MC-Rx

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Insights on the Drugs Pipeline

Exploring the changes in the drugs market.

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Pharmacy Benefit Management

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

Oral Antivirals for COVID-19

Two oral antiviral drugs (Paxlovid and Molnupiravir) for the treatment of COVID-19 infections, received an Emergency Use Authorizationa (EUA) from the U.S. Food and Drug Administration (FDA) to treat mild-to-moderate COVID-19 for adults who have positive results from 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 authorized by FDA are either inaccessible or clinically inappropriate.

Medication	Paxlovid (12/22/2021)*	Molnupiravir (12/23/2021)*
Age population	12 years or older	18 years or older
Dosification	300mg (two tablets) of Paxlovid plus one 100mg ritonavir tablet	800mg of Molnupiravir (four capsules) every 12 hours
Frequency of Administration	Twice daily	Twice daily
Dosage Form	Tablets	Capsules
Duration of treatment	5 days	5 days
Manufacturer	Pfizer	Merck

*Approval Dates

Take-Away Points

- The FDA granted an Emergency Use Authorization (EUA) for the oral antiviral drugs, Paxlovid and Molnupiravir.
- Both drugs should be started as soon as possible. In the clinical studies both medications were taken within 3-5 days of symptom onset in order for it to be effective.
- Molnupiravir should not be used during pregnancy, but it should still be available in cases when the benefit outweighs the risks.
- Neither of the drugs prevent COVID-19 infections and should not be used for patients who are hospitalized with severe cases of the disease.
- Paxlovid and Molnupiravir are a faster way to treat early COVID-19 infections, all of the previously authorized drugs against the disease require an injection and must be administered intravenously in a healthcare facility.
- Paxlovid is expected to be available for the public late January 2022.

COVID-19 Update

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

- The U.S. government will be distributing Paxlovid and Molnupiravir, as it has done with the other COVID-19 treatments that obtained EUA. Up till today the U.S. government has purchased 10 million doses of Paxlovid and 3.1 million doses of Molnupiravir.
- According to a recent press release, in Puerto Rico the medications will be distributed through specific assigned community and hospital pharmacies, including certain Walgreens chain pharmacies.

At MC-Rx, we will continue to update our clients on the latest news regarding COVID-19 treatments.

Specialty Pipeline

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

Pipeline Drug	Current Status	Anticipated Approval	What is this drug being developed for?
adagrasib (Mirati Therapeutics)	Phase 2	2022	KRAS G12C specific inhibitor for the treatment of KRAS G12Cmutated locally advanced or metastatic non-small cell lung cancer (NSCLC); oral
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
bardoxolone methyl (Reata Pharmaceuticals)	NDA Filed	2022	antioxidant inflammation inhibitor that acts on Nrf2 for the treatment of chronic kidney disease caused by Alport Syndrome; oral
betibeglogene autotemcel (Zynteglo – Bluebird Bio)	BLA Filed	2022	Gene therapy for the treatment of β-globin gene therapy for the treatment of transfusion-dependent β thalassemia; IV infusion
bimekizumab (UCB)	BLA Filed	2022	Monoclonal antibody that blocks the effects of IL-17A and IL17F for the treatment of moderate-to-severe plaque psoriasis; SC injection
ciltacabtagene autoleucel (JNJ4528 – Janssen)	BLA Filed	2022	B-cell maturation antigen (BCMA)-directed chimeric antigen receptor T cell (CAR-T) therapy in previously treated patients with multiple myeloma; IV infusion
cipaglucosidase alfa (Amicus Therapeutics)	BLA Filed	2022	Recombinant human acid α-glucosidase (rhGAA) enzyme replacement therapy/ chaperone therapy for the treatment of late-onset Pompe disease; IV infusion
deucravacitinib (Bristol Myers Squibb)	NDA Filed		tyrosine kinase 2 (TYK2) inhibitor for use in patients with moderate to severe plaque psoriasis; oral therapy.
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

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

Biosimilar Pipeline

Products Under FDA Review

Pipeline Drug	Manufacturer	Current Status	Anticipated Approval	Comments
pegfilgrastim biosimilar	Adello Biologic	351(k) Filed	2022	Pegfilgrastim (Neulasta) biosimilar to reduce the incidence of infection, as manifested by febrile neutropenia, in patients with nonmyeloid malignancies receiving myelosuppressive anticancer drugs associated with a clinically significant incidence of febrile neutropenia; SC
bevacizumab biosimilar	Amneal	BLA Filed	2022	Biosimilar to Avastin (bevacizumab); intravenous
bevacizumab biosimilar	Biothera	351(k) Filed	2022	Biosimilar to Avastin, an angiogenesis inhibitor, for the treatment of cancer; IV infusion
ranibizumab biosimilar	Bioeq	351(k) Filed	2022	ucentis® biosimilar for the treatment of retinopathies; intra-vitreal
bevacizumab biosimilar	Viatris	351(k) Filed	2022	Biosimilar to Avastin, angiogenesis inhibitor, for the treatment of cancer; IV infusion

New Molecular Entities

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

Ropeginterferon alfa-2b-njft (Besremi)	**Dose:** Injection: 500 mcg/mL solution in a single-dose prefilled syringe **Indication:** Is an interferon alfa-2b indicated for the treatment of adults with polycythemia vera. **Comparables:** Hydroxyurea, Jakafi **Guidelines:** https://rarediseases.org/rare-diseases/polycythemia-vera/
Vosoritide (Voxzogo)	**Dose:** For injection: 0.4 mg, 0.56 mg, or 1.2 mg lyophilized powder in a single-dose vial for reconstitution. **Indication:** Is a C type natriuretic peptide (CNP) analog indicated to increase linear growth in pediatric patients with achondroplasia who are 5 years of age and older with open epiphyses. **Comparables:** N/A **Voxzogo is the first FDA-approved treatment for achondroplasia** **Guidelines:** https://rarediseases.org/rare-diseases/achondroplasia/
Maribavir (Livtencity)	**Dose:** Tablets: 200 mg of maribavir. **Indication:** Is a cytomegalovirus (CMV) pUL97 kinase inhibitor indicated for the treatment of adults and pediatric patients (12 years of age and older and weighing at least 35 kg) with post-transplant CMV infection/disease that is refractory to treatment (with or without enotypic resistance) with ganciclovir, valganciclovir, cidofovir or foscarnet. **Comparables:** Foscarnet (Not a true comparable, but can be used as a reference point, Livtencity is the first FDA-approved drug for refractory CMV) **Guidelines:** https://onlinelibrary.wiley.com/doi/10.1111/ctr.13512
Efgartigimod alfa-fcab	**Dose:** Injection: 400 mg in 20 mL (20 mg/mL) single-dose vial. **Indication:** For the treatment of generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) antibody positive. **Comparables:** Eculizumab (Soliris) **Guidelines:** https://n.neurology.org/content/neurology/96/3/114.full.pdf
Insulin glargine-aglr (Rezvoglar)	**Dose:** Injection: 100 units/mL (U-100) available as: 3 mL single-patient-use REZVOGLAR™ KwikPen® prefilled pen **Indication:** To improve glycemic control in adults and pediatric patients with type 1 diabetes mellitus and in adults with type 2 diabetes mellitus. **Comparables:** Lantus, Basaglar, Semglee **Guidelines:** https://care.diabetesjournals.org/content/44/Supplement_1/S111

New Molecular Entities

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

Adalimumab-aqvh (Yusimry)	**Dose:** Injection: 40 mg/0.8 mL in a single-dose prefilled glass syringe **Indication:** Rheumatoid Arthritis (RA), Juvenile Idiopathic Arthritis (JIA), PsoriaticArthritis (PsA), Ankylosing Spondylitis (AS), Crohn's Disease (CD), Ulcerative Colitis (UC), Plaque Psoriasis (Ps) **Comparables:** (Adalimumab) Humira **Guidelines:** https://www.rheumatology.org/Portals/0/Files/2021-ACR-Guideline-for-Treatment-Rheumatoid-Arthritis-Early-View.pdf
Inclisiran (Leqvio)	**Dose:** Injection: 284 mg/1.5 mL (189 mg/mL) in a single-dose prefilled syringe **Indication:** As an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia (HeFH) or clinical atherosclerotic cardiovascular disease (ASCVD), who require additional lowering of low density lipoprotein cholesterol (LDL-C). **Comparables:** Repatha, Praluent **Guidelines:** https://www.jacc.org/doi/pdf/10.1016/j.jacc.2018.11.003
Tralokinumab (Adbry)	**Dose:** Injection: 150 mg/mL solution in a single-dose prefilled syringe with needle guard. **Indication:** for the treatment of moderate-to-severe atopic dermatitis in adult patients whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. **Comparables:** Dupilumab (Dupixent) **Guidelines:** https://www.aad.org/member/clinical-quality/guidelines/atopic-dermatitis
Levoketoconazole (Recorlev)	**Dose:** Tablets: 150 mg **Indication:** for the treatment of endogenous hypercortisolemia in adult patients with Cushing's syndrome for whom surgery is not an option or has not been curative. **Comparables:** Isturisa, Signifor, Signifor LAR **Guidelines:** https://eje.bioscientifica.com/view/journals/eje/175/2/G1.xml
Daridorexant (Quviviq)	**Dose:** Tablets: 25 mg, 50 mg. **Indication:** for treatment of adult patients with insomnia, characterized by difficulties with sleep onset and/or sleep maintenance. **Comparables:** Lemborexant (Dayvigo), Suvorexant (Belsomra) **Guidelines:** https://www.aafp.org/afp/2017/0515/p669.html

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Hepatitis B Recombinant (PreHevbrio)	**Dose:** injectable suspension, for intramuscular use supplied as a single-dose vial. **Indication:** for prevention of infection caused by all known subtypes of hepatitis B virus. PREHEVBRIO is approved for use in adults 18 years of age and older. **Comparables:** Engerix-B, Recombivax HB, Heplisav-B **Guidelines:** https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/hepb.html
Abrocitinib (Cibinqo)	**Dose:** Tablets: 50 mg, 100 mg, and 200 mg **Indication:** for the treatment of adults with refractory, moderate-to-severe atopic dermatitis whose disease is not adequately controlled with other systemic drug products, including biologics, or when use of those therapies is inadvisable. **Comparables:** Upadacitinib (Rinvoq) **Guidelines:** https://www.jaad.org/action/showPdf?pii=S0190-9622%2814%2901257-2

New Drug Indications

Rituximab-pvvr (Ruxience)	**Dose:** Injection: 100 mg/10 mL (10 mg/mL) and 500 mg/50 mL (10 mg/mL) solution in single-dose vials. **New Indication:** Rheumatoid Arthritis (RA) in combination with methotrexate in adult patients with moderately-to severely-active RA who have inadequate response to one or more TNF antagonist therapies. **Comparables:** Rituxan **Guidelines:** https://www.rheumatology.org/Portals/0/Files/2021-ACR-Guideline-for-Treatment-Rheumatoid-Arthritis-Early-View.pdf
Bevacizumab-awwb (Mvasi)	**Dose:** Injection: 100 mg/4 mL (25 mg/mL) or 400 mg/16 mL (25 mg/mL) in a single-dose vial **New Indication:** Epithelial ovarian, fallopian tube, or primary peritoneal cancer chemotherapy regimens. **Comparables:** Avastin **Guidelines:** https://www.nccn.org/guidelines/guidelines-detail?category=1&id=1453

New Drug Indications

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Ferric carboxymaltose (Injectafer)	**Dose:** Injection: 50 mg/mL. **New Patient population:** Adults and pediatric patients 1 year of age and older who have either intolerance to oral iron or an unsatisfactory response to oral iron. **Comparables:** INFeD **Guidelines:** https://kdigo.org/guidelines/anemia-in-ckd/
Rituximab (Rituxan)	**Dose:** Injection: 100 mg/10 mL (10 mg/mL) and 500 mg/50 mL (10 mg/mL) solution in single-dose vials. **New Indication:** Pediatric patients aged 6 months and older with mature B-cell NHL and mature B-cell acute leukemia (B-AL) **Comparables:** N/A **Guidelines:** https://www.nccn.org/professionals/physician_gls/pdf/b-cell.pdf
Bupivacaine and meloxicam (Zynrelef)	**Dose:** For injection: 10 mg of loncastuximab tesirine-lpyl as a lyophilized powder in a single-dose vial for reconstitution and further dilution **New Indication:** Sustained perioperative pain relief for up to72 hours after foot and ankle, small-to-medium open abdominal, and lower extremity total joint arthroplasty surgical procedures. **Comparables:** Bupivacaine solution **Guidelines:** https://pubmed.ncbi.nlm.nih.gov/34552003/
Carfilzomib (Kyprolis)	**Dose:** For injection: 10 mg, 30 mg or 60 mg lyophilized powder in single-dose vial for reconstitution. **New Indication:** For the treatment of adult patients with relapsed or refractory multiple myeloma who have received one to three lines of therapy in combination with: • Lenalidomide and dexamethasone; or • Dexamethasone; or • Daratumumab and dexamethasone; or • Daratumumab and hyaluronidase-fihj and dexamethasone **Comparables:** (Bortezomib/Lenalidomide/Dexamethasone), and (Ixazomib/Lenalidomide/Dexamethasone). **Guidelines:** https://www.nccn.org/professionals/physician_gls/pdf/myeloma.pdf

New Drug Indications

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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 **New Indication:** For the treatment of multiple myeloma in combination with carfilzomib and dexamethasone in patients with relapsed or refractory multiple myeloma who have received one to three prior lines of therapy. **Comparables:** (Bortezomib/Lenalidomide/Dexamethasone), and (Ixazomib/Lenalidomide/Dexamethasone). **Guidelines:** https://www.nccn.org/professionals/physician_gls/pdf/myeloma.pdf
Elbasvir and grazoprevir (Zepatier)	**Dose:** Tablets: 50 mg elbasvir and 100 mg grazoprevir **New Indication:** is indicated for treatment of chronic HCV genotype 1 or 4 infection in adult and pediatric patients 12 years of age and older or weighing at least 30 kg. **Comparables:** Mavyret, Harvoni, Epclusa **Guidelines:** https://www.hcvguidelines.org/announcements/09292021-0000/what%E2%80%99s-new-updates-and-changes-guidance
Tofacitinib (Xeljanz)	**Dose:** XELJANZ Tablets: 5 mg, 10 mg tofacitinib; XELJANZ XR Tablets: 11 mg, 22 mg tofacitinib **New Indication:** for the treatment of adult patients with active ankylosing spondylitis who have had an inadequate response or intolerance to one or more TNF blockers. **Comparables**: Cosentyx, Talz **Guidelines:** https://pubmed.ncbi.nlm.nih.gov/31436026/
Abatacept (Orencia)	**Dose:** Intravenous Infusion: I. For injection: 250 mg lyophilized powder in a single-dose vial (may use less than full contents of vial or use more than one vial). II. Subcutaneous Use: Injection: 50 mg/0.4 mL, 87.5 mg/0.7 mL, 125 mg/mL solution in singledose prefilled syringes. III. Injection: 125 mg/mL solution in a single-dose prefilled ClickJect autoinjectors. **New Indication:** the prophylaxis of acute graft versus host disease (aGVHD), in combination with a calcineurin inhibitor and methotrexate, in adults and pediatric patients 2 years of age and older undergoing hematopoietic stem cell transplantation (HSCT) from a matched or 1 allele-mismatched unrelated donor. **Comparables:** Cyclosporine **Guidelines:** https://www.ncbi.nlm.nih.gov/books/NBK554020/

New Drug Indications

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

Lumateperone (Caplyta)	**Dose:** Capsules: 42 mg **New Indication:** Depressive episodes associated with bipolar I or II disorder (bipolar depression) in adults, as monotherapy and as adjunctive therapy with lithium or valproate. **Comparables:** Lurasinode (Latuda), Ziprasidone (Geodon) **Guidelines:** https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5310104/
Apremilast (Otezla)	**Dose:** Tablets: 10 mg, 20 mg, 30 mg **New Indication:** Adult patients with plaque psoriasis who are candidates for phototherapy or systemic therapy. **Comparables:** Xeljanz **Guidelines:** https://www.jaad.org/article/S0190-9622(20)30284-X/fulltext
Cabotegravir (Vocabria)	**Dose:** Tablets: 30 mg **New Indication:** VOCABRIA is indicated in at-risk adults and adolescents weighing at least 35 kg for short-term pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 infection. Individuals must have a negative HIV-1 test prior to initiating VOCABRIA for HIV-1 PrEP. **Comparables:** Descovy, Truvada **Guidelines:** https://jamanetwork.com/journals/jama/article-abstract/2771873
Upadacitinib (Rinvoq)	**Dose:** Extended-release tablets: 15 mg **New Indication:** I. For the treatment of: adults with moderately to severely active rheumatoid arthritis who have had an inadequate response or intolerance to one or more TNF blockers. II. Adults with active psoriatic arthritis who have had an inadequate response or intolerance to one or more TNF blockers. III. Adults and pediatric patients 12 years of age and older with refractory, moderate to severe atopic dermatitis whose disease is not adequately controlled with other systemic drug products, including biologics, or when use of those therapies are inadvisable. **Comparables:** Xeljanz **Guidelines:** https://www.rheumatology.org/Portals/0/Files/2021-ACR-Guideline-for-Treatment-Rheumatoid-Arthritis-Early-View.pdf https://www.jaad.org/action/showPdf?pii=S0190-9622%2814%2901257-2

New Drug Indications

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Secukinumab (Cosentyx)	**Dose:** Injection: 75 mg/0.5 mL solution in a single-dose prefilled syringe (for pediatric patients). **New Indication:** I. Active psoriatic arthritis (PsA) in patients 2 years of age and older. II. Active enthesitis-related arthritis (ERA) in patients 4 years of age and older. **Guidelines**: https://pubmed.ncbi.nlm.nih.gov/31436026/
Brexpiprazole (Rexulti)	**Dose:** Tablets: 0.25 mg, 0.5 mg, 1 mg, 2 mg, 3 mg, and 4 mg **New Indication:** Treatment of schizophrenia in adults and pediatric patients ages 13 years and older. **Comparables:** Aripiprazole (Abilify) **Guidelines:** https://psychiatryonline.org/doi/pdf/10.1176/appi.books.9780890424841
Ribociclib (Kisqali)	**Dose:** Tablets: 200 mg **New Indication:** for the treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer in combination with: o an aromatase inhibitor as initial endocrine-based therapy; or o fulvestrant as initial endocrine-based therapy or following disease progression on endocrine therapy in postmenopausal women or in men. **Comparables:** Abemaciclib (Verzenio), Palbociclib (Ibrance) **Guidelines:** https://www.nccn.org/professionals/physician_gls/pdf/breast_blocks.pdf
Emtricitabine and tenofovir alafenamide (Descovy)	**Dose:** Tablets: 200 mg/25 mg and 120 mg/15 mg of FTC and TAF respectively **New Indication:** I. In combination with other antiretroviral agents for the treatment of HIV-1 infection in adults and pediatric patients weighing at least 35 kg. II. In combination with other antiretroviral agents other than protease inhibitors that require a CYP3A inhibitor for the treatment of HIV-1 infection in pediatric patients weighing at least 14 kg and less than 35 kg. **Comparables:** Truvada **Guidelines:** https://jamanetwork.com/journals/jama/article-abstract/2771873

New Drug Indications

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

Remdesivir (Veklury)	**Dose:** (a) For injection: 100 mg of remdesivir as a lyophilized powder, in a single-dose vial. (b) Injection: 100 mg/20 mL (5 mg/mL) remdesivir, in a single-dose vial. **New Indication:** For the treatment of coronavirus disease 2019 (COVID-19) in adults and pediatric patients (12 years of age and older and weighing at least 40 kg) with positive results of direct severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) viral testing, who are: • Hospitalized, or • Not hospitalized and have mild-to-moderate COVID-19, and are at high risk for progression to severe COVID-19, including hospitalization or death. **Comparables:** None **Guidelines:** https://www.covid19treatmentguidelines.nih.gov/
Risankizumab-rzaa (Skyrizi)	**Dose:** Injection: (a) 150 mg/mL in each single-dose prefilled pen. (b) Injection: 150 mg/mL in each single-dose prefilled syringe. (c) Injection: 75 mg/0.83 mL in each single-dose prefilled syringe. **New Indication:** For the treatment of active psoriatic arthritis in adults. **Comparables:** Secukinumab (Cosentyx), Ixekizumab (Talz), Guselkumab (Tremfya) **Guidelines:** https://pubmed.ncbi.nlm.nih.gov/31436026/

New Drug Formulations

Topiramate (Eprontia)	**New Dosage Form:** 25 mg/mL oral solution **Indication:** Treatment of partial-onset or primary generalized tonic-clonic seizures in patients 2 years of age and older; an adjunctive therapy for treatment of partial-onset seizures, primary generalized tonic-clonic seizures or seizures associated with Lennox-Gastaut syndrome in patients 2 years of age and older; and, as a preventive treatment of migraine in patients 12 years of age and older. **Comparables:** Keppra oral solution, Topiramate tablet **Guidelines:** https://www.aan.com/Guidelines/home/GuidelineDetail/915
Sirolimus protein-bound particles (Fyarro)	**New Dosage Form:** 100 mg injectable suspension **Indication:** For the treatment of adult patients with locally advanced unresectable or metastatic malignant perivascular epithelioid cell tumor (PEComa). **Comparables:** N/A **Fyarro is the first FDA-approved treatment for advanced malignant PEComa**

New Drug Formulations

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

Baclofen (Lyvispah)	**New Dosage Form:** Oral granules (5 mg, 10 mg or 20 mg) **Indication:** Indicated to treat patients who are 12 years old or older for spasticity caused by multiple sclerosis (MS). Noting that it also may be helpful for some patients who have spinal cord injuries. **Comparables:** Baclofen tablet **Guidelines:** https://www.aan.com/Guidelines/home/GuidelineDetail/898
Clindamycin phosphate (Xaciato)	**New Dosage Form:** Vaginal gel 2% **Indication:** Indicated to treat bacterial vaginosis for patients at least 12 years old. **Comparables:** Clindamycin vaginal, Metronidazole intravaginal gel **Guidelines:** https://www.cdc.gov/std/treatment-guidelines/bv.htm
Finasteride and tadalafil (Entadfi)	**New Dosage Form:** Capsules: fixed dose combination containing finasteride 5 mg and tadalafil 5 mg **Indication:** indicated to initiate treatment of the signs and symptoms of benign prostatic hyperplasia (BPH) in men with an enlarged prostate for up to 26 weeks. **Comparables:** Finasteride (Proscar) & Tadalafil (Cialis) **Guidelines:** https://www.auanet.org/guidelines/guidelines/benign-prostatic-hyperplasia-(bph)-guideline#x8196
Budesonide (Tarpeyo)	**New Dosage Form:** Delayed release capsules: 4 mg **Indication:** to reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk of rapid disease progression, generally a urine protein-to-creatinine ratio (UPCR) ≥ 1.5 g/g. **Comparables:** None **Guidelines:** https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4956709/
Glycopyrrolate (Dartisla ODT)	**New Dosage Form:** Orally Disintegrating Tablets: 1.7 mg of glycopyrrolate **Indication:** to reduce symptoms of a peptic ulcer as an adjunct to treatment of peptic ulcer. **Comparables:** Glycopyrrolate (Robinul) **Guidelines:** https://gi.org/practice-management/
Voxelotor (Oxbryta)	**New Dosage Form:** Tablets for oral suspension: 300 mg **Indication:** for the treatment of sickle cell disease in adults and pediatric patients 4 years of age and older. **Comparables:** Hydroxyurea, Adakveos, Siklos, En-dari **Guidelines:** https://ashpublications.org/bloodadvances/article/5/18/3668/476988/American-Society-of-Hematology-2021-guidelines-for

New Drug Formulations

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

Rivaroxaban (Xarelto)	**New Dosage Form:** For oral suspension: 1 mg/mL once reconstituted **Indication:** I. For treatment of VTE and reduction in the risk of recurrent VTE in pediatric patients from birth to less than 18 years II. For thromboprophylaxis in pediatric patients 2 years and older with congenital heart disease after the Fontan procedure. **Comparables:** Pradaxa Pellets **Guidelines:** https://journal.chestnet.org/article/S0012-3692(18)32244-X/fulltext#secsectitle0450
Cabotegravir (Apretude) Cost Available	**New Dosage Form:** Injection: Single-dose vial of 600 mg/3 mL (200 mg/mL) of cabotegravir See 17 for PATIENT COUNSELING INFORMATION and extended-release injectable suspension. **Indication:** indicated in at-risk adults and adolescents weighing at least 35 kg for PrEP to reduce the risk of sexually acquired HIV-1 infection. **Comparables:** Cabotegravir (Vocabria), Truvada, Descovy **Guidelines:** https://jamanetwork.com/journals/jama/article-abstract/2771873 https://pubmed.ncbi.nlm.nih.gov/33052386/
Fingolimod (Tascenso ODT)	**New Dosage Form:** Orally disintegrating tablets: 0.25 mg **Indication:** for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in pediatric patients 10 years of age and older and weighing less than or equal to 40 kg. **Comparables:** Fingolimod (Gilenya)
Olopatadine hydrochloride and mometasone furoate monohydrate nasal spray (Ryaltris)	**New Dosage Form:** Nasal spray: 665 mcg of olopatadine hydrochloride and 25 mcg of mometasone furoate in each spray. **Indication:** for the treatment of symptoms of seasonal allergic rhinitis in adult and pediatric patients 12 years of age and older. **Comparables:** Mometasone Nasal Spray (Nasonex), Olopatadine Nasal (Patanase)

New Generics

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

First-Time Generic Approval

Generic Name	Applicant	Brand Name	Approval Date	Indication
Ivabradine Tablets, 5 mg and 7.5 mg	Centaur Pharmaceuticals Private Limited	Corlanor (Ivabradine) Tablets, 5 mg and 7.5 mg	12/30/2021	To reduce the risk of hospitalization for worsening heart failure in adult patients with stable, symptomatic chronic heart failure with reduced left ventricular ejection fraction
Vasopressin Injection, USP, 20 Units/mL Multiple Dose Vials	Eagle Pharmaceuticals, Inc.	Vasostrict (Vasopressin) Injection, 20 units/mL	12/15/2021	To increase blood pressure in adults with vasodilatory shock who remain hypotensive despite fluids and catecholamines
Amphotericin B Liposome for Injection, 50 mg/vial Single-Dose Vial	Sun Pharmaceutical Industries Limited	AmBisome (Amphotericin B) Liposome for Injection, 50 mg/vial	12/14/2021	For the empirical therapy for presumed fungal infection in febrile, neutropenic patients; for the treatment of Cryptococcal Meningitis in HIV-infected patients; treatment of patients with Aspergillus species, Candida species and/or Cryptococcus; treatment of visceral leishmaniasis
Timolol Maleate Ophthalmic Solution USP, 0.25% (base) and 0.5% (base), Single-Dose Vials	IdentiRx Pharmaceuticals, LLC	Timoptic (Timolol Maleate) in Ocudose Ophthalmic Solution, 0.25% and 0.5%	12/13/2021	For the treatment of elevated intraocular pressure in patients with ocular hypertension or open-angle glaucoma
Glycerol Phenylbutyrate Oral Liquid, 1.1 grams/mL	Par Pharmaceutical, Inc.	Ravicti (Glycerol Phenylbutyrate) Oral Liquid, 1.1 grams/mL	12/2/2021	For the chronic management of patients 2 years of age and older with urea cycle disorders (UCDs) who cannot be managed by dietary protein restriction and/or amino acid supplementation alone

New Generics

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

Generic Name	Applicant	Brand Name	Approval Date	Indication
Lubiprostone Capsules, 8 mcg and 24 mcg	Amneal Pharmaceuticals LLC	Amitiza (Lubiprostone) Capsules, 8 mcg and 24 mcg	11/30/2021	For the treatment of opioid-induced constipation (OIC) in adult patients with chronic, non-cancer pain, including patients with chronic pain related to prior cancer or its treatment who do not require frequent (e.g.,weekly) opioid dosage escalation
Atropine Sulfate Ophthalmic Solution USP, 1%	Apotex Inc.	Atropine Sulfate Ophthalmic Solution, 1%	11/26/2021	For the treatment of cycloplegia, mydriasis, and for the penalization of the healthy eye in the treatment of amblyopia
Betaine Anhydrous for Oral Solution, 180 grams/bottle	Novitium Pharma LLC	Cystadane (Betaine Anhydrous) For Oral Solution, 180 grams/bottle	11/23/2021	For the treatment of homocystinuria to decrease elevated homocysteine blood concentrations
Dasatinib Tablets, 80 mg and 140 mg	Apotex Inc.	Sprycel (Dasatinib) Tablets, 80 mg and 140 mg	11/23/2021	For the treatment of newly diagnosed adults with Philadelphia chromosome-positive chronic myeloid leukemia (CML) in chronic phase; adults with chronic, accelerated, or myeloid or lymphoid blast phase Ph+ CML with resistance or intolerance to prior therapy including imatinib; adults with Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ ALL) with resistance or intolerance to prior therapy; pediatric patients 1 year of age and older with Ph+ CML in chronic phase; pediatric patients 1 year of age and older with newly diagnosed Ph+ ALL in combination with chemotherapy

New Generics

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

Generic Name	Applicant	Brand Name	Approval Date	Indication
Nelarabine Injection, 250 mg/50 mL (5 mg/mL), Single Dose Vial	Zydus Pharmaceuticals (USA) Inc.	Arranon (Nelarabine) Injection, 250 mg/50 mL	11/17/2021	For the treatment of patients with T-cell acute lymphoblastic leukemia and T-cell lymphoblastic lymphoma in adult and pediatric patients age 1 year and older whose disease has not responded to or has relapsed following treatment with at least two chemotherapy regimens
Fingolimod Capsules, 0.25 mg	Teva Pharmaceuticals USA, Inc.	Gilenya (Fingolimod) Capsules, 0.25 mg	11/12/2021	For the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in patients 10 years of age and older
Potassium Chloride (20 mEq) in Lactated Ringer's and 5% Dextrose Injection USP, Single-Dose Containers	Fresenius Kabi USA, LLC	Potassium Chloride (20 mEq) in Lactated Ringer's and 5% Dextrose Injection	11/9/2021	For patients requiring parenteral administration of potassium chloride and the replacement of extracellular losses of fluids and electrolytes with minimal carbohydrate calories
Valsartan Oral Solution, 20 mg/5 mL (4 mg/mL)	Novitium Pharma LLC	Prexxartan (Valsartan) Oral Solution, 20 mg/5 mL	11/2/2021	For the treatment of hypertension, for the treatment of heart failure and to reduce risk of cardiovascular death in patients following myocardial infarction who are unable to swallow valsartan tablets

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

Recall

Date	Brand Name(s)	Product Description	Recall Reason Description	Company Name
01/31/2022	**Hard Dawn**	Hard Dawn Rise and Shine capsules	Undeclared Tadalafil	Esupplementsales, LLC
01/28/2022	**Auromedics**	Polymyxin B for Injection USP, 500,000 Units/Vial	Presence of Particulate Matter	AuroMedics Pharma LLC
01/19/2022	**Semglee**	Insulin glargine injection), 100 units/ml (U-100), 3mL prefilled pens	Missing Label	Mylan Pharmaceutical Inc.
01/12/2022	**Viona**	Metformin Hydrochloride Extended-Release Tablets	N-Nitrosodimethylamine (NDMA) Impurity	Viona Pharmaceuticals, Inc.
01/12/2022	**AVpak**	Senna Syrup 5mL	Potential microbial contamination	Lohxa LLC
12/30/2021	**Taro**	Clobetasol Propionate	Presence of Ralstonia pickettii bacteria	Taro Pharmaceuticals USA, Inc.
12/27/2021	**Perrigo**	Nitroglycerin Lingual Spray	Unit may not properly dispense medication.	Padagis
12/10/2021	**Rompe Pecho**	Liquid Cold & Flu symptom relief	Microbial contamination	Efficient Laboratories, Inc

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

Safety

FDA investigating possible increased risk of death with lymphoma medicine Ukoniq (umbralisib)

Consider risks and benefits of continued use versus other treatments

2-3-2022 FDA Drug Safety Communication

The U.S. Food and Drug Administration (FDA) is investigating a possible increased risk of death with the cancer medicine Ukoniq (umbralisib) approved to treat two specific types of lymphomas, which are cancers that affect the body's immune system. We determined that initial findings from a clinical trial evaluating Ukoniq to treat a related type of cancer found a possible increased risk of death in patients taking the medicine. Because of the seriousness of this safety concern and the similarities between the two types of cancer for which this drug is approved and the type of cancer that was studied in the clinical trial, we are alerting patients and health care professionals that we are re-evaluating this risk against the benefits of Ukoniq for its approved uses.

Health care professionals should review patients' progress on Ukoniq and discuss with them the risks and benefits of continuing Ukoniq in the context of other available treatments.

Patients should talk to your health care professionals about the risks and benefits of Ukoniq or any concerns you may have, including about possible alternative treatments.

Updated Drug Shortages

February 02, 2022
- Omeprazole and Sodium Bicarbonate Powder for Suspension (Discontinuation)
- Potassium Chloride Concentrate Injection (Currently in Shortage)
- Propafenone Hydrochloride Tablets (Discontinuation)

January 31, 2022
- Doxycycline Capsules (Discontinuation)
- Sodium Bicarbonate Injection (Currently in Shortage)

January 24, 2022
- Potassium Chloride Concentrate Injection (Currently in Shortage)

January 21, 2022
- Cefixime Oral Capsules (Currently in Shortage)

January 20, 2022
- Dicyclomine Hydrochloride Oral Capsules (Discontinuation)

Off Market

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

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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FEBRUARY 2022

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