MC-Rx

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Insights on the Drugs Pipeline

Exploring the changes in the drugs market.

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

Here you will find

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

Clinical Pipeline

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

COVID-19 Therapies Update:

Therapy	FDA status	IDSA recommended usage
Remdesivir	FDA approved to treat COVID-19	Recommended for hospitalized severe or critically ill patients with COVID-19.
Bamlanvimab/Etesevimab	EUA to treat COVID-19	Ambulatory patients with mild to moderate COVID-19 at high risk for progression to severe disease.
Baricitinib with remdesivir	EUA to treat COVID-19	Hospitalized patients with severe COVID-19 who cannot receive corticosteroids because of a contraindication.
Tocilizumab in addition to standard of care	EUA to treat COVID-19	Hospitalized adults with progressive severe or critical COVID-19 disease who have elevated markers of systemic inflammation.
Dexamethasone	EUA to treat COVID-19	Hospitalized patients with severe but non-critical COVID-19.

**IDSA: Infectious Disease Society of America, FDA: Food and Drug Administration, EUA: Emergency Use Authorization*

Currently, three vaccines are authorized and recommended to prevent COVID-19 by the FDA in the United States of America:

- Pfizer-BioNTech COVID-19 vaccine
- Moderna COVID-19 vaccine
- Johnson & Johnson's Janssen COVID-19 vaccine

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

Johnson & Johnson's Janssen COVID-19 vaccine: On April 13, 2021 the FDA issued a joint statement with the CDC in which they recommended a pause in the use of this vaccine due to six reported cases of a rare and severe type of blood clot in individuals after receiving the vaccine. Following a thorough safety review this recommended pause was lifted on April 23, 2021.

COVID-19 Authorized Vaccines Comparative Table

Vaccine	Pfizer/BioNTech	Moderna	Johnson & Johnson
Effectiveness	First Dose: 52% Second Dose: 95%	First Dose: 80% Second Dose: 94%	First Dose: 66%
Common Side Effects	Injection site pain, fatigue, headache, chills, muscle pain.	Injection site pain, fever, muscle aches, headaches lasting a few days.	Injection site pain, headache, fatigue, muscle pain.
Route/Doses	Intramuscular Two doses, 3 weeks apart	Intramuscular Two doses, 4 weeks apart	Intramuscular 1 dose
Authorized Population	Individuals 16 years and older	Individuals 18 years and older	Individuals 18 years and older
Date of EUA issuance	December 11, 2020	December 18, 2020	February 27, 2021

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

Specialty Pipeline

There is a growing trend of specialty drugs in the market. It is predicted that 2021 will be the year 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.

Table 1. Top 20 Specialty Pipeline Drugs

Pipeline Drug/ (Manufacturer)	Indication	Current Status	Expected Approval
Bimekizumab (UCB)	Monoclonal antibody that blocks the effects of IL-17A and IL17F for the treatment of moderate-to-severe plaque psoriasis; SC injection	BLA Filed	07/22/2021
Ciltacabtagene autoleucel (JNJ4528 – Janssen)	B cell maturation antigen (BCMA)-directed chimeric antigen receptor T cell (CAR-T) therapy in previously treated patients with multiple myeloma; IV infusion	BLA Filed	2021
Deucravacitinib (Bristol Myers Squibb)	Tyrosine kinase 2 (TYK2) inhibitor for use in patients with moderate to severe plaque psoriasis; oral therapy	Phase 3	2021
Efgartigimod (Argenx)	FcRn-targeting antibody fragment designed to depleted pathogenic IgGs for the treatment of myasthenia gravis (MG); IV infusion	BLA Filled	12/17/2021
Eladocagene exuparvovec (PTC Therapeutics)	Recombinant, adeno-associated virus, containing the human cDNA encoding the AADC enzyme for the treatment of AADC deficiency; intracerebral infusion	Phase 3	2021
Idecabtagene vicleucel (Ide-cel - Bluebird Bio/ Bristol Myers Squibb)	B cell maturation antigen (BCMA)-directed chimeric antigen receptor T cell (CAR-T) therapy for the treatment of previously treated multiple myeloma; IV infusion	BLA Filed	03/27/2021
Inclisiran (Leqvio - Novartis)	Proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor that uses RNA interference (RNAi) to treat elevated levels of low-density cholesterol (LDL-C); subcutaneous injection (administration by a healthcare professional)	Complete Response	2021

Clinical Pipeline

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

Pipeline Drug/ (Manufacturer)	Indication	Current Status	Expected Approval
Eladocagene exuparvovec (PTC Therapeutics)	Recombinant, adeno-associated virus, containing the human cDNA encoding the AADC enzyme for the treatment of AADC deficiency; intracerebral infusion	Phase 3	2021
Obeticholic acid (Intercept Pharmaceuticals)	Farnesoid X receptor (FXR) agonist for the treatment of nonalcoholic steatohepatitis (NASH); oral	Complete Response	2022
Pegcetacoplan (Apellis)	Synthetic cyclic peptide conjugated to a polyethylene glycol (PEG) polymer that binds specifically to C3 and C3b, effectively blocking all three pathways of complement activation (classical, lectin, and alternative) for the treatment of paroxysmal nocturnal hemoglobinuria (PNH); SC	NDA Filed	05/14/2021
Ponesimod (Janssen)	Sphingosine-1-phosphate receptor 1 (S1P-1) agonist for the treatment of relapsing-remitting multiple sclerosis (MS); oral	NDA Filed	03/18/2021
Sotorasib (Amgen)	KRAS G12C inhibitor for the treatment of patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with KRAS G12C mutation, as determined by an FDA-approved test, following at least one prior systemic therapy; oral	NDA Filed	08/16/2021
Sutimlimab (Sanofi)	Anti-C1s antibody for the treatment of primary cold agglutinin disease (CAD); IV infusion	Complete Response	2021
Tralokinumab (LEO Pharma)	Anti-IL-13 for the treatment of moderate to severe atopic dermatitis (AD); SC	BLA Filed	04/27/2021
Valoctocogene roxaparvovec (Roctavian – BioMarin Pharmaceuticals)	Adenovirus-associated virus vector-mediated the transfer of Human Factor VIII gene in patients with severe hemophilia A; IV infusion	Complete Response	2022
Vosoritide (BioMarin)	Analog of C-type Natriuretic Peptide (CNP) for the treatment of children with achondroplasia; SC	NDA Filed	08/20/2021

New Drug Approvals

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

Serdexmethylphenidate and dexmethylphenidate (Azstarys)

Dose: Recommended starting dosage is 39.2 mg/7.8 mg orally once daily in the morning. Dosage may be increased to 52.3 mg/10.4 mg daily or decreased to 26.1 mg/5.2 mg daily after one week. Maximum recommended dosage is 52.3 mg/10.4 mg once daily.
Indication: Treatment of Attention Deficit Hyperactivity Disorder (ADHD) in patients 6 years of age and older.
Guidelines: AAP ADHD Diagnosis and Treatment Guidelines: A Historical Perspective. https://pediatrics.aappublications.org/content/144/4/e20191682#sec-2
Comparables: Dexmethylphenidate (Focalin XR)

Roszet (Rosuvastatin and Ezetimibe)

Dose: 5 mg/10 mg to 40 mg/10 mg once daily.
Indication: As an adjunct to diet in patients with primary non-familial hyperlipidemia to reduce low-density lipoprotein cholesterol (LDL-C). Alone or as an adjunct to other LDL-C-lowering therapies in patients with homozygous familial hypercholesterolemia (HoFH) to reduce LDL-C.
Guidelines: AHA/ACC/American Association of Cardiovascular and Pulmonary Rehabilitation (AACVPR)/American Academy of Physician Assistants (AAPA)/Association of Black Cardiologists (ABC)/American College of Preventive Medicine (ACPM)/American Diabetes Association (ADA)/American Geriatrics Society (AGS)/American Pharmacists Association (APhA)/American Society for Preventive Cardiology (ASPC)/National Lipid Association (NLA)/Preventive Cardiovascular Nurses Association (PCNA): Guideline on the management of blood cholesterol
Comparables: Simvastatin and Ezetimibe (Vytorin)

New Indications

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

Edurant (Rilpivirine)

Dose: 25 mg tablet once daily
Indication: In combination with Vocabria (Cabotegravir), for short-term treatment of HIV-1 infection in adults who are virologically suppressed (HIV-1 RNA less than 50 copies/mL) on a stable regimen with no history of treatment failure and with no known or suspected resistance to either Cabotegravir or Rilpivirine.
Guidelines: Centers for Disease Control and Prevention (CDC): Persons with HIV – Prevention and care: Guidelines
Comparables: Cabotegravir/Rilpivirine (Cabenuva), Cabotegravir Sodium (Vocabria)

Rapivab (Peramivir)

Dose: Injection: 200 mg in 20 mL (10 mg/mL) in a single-use
Indication: Expands the patient population of Rapivab (peramivir) for the treatment of acute uncomplicated influenza to patients 6 months and older who have been symptomatic for no more than two days.
Comparables: Zanamivir (Relenza), Oseltamivir (Tamiflu)

Nplate (Romiplostim)

Dose: For injection: 125 mcg, 250 mcg or 500 mcg of deliverable Romiplostim as a lyophilized powder in single-dose vials.
Indications: To increase survival in adults and in pediatric patients (including term neonates) acutely exposed to myelosuppressive doses of radiation (Hematopoietic Syndrome of Acute Radiation Syndrome [HSARS]).

Gocovri (Amantadine)

Dose: 137 mg once daily; after 1 week, increase to usual dose of 274 mg once daily.
Indications: As adjunctive treatment to levodopa/carbidopa in patients with Parkinson's disease experiencing "off" episodes.
Comparables: Safinamide Mesylate (Xadago), Amantadine (Symmetrel)

New Indications

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

Libtayo (Cemiplimab-rwlc)

Dose: Injection: 350 mg/7 mL (50 mg/mL) solution in a single-dose vial.
Indications: Basal Cell Carcinoma (BCC)
• For the treatment of patients with locally advanced BCC (laBCC) previously treated with a hedgehog pathway inhibitor or for whom a hedgehog pathway inhibitor is not appropriate.
• For the treatment of patients with metastatic BCC (mBCC) previously treated with a hedgehog pathway inhibitor or for whom a hedgehog pathway inhibitor is not appropriate. The mBCC indication is approved under accelerated approval based on tumor response rate and durability of response. Continued approval for mBCC may be contingent upon verification and description of clinical benefit.
Guidelines: NCCN Clinical Practices Guidelines in Oncology. Basal Cell Skin Cancer. Version 2.2021, February 25, 2021. https://www.nccn.org/professionals/physician_gls/pdf/nmsc.pdf

Humira (Adalimumab)

Dose: The recommended subcutaneous dosage of Humira for adult patients with ulcerative colitis is 160 mg initially on Day 1 (given in one day or split over two consecutive days), followed by 80 mg two weeks later (Day 15). Two weeks later (Day 29) continue with a dosage of 40 mg every other week.
Indications: Treatment of moderately to severely active ulcerative colitis in adults and pediatric patients 5 years of age and older. Limitations of Use: Effectiveness has not been established in patients who have lost response to or were intolerant to TNF blockers.
Guidelines: AGA Clinical Practice Guidelines on the Management of Moderate to Severe Ulcerative Colitis.
Comparables: Infliximab (Remicade)

Lorbrena (Lorlatinib)

Dose: 100 mg orally once daily, with or without food, until disease progression or unacceptable toxicity.
Indications: Is a kinase inhibitor indicated for the treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) whose tumors are anaplastic lymphoma kinase (ALK)-positive as detected by an FDA-approved test.
Guidelines: NCCN Clinical Practices Guidelines in Oncology. Non-Small Cell Lung Cancer. Version 4.2021. March 3, 2021. https://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf
Comparables: Alectinib (Alecensa), Brigatinib (Alunbrig)

Yescarta (Axicabtagene ciloleucel)

Dose: Each single infusion bag of Yescarta contains a suspension of chimeric antigen receptor (CAR)-positive T cells in approximately 68 mL. The target dose is 2 × 106 CAR-positive viable T cells per kg body weight, with a maximum of 2 × 108 CAR-positive viable T cells.
Indications: Adult patients with relapsed or refractory follicular lymphoma (FL) after two or more lines of systemic therapy.
Guidelines: NCCN Clinical Practices Guidelines in Oncology. T-Cell Lymphomas. Version 1.2021. October 5, 2020. https://www.nccn.org/professionals/physician_gls/pdf/t-cell.pdf
Comparables: Tisagenlecleucel (Kymriah), Lisocabtagene maraleucel (Breyanzi)

Actemra (Tocilizumab)

Dose: 162 mg given once every week as a subcutaneous injection.
Indications: Slowing the rate of decline in pulmonary function in adult patients with systemic sclerosis-associated interstitial lung disease (SSc-ILD).

New Indications

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Zirabev (Bevacizumab-bvzr)

Dose: The recommended dosage is 15 mg/kg intravenously every 3 weeks in combination with carboplatin and paclitaxel for up to 6 cycles, followed by Zirabev 15 mg/kg every 3 weeks as a single agent for a total of up to 22 cycles or until disease progression, whichever occurs earlier.
Indications: Epithelial ovarian, fallopian tube, or primary peritoneal cancer in combination with carboplatin and paclitaxel, followed by Zirabev as a single agent, for stage III or IV disease following initial surgical resection. In combination with paclitaxel, PEGylated liposomal doxorubicin, or Topotecan for platinum-resistant recurrent disease who received no more than 2 prior chemotherapy regimens. In combination with carboplatin and paclitaxel or carboplatin and gemcitabine, followed by Zirabev as a single agent, for platinum sensitive recurrent disease.
Guidelines: NCCN Clinical Practices Guidelines in Oncology. Ovarian Cancer. Version 1.2021. February 26, 2021. https://www.nccn.org/professionals/physician_gls/pdf/ovarian.pdf
Comparables: Bevacizumab (Avastin)

Panzyga (Immune globulin [human])

Dose: 300 to 600 mg/kg body weight (3-6 mL/kg) administered every 3 to 4 weeks.
Indication: Primary humoral immunodeficiency (PI) in patients 2 years of age and older. This includes, but is not limited to, congenital agammaglobulinemia, common variable immunodeficiency, X-linked agammaglobulinemia, WiskottAldrich syndrome, and severe combined immunodeficiencies.
Comparables: Immune Globulin human (Hizentra)

Entresto (Sacubitril/Valsartan)

Dose: The recommended starting dose of Entresto is 49/51 mg orally twice-daily. Double the dose of Entresto after 2 to 4 weeks to the target maintenance dose of 97/103 mg twice daily, as tolerated by the patient.
Indication: To reduce the risk of cardiovascular death and hospitalization for heart failure in adult patients with chronic heart failure. Benefits are most clearly evident in patients with left ventricular ejection fraction (LVEF) below normal.
Comparables: Diovan (ARBs)

Arcalyst (Rilonacept)

Dose: Initiate treatment with a loading dose of 320 mg delivered as two, 2-mL, subcutaneous injections of 160 mg each, administered on the same day at two different injection sites. Continue dosing with a once-weekly injection of 160 mg administered as a single, 2-mL, subcutaneous injection.
Indications: Treatment of recurrent pericarditis (RP) and reduction in risk of recurrence in adults and children 12 years and older.
Comparables: Anakinra (Kineret) Off label use

New Indications

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

Keytruda (Pembrolizumab)

Dose: 200 mg every 3 weeks or 400 mg every 6 weeks.
Indication: For the treatment of patients with locally advanced or metastatic esophageal or gastroesophageal junction (GEJ) (tumors with epicenter 1 to 5 centimeters above the GEJ) carcinoma that is not amenable to surgical resection or definitive chemo radiation either or in combination with platinum- and fluoropyrimidine-based chemotherapy, or o as a single agent after one or more prior lines of systemic therapy for patients with tumors of squamous cell histology that express PD-L1 (CPS ≥10) as determined by an FDA-approved test.
Guidelines: NCCN Clinical Practices Guidelines in Oncology. Esophageal and Esophagogastric Junction Cancers. Version 2.2021. March 9, 2021. https://www.nccn.org/professionals/physician_gls/pdf/esophageal.pdf

Agalsidase beta (Fabrazyme)

Dose: 1.0 mg/kg body weight infused every 2 weeks as an IV infusion.
Indication: Fabrazyme (Agalsidase beta) is indicated for use in patients with Fabry disease. Fabrazyme reduces globotriaosylceramide (GL-3) deposition in capillary endothelium of the kidney and certain other cell types.
Comparables: Migalastat (Galafold)

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

Vocabria (Cabotegravir)

Dose: Recommended dosing is one tablet (30mg) daily.
Indication: In combination with Edurant (Rilpivirine) for short-term treatment of HIV-1 infection in adults who are virologically suppressed (HIV-1 RNA less than 50 copies/mL) on a stable antiretroviral regimen with no history of treatment failure and with no known or suspected resistance to either Cabotegravir or Rilpivirine, for use as:
• Oral lead-in to assess the tolerability of Cabotegravir prior to administration of Cabenuva (Cabotegravir; Rilpivirine) extended-release injectable suspensions.
• Oral therapy for patients who will miss planned injection dosing with Cabenuva.
Guidelines: Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV.https://clinicalinfo.hiv.gov/sites/default/files/guidelines/documents/AdultandAdolescentGL.pdf
Comparables: Edurant (Rilpivirine), Cabenuva (Cabotegravir/Rilpivirine)

Cabenuva (Carbotegravir extended-release injectatable suspension; Rilpivirine extended-release injectatable suspension)

Dose: Injectable suspension co-packaged for intramuscular use
Indication: As a complete regimen for the treatment of HIV-1 infection in adults 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 with no known or suspected resistance to either Cabotegravir or Rilpivirine.
Guidelines: Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV.https://clinicalinfo.hiv.gov/sites/default/files/guidelines/documents/AdultandAdolescentGL.pdf
Comparables: Vocabria (Cabotegravir), Edurant (Rilpivirine)

Tepmetko (Tepotinib)

Dose: 450 mg once daily until disease progression or unacceptable toxicity.
Indications: For the treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) harboring mesenchymal epithelial transition (MET) exon 14 skipping alterations.
Guidelines: NCCN Clinical Practices Guidelines in Oncology. Non-Small Cell Lung Cancer. Version 4.2021. March 3, 2021. https://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf
Comparables: Tabrecta (Capmatinib), Xalkori (Crizotinib)

Ukoniq (Umbralisib)

Dose: 800 mg daily
Indications: For the treatment of adult patients with relapsed or refractory marginal zone lymphoma (MZL) who have received at least one prior anti-CD20-based regimen or for relapsed or refractory follicular lymphoma (FL) who have received at least three prior lines of systemic therapy.
Guidelines: NCCN Clinical Practices Guidelines in Oncology. B-Cell Lymphomas Version 3.2021. March 16, 2021. https://www.nccn.org/professionals/physician_gls/pdf/b-cell.pdf
Comparables: Revlimid (Lenalidomide), Zydelig (Idelalisib), Aliqopa (Copanlisib), Copiktra (Duvelisib), Tazverik (Tazemetostat)

In Market Brand

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

Breyanzi (Lisocabtagene maraleucel)

Dose: A single dose of Breyanzi contains 50 to 110 × 106 CAR-positive viable T cells (consisting of 1:1 CAR-positive viable T cells of the CD8 and CD4 components), with each component supplied separately in one to four single-dose 5 mL vials (3). Each mL contains 1.5 × 106 to 70 × 106 CAR-positive viable T cells.
Indications: For the treatment of adult patients with relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy, including diffuse large B-cell lymphoma (DLBCL) not otherwise specified (including DLBCL arising from indolent lymphoma), high-grade B-cell lymphoma, primary mediastinal large B-cell lymphoma, and follicular lymphoma grade 3B.
Guidelines: NCCN Clinical Practice Guidelines. B-Cell Lymphomas Version 3. 2021, March 16, 2021. https://www.nccn.org/professionals/physician_gls/pdf/b-cell.pdf
Comparables: Axicabtagene ciloleucel (Axi-cel) and Tisagenlecleucel (Kymriah)

Evkeeza (Evinacumab-dgnb)

Dose: The recommended dose of Evkeeza is 15 mg/kg administered by intravenous (IV) infusion once monthly (every 4 weeks).
Indications: Homozygous familial hypercholesterolemia: Treatment of Homozygous familial hypercholesterolemia (HoFH), as adjunct to other low-density lipoprotein-cholesterol lowering therapies in adults and pediatric Patients' ≥ 12 years.
Guidelines: 2018 ACC/AHA/AACVPR/AAPA/ABC/ACPM/ADA/AGS/APhA/ASPC/NLC/PCNA Guideline on the Management of Blood Cholesterol. https://www.jacc.org/doi/pdf/10.1016/j.jacc.2018.11.003
Comparables: Lomitapide (Juxtapid)

Cosela (Trilaciclib)

Dose: Cosela is 240 mg/m2 per dose. Administer as a 30-minute intravenous infusion completed within 4 hours prior to the start of chemotherapy on each day chemotherapy is administered.
Indication: To decrease the incidence of chemotherapy-induced myelosuppression in adult patients when administered prior to a platinum/etoposide-containing regimen or Topotecan containing regimen for extensive-stage small cell lung cancer (ES-SCLC).
****First drug to treat chemotherapy-induced myelosuppression****

Amondys (Casimersen)

Dose: The recommended dosage of Amondys 45 is 30 milligrams per kilogram administered once weekly as a 35 to 60-minute intravenous infusion via an in-line 0.2 micron filter.
Indications: Indicated for the treatment of Duchenne muscular dystrophy (DMD) in patients who have a confirmed mutation of the DMD gene that is amenable to exon 45 skipping.
Comparables: Eteplirsen (Exondys 51), Golodirsen (Vyondys 53), Vitolarsen (Viltepso)

Nulibry (Fosdenopterin)

Dose: Administer as an intravenous infusion once daily at a rate of 1.5 mL/minute with non-DEHP tubing with a 0.2 micron filter. Volumes below 2 mL may require syringe administration through slow intravenous push.
Indications: To reduce the risk of mortality in patients with molybdenum cofactor deficiency (MoCD) Type A.
****First drug to treat Molybdenum cofactor deficiency Type A****

In Market Brand

Pepaxto (Melphalan flufenamide)

Dose: 40 mg intravenously over 30 minutes on Day 1 of each 28-day treatment cycle, in combination with dexamethasone.
Indications: In combination with dexamethasone, for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy and whose disease is refractory to at least one proteasome inhibitor, one immunomodulatory agent, and one CD38-directed monoclonal antibody.
Guidelines: NCCN Clinical Practice Guidelines. Multiple Myeloma Version 6. 2021, April 12, 2021. https://www.nccn.org/professionals/physician_gls/pdf/myeloma.pdf
Comparables: Xpovio (Selinexor)

Fotivda (Tivozanib)

Dose: 1.34 mg once daily with or without food for 21 days on treatment followed by 7 days off treatment (28-day cycle) until disease progression or unacceptable toxicity.
Indications: Kinase inhibitor indicated for the treatment of adult patients with relapsed or refractory advanced renal cell carcinoma (RCC) following two or more prior systemic therapies.
Guidelines: NCCN Clinical Practice Guidelines. Kidney Cancer Version 4. 2021, April 19, 2021. https://www.nccn.org/professionals/physician_gls/pdf/kidney.pdf
Comparables: Cabozantinib (Cabometyx), Lenvatinib (Lenvima), Sunitinib (Sutent)

Ponvory (Ponesimod)

Dose: Titration is required for treatment initiation. The recommended maintenance dosage is 20 mg taken orally once daily.
Indications: Indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.
Guidelines: AAN Practice Guideline recommendations summary: Disease-Modifying Therapies for Adults with Multiple Sclerosis. https://www.aan.com/Guidelines/home/GuidelineDetail/898
Comparables: Fingolimod (Gilenya), Siponimod (Mayzent), Ozanimod (Zeposia)

Zegalogue (Dasiglucagon)

Dose: The dose in adults and pediatric patients aged 6 years and older is 0.6 mg injected subcutaneously.
Indications: For the treatment of severe hypoglycemia in pediatric and adult patients with diabetes aged 6 years and above.
Guidelines: ADA Standards of Medical Care in Diabetes 2021. https://care.diabetesjournals.org/content/44/Supplement_1
Comparables: Glucagon, Gvoke (Glucagon), Baqsimi (Glucagon)

Generic Available -
First-Time Generic Approval

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

Generic Name	Manufacturer	Brand Name	Approval Date	Indication
Ibrutinib Capsules, 70 mg and 140 mg	Zydus Worldwide DMCC	Imbruvica (Ibrutinib) Capsules, 70 mg and 140 mg	3/31/2021	For the treatment of adult patients with mantle cell lymphoma, chronic lymphocytic leukemia, small lymphocytic lymphoma , Waldenström's macroglobulinemia, marginal zone lymphoma, or chronic graft versus host disease.
Isotretinoin Capsules USP, 10 mg, 20 mg, 25 mg, 30 mg, 35 mg and 40 mg	Actavis Laboratories FL, Inc.	Absorica (Isotretinoin) Capsules USP, 10 mg, 20 mg, 25 mg, 30 mg, 35 mg and 40 mg	3/31/2021	For the treatment of severe recalcitrant nodular acne in non-pregnant patients 12 years of age and older with multiple inflammatory nodules with a diameter of 5 mm or greater.
Droxidopa Capsules, 100 mg, 200 mg, 300 mg	Ajanta Pharma Limited, Aurobindo Pharma Limited, Sun Pharmaceutical Industries Limited, ScieGen Pharmaceuticals, Inc., Alkem Laboratories Limited, Teva Pharmaceuticals USA, Inc., Lupin Limited, Zydus Pharmaceuticals (USA) Inc.,	Northera (Droxidopa) Capsules, 100 mg, 200 mg, 300 mg	2/18/2021	For the treatment of orthostatic dizziness or lightheadedness in adult patients with symptomatic neurogenic orthostatic hypotension.
Apremilast Tablets, 10 mg, 20 mg and 30 mg	Unichem Laboratories Limited.	Otezla (Apremilast) Tablets, 10 mg, 20 mg and 30 mg	2/18/2021	For the treatment of adult patients with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy.
Loteprednol Etabonate Ophthalmic Gel, 0.5%	Akorn Operating Company LLC.	Lotemax (Loteprednol) Etabonate Ophthalmic Gel, 0.5%	2/10/2021	For the treatment of post-operative inflammation and pain following ocular surgery.
Linaclotide Capsules, 145 mcg and 290 mcg	Mylan Pharmaceuticals Inc.	Linzess (Linaclotide) Capsules, 145 mcg and 290 mcg	2/9/2021	For the treatment of irritable bowel syndrome with constipation and chronic idiopathic constipation.
Topiramate Extended-Release Capsules, 25 mg, 50 mg, 100 mg, 150 mg, and 200 mg	Glenmark Pharmaceuticals Inc., USA	Qudexy XR (Topiramate Extended-Release) Capsules, 25 mg, 50 mg, 100 mg, 150 mg, and 200 mg	2/1/2021	For the treatment of partial-onset or primary generalized tonic-clonic seizures in patients 2 years of age and older; adjunctive therapy for the 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; preventive treatment of migraine in patients 12 years of age and older.

Drug Recalls and Safety Alerts

R&D | FDA Approval | In Market Brand | Generic Available | Recalls Safety

ChloraPrep

Brand/Manufacturer: Becton, Dickinson and Company
Recall reason: Voluntary recall of specified lots of the ChloraPrep™ Hi-Lite Orange™ 26 mL Applicator (2% w/w Chlorhexidine Gluconate (CHG) and 70% v/v Isopropyl Alcohol (IPA)) to the user level due to a defective applicator. The product is used as an antiseptic for the preparation of the patient's skin prior to surgery to help reduce bacteria that potentially can cause skin infection.
Date of recall: 04/20/2021

Acetaminophen Extra Strength 500 mg

Brand/Manufacturer: A-S Medication Solutions, LLC
Recall reason: Libertyville, IL, A-S Medication Solutions, LLC (ASM) is voluntarily recalling 198,350 bottles of Acetaminophen Extra Strength 500 mg Tablets, 100 ct. bottles (NDC# 50090-5350-0) contained in Health Essentials Kits distributed by Humana to its members. See the photo below. This recall is being conducted to the consumer level. These over-the-counter (OTC) analgesic products contain an incomplete prescription drug label rather than the required OTC Drug Facts label.
Date of recall: 04/02/2021

Guanfacine Extended Release 2 mg

Brand/Manufacturer: Apotex Corp.
Recall Reason: Apotex Corp is voluntarily recalling three (3) lots of Guanfacine Extended-Release Tablets 2mg to the consumer level due to trace amounts of Quetiapine Fumarate in one lot RX1663. Out of an abundance of caution, lots RX1662 and RX1664 are also included in the scope of this voluntary recall, as they were manufactured in the same campaign as lot RX1663.
Date of Recall: 03/31/2021

Acyclovir Sodium Injection, 50mg/mL, 10mL and 20mL vials

Brand/Manufacturer: Zydus Pharmaceuticals
Recall Reason: Pennington, NJ, Zydus Pharmaceuticals (USA) Inc. is voluntarily recalling four lots of Acyclovir Sodium Injection, 50 mg/mL, 10 mL and 20 mL vials, to the Hospital/User level after receiving several complaints of crystallization in vials.
Date of Recall: 03/25/2021

Telmisartan 20 mg Tablets

Brand/Manufacturer: Alembic Pharmaceuticals, Inc.
Recall Reason: Voluntary recall of one lot of Telmisartan Tablets, USP, 20 mg, packaged in 30-count bottles, Lot No. 1905005661 to the consumer level. The product is being recalled due to a market complaint received which stated that one bottle labelled as 30-count Telmisartan Tablets, USP, 20 mg incorrectly contained 30 tablets of Telmisartan Tablets, USP, 40mg.
Date of Recall: 03/24/2021

Phenylephrine Hydrochloride Injection

Brand/Manufacturer: Sagent Pharmaceuticals, Inc.
Recall Reason: Voluntary nationwide recall of three lots of Phenylephrine Hydrochloride Injection, USP (10 mg/mL). This product was manufactured by Indoco Remedies Ltd. and distributed by Sagent Pharmaceuticals, Inc. Sagent has initiated this voluntary recall of Phenylephrine Hydrochloride Injection, USP to the user level as the result of a customer complaint due to potentially loose crimped vial overseals. A non-integral crimped vial overseal may result in a non-sterile product.
Date of Recall: 03/11/2021

R&D | FDA Approval | In Market Brand | Generic Available | Recalls Safety

Spironolactone 25 mg and 50 mg tablets

Brand/Manufacturer: Bryant Ranch Prepack Pharmaceuticals
Recall Reason: Voluntary recall of a total 47 bottles of Spironolactone tablets (four different lots) to the consumer level. The products have been found to be mislabeled, displaying the incorrect strength. Prepackaged bottles labeled Spironolactone 50 mg may contain Spironolactone 25 mg tablets and prepackaged bottles of Spironolactone 25 mg may contain Spironolactone 50 mg tablets.
Date of Recall: 03/09/2021

Drug Shortages

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

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
- https://www.ashp.org/-/media/assets/pharmacy-practice/resource-centers/Coronavirus/docs/Vaccine-candidate-tracking-table.ashx?la=en&hash=445ED31EC216D4F4E33C920AE151530C986F9255
- https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines
- https://www.fda.gov/drugs/drug-safety-and-availability/drug-recalls
- https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts
- https://www.uptodate.com/contents/whats-new-in-drug-therapy?source=history_widget
- https://www.fda.gov/drugs/new-drugs-fda-cders-new-molecular-entities-and-new-therapeutic-biological-products/novel-drug-approvals-2020
- https://www.fda.gov/drugs/drug-and-biologic-approval-and-ind-activity-reports/first-generic-drug-approvals
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- https://www.fda.gov/drugs/new-drugs-fda-cders-new-molecular-entities-and-new-therapeutic-biological-products/new-drug-therapy-approvals-2020
- https://www.fda.gov/news-events/press-announcements/fda-issues-emergency-use-authorization-third-covid-19-vaccine

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