnaty Guidelines: · Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States (CDC; Last reviewed on February 17, 2022) - https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html · COVID-19 ACIP Vaccine Recommendations (CDC; Last reviewed: February 3, 2022) - https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/covid-19.html

This information is up-to-date as of May 17th, 2022.

New Drug Entities

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

Ciltacabtagene autoleucel (Carvykti)	Dose: Suspension for intravenous infusion. A single dose of CARVYKTI contains a cell suspension of 0.5-1.0×106 CAR-positive viable T cells per kg body weight in one infusion bag. Indication: For the treatment of adult patients with relapsed or refractory multiple myeloma after four or more prior lines of therapy, including a proteasome inhibitor (PI), an immunomodulatory agent (IMiD), and an anti-CD38 monoclonal antibody. Comparables: Idecabtagene vicleucel (Abecma), Belantamab mafodotin-blmf (Blenrep) Guidelines: NCCN Guidelines – Multiple Myeloma (Version 5.2022 – March 9, 2022)
Ganaxolone (Ztalmy)	Dose: Oral suspension 50 mg/mL Indication: for the treatment of seizures associated with cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder (CDD) in patients 2 years of age and older. Comparables: First FDA approved drug for epileptic seizures associated with a rare genetic condition, CDKL-5 deficiency disorder (CDD). Guidelines: CDKL5 Deficiency Disorder (NORD - National Organization for Rare Disorders) - https://rarediseases.org/rare-diseases/cdkl5/
Nivolumab and relatlimab-rmbw (Opdualag)	Dose: Injection: 240 mg of nivolumab and 80 mg of relatlimab per 20 mL (12 mg and 4 mg per mL) in a single-dose vial. Indication: For the treatment of adult and pediatric patients 12 years of age or older with unresectable or metastatic melanoma. Comparables: Nivolumab (Opdivo), Pembrolizumab (Keytruda), Ipilimumab (Yervoy) *Relatlimab-rmbw is the first agent of a new therapy class that is known as lymphocyte-activation gene 3 (LAG-3) blockers.* Guidelines: NCCN Guidelines – Melanoma: Cutaneous (Version 2.2022 – January 26, 2022)
Lutetium Lu 177 vipivotide tetraxetan (Pluvicto)	Dose: Injection: 1,000 MBq/mL (27 mCi/mL) in a single-dose vial. Indication: for the treatment of adult patients with prostate-specific membrane antigen (PSMA)-positive metastatic castration-resistant prostate cancer (mCRPC) who have been treated with androgen receptor (AR) pathway inhibition and taxane-based chemotherapy. Comparables: First targeted radioligand therapy for treatment of progressive, PSMA positive metastatic castration-resistant prostate cancer. Other radiopharmaceutical options for prostate cancer: Radium Ra 223 Dichloride (Xofigo) Guidelines: NCCN Guidelines – Prostate Cancer (Version 3.2022 – January 10, 2022)

This information is up-to-date as of May 17th, 2022.

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

New Drug Formulations

Amlodipine (Norliqva)	Dose: Oral solution: 1 mg/mL. Indications: · Hypertension - NORLIQVA is indicated for the treatment of hypertension in adults and children 6 years of age and older, to lower blood pressure. Lowering blood pressure reduces the risk of fatal and nonfatal cardiovascular events, primarily strokes and myocardial infarctions. · Coronary Artery Disease: o Chronic Stable Angina o Vasospastic Angina (Prinzmetal's or Variant Angina) o Angiographically Documented Coronary Artery Disease in patients without heart failure or an ejection fraction. Comparables: Amlodipine tab (Norvasc), Amlodipine oral suspension (Katerzia). Guidelines: · 2020 International Society of Hypertension Global Hypertension Practice Guidelines: https://www.ahajournals.org/doi/epdf/10.1161/HYPERTENSIONAHA.120.15026 · 2017 ACC/AHA/AAPA/ABC/ACPM/AGS/APhA/ASH/ASPC/NMA/PCNA Guideline for the Prevention, Detection, Evaluation, and Management of High Blood Pressure in Adults: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines: https://www.jacc.org/doi/pdf/10.1016/j.jacc.2017.11.006 · Stable Coronary Artery Disease: Treatment (American Academy of Family Physicians 2018) - https://www.aafp.org/afp/2018/0315/afp20180315p376.pdf
Ranolazine (Aspruzyo Sprinkle)	Dose: Extended-release granules: 500 and 1000 mg Indication: for the treatment of chronic angina. Comparables: Ranolazine tablets (Ranexa) Guidelines: · Stable Coronary Artery Disease: Treatment (American Academy of Family Physicians 2018) - https://www.aafp.org/afp/2018/0315/afp20180315p376.pdf

This information is up-to-date as of May 17th, 2022.

New Drug Formulations

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

Donepezil transdermal system (Adlarity)	Dose: Transdermal System: 5 mg/day and 10 mg/day Indication: Is an acetylcholinesterase inhibitor indicated for the treatment of mild, moderate, and severe dementia of the Alzheimer's type. Comparables: Other Donepezil Formulations: Donepezil hydrochloride tablets (Aricept), Donepezil hydrochloride orally disintegrating tablets (Aricept ODT) Other patch available for Alzheimer's type: Rivastigmine transdermal system (Exelon Patch) Guidelines: · Alzheimer Disease: Pharmacologic and Nonpharmacologic Therapies for Cognitive and Functional Symptoms https://www.aafp.org/afp/2017/0615/p771.html · Practice Guideline For The Treatment Of Patients With Alzheimer's Disease And Other Dementias – American Psychiatric Association (2014) https://psychiatryonline.org/pb/assets/raw/sitewide/practice_guidelines/guidelines/alzheimerwatch.pdf
Dextroamphetamine (Xelstrym)	Dose: Transdermal system: 4.5 mg/9 hours, 9 mg/9 hours, 13.5 mg/9 hours, 18 mg/9 hours. Indication: for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in adults and pediatric patients 6 years and older. Comparables: First-and-Only Approved Amphetamine Patch for the Treatment of ADHD. Other dextroamphetamines: Dexedrine (dextroamphetamine sulfate capsule), Zenzedi (dextroamphetamine sulfate tablets), ProCentra (dextroamphetamine sulfate oral solution) Other patch available for ADHD: Daytrana (methylphenidate extended release) Guidelines: Clinical Practice Guideline for the Diagnosis, Evaluation, and Treatment of Attention-Deficit/Hyperactivity Disorder in Children and Adolescents – American Academy of Pediatrics (2019) https://publications.aap.org/pediatrics/article/144/4/e20192528/81590/Clinical-Practice-Guideline-for-the-Diagnosis
Sirolimus (Hyftor)	Dose: Topical gel 0.2%. Indication: for the treatment of facial angiofibroma associated with tuberous sclerosis in adults and pediatric patients 6 years of age and older. Comparables: Current treatments include laser surgery, cryotherapy, dermabrasion, which, in addition to being painful and causing scarring, don't prevent recurrence of lesions. Sirolimus is also available in tablet, oral solution, and intravenous powder for use in other conditions such as cancer, and for the prophylaxis of organ rejection. Guidelines: Rare Diseases Database - Tuberous Sclerosis: https://rarediseases.org/rare-diseases/tuberous-sclerosis/

This information is up-to-date as of May 17th, 2022.

New Drug Indications

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

Doravirine (Pifeltro)	Dose: Tablets: 100 mg doravirine New Indication: indicated in combination with other antiretroviral agents for the treatment of HIV-1 infection in adults and pediatric patients weighing at least 35 kg: • with no prior antiretroviral treatment history, OR • to replace the current antiretroviral regimen in those who are virologically suppressed (HIV-1 RNA less than 50 copies per mL) on a stable antiretroviral regimen with no history of treatment failure and no known substitutions associated with resistance to doravirine. Previous Indication: for the treatment of HIV-1 infection in adult patients. Guidelines: Guidelines for the Use of Antiretroviral Agents in Pediatric HIV Infection - HHS Panel on Antiretroviral Therapy and Medical Management of Children Living with HIV (Reviewed Dec. 30, 2021) https://clinicalinfo.hiv.gov/sites/default/files/guidelines/documents/PedARV_GL.pdf
Doravirine/ lamivudine/ tenofovir disoproxil fumarate (Delstrigo)	Dose: Tablets: 100 mg of doravirine, 300 mg of lamivudine, and 300 mg of tenofovir disoproxil fumarate. New Indication: indicated as a complete regimen for the treatment of HIV-1 infection in adults and pediatric patients weighing at least 35 kg: • with no antiretroviral treatment history, OR • to replace the current antiretroviral regimen in those who are virologically suppressed (HIV-1 RNA less than 50 copies per mL) on a stable antiretroviral regimen with no history of treatment failure and no known substitutions associated with resistance to the individual components of DELSTRIGO. Previous Indication: for the treatment of HIV-1 infection in adult patients. Guidelines: Guidelines for the Use of Antiretroviral Agents in Pediatric HIV Infection - HHS Panel on Antiretroviral Therapy and Medical Management of Children Living with HIV (Reviewed Dec. 30, 2021) https://clinicalinfo.hiv.gov/sites/default/files/guidelines/documents/PedARV_GL.pdf
Secnidazole (Solosec)	Dose: Oral granules: 2 g secnidazole, in a unit-of-use child-resistant foil packet. New Indications: • Treatment of bacterial vaginosis in female patients 12 years of age and older. • Treatment of trichomoniasis in patients 12 years of age and older. Previous Indications: • Treatment of bacterial vaginosis in adult women. • Treatment of trichomoniasis in adults. Guidelines: • Bacterial Vaginosis – STI Treatment Guidelines (CDC, Last Review: July 22, 2021) https://www.cdc.gov/std/treatment-guidelines/bv.htm • Trichomoniasis – STI Treatment Guidelines (CDC, Last Review: July 22, 2021) https://www.cdc.gov/std/treatment-guidelines/trichomoniasis.htm

This information is up-to-date as of May 17th, 2022.

New Drug Indications

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

Dapagliflozin and Metformin Hydrochloride (Xigduo XR)	Dose: 2.5 mg dapagliflozin/1000 mg metformin HCl extended-release; 5 mg dapagliflozin/500 mg metformin HCl extended-release New Indication: Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Dapagliflozin is indicated to reduce: • the risk of hospitalization for heart failure in adults with type 2 diabetes mellitus and established cardiovascular disease or multiple cardiovascular risk factors. • the risk of cardiovascular death and hospitalization for heart failure in adults with heart failure (NYHA class II-IV) with reduced ejection fraction. Comparables: Synjardy/Synjardy XR, Invokamet/ Invokamet XR, Segluromet Guidelines: Standards of Medical Care in Diabetes – American Diabetes Association (2022) https://diabetesjournals.org/care/issue/45/Supplement_1
Empagliflozin (Jardiance)	Dose: Tablets: 10 mg, 25 mg Indication: To reduce the risk of cardiovascular death and hospitalization for heart failure in adults with heart failure. Other indications: • to reduce the risk of cardiovascular death in adults with type 2 diabetes mellitus and established cardiovascular disease. • as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Comparables: Dapagliflozin (Farxiga) Guidelines: 2021 Update to the 2017 ACC Expert Consensus Decision Pathway for Optimization of Heart Failure Treatment: Answers to 10 Pivotal Issues About Heart Failure With Reduced Ejection Fraction https://www.jacc.org/doi/pdf/10.1016/j.jacc.2020.11.022
Upadacitinib (Rinvoq)	Dose: Extended-release tablets: 15 mg, 30 mg, and 45 mg (new) Indication: Adults with moderately to severely active ulcerative colitis who have had an inadequate response or intolerance to one or more TNF blockers. Comparables: Tofacitinib (Xeljanz), Ozanimod (Zeposia) Guidelines: AGA Clinical Practice Guidelines on the Management of Moderate to Severe Ulcerative Colitis (2020) – https://www.gastrojournal.org/action/showPdf?pii=S0016-5085%2820%2930018-4

This information is up-to-date as of May 17th, 2022.

New Drug Indications

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

Nivolumab (Opdivo)	Dose: Injection: 40 mg/4 mL, 100 mg/10 mL, 120 mg/12 mL, and 240 mg/24 mLsolution in a single-dose vial. Indication: Non-Small Cell Lung Cancer (NSCLC) in Adult patients with resectable (tumors ≥4 cm or node positive) non-small cell lung cancer in the neoadjuvant setting, in combination with platinum-doublet chemotherapy. Comparables: None Guidelines: NCCN Guidelines – Non-Small Cell Lung Cancer (Version 3.2022 – March 16, 2022)
Olaparib (Lynparza)	Dose: Tablets: 150 mg, 100 mg Indication: Breast cancer: for the adjuvant treatment of adult patients with deleterious or suspected deleterious gBRCAm human epidermal growth factor receptor 2 (HER2)-negative high risk early breast cancer who have been treated with neoadjuvant or adjuvant hemotherapy. Select patients for therapy based on an FDA-approved companion diagnostic for Lynparza. Comparables: None Guidelines: NCCN Guidelines – Breast Cancer (Version 2.2022 – December 20, 2021)
Pembrolizumab (Keytruda)	Dose: Injection: 100 mg/4 mL (25 mg/mL) solution in a single-dose vial Indication: Endometrial cancer: as a single agent, for the treatment of patients with advanced endometrial carcinoma that is MSI-H or dMMR, as determined by an FDA-approved test, who have disease progression following prior systemic therapy in any setting and are not candidates for curative surgery or radiation. Comparables: None Guidelines: NCCN Guidelines – Uterine Neoplasms (Version 1.2022 – November 4, 2021)

This information is up-to-date as of May 17th, 2022.

In-Market Brand

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

Mitapivat (Pyrukynd)	Dose: Tablets: 5 mg, 20 mg, and 50 mg. Indication: for the treatment of hemolytic anemia in adults with pyruvate kinase (PK) deficiency. Comparables: First FDA-approved medicine for this rare and debilitating blood disorder. Before the approval, the only options for treatment were red blood cell transfusions or spleen removal surgery. Guidelines: Pyruvate Kinase Deficiency - National Organization for Rare Disorders https://rarediseases.org/rare-diseases/pyruvate-kinase-deficiency/
Tebentafusp-tebn (Kimmtrak)	Dose: Injection: 100 mcg/0.5 mL solution in a single-dose vial Indication: Is a bispecific gp100 peptide-HLA-directed CD3 T cell engager indicated for the treatment of HLA-A*02:01-positive adult patients with unresectable or metastatic uveal melanoma. Comparables: First FDA approval for a rare cancer of the eye that has spread elsewhere or grown too large to be surgically removed. Uveal melanoma is version of the aggressive skin cancer that appears in eye tissue. Less than 2,500 cases are diagnosed each year worldwide, with an estimated 400 eligible patients in the U.S. Guidelines: NCCN Guidelines – Melanoma: Uveal (Version 2.2021 – June 25,2021)
Faricimab-svoa (Vabysmo)	Dose: Injection: 120 mg/mL solution in a single-dose vial Indication: Is a vascular endothelial growth factor (VEGF) and angiopoietin-2 (Ang-2) inhibitor indicated for the treatment of patients with: Neovascular (Wet) Age-Related Macular Degeneration (nAMD), Diabetic Macular Edema (DME). Comparables: Lucentis, Eylea, Avastin (off label). *Vabysmo is the first bispecific antibody for the eye, to treat two leading causes of vision loss and the only FDA-approved injectable eye medicine for nAMD and DME that improves and maintains vision with treatments from one to four months apart in the first year following four initial monthly doses.* Guidelines: • American Academy of Ophthalmology, Retina/Vitreous Panel. Diabetic Retinopathy Preferred Practice Pattern Guidelines (2019) https://www.aao.org/preferred-practice-pattern/diabetic-retinopathy-ppp • American Academy of Ophthalmology, Retina/Vitreous Panel. Age-Related Macular Degeneration Preferred Practice Pattern Guidelines (2019) https://www.aao.org/preferred-practice-pattern/age-related-macular-degeneration-ppp

This information is up-to-date as of May 17th, 2022.

In-Market Brand

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

Sutimlimab-jome (Enjaymo)	Dose: Injection: 1,100 mg/22 mL (50 mg/mL) in a single-dose vial. Indication: Is a classical complement inhibitor indicated to decrease the need for red blood cell (RBC) transfusion due to hemolysis in adults with cold agglutinin disease (CAD). Comparables: First FDA approved agent for cold agglutinin disease (CAD). *CAD is a rare autoimmune disorder characterized by the premature destruction of red blood cells (hemolysis). Autoimmune diseases occur when one's own immune system attacks healthy tissue. More specifically, CAD is a subtype of autoimmune hemolytic anemia.* Guidelines: Cold Agglutinin Disease - National Organization for Rare Disorders https://rarediseases.org/rare-diseases/cold-agglutinin-disease
Pacritinib (Vonjo)	Dose: Capsules: 100 mg Indication: For the treatment of adults with intermediate or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis with a platelet count below 50 × 109/L. Comparables: Ruxolitinib (Jakafi), Fedratinib (Inrebic) Guidelines: NCCN Guidelines – Myeloproliferative Neoplasms (Version 1.2022 – February 28,2022)
Filgrastim-ayow (Releuko)	Dose: Vial • Injection: 300 mcg/mL in a single-dose vial, • Injection: 480 mcg/1.6 mL in a single-dose vial, Prefilled Syringe Injection: 300 mcg/0.5 mL in a single-dose prefilled syringe, • Injection: 480 mcg/0.8 mL in a single-dose prefilled syringe. Indications: • To decrease the incidence of infection, as manifested by febrile neutropenia, in patients with nonmyeloid malignancies receiving myelosuppressive anti- cancer drugs associated with a significant incidence of severe eutropenia with fever. • To reduce the time to neutrophil recovery and the duration of fever, following induction or consolidation chemotherapy treatment of patients with acute myeloid leukemia (AML). • To reduce the duration of neutropenia and neutropenia-related clinical sequelae, e.g., febrile neutropenia, in patients with nonmyeloid malignancies undergoing myeloablative chemotherapy followed by bone marrow transplantation (BMT). • To reduce the incidence and duration of sequelae of severe neutropenia, (e.g., fever, infections, oropharyngeal ulcers) in symptomatic patients with congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia. *Releuko is biosimilar* to Neupogen® (filgrastim)* Comparables: Filgrastim (Neupogen), Filgrastim-sndz (Zarxio), Filgrastim-aafi (Nivestym) Guidelines: NCCN Guidelines – Hematopoietic Growth Factors (Version 1.2022 – December 22, 2021)

This information is up-to-date as of May 17th, 2022.

New Generics

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

Breyna (Budesonide and Formoterol Fumarate Dihydrate) Inhalation Aerosol 160/4.5 mcg/ actuation and 80/4.5 mcg/ actuation	Mylan Pharmaceuticals Inc., a Viatris Company	Symbicort (Budesonide and Formoterol Fumarate Dihydrate) Inhalation Aerosol	3/15/2022	For the treatment of asthma in patients 6 years of age and older and for the maintenance treatment of airflow obstruction and reducing exacerbations in patients with chronic obstructive pulmonary disease (COPD) including chronic bronchitis and/or emphysema
Cyclosporine Ophthalmic Emulsion, 0.05%	Mylan Pharmaceuticals Inc.	Restasis) Cyclosporine Ophthalmic Emulsion	2/2/2022	To increase tear production in patients whose tear production is presumed to be suppressed due to ocular inflammation associated with keratoconjunctivitis sicca
Cysteine Hydrochloride Injection USP, 500 mg/10 mL (50 mg/ mL), Single-dose Vial	Eton Pharmaceuticals, Inc.	Elcys (Cysteine Hydrochloride) Injection	4/8/2022	Indicated to meet the nutritional requirements of newborn infants requiring total parenteral nutrition (TPN); and of adult and pediatric patients with severe liver disease who may have impaired enzymatic processes and require TPN
Dapagliflozin Tablets, 5 mg and 10 mg	Zydus Pharmaceuticals (USA) Inc.	Farxiga (Dapagliflozin) Tablets	2/22/2022	As an adjunct to diet and exercise to improve glycemic control
Lacosamide Injection USP, 200 mg/20 mL (10 mg/ mL) AND Lacosamide Tablets USP, 50 mg, 100 mg, 150 mg, and 200 mg	Multiple Manufacturers	Vimpat (Lacosamide)	4/7/2022	For the treatment of partial-onset seizures in patients 4 years of age and older

This information is up-to-date as of May 17th, 2022.

New Generics

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

Maraviroc Tablets, 150 mg and 300 mg	Hetero Labs Limited, Unit III	Selzentry (Maraviroc) Tablets	2/7/2022	For the treatment of only CCR5-tropic HIV-1 infection in adults and pediatric patients weighing at least 2 kg
Regadenoson Injection, 0.4 mg/5 mL (0.08 mg/mL) Single-Dose Pre-filled Syringe	Multiple Manufacturers.	Lexiscan (Regadenoson)	4/11/2022	Indicated for radionuclide myocardial perfusion imaging (MPI) in patients unable to undergo adequate exercise stress

References

- First Generic Drug Approvals: https://www.fda.gov/drugs/drug-and-biologic-approval-and-ind-activity-reports/first-generic-drug-approvals

Recall Notifications

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

5/2/2022	Fagron	SyrSpend SF 500mL and 4L	Drugs	Potential contamination with Burkholderia gladioli	Fagron Inc.
4/22/2022	Pfizer	Accupril (Quinapril HCl) tablets 10mg, 20mg, 40 mg	Drugs	Due to N-Nitroso-Quinapril Content	Pfizer
4/12/2022	Mylan	Insulin Glargine (Insulin glargine-yfgn) Injection	Drugs	Label may be missing on some vials	Mylan Pharmaceuticals, Inc. a Viatris Company

This information is up-to-date as of May 17th, 2022.

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

Recall Notifications

3/29/2022	Teva Pharmaceuticals	IDArubicin Hydrochloride Injection USP	Drugs	Potential Particulate Matter (silica and iron oxide)	Teva Pharmaceuticals
3/24/2022	Major Pharmaceuticals	Magnesia Oral Suspension 2400 mg/30 mL, Magnesium Hydroxide 1200mg/ Aluminum Hydroxide 1200mg/Simethicone 120mg per 30 mL, and Acetaminophen 650mg/ 20.3mL	Drugs	Microbial Contamination	Plastikon Healthcare, LLC
3/22/2022	Sandoz	Orphenadrine Citrate 100 mg Extended Release (ER) Tablets	Drugs	Presence of a Nitrosamine Impurity	Sandoz, Inc.
3/22/2022	Adamis Pharmaceuticals Corporation	SYMJEPI (epinephrine) Injection 0.15 mg (0.15 mg/0.3 mL) and 0.3 mg (0.3 mg/0.3 mL) Pre-Filled Single-Dose Syringes	Drugs	Potential clogging of the needle preventing the dispensing of epinephrine	Adamis Pharmaceuticals Corporation
3/22/2022	Accuretic, Greenstone Brand	Accuretic™ (quinapril HCl/ hydrochlorothiazide); quinapril and hydrochlorothiazide; and quinapril HCl/ hydrochlorothiazide tablets	Drugs	Presence of a nitrosamine, N-nitroso-quinapril	Pfizer
3/7/2022	Fresenius Kabi USA	Sodium Acetate Injection, USP, 400 mEq/100 mL (4 mEq/ mL), 100 mL fill in a 100 mL vial	Drugs	Due to the presence of particulate matter found in reserve and/or stability sample vials	Fresenius Kabi, USA

References:

- Recalls, Market Withdrawals, & Safety Alerts: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts

This information is up-to-date as of May 17th, 2022.

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

Safety Notifications

Device Name	Date
Do Not Use Skippack Medical Lab SARS-CoV-2 Antigen Rapid Test: FDA Safety Communication	05/10/2022
Genetic Non-Invasive Prenatal Screening Tests May Have False Results: FDA Safety Communication	04/19/2022
Use Duodenoscopes with Innovative Designs to Enhance Safety: FDA Safety Communication	04/05/2022
Use and Store At-Home COVID-19 Tests Properly to Avoid Potential Harm: FDA Safety Communication	03/18/2022
FDA Warns Against Use of Renuvion/J-Plasma Device for Certain Aesthetic Procedures: FDA Safety Communication	03/14/2022
Do Not Use Certain ACON Flowflex COVID-19 Tests: FDA Safety Communication	03/01/2022
Do Not Use SD Biosensor STANDARD Q COVID-19 Ag Home Tests: FDA Safety Communication	03/01/2022
Do Not Use Certain Celltrion DiaTrust COVID-19 Tests: FDA Safety Communication	03/01/2022

References

- 2022 Safety Communications: https://www.fda.gov/medical-devices/safety-communications/2022-safety-communications

Shortages (New)

Date	Drug Name
5/6/2022	Fludarabine Phosphate Injection (Currently in Shortage)
5/7/2022	Potassium Chloride Concentrate Injection (Currently in Shortage)
5/9/2022	Iodixanol (Visipaque) Injection (Currently in Shortage)
5/9/2022	Iohexol (Omnipaque) Injection (Currently in Shortage)
5/9/2022	Methocarbamol Injection (Discontinuation)
5/9/2022	Potassium Chloride Concentrate Injection (Currently in Shortage)
5/9/2022	Risedronate Sodium Tablets (Discontinuation)

This information is up-to-date as of May 17th, 2022.

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

Shortages (New)

Date	Drug Name
5/10/2022	Atropine Sulfate Injection (Currently in Shortage)
5/10/2022	Bacteriostatic 0.9% Sodium Chloride Injection (Currently in Shortage)
5/10/2022	Bacteriostatic Water for Injection (Currently in Shortage)
5/10/2022	Bupivacaine Hydrochloride Injection (Currently in Shortage)
5/10/2022	Dexmedetomidine Injection (Currently in Shortage)
5/10/2022	Dextrose 50% Injection (Currently in Shortage)
5/10/2022	Diltiazem Hydrochloride Injection (Currently in Shortage)
5/10/2022	Disopyramide Phosphate (Norpace) Capsules (Currently in Shortage)
5/10/2022	Dobutamine Hydrochloride Injection (Currently in Shortage)
5/10/2022	Dopamine Hydrochloride Injection (Currently in Shortage)
5/10/2022	Epinephrine Injection, 0.1 mg/mL (Currently in Shortage)
5/10/2022	Fentanyl Citrate (Sublimaze) Injection (Currently in Shortage)
5/10/2022	Furosemide Injection (Currently in Shortage)
5/10/2022	Hydromorphone Hydrochloride Injection (Currently in Shortage)
5/10/2022	Ibutilide Fumarate Injection (Currently in Shortage)
5/10/2022	Lorazepam Injection (Currently in Shortage)
5/10/2022	Methylprednisolone Acetate Injection (Currently in Shortage)
5/10/2022	Midazolam Injection (Currently in Shortage)
5/10/2022	Morphine Sulfate Injection (Currently in Shortage)
5/10/2022	Pantoprazole Sodium for Injection (Currently in Shortage)
5/10/2022	Pentostatin Injection (Currently in Shortage)
5/10/2022	Potassium Chloride Concentrate Injection (Currently in Shortage)
5/10/2022	Propofol Injectable Emulsion (Currently in Shortage)
5/10/2022	Ropivacaine Hydrochloride Injection (Currently in Shortage)

This information is up-to-date as of May 17th, 2022.

Shortages (New)

Date	Drug Name
5/10/2022	Sodium Chloride 0.9% Injection Bags (Currently in Shortage)
5/10/2022	Sodium Chloride Injection USP, 0.9% Vials and Syringes (Currently in Shortage)
5/10/2022	Sterile Water for Injection (Currently in Shortage)
5/10/2022	Sulfasalazine Tablets (Currently in Shortage)
5/12/2022	Methylprednisolone Acetate Injection (Currently in Shortage)
5/12/2022	Potassium Acetate Injection (Currently in Shortage)
5/12/2022	Rifampin Injection (Currently in Shortage)
5/12/2022	Sodium Acetate Injection (Currently in Shortage)
5/12/2022	Sodium Phosphates Injection (Currently in Shortage)
5/16/2022	Dexmedetomidine Injection (Currently in Shortage)
5/16/2022	Lidocaine Hydrochloride (Xylocaine) Injection (Currently in Shortage)
5/16/2022	Lutetium Lu 177 Dotatate (LUTATHERA) Injection (Currently in Shortage)
5/16/2022	Pantoprazole Sodium for Injection (Currently in Shortage)
5/16/2022	Potassium Acetate Injection (Currently in Shortage)
5/16/2022	Vecuronium Bromide for Injection (Currently in Shortage)
5/17/2022	Daptomycin Injection (Discontinuation)
5/17/2022	Sodium Bicarbonate Injection (Currently in Shortage)
5/18/2022	Nedocromil Sodium Ophthalmic Solution (Discontinuation)
5/18/2022	Umbrasilib Tosylate Tablets (Discontinuation)

References

- FDA Drug Shortages: https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm

This information is up-to-date as of May 17th, 2022.

MC-Rx
Powered by ProCare Rx

CONTACT INFORMATION:

787-286-6032
www.mc-rx.com

MC-Rx
Call Box 4908, Caguas, P.R. 00726

Physical Address:
Road #1 Km. 33.3 Lot #4, Angora Industrial Park, Bo. Bairoa, Caguas, P.R. 00725

asuntosdelcliente@mc-21.com

URAC ACCREDITED
Pharmacy Benefit Management
Expires 01/01/2025

JUNE 2022