MC-Rx

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Insights on the Drug Pipeline

Exploring the changes in the drugs market.

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

Here you will find

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

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

COVID-19 Vaccines Summary

Vaccine	Manufacturer/ Sponsor	Route	Status (Phase)
BNT-162b2*	Pfizer/BioNTech	Intramuscular (two doses)	2 & 3 with **EUA**
mRNA-1273*	Moderna	Intramuscular (two doses)	2 & 3 with **EUA**
ChAdOx1 nCoV-19/ AZD 1222*	Oxford/Astra Zeneca	Intramuscular/ (two doses)	3
Ad26.COV2.S*	Johnson & Johnson	Intramuscular (one dose)	3 with **EUA**
NVX-CoV2373*	Novavax	Intramuscular (two doses)	3
V591*	Merck	Intramuscular (one or two doses)	Discontinued
SCB-2019*	Sanofi Pasteur/GSK	Intramuscular (two doses)	On- Hold*
CoVLP	Medicago/GSK	Intramuscular (two doses)	2/3

**On-Hold- Preliminary studies show lowered immune response in elderly. Study halted to increase antigen concentration. Expected in 2022.*

Currently, three vaccines are authorized and recommended to prevent COVID-19:
- 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

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. Especially after the second dose.	Injection site pain, fever, muscle aches, headaches lasting a few days. Especially after the second dose.	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

Specialty Pipeline

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

There is a growing trend of specialty drugs in the market. It is predicted that 2021 will be 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
Abrocitinib (Pfizer)	Janus kinase 1 (JAK1) inhibitor for the treatment of patients with moderate-to-severe atopic dermatitis (AD); oral	NDA Filed	04/25/2021
aducanumab (Aduhelm - Biogen/Eisai)	Monoclonal antibody targeting beta amyloid for the treatment of Alzheimer's disease; IV infusion	BLA Filed	06/07/2021
arimoclomol (Orphazyme)	Molecular chaperone activator that stimulates the normal cellular protein repair pathway for the treatment of NiemannPick Disease Type C (NPC); oral	NDA Filed	06/17/2021
beta beglogene darolentivec (Zynteglo - Bluebird Bio)	Gene therapy for the treatment of globin gene therapy, also for the treatment of transfusion-dependent thalassemia; IV infusion	Phase 3	2022
casimersen (Amondys 45 - Sarepta)	Phosphorodiamidate morpholino oligomer (PMO) designed to skip exon 45 for the treatment of patients with Duchenne muscular dystrophy (DMD) with deletions amenable to exon 45 skipping; IV infusion	NDA Filed	02/25/2021
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

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
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
lisocabtagene maraleucel (Breyanzi - Bristol-Myers Squibb)	CD19-directed CAR-T cell therapy for the treatment of patients with relapsed or refractory (R/R) large B-cell lymphoma (LBCL); IV infusion (one time)	Approved	02/05/2021
obeticholic acid (Intercept Pharmaceuticals)	Farnesoid X receptor (FXR) agonist for the treatment of nonalcoholic steatohepatitis (NASH); oral	Complete Response	2021
pegcetacoplan (Apellis)	A 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
pegunigalsidase alfa (Protalix BioTherapeutics)	Plant cell-expressed, recombinant alpha-galactosidase-A enzyme for the treatment of Fabry disease; IV infusion (monthly)	BLA Filed	04/27/2021
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

Clinical Pipeline

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

Pipeline Drug/ (Manufacturer)	Indication	Current Status	Expected Approval
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	NDA Filed	2021
tralokinumab (LEO Pharma)	Anti-IL-13 for the treatment of moderate to severe atopic dermatitis (AD); SC	BLA filed	04/27/2021
umbralisib (TG Therapeutics)	dual inhibitor of PI3K-delta and CK1-epsilon, as a treatment for patients with previously treated marginal zone lymphoma (MZL) and follicular lymphoma (FL); oral	Approved	02/05/2021
valoctocogene roxaparvovec (Roctavian – Bio Marin 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

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

FDA Approvals for 2020: A Year in Review

Overall, the FDA approved 52 new medications in 2020, including 36 specialty drugs and 16 traditional drugs. The agency approved 49 new drugs and four diagnostic agents through the Center for Drug Evaluation and Research (CDER), the division of the FDA that approves new drugs. CDER also approved three biosimilar medications. An additional three drug products were approved through the Center for Biologic Evaluation and Research (CBER), the division of the FDA that approves new biologic therapies. CBER approved three biological products and two vaccines, as well. Government funding for Operation Warp Speed greatly accelerated the approval process for breakthrough vaccines in the fight against COVID-19. The extent that some of the techniques will spill over into the current approval process is not yet known.

The COVID-19 pandemic is limiting on-site inspections for pharmaceutical laboratory and manufacturing facilities, possibly delaying some approvals. New drugs continued the FDA's emphasis on approving Orphan Drugs with 30 (57%) being designated to treat rare conditions and 23 (44%) of the new products were deemed Breakthrough Therapies. As for oncology: 15 (29%) new oncology medications were approved in 2020.

COVID-19

Bamlanivimab and etesevimab

Manufacturer: Eli Lilly
FDA approved Indication/Use: For the treatment of mild to moderate COVID-19 in adults and pediatric patients (12 years of age or older weighing at least 40 kilograms [about 88 pounds]) who test positive for SARS-CoV-2 and who are at high risk for progressing to severe COVID-19.
Bamlanivimab and etesevimab are not authorized for use in patients: who are hospitalized due to COVID-19, OR o who require oxygen therapy due to COVID-19, OR o who require an increase in baseline oxygen flow rate due to COVID-19 in those on chronic oxygen therapy due to underlying non-COVID-19 related comorbidity.
Dosage Form: Bamlanivimab and etesevimab solution for infusion should be prepared by a qualified healthcare professional using aseptic technique.
The dosage of bamlanivimab and etesevimab 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) is: bamlanivimab 700 mg & etesevimab 1,400 mg.

New Drug Approvals

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

Johnson & Johnson's Janssen COVID-19 Vaccine

Manufacturer: Janssen
FDA Authorization: The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) to permit the emergency use of the unapproved product, Janssen COVID-19 Vaccine, for active immunization to prevent COVID-19 in individuals 18 years of age and older.

- The Janssen COVID-19 Vaccine is a suspension for intramuscular injection administered as a single dose (0.5 mL).
- The Janssen COVID-19 Vaccine is manufactured using a specific type of virus called adenovirus type 26 (Ad26). The vaccine uses Ad26 to deliver a piece of the DNA, or genetic material, that is used to make the distinctive "spike" protein of the SARS-CoV-2 virus. While adenoviruses are a group of viruses that are relatively common, Ad26, which can cause cold symptoms and pink eye, has been modified for the vaccine so that it cannot replicate in the human body to cause illness.
- The effectiveness data to support the EUA include an analysis of 39,321 participants in the ongoing randomized, placebo-controlled study being conducted in South Africa, certain countries in South America, Mexico, and the U.S. who did not have evidence of SARS-CoV-2 infection prior to receiving the vaccine. Among these participants, 19,630 received the vaccine and 19,691 received saline placebo. Overall, the vaccine was approximately 67% effective in preventing moderate to severe/critical COVID-19 occurring at least 14 days after vaccination and 66% effective in preventing moderate to severe/critical COVID-19 occurring at least 28 days after vaccination.
- Additionally, the vaccine was approximately 77% effective in preventing severe/critical COVID-19 occurring at least 14 days after vaccination and 85% effective in preventing severe/critical COVID-19 occurring at least 28 days after vaccination.

Ansuvimab-zykl (Ebanga)

Dose: For adult and pediatric patients 50 mg/kg reconstituted and administered as a single intravenous infusion over 60 minutes
Indication: A Zaire ebolavirus glycoprotein (EBOV GP)-directed human monoclonal antibody indicated for the treatment of infection caused by Zaire ebolavirus in adult and pediatric patients, including neonates born to a mother who is RT-PCR positive for Zaire ebolavirus infection.
Guidelines: Centers for Disease Control and Prevention (CDC): Ebola (Ebola virus disease) – For clinicians: https://www.cdc.gov/vhf/ebola/treatment/index.html
Comparable: Inmazeb

****Second FDA-approved treatment for Zaire ebolavirus. There are currently two treatments approved by the U.S. Food and Drug Administration (FDA) to treat EVD caused by the Ebola virus, species Zaire ebolavirus, in adults and children.**

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

Hetlioz (tasimelteon)

Dose: Patients between the ages of three and 16 and who weigh at least 28kg (about 62 pounds) will take 0.7mg/kg of liquid Hetlioz; patients age 16 and older will take one 20mg capsule daily 1 hour before bedtime.
Indication: Hetlioz capsules are indicated for the treatment of Non-24-hour Sleep-Wake Disorder. Also indicated by the FDA as the first drug to treat irregular sleep patterns resulting from Smith-Magenis Syndrome (SMS). The new indication was granted on Dec. 1, 2020, the same day that a new liquid formulation, Hetlioz LQ oral suspension, also was FDA approved.
Guidelines: Clinical Practice Guideline for the Treatment of Intrinsic Circadian Rhythm Sleep-Wake Disorders. American Academy of Sleep Medicine Clinical Practice Guideline: https://aasm.org/resources/clinicalguidelines/crswd-intrinsic.pdf
Comparables: Rozerem, Belsomra

Thyquidity (levothyroxine sodium)

Dose: Once daily. Adequacy of therapy determined with periodic monitoring of TASH and/or T4 as well as clinical status.
Indication: As replacement therapy in primary (thyroidal), secondary (pituitary), and tertiary (hypothalamic) congenital or acquired hypothyroidism. Also indicated as an adjunct to surgery and radioiodine therapy in the management of thyrotropin-dependent well-differentiate thyroid cancer.
Guidelines: 2016 American Thyroid Association Guidelines for Diagnosis and Management of Hyperthyroidism and Other Causes of Thyrotoxicosis. https://www.liebertpub.com/doi/pdf/10.1089/thy.2016.0229
Comparables: Tirosint - SOL

New Indications

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

Xolair (omalizumab)

Dose: Doses vary based on the patient's weight and IgE blood levels, Xolair will be administered by a healthcare provider as a subcutaneous (SC) injection once every two weeks or once every four weeks.
Indication: The new approval is to treat adults who have nasal polyps that have not responded to nasally inhaled corticosteroids. Patients should stay under observation at the provider site for enough time after each injection to be sure no reaction will occur. Originally indicated to treat patients at least six years old for persistent allergic asthma that resists inhaled corticosteroid treatment, Xolair has an additional FDA approval for patients age 12 and older who have hives due to chronic idiopathic urticaria (CIU) that has not responded adequately to antihistamines.
Guidelines: 2020 Focused Updates to the Asthma Management Guidelines. A Report from the National Asthma Education and Prevention Program Coordinating Committee Expert Panel Working Group: https://www.nhlbi.nih.gov/health-topics/all-publications-and-resources/2020-focused-updates-asthma-management-guidelines
Comparables: Fasenra

Gavreto (pralsetinib)

Dose: To treat one of the RET+ thyroid cancers, Gavreto's recommended dose is 400mg (four capsules) once every day at least two hours after and one hour before eating.
Indication: Now indicated for patients 12 years old and older who need systemic treatment for metastatic or progressed RET+ medullary thyroid cancer (MTC) or for RET+ thyroid cancer that cannot be treated by radioactive iodine.
Guidelines: NCCN Clinical Practice Guidelines in Oncology: Thyroid Carcinoma. Version 3.2020, February 2, 2021. NCCN.org: https://www.nccn.org/professionals/physician_gls/pdf/thyroid.pdf
Comparables: Retevmo

Tagrisso (Osimertinib)

Dose: 80 mg tablet once daily
Indications: Ajuvant therapy after tumor resection in adult patients with non-small cell lung cancer (NSCLC) whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations, as detected by an FDA-approved test.
Guidelines: NCCN Clinical Practices Guidelines in Oncology. Non-Small Cell Lung Cancer. Version 3. 2021, February 19, 2021. https://www.nccn.org/professionals/physician_gls/pdf/nscl_blocks.pdf
Comparables: Iressa, Tarceva,

Benlysta (belimumab)

Dose: The subcutaneous version is indicated only for treating adults who have SLE and lupus nephritis; it has not been approved for use by patients under the age of 18. By IV, dosing for lupus nephritis is 10mg/kg once every two weeks for the first three doses, then once every four weeks. SC doses are given weekly at 400mg (two prefilled syringes or two auto-injectors) for four weeks, then reduced to 200mg
Indications: BENLYSTA is a B-lymphocyte stimulator (BLyS)-specific inhibitor now indicated for the treatment of:

- adult patients with active lupus nephritis who are receiving standard therapy.

Guidelines: 2019 Update of the Joint European League Against Rheumatism and European Renal Association–European Dialysis and Transplant Association (EULAR/ERA–EDTA) recommendations for the management of lupus nephritis. https://ard.bmj.com/content/annrheumdis/79/6/713.full.pdf
Comparables: Lupkynis

New Indications

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

Iclusig (ponatinib)

Dose: The recommended starting dosage is 45 mg orally once daily with a reduction to 15 mg orally once daily upon achievement of ≤1% BCR-ABL1IS. Patients with loss of response can re-escalate the dose of Iclusig to a previously tolerated dosage of 30 mg or 45 mg orally once daily. Continue Iclusig until loss of response at the re-escalated dose or unacceptable toxicity. Consider discontinuing Iclusig if hematologic response has not occurred by 3 months.
Indications: Chronic phase (CP) chronic myeloid leukemia (CML) with resistance or intolerance to at least two prior kinase inhibitors.
Guidelines: NCCN Clinical Practices Guidelines in Oncology. Chronic Myeloid Leukemia. Version 3.2021, January 12, 2021. https://www.nccn.org/professionals/physician_gls/pdf/cml_blocks.pdf
Comparables: Synribo, Sprycel

Opdivo and Cabometyx injections (nivolumab and cabozantinib)

Dose: 240 mg every 2 weeks or 480 mg every 4 weeks (30-minute intravenous infusion) Administer OPDIVO in combination with cabozantinib 40 mg orally once daily without food. Until disease progression, unacceptable toxicity, or up to 2 years.
Indications: For patients with advanced renal cell carcinoma, as a first-line treatment in combination with cabozantinib.
Guidelines: NCCN Clinical Practices Guidelines in Oncology. Kidney Cancer. Version 2.2021. February 3, 2021. https://www.nccn.org/professionals/physician_gls/pdf/kidney.pdf
Comparables: Keytruda, Yervoy

Xpovio (Selinexor)

Dose: For Multiple Myeloma in Combination with Bortezomib and Dexamethasone (SVd): Recommended dosage is 100 mg taken orally once weekly in combination with bortezomib and dexamethasone. For Multiple Myeloma in combination with dexamethasone (Sd): Recommended dosage is 80 mg in combination with dexamethasone taken orally on Days 1 and 3 of each week.
Indications: Nuclear export inhibitor indicated in combination with bortezomib and dexamethasone for the treatment of adult patients with multiple myeloma who have received at least one prior therapy.
Guidelines: NCCN Clinical Practices Guidelines in Oncology. Multiple Myeloma. Version 4.2021. December 10, 2020. https://www.nccn.org/professionals/physician_gls/pdf/myeloma.pdf
Comparables: Empliciti, Sarclysa, Pomalist

Xalkori (Crizotinib)

Dose: For Systemic ALCL: The recommended dosage is 280 mg/m2 orally twice daily based on body surface area. Dosage adjustments by indication for patients with moderate or severe hepatic impairment or severe renal impairment
Indications: Pediatric patients 1 year of age and older and young adults with relapsed or refractory, systemic anaplastic large cell lymphoma (ALCL) that is ALK-positive. t is the First biomarker-driven therapy for children and young adults with ALCL.
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: Adcetris

New Indications

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

Darzalex Faspro (Daratumumab; Hyaluronidase-fihj

Dose: The recommended dosage of DARZALEX FASPRO is (1,800 mg daratumumab and 30,000 units hyaluronidase) administered subcutaneously into the abdomen over approximately 3 to 5 minutes.
Indications: For the treatment of multiple myeloma in combination with bortezomib, thalidomide, and dexamethasone in newly diagnosed patients who are eligible for autologous stem cell transplant. Also indicated for the treatment of light chain (AL) amyloidosis in combination with bortezomib, cyclophosphamide and dexamethasone in newly diagnosed patients.
Guidelines: NCCN Clinical Practices Guidelines in Oncology. Multiple Myeloma. Version 4.2021. December 10, 2020. https://www.nccn.org/professionals/physician_gls/pdf/myeloma.pdf

Margenza (margetuximab-cmkb)

Dose: Once every three weeks as IV infusions at 15mg/kg. After the first dose is given over two hours, later infusion times can be reduced to as little as 30 minutes, depending on patient tolerance.
Indications: For treating adults who have (HER2+) breast cancer that has been treated at least twice with other HER2 inhibitors. One or more of the previous treatments must have been administered following metastasis. Chemotherapy (chemo) will be given along with Margenza. Launch is planned for March 2021in the U.S.
Guidelines: NCCN Clinical Practices Guidelines in Oncology. Breast Cancer. Version 1.2021. January 15, 2021. https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf
Comparables: Herceptin, Kadcyla,Perjeta, Tykerb.

Xeomin (incobotulinumtoxinA)

Dose: Dosing in children, which is based on body weight, is administered in a 3:2 dose ratio into the parotid glands and submandibular glands, respectively. Treatment sessions should occur no more frequently than once every 16 weeks.
Indication: To treat chronic sialorrhea for children as young as two years old.

Kineret (anakinra- Sobi)

Dose: SC dose of 1mg/kg/day to 2mg/kg/day, doses can be modified to a maximum of 8mg/day, if needed to control severe inflammation.
Indication: To treat deficiency of interleukin-1 receptor (IL-1R) antagonist (DIRA), a very rare autoimmune disorder with only a few known cases worldwide.

In Market Brand

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

Gemtesa (vibegron)

Dose: Recommended dosing is one tablet (75mg) daily.
Indication: For the treatment of overactive bladder (OAB) symptoms of urge urinary incontinence, urgency, and frequency in adults.
Guidelines: Diagnosis and Treatment of Non-Neurogenic Overactive Bladder (OAB) in Adults: an AUA/SUFU Guideline (2019). https://www.auanet.org/guidelines/overactive-bladder-(oab)-guideline
Comparables: Myrbetriq

Orladeyo (berotralstat)

Dose: One capsule (150 mg) taken orally once daily with food.
Indication: First oral drug indicated to prevent attacks of hereditary angioedema (HAE) for patients who are at least 12 years old.
Guidelines: US HEAE Medical Advisory Board 2020 Guidelines for the Management of Hereditary Angioedema. https://www.haea.org/assets/img/2020MAB_guidelines.pdf
Comparables: Takhzyro, Haegarda, Cinryze, Fyrazyr, Kalbitor, Ruconest, Berinert

Zokinvy (lonafarnib)

Dose: The starting dosage of Zokinvy for patients with a BSA of 0.39 m2 and above is 115 mg/m2 twice daily with morning and evening meals (see Table 1) to reduce the risk of gastrointestinal adverse reactions. After 4 months, increase to 150 mg/m2 twice daily
Indications: Indicated in patients 12 months of age and older with a body surface area of 0.39 m2 and above:

- To reduce risk of mortality in Hutchinson-Gilford Progeria Syndrome
- For treatment of processing-deficient Progeroid Laminopathies with either:
  - Heterozygous LMNA mutation with progerin-like protein accumulation
  - Homozygous or compound heterozygous ZMPSTE24 mutations

*** First Treatment for Hutchinson-Gilford Progeria Syndrome and Some Progeroid Laminopathies**

Klysiry (Tirbanibulin)

Dose: Apply to the treatment field on the face or scalp once daily for 5 consecutive days using 1 single dose packet per application.
Indications: For the topical treatment of actinic keratosis of the face or scalp.
Guidelines: Journal of the American Academy of Dermatology. https://www.jaad.org/article/S0190-9622(04)03369-9/abstract
Comparables: Efudex, Picato, Tola, Fluorac

In Market Brand

Orgovyx (Relugolix)

Dose: 360 mg on the first day of treatment followed by 120 mg taken orally once daily, at approximately the same time each day.
Indications: For the treatment of adult patients with advanced prostate cancer.
Guidelines: NCCN Clinical Practice Guidelines. Prostate Cancer Version 2. 2021, February 17, 2021. https://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf
Comparables: Lupron Depot

Verquvo (vericiguat)

Dose: 2.5 mg tablet orally once daily with food.
Indications: Indicated to reduce the risk of cardiovascular death and heart failure (HF) hospitalization following a hospitalization for heart failure or need for outpatient IV diuretics, in adults with symptomatic chronic HF and ejection fraction less than 45%.
Guidelines: 2017 ACC/AHA/HFSA Focused Update of the 2013 ACCF/AHA. https://www.ahajournals.org/doi/10.1161/cir.0000000000000509 Guideline for the Management of Heart Failure
Comparables: Corlanor

Lupkynis (Voclosporin)

Dose: 23.7 mg orally, twice a day.
Indications: Lupkyinis is a calcineurin-inhibitor immunosuppressant indicated in combination with a background immunosuppressive therapy regimen for the treatment of adult patients with active lupus nephritis.
Guidelines: 2019 Update of the Joint European League Against Rheumatism and European Renal Association–European Dialysis and Transplant Association (EULAR/ERA–EDTA) recommendations for the management of lupus nephritis. https://ard.bmj.com/content/annrheumdis/79/6/713.full.pdf
Comparables: Benlysta

Oxlumo (lumasiran)

Dose: Loading dose once monthly for 3 doses based on body weight and maintenance dose monthly; by subcutaneous injection.
Indications: HAO1-directed small interfering ribonucleic acid (siRNA) indicated for the treatment of primary hyperoxaluria type 1 (PH1) to lower urinary oxalate levels in pediatric and adult patients.
References: https://rarediseases.org/rare-diseases/primary-hyperoxaluria/
*** First Drug to Treat Rare Metabolic Disorder primary hyperoxaluria type 1, which causes recurrent kidney stones and loss of kidney function**

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

Imcivree (setmelanotide)

Dose: Starting dose 2 mg (0.2 mL) subcutaneously once daily for 2 weeks. Increase to 3 mg once daily if tolerated.
Indications: A melanocortin 4 (MC4) receptor agonist indicated for chronic weight management in adult and pediatric patients 6 years of age and older with obesity due to proopiomelanocortin (POMC), proprotein convertase subtilisin/kexin type 1 (PCSK1), or leptin receptor (LEPR) deficiency confirmed by genetic testing demonstrating variants in POMC, PCSK1, or LEPR genes that are interpreted as pathogenic, likely pathogenic, or of uncertain significance.
References: https://rarediseases.info.nih.gov/diseases/10823/proopiomelanocortindeficiency
*** First treatment for weight management for people with certain rare genetic conditions: proopiomelanocortin (POMC), proprotein convertase subtilisin/kexin type 1 (PCSK1), or leptin receptor (LEPR) deficiency**

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
Imiquimod Cream USP, 3.75%	Taro Pharmaceutical Industries Limited	Zyclara (Imiquimod) Cream, 3.75%	1/26/2021	For the topical treatment of clinically typical, visible or palpable actinic k eratoses of the full face or balding scalp in immunocompetent adults; for the topical treatment of external genital and perianal warts/condyloma acuminata in patients 12 years or older
Argatroban Injection, 50 mg/50 mL (1 mg/mL) Single-Dose Vial	Caplin Steriles Limited	Argatroban Injection, 50 mg/50 mL (1 mg/mL) Single-Dose Vial	1/21/2021	For the prophylaxis or treatment of thrombosis in adult patients with heparin-induced thrombocytopenia; as an anticoagulant in adults patients with or at risk for HIT undergoing percutaneous coronary intervention
Epoprostenol for Injection, 0.5 mg/Vial and 1.5 mg/Vial	Sun Pharmaceutical Industries Limited	Veletri (Epoprostenol for Injection), 0.5 mg/Vial and 1.5 mg/Vial	1/15/2021	For the treatment of pulmonary arterial hypertension (WHO Group 1) to improve exercise capacity
Ferumoxytol Injection, 510 mg Iron/17 mL (30 mg/mL) Single-Dose Vials	Sandoz Inc.	Feraheme (Ferumoxytol) Injection, 510 mg Iron/17 mL(30 mg/mL) Single-Dose Vials	1/15/2021	For the treatment of iron deficiency anemia in adult patients who: have intolerance to oral iron or have had unsatisfactory response to oral iron; or who have chronic kidney disease
Levothyroxine Sodium Capsules, 88 mcg, 100 mcg, and 125 mcg	Teva Pharmaceuticals USA, Inc.	Tirosint (Levothyroxine Sodium) Capsules, 88 mcg, 100 mcg, and 125 mcg	1/6/2021	For adults and pediatric patients 6 years and older with hypothyroidism
Efinaconazole Topical Solution, 10%	Perrigo Pharma International DAC and Teva Pharmaceuticals USA, Inc.	Jublia (Efinaconazole) Topical Solution, 10%	12/16/2020	For the topical treatment of onychomycosis of the toenail(s) due to Trichophyton rubrum and Trichophyton mentagrophytes
Asenapine Sublingual Tablets, 2.5, 5 mg and 10 mg	Sigmapharm Laboratories, LLC, Alembic Pharmaceuticals Limited and Breckenridge Pharmaceutical, Inc.	Saphris (Asenapine) Sublingual Tablets, 5 mg and 10 mg	12/10/2020	For the treatment of schizophrenia in adults and bipolar I disorder

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

Enoxaparin Sodium injection

Brand/Manufacturer: Apotex Corp.
Recall reason: Apotex Corp voluntarily recalled two (2) batches of Enoxaparin Sodium Injection, USP to consumer level due to a packaging error resulting in some syringes barrels containing 150 mg/mL markings (corresponding to 120 mg/0.8mL strength) instead of 100 mg/mL markings (corresponding to 100 mg/mL strength) on the syringe barrel and vice versa. The packaging error was discovered during a customer complaint investigation. To date, Apotex has not received any reports of adverse events related to use of these two batches.
Date of recall: 02/03/2021

Cisatracurium Besylate injection

Brand/Manufacturer: Meitheal Pharmaceuticals
Recall reason: Voluntary recall of one (1) lot of Cisatracurium Besylate Injection, USP 10mg per 5mL to the user level. The decision to recall the product was made after a product complaint revealed that a portion of Lot C11507A of cartons labeled as Cisatracurium Besylate Injection, USP 10mg per 5mL, containing 10-vials per carton, contained 10-vials mis-labeled as Phenylephrine Hydrochloride Injection, USP 100mg per 10mL. To date, Meitheal has not received reports of any adverse events or identifiable safety concerns attributed to the lot.
Date of recall: 01/27/2021

Metformin HCL Extended Release 750 mg

Brand/Manufacturer: Nostrum Laboratories
Recall Reason: Voluntary recall of one lot of Metformin HCl Extended-Release Tablets, USP 750 mg (generic equivalent to Glucophage Tablets) to the consumer level. The Metformin HCl Extended-Release Tablets, USP 750 mg (generic equivalent to Glucophage Tablets) have been found to contain levels of nitrosamine impurities above the ADI limit of 96 ng/day as published in the FDA Guidance Document issued September, 2020. This is an expansion of the recall initially announced on November 2, 2020.
Date of Recall: 01/04/2021

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/Vaccinecandidate-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-therapeuticbiological-products/novel-drug-approvals-2020
- https://www.fda.gov/drugs/drug-and-biologic-approval-and-ind-activity-reports/first-generic-drugapprovals
- https://clinicaltrials.gov
- https://www.fda.gov/drugs/new-drugs-fda-cders-new-molecular-entities-and-new-therapeuticbiological-products/new-drug-therapy-approvals-2020
- https://www.fda.gov/news-events/press-announcements/fda-issues-emergency-use-authorizationthird-covid-19-vaccine

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