MC-Rx

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Insights on the Drugs Pipeline

Exploring the changes in the drugs market.

June 2024

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

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Last Updated May 23, 2024.

Update: New CMS Guidance Confirms Medicare Part D Plans Can Cover Anti-Obesity Medications That Have Medically-Accepted Indications

On March 20, 2024, the Centers for Medicare and Medicaid Services (CMS) issued new guidance to Medicare Part D plans stating that coverage can be provided for FDA-approved anti-obesity medications (AOMs) that receive approval for additional medically-accepted indication(s), such as reducing the incidence of major adverse cardiovascular events (MACEs). The guidance clarified that Part D programs are still prohibited from providing coverage of these drugs for weight loss alone, in the absence of a medically-accepted indication.

However, there are active congressional efforts to overturn this prohibition and broaden Medicare coverage to include treatments for weight loss, such as the Treat and Reduce Obesity Act of 2023. Also on March 20, 2024, the Congressional Budget Office (CBO) presented its analysis on Medicare coverage of AOMs. The analysis concluded that, at current prices, AOMs would cost the federal government more than it would save from reducing other healthcare spending; thus, Medicare coverage of AOMs would lead to an overall increase in the federal deficit over the next 10 years. However, the analysis acknowledges that future prices of AOMs and the long-term effects on the use of other healthcare products and services, could change the budgetary effect in the future. Specifically, CBO expects semaglutide to be selected for Medicare drug price negotiations within the next few years. At the time of this publication, the new guidance applies solely to Novo Nordisk’s Wegovy (semaglutide), which was initially approved in June 2021 for weight loss, but recently received an expanded indication to reduce the risk of MACEs in adults with established cardiovascular disease (CVD) and who are either obese or overweight.

The Phase 3 SELECT trial showed Wegovy decreased the incidence of MACEs by 20% versus placebo when added to standard care. However, Wegovy, Eli Lilly’s Zepbound (tirzepatide), and other pipeline AOMs are actively being studied in other indications that may be considered a medically accepted indication. The ongoing cardiovascular outcomes trial of Zepbound (SURMOUNT-MMO) is evaluating both secondary prevention and primary prevention in patients with no history of CVD. If the trial finds benefit in primary prevention and FDA approves an expanded indication, this will greatly increase the eligible population. SURMOUNT-MMO is expected to complete in October 2027, making label expansion possible in 2028.

For Part D plans that intend to provide coverage of Wegovy for the MACE reduction indication, MC-Rx recommends prior authorization with criteria requiring a confirmation of established CVD, in addition to body mass index (BMI) minimums from the trial (27 kg/m2). The SELECT trial defined established CVD as prior nonfatal myocardial infarction or stroke (ischemic or hemorrhagic), or symptomatic peripheral arterial disease. Limiting coverage to overweight or obese patients within this secondary prevention population will significantly reduce payer financial impact. MC-Rx will continue to update as more information becomes available.

References:

1. IPD Analytics | The Industry Leader in Drug Life-Cycle Insights Accessed: www.ipdanalytics.com

Last Updated May 23, 2024.

Specialty Pipeline

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

Generic Name (Brand Name - Manufacturer)	Current Status	Anticipated Approval	What is this drug being developed for?
Acoramidis (BridgeBio Pharma)	NDA Filed	11/29/2024	transthyretin (TTR) stabilizer for the treatment of patients with symptomatic transthyretin amyloidosis (ATTR) cardiomyopathy; oral
arimoclomol (Zevra Therapeutics)	NDA Filed	9/21/2024	Molecular chaperone activator that stimulates the normal cellular protein repair pathway for the treatment of Niemann-Pick Disease Type C (NPC); oral
concizumab (Novo Nordisk)	Complete Response	2024	A humanized monoclonal antibody against tissue factor pathway inhibitor (TFPI) for the prevention and treatment of bleeding in patients with haemophilia A and B with inhibitors; subcutaneous therapy.
crovalimab (Genentech)	BLA Filed	7/27/2024	C5 inhibitor for the treatment of paroxysmal nocturnal hemoglobinuria; SC injection
donanemab (Eli Lilly)	BLA Filed	2024	antibody that targets a modified form of beta amyloid called N3pG for the treatment of patients with early symptomatic Alzheimer's disease; IV infusion
eladocagene exuparvovec (Upstaza - PTC Therapeutics)	BLA Filed	3/19/2025	Recombinant, adeno-associated virus, containing the human cDNA encoding the AADC enzyme for the treatment of AADC deficiency; intracerebral infusion
garadacimab - CSL Behring	BLA Filed	Jun-July 2024	fully human recombinant FXIIa antagonist monoclonal antibody for the prevention and treatment of hereditary angioedema (HAE); SC
lebrikizumab (Eli Lilly)	Complete Response	2024	Humanized monoclonal antibody targeting interleukin 13 (IL13) for the treatment of atopic dermatitis; SC
marstacimab (Pfizer)	BLA Filed	2024	anti-tissue factor pathway inhibitor (anti-TFPI) to prevent bleeds in patients with hemophilia A or hemophilia B without inhibitors to Factor VIII (FVIII) or Factor IX (FIX); SC (once weekly)
odronextamab (Regeneron)	Complete Response	2025	CD20xCD3 bispecific antibody for the treatment of relapsed or refractory (R/R) B-cell non-Hodgkin lymphoma (B-NHL); IV infusion

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Specialty Pipeline

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Generic Name (Brand Name - Manufacturer)	Current Status	Anticipated Approval	What is this drug being developed for?
olezarsen (Ionis Pharmaceuticals)	Phase 3	2024	Antisense drug that targets the ApoC-III protein to reduce serum triglycerides for the treatment of familial chylomicronemia syndrome (FCS); SC (weekly)
revumenib (Syndax Pharmaceuticals)	NDA Filed	9/26/2024	menin inhibitor for the treatment of adult and pediatric patients with relapsed or refractory (R/R) acute leukemia harboring a KMT2A rearrangement (KMT2Ar); oral
seladelpar (Gilead)	NDA Filed	8/14/2024	selective peroxisome proliferator-activated receptor delta (PPARδ) agonist under development for the treatment of primary biliary cholangitis; oral
vanzacaftor/tezacaftor/deutivacaftor (vanza triple; vanza triple; VX-121/VX-661/VX-561 - Vertex)	Phase 3	2025	triple combination for the treatment of patients with cystic fibrosis (CF) heterozygous for F508del and a minimal function mutation (F/MF); oral

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Biosimilar Pipeline

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

Product Name / Investigational Name	Manufacturer(s)	Reference Biological	Possible FDA approval date	Potential launch date
aflibercept biosimilar	Coherus Biosciences	Eylea (aflibercept)	6/29/2024	TBD (2024-2032)
insulin glargine biosimilar (Basalin)	Sandoz/Gan & Lee	Lantus (insulin glargine)	6/30/2024	TBD (Pending FDA Approval)
insulin aspart biosimilar	Sandoz/Gan & Lee	Novolog (insulin aspart)	H1:2024	TBD (Pending FDA Approval)
insulin lispro biosimilar (Prandilin)	Sandoz/Gan & Lee	Humalog (insulin lispro)	H1:2024	TBD (Pending FDA Approval)
rituximab biosimilar	Dr. Reddy's/Fresenius	Rituxan (rituximab)	Q2:2024	TBD (Pending FDA Approval)
aflibercept biosimilar (	Celltrion	Eylea (aflibercept)	Q2:2024	TBD (2024-2032)
ustekinumab biosimilar	Celltrion	Stelara (ustekinumab)	6/30/2024	Settlement: Mar. 7, 2025
eculizumab biosimilar	Amgen/Daiichi Sankyo	Soliris (eculizumab)	H1:2024	Settlement: March 1, 2025
eculizumab biosimilar (Epysqli)	Merck/Samsung Bioepis	Soliris (eculizumab)	H1:2024	TBD
denosumab biosimilar	Celltrion	Prolia (denosumab)	9/30/2024	TBD (Feb 2025?)
aflibercept biosimilar	Amgen	Eylea (aflibercept)	Q3:2024	TBD (2024-2032)
ustekinumab biosimilar	Accord /Intas	Stelara (ustekinumab)	11/4/2024	TBD
aflibercept biosimilar (Yesafili)	Momenta/Biocon	Eylea (aflibercept)	2024	TBD (2024-2032)
filgrastim biosimilar	Tanvex BioPharma	Neupogen (filgrastim)	2024	TBD (Pending FDA Approval)
bevacizumab biosimilar (Equidacent)	Centus	Avastin (bevacizumab)	2024	TBD (Pending FDA Approval)

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Biosimilar Pipeline

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

Product Name / Investigational Name	Manufacturer(s)	Reference Biological	Possible FDA approval date	Potential launch date
bevacizumab biosimilar (Aybintio)	Samsung Bioepis/ Organon	Avastin (bevacizumab)	2024	TBD (Pending FDA Approval)
pegfilgrastim biosimilar (Lupifil-P)	Lupin	Neulasta (pegfilgrastim)	2024-2025	TBD (Pending FDA Approval)
bevacizumab biosimilar (Abevmy)	Biocon	Avastin (bevacizumab)	2024	TBD (Pending FDA Approval)
trastuzumab biosimilar	Tanvex BioPharma	Herceptin (trastuzumab)	2024	TBD (Pending FDA Approval)
ranibizumab biosimilar (Xlucane)	Xbrane Biopharma	Lucentis (ranibizumab)	2025	TBD (upon approval?)

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New Drug Entities

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

New Drug Entities	Details
Lifileucel (Amtagvi)	**Dosage form:** suspension for intravenous infusion. Amtagvi is manufactured using tumor-infiltrating leukocyte (TIL) cells that are collected from a patient's tumor tissue, treated in culture, and then infused back to the patient following lymphodepletion. **Indication:** Accelerated approval: a tumor-derived autologous T cell immunotherapy, for adult patients with unresectable or metastatic melanoma previously treated with a PD-1 blocking antibody, and if BRAF V600 positive, a BRAF inhibitor with or without a MEK inhibitor. **Comparables:** None. **Guidelines:** • NCCN Guidelines by Cancer Type (2024). https://www.nccn.org/guidelines
Cefepime and enmetazobactam (Exblifep)	**Dosage form:** 2.5 grams (cefepime and enmetazobactam) for injection, is supplied as a sterile powder for reconstitution in single-dose vials containing 2 grams cefepime and 0.5 grams enmetazobactam. **Indication:** Is a combination of cefepime, a cephalosporin antibacterial, and enmetazobactam, a beta-lactamase inhibitor, indicated for the treatment of patients 18 years and older with complicated urinary tract infections (cUTI) including pyelonephritis caused by designated susceptible microorganisms. **Guidelines:** • Infectious Diseases Society of America (IDSA) Practice Guidelines
Denosumab-bbdz (Jubbonti) is biosimilar* to PROLIA® (denosumab)	**Dosage form:** Injection: Single-dose prefilled syringe containing 60 mg in a 1 mL solution. **Indication:** Is a RANK ligand (RANKL) inhibitor indicated for: • Treatment of postmenopausal women with osteoporosis at high risk for fracture. • Treatment to increase bone mass in men with osteoporosis at high risk for fracture. • Treatment of glucocorticoid-induced osteoporosis in men and women at high risk for fracture. • Treatment to increase bone mass in men at high risk for fracture receiving androgen deprivation therapy for nonmetastatic prostate cancer. • Treatment to increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer. **Guideline:** • 2022 The Clinician's Guide to Prevention and Treatment of Osteoporosis

Last Updated May 23, 2024.

New Drug Entities

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

New Drug Entities	Details
Denosumab-bbdz (Wyost) is biosimilar* to XGEVA® (denosumab)	**Dosage form:** For subcutaneous use is interchangeable with US-licensed Xgeva (denosumab) injection, 120 mg/1.7 mL (70 mg/mL) single-dose vial for subcutaneous use. Injection: 120 mg/1.7 mL (70 mg/mL) solution in a single-dose vial. **Indication:** Is a RANK ligand (RANKL) inhibitor indicated for: • Prevention of skeletal-related events in patients with multiple myeloma and in patients with bone metastases from solid tumors. • Treatment of adults and skeletally mature adolescents with giant cell tumor of bone that is unresectable or where surgical resection is likely to result in severe morbidity. • Treatment of hypercalcemia of malignancy refractory to bisphosphonate therapy. **Guideline:** • NCCN Guidelines by Cancer Type (2024)
Tislelizumab-jsgr (Tevimbra)	**Dosage form:** Injection, for intravenous use 100 mg/10mL **Indication:** is a programmed death receptor-1 (PD-1) blocking antibody indicated for the treatment of adult patients with unresectable or metastatic esophageal squamous cell carcinoma (ESCC) after prior systemic chemotherapy that did not include a PD-(L)1 inhibitor **Comparables:** Yervoy® (ipilimumab), Opdivo® (nivolumab), Vitrakvi® (larotrectinib) capsules **Guidelines:** • NCCN Guidelines by Cancer Type (2024). https://www.nccn.org/guidelines
Resmetirom (Rezdiffra)	**Dosage form:** Tablets: 60 mg, 80 mg, and 100 mg. **Indication:** is a thyroid hormone receptor-beta (THR-beta) agonist indicated in conjunction with diet and exercise for the treatment of adults with noncirrhotic nonalcoholic steatohepatitis (NASH) with moderate to advanced liver fibrosis (consistent with stages F2 to F3 fibrosis). **Comparables:** None. **Guidelines:** • 2023 AASLD Practice Guidance on the clinical assessment and management of nonalcoholic fatty liver disease

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New Drug Entities

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New Drug Entities	Details
Aprocitentan (Tryvio)	**Dosage form:** Tablets: 12.5 mg Indication: Is an endothelin receptor antagonist indicated for the treatment of hypertension in combination with other antihypertensive drugs, to lower blood pressure in adult patients who are not adequately controlled on other drugs. Lowering blood pressure reduces the risk of fatal and non-fatal cardiovascular events, primarily strokes and myocardial infarctions. **Guidelines:** • US Preventive Services Task Force (USPSTF): Final recommendation statement on hypertension in adults – Screening (2021) • American College of Cardiology (ACC)/American Heart Association (AHA): Guideline on the primary prevention of cardiovascular disease (2019) • ACC/AHA/American Academy of Physician Assistants (AAPA)/Association of Black Cardiologists (ABC)/American College of Preventive Medicine (ACPM)/American Geriatrics Society (AGS)/American Pharmacists Association (APhA)/American Society of Hypertension (ASH)/American Society for Preventive Cardiology (ASPC)/National Medical Association (NMA)/Preventive Cardiovascular Nurses Association (PCNA): Guideline for the prevention, detection, evaluation, and management of high blood pressure in adults (2017)
Givinostat (Duvyzat)	**Dosage form:** Oral suspension: 8.86 mg/mL givinostat. **Indication:** PRIORITY; Orphan, is a histone deacetylase inhibitor indicated for the treatment of Duchenne muscular dystrophy (DMD) in patients 6 years of age and older. **Comparables:** Elevidys, Exondys 51 (eteplirsen), Vyondys 53 (golodirsen), Amondys 45 (casimersen), Viltepso® (viltolarsen), Emflaza™ (deflazacort) **Guidelines:** • American Academy of Neurology (AAN): Practice guideline update summary – Corticosteroid treatment of Duchenne muscular dystrophy (2016, reaffirmed 2022)
Vadadustat (Vafseo)	**Dosage form:** Tablets: 150 mg, 300 mg and 450 mg. **Indication:** Is a hypoxia-inducible factor prolyl hydroxylase (HIF PH) inhibitor indicated for the treatment of anemia due to chronic kidney disease (CKD) in adults who have been receiving dialysis for at least three months. **Comparables:** Jesduvroq (daprodustat) **Guidelines:** • 2019 US Department of Veterans Affairs (VA)/Department of Defense (DoD): Clinical practice guideline for the management of chronic kidney disease (CKD) • 2012 KDOQI: Clinical practice guideline for diabetes and CKD, update

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New Drug Entities

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New Drug Entities	Details
Ceftobiprole medocaril sodium (Zevtera)	**Dosage form:** For injection: 667 mg of ceftobiprole medocaril sodium (equivalent to 500 mg of ceftobiprole) as a lyophilized powder for reconstitution in a single-dose vial. **Indication:** Priority: is a cephalosporin antibacterial indicated for the treatment of: Adult patients with Staphylococcus aureus bloodstream infections (bacteremia) (SAB), including those with right-sided infective endocarditis, Adult patients with acute bacterial skin and skin structure infections (ABSSSI), and Adult and pediatric patients (3 months to less than 18 years old) with community-acquired bacterial pneumonia (CABP). **Guidelines:** • Infectious Diseases Society of America (IDSA) Practice Guidelines
Ustekinumab-aekn (Selarsdi)	**Dosage form:** Subcutaneous Injection: 45 mg/0.5 mL or 90 mg/mL solution in a single-dose prefilled syringe. **Indication:** Is a human interleukin-12 and -23 antagonist indicated for the treatment of: Adult patients with: • moderate to severe plaque psoriasis (PsO) who are candidates for phototherapy or systemic therapy. • active psoriatic arthritis (PsA). Pediatric patients 6 years and older with: • moderate to severe plaque psoriasis, who are candidates for phototherapy or systemic therapy. • active psoriatic arthritis (PsA). **Comparables:** Stelara, biosimilars **Guidelines:** • 2021 Group for Research and Assessment of Psoriasis and Psoriatic Arthritis (GRAPPA): updated treatment recommendations for psoriatic arthritis • 2020 Joint American Academy of Dermatology National Psoriasis Foundation guidelines of care for the management of psoriasis with systemic non-biologic therapies • 2019 Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics • 2019 Joint American Academy of Dermatology National Psoriasis Foundation guidelines of care for the management and treatment of psoriasis in pediatric patients

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New Drug Entities

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New Drug Entities	Details
Atidarsagene autotemcel (Lenmeldy)	**Dosage form:** intravenous infusion **Indication:** Is an autologous hematopoietic stem cell-based gene therapy indicated for the treatment of children with pre-symptomatic late infantile (PSLI), pre-symptomatic early juvenile (PSEJ) or early symptomatic early juvenile (ESEJ) metachromatic leukodystrophy (MLD). **Comparables:** Current treatment for MLD centers on relieving symptoms. No other drug is indicated to treat the underlying cause. **Guidelines:** • National Organization of Rare Disorders: Metachromatic Leukodystrophy
ANKTIVA® (nogapendekin alfa inbakicept-pmln)	**Dosage form:** For Intravesical Use Only **Indication:** is an interleukin-15 (IL-15) receptor agonist indicated with Bacillus Calmette-Guérin (BCG) for the treatment of adult patients with BCG unresponsive nonmuscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) with or without papillary tumors. **Guidelines:** • NCCN Guidelines by Cancer Type (2024). https://www.nccn.org/guidelines

Last Updated May 23, 2024.

New Drug Formulations

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

New Drug Formulations	Details
Acetylcysteine (Legubeti)	**New Dosage form:** Oral solution: 500 mg base/packet, 2.5 gm base/packet **Indication:** Is indicated as an antidote to prevent or lessen hepatic injury, which may occur following the ingestion of a potentially hepatotoxic quantity of acetaminophen, in adults and pediatric patients. It is essential to initiate treatment as soon as possible after the overdose and, in any case, within 24 hours of acetaminophen ingestion. 1.**Comparables:** IV Acetylcysteine **Guidelines:** • 2023 America's Poison Centers, AACT, American College of Medical Toxicology (ACMT), and Canadian Association of Poison Control Centers (CAPCC): Management of acetaminophen poisoning in the US and Canada – A consensus statement
Iloprost (Aurlumyn)	**New Dosage form:** Injection: 100 mcg per mL in a single dose vial. **Indication:** "PRIORITY; Orphan. Is a prostacyclin mimetic indicated for the treatment of severe frostbite in adults to reduce the risk of digit amputations. Effectiveness was established in young, healthy adults who suffered frostbite at high altitudes." **Comparables:** None. **Guidelines:** • Wilderness Medical Society (WMS): Clinical practice guidelines for prevention and management of avalanche and non-avalanche snow burial accidents, update (2024) • WMS: Clinical practice guidelines for the prevention and treatment of frostbite, update (2019)
Rilpivirine (Edurant Ped)	**New Dosage form:** NDF: 2.5 mg tablet, for oral suspension. Other dosage: 25 mg tablets. **Indication:** "Provides for the use of Edurant PED in combination with other antiretroviral agents for the treatment of HIV-1 infection in treatment naïve pediatric patients with HIV-1 RNA less than or equal to 100,000 copies/mL who are 2 years of age and older and weigh at least 14 kg to less than 25 kg. **Guidelines:** • 2024 Guidelines for the Use of Antiretroviral Agents in Pediatric HIV Infection

Last Updated May 23, 2024.

New Drug Formulations

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

New Drug Formulations	Details
Risperidone (Risvan)	**New Dosage form:** For extended-release injectable suspension: 75 mg and 100 mg risperidone. **Indication:** Is an atypical antipsychotic indicated for the treatment of schizophrenia in adults. **Comparables:** Risperidone **Guidelines:** • 2020 The American Psychiatric Association Practice Guideline For The Treatment Of Patients With Schizophrenia, Third Edition
Hydroxyurea (Xxromi)	**New Dosage form:** Oral Solution: 100 mg/mL in a 150 mL multiple-dose bottle. **Indication:** PRIORITY; Orphan, Is an antimetabolite indicated to reduce the frequency of painful crises and reduce the need for blood transfusions in pediatric patients aged 6 months of age to less than 2 years with sickle cell anemia with recurrent moderate to severe painful crises. **Comparables:** Droxia; Hydrea; Siklos **Guidelines:** • American Society of Hematology (ASH): Guidelines for sickle cell disease – Stem cell transplantation (2021) • ASH: Guidelines for sickle cell disease – Management of acute and chronic pain (2020) • ASH: Guidelines for sickle cell disease – Prevention, diagnosis, and treatment of cerebrovascular disease in children and adults (2020) • ASH: Guidelines for sickle cell disease – Transfusion support (2020) • ASH: Guidelines for sickle cell disease – Cardiopulmonary and kidney disease (2019) • American Thoracic Society (ATS): An official clinical practice guideline on home oxygen therapy for children (2019)
Sacubitril/valsartan (Entresto Sprinkle) oral pellets NDF & NI	**New Dosage form:** Film-coated oral pellets within capsules: 6 mg/6 mg; 15 mg/16 mg. **New Patient Population:** Indicated for the treatment of symptomatic heart failure with systemic left ventricular systolic dysfunction in pediatric patients aged 1 year and older. **Comparables:** Entresto tablets **Guidelines:** • 2022 AHA/ACC/HFSA Guideline for the Management of Heart Failure: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines

Last Updated May 23, 2024.

New Indications

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

New Indications	Details
Baloxavir marboxil (Xofluza)	New Patient Population: Expand the patient population to include the treatment of pediatric patients between the ages of 5 to <12 years old with acute uncomplicated influenza who are at high risk of developing influenza-related complications.
Amivantamab-vmjw (Rybrevant)	A new indication of amivantamab in combination with carboplatin and pemetrexed for the first-line treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 20 insertion mutations, as detected by an FDA-approved test.
Nivolumab (Opdivo)	In combination with cisplatin and gemcitabine for first-line treatment of adult patients with unresectable or metastatic urothelial carcinoma (UC).
Inotuzumab ozogamicin (Besponsa)	A is a CD22-directed antibody and cytotoxic drug conjugate indicated for the treatment of relapsed or refractory CD22-positive B-cell precursor acute lymphoblastic leukemia (ALL) in adult and pediatric patients 1 year and older.
Zanubrutinib (Brukinsa)	For the treatment of adult patients with relapsed or refractory follicular lymphoma (FL), in combination with obinutuzumab, after two or more lines of systemic therapy.
Talazoparib (Talzenna)	For the treatment of adult patients with deleterious or suspected deleterious germline BRCA-mutated (gBRCAm) HER2-negative locally advanced or metastatic breast cancer and in combination with enzalutamide for the treatment of adult patients with HRR gene mutated metastatic castration-resistant prostate cancer.
Semaglutide (Wegovy)	Is indicated in combination with a reduced calorie diet and increased physical activity to reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) in adults with established cardiovascular disease and either obesity or overweight.
Alirocumab (Praluent)	As an adjunct to diet and other LDL-C-lowering therapies in pediatric patients aged 8 years and older with HeFH to reduce LDL-C.
Lisocabtagene maraleucel (Breyanzi)	The first CAR-T cell therapy to gain the FDA's Accelerated Approval for treating adults who have relapsed or refractory chronic lymphocytic leukemia (r/rCLL) or small lymphocytic lymphoma (r/rSLL).
Fluticasone propionate (Xhance)	For the new indication of chronic rhinosinusitis without nasal polyps (CRSsNP) in adults.
Spesolimab-sbzo (Spevigo)	For the treatment of generalized pustular psoriasis (GPP) in adults and pediatric patients 12 years of age and older and weighing at least 40 kg.

Last Updated May 23, 2024.

New Indications

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New Indications	Details
Bempedoic acid (Nexletol)	Indicated to reduce the risk of myocardial infarction and coronary revascularization in adults who are unable to take recommended statin therapy (including those not taking a statin) with: • established cardiovascular disease (CVD), or • a high risk for a CVD event but without established CVD.
Bempedoic acid and ezetimibe (Nexlizet)	To reduce the risk of myocardial infarction and coronary revascularization in adults who are unable to take recommended statin therapy (including those not taking a statin) with: • established cardiovascular disease (CVD), or • a high risk for a CVD event but without established CVD.
Tenofovir alafenamide (Vemlidy)	New Patient Population: To update labeling to support the use of Vemlidy for the treatment of chronic hepatitis B virus (HBV) infection in pediatric patients 6 to less than 12 years of age and weighing at least 25 kg.
Iloperidone (Fanapt)	Indication for acute treatment of manic or mixed episodes associated with bipolar I disorder in adults.
Dolutegravir and lamivudine (Dovato)	Indicated as a complete regimen for the treatment of HIV1 infection in adults and adolescents 12 years of age and older and weighing at least 25 kg with no antiretroviral treatment history or to replace the current antiretroviral regimen in those who are virologically suppressed (HIV-1 RNA less than 50 copies/mL) on a stable antiretroviral regimen with no history of treatment failure and no known substitutions associated with resistance to the individual components of DOVATO.
Fam-trastuzumab deruxtecan-nxki (Enhertu)	Adult patients with unresectable or metastatic HER2-positive (IHC 3+) solid tumors who have received prior systemic treatment and have no satisfactory alternative treatment options. Accelerated approval.
Vedolizumab (Entyvio)	Sub Q formulation gained new indication for Crohn's disease. Recommended Dosage changes for the treatment of adults with moderately to severely active Crohn's disease.
Mirvetuximab soravtansine-gynx (Elahere)	Folate receptor alpha (FRα)-directed antibody and microtubule inhibitor conjugate indicated for the treatment of adult patients with FRα positive, platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer, who have received one to three prior systemic treatment regimens. Select patients for therapy based on an FDA-approved test. Accelerated approval.
Alectinib (Alecensa)	Provides for the following new indication for Alecensa capsules: adjuvant treatment in adult patients following tumor resection of anaplastic lymphoma kinase (ALK)-positive non-small cell lung cancer (NSCLC) (tumors ≥ 4 cm or node positive), as detected by an FDA-approved test.

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New Indications

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New Indications	Details
Influenza Vaccine (Flucelvax)	To include a trivalent influenza vaccine formulation FLUCELVAX for use in individuals 6 months of age and older.
Ponatinib (Iclusig)	For the treatment of adult patients with newly diagnosed Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ ALL) in combination with chemotherapy.
Coagulation Factor IX (Recombinant) (Ixinity)	To expand the label to include pediatric patients <12 years of age for the treatment of Hemophilia B based on the data derived from the PMR study.
Von Willebrand Factor/ Coagulation Factor VIII Complex Human (Wilate)	To include the WIL-30 clinical study data in the Prescribing Information to fulfill PREA requirements for children 1<12 years of age for the treatment of Hemophilia A.
Lutetium Lu 177 dotatate (Lutathera)	New Patient Population: For pediatric patients 12 years and older with somatostatin receptor (SSTR)-positive gastroenteropancreatic neuroendocrine tumors (GEP-NETs), including foregut, midgut, and hindgut neuroendocrine tumors. Lutetium Lu 177 dotatate received approval for this indication for adults in 2018.
Lipid injectable emulsion (Clinolipid)	New Patient Population is indicated in adults and pediatric patients, including term and preterm neonates, as a source of calories and essential fatty acids for parenteral nutrition (PN) when oral or enteral nutrition is not possible, insufficient, or contraindicated.
Apremilast (Otezla)	Indicated for the treatment of: adult patients with plaque psoriasis who are candidates for phototherapy or systemic therapy and; pediatric patients 6 years of age and older and weighing at least 20 kg with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy.
Tisotumab vedotin-tftv (Tivdak)	For recurrent or metastatic cervical cancer with disease progression on or after chemotherapy. Tisotumab vedotin-tftv previously received accelerated approval for this indication.

Last Updated May 23, 2024.

In-Market Brand

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

In-Market-Brands	Details
Budesonide (Eohilia)	**New Dosage form:** Oral suspension 2 mg/10 mL **Indication:** PRIORITY; Orphan. Is a corticosteroid indicated for 12 weeks of treatment in adult and pediatric patients 11 years of age and older with eosinophilic esophagitis (EoE). **Comparables:** other dose forms of budesonide, are used off-label to treat EoE, the only other drug FDA approved to treat it is Dupixent® (dupilumab) subcutaneous (SC) injection **Guidelines:** • 2020 AGA Institute and the Joint Task Force on Allergy-Immunology Practice Parameters Clinical Guidelines for the Management of Eosinophilic Esophagitis
Macitentan and tadalafil (Opsynvi)	**New Dosage form:** One 10 mg/20 mg or 10 mg/40 mg tablet taken orally once daily with or without food. **Indication:** Is a combination of macitentan, an endothelin receptor antagonist (ERA), and tadalafil, a phosphodiesterase 5 (PDE5) inhibitor, indicated for chronic treatment of pulmonary arterial hypertension (PAH, WHO Group I) in adult patients of WHO functional class (FC) II-III. **Comparables:** Opsumit (macitentan), Adcirca (tadalafi)l **Guidelines:** • 2019 Therapy for Pulmonary Arterial Hypertension in Adults: Update of the CHEST Guideline and Expert Panel Report

Last Updated May 23, 2024.

In Market Brand

In-Market-Brands	Details
Adalimumab-ryvk (Simlandi) is biosimilar* to HUMIRA® (adalimumab)	**Dosage form:** Injection: 40 mg/0.4 mL single-dose autoinjector. **Indication:** "Is a tumor necrosis factor (TNF) blocker indicated for: • Rheumatoid Arthritis (RA): Reducing signs and symptoms, inducing major clinical response, inhibiting the progression of structural damage, and improving physical function in adult patients with moderately to severely active RA. • Juvenile Idiopathic Arthritis (JIA): Reducing signs and symptoms of moderately to severely active polyarticular JIA in patients 2 years of age and older. • Psoriatic Arthritis (PsA): Reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in adult patients with active PsA. Ankylosing Spondylitis (AS): Reducing signs and symptoms in adult patients with active AS. • Crohn's Disease (CD): Treatment of moderately to severely active Crohn's disease in adults and pediatric patients 6 years of age and older. • Ulcerative Colitis (UC): Treatment of moderately to severely active ulcerative colitis in adult patients. Plaque Psoriasis (Ps): • Treatment of adult patients with moderate to severe chronic plaque psoriasis who are candidates for systemic therapy or phototherapy, and when other systemic therapies are medically less appropriate. • Hidradenitis Suppurativa (HS): treatment of moderate to severe hidradenitis suppurativa in adult patients. • Uveitis (UV): treatment of non-infectious intermediate, posterior, and panuveitis in adult patients. **Guidelines:** • 2021 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis • 2021 Group for Research and Assessment of Psoriasis and Psoriatic Arthritis (GRAPPA): updated treatment recommendations for psoriatic arthritis • 2020 Joint American Academy of Dermatology National Psoriasis Foundation guidelines of care for the management of psoriasis with systemic non-biologic therapies • 2019 Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics • 2019 Joint American Academy of Dermatology National Psoriasis Foundation guidelines of care for the management and treatment of psoriasis in pediatric patients • 2019 Update of the American College of Rheumatology/Spondylitis Association of America: Spondyloarthritis Research and Treatment Network Recommendations for the Treatment of Ankylosing Spondylitis and Nonradiographic Axial Spondyloarthritis

Last Updated May 23, 2024.

In Market Brand

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In-Market-Brands	Details
Tocilizumab-aazg (Tyenne) is biosimilar* to ACTEMRA® (tocilizumab).	**Dosage form:** Intravenous Infusion Injection: 80 mg/4 mL (20 mg/mL), 200 mg/10 mL (20 mg/mL), 400 mg/20 mL (20 mg/mL) in single-dose vials for further dilution prior to intravenous infusion, Subcutaneous Injection Injection: 162 mg/0.9 mL in a single-dose prefilled syringe or single-dose prefilled autoinjectorIndication: Is an interleukin-6 (IL-6) receptor antagonist indicated for treatment of: Rheumatoid Arthritis (RA) **Indication:** Is an interleukin-6 (IL-6) receptor antagonist indicated for treatment of: Rheumatoid Arthritis (RA) • Adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response to one or more Disease-Modifying Anti-Rheumatic Drugs (DMARDs). Giant Cell Arteritis (GCA) • Adult patients with giant cell arteritis. Polyarticular Juvenile Idiopathic Arthritis (PJIA) • Patients 2 years of age and older with active polyarticular juvenile idiopathic arthritis. Systemic Juvenile Idiopathic Arthritis (SJIA) • Patients 2 years of age and older with active systemic juvenile idiopathic arthritis. **Guideline:** • 2021 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis
Sotatercept-csrk (Winrevair)	**Dosage form:** • For injection: 45 mg lyophilized cake or powder in a single-dose vial • For injection: 60 mg lyophilized cake or powder in a single-dose vial **Indication:** Orphan: Is an activin signaling inhibitor indicated for the treatment of adults with pulmonary arterial hypertension (PAH, WHO Group 1) to increase exercise capacity, improve WHO functional class (FC) and reduce the risk of clinical worsening events. **Guidelines:** • 2019 Therapy for Pulmonary Arterial Hypertension in Adults: Update of the CHEST Guideline and Expert Panel Report
Danicopan (Voydeya)	**Dosage form:** Tab Therapy Pack 50 mg & 100 mg. Tab 100 mg **Indication:** is a complement factor D inhibitor indicated as add-on therapy to ravulizumab or eculizumab for the treatment of extravascular hemolysis (EVH) in adults with paroxysmal nocturnal hemoglobinuria (PNH). **Comparables:** Ultomiris, Soliris, Fabhalta, Empaveli **Guidelines:** • Hematol Transfus Cell Ther. 2021 Jul-Sep; 43(3): 341–348.Published online 2020 Jul 6. doi: 10.1016/j.htct.2020.06.006 Consensus statement for diagnosis and treatment of paroxysmal nocturnal haemoglobinuria

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New Generics

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Generic Name	ANDA Applicant	Brand Name	ANDA Approval Date	ANDA Indications
Midostaurin Capsules, 25 mg	Teva Pharmaceuticals Development, Inc	Rydapt (Midostaurin) Capsules	4/29/2024	For the treatment of adult patients with newly diagnosed acute myeloid leukemia (AML) who are FLT3 mutation-positive; for the treatment of adult patients with aggressive systemic mastocytosis, systemic mastocytosis with associated hematological neoplasm, or mast cell leukemia
Deflazacort Oral Suspension, 22.75 mg/mL	Tris Pharma, Inc.	Emflaza (Deflazacort) Oral Suspension	4/25/2024	For the treatment of Duchenne muscular dystrophy (DMD) in patients 5 years of age and older
Deflazacort Tablets, 6 mg, 18 mg, 30 mg, and 36 mg	Aurobindo Pharma Limited	Emflaza (Deflazacort) Tablets	2/9/2024	For the treatment of Duchenne muscular dystrophy (DMD) in patients 5 years of age and older
Eltrombopag for Oral Suspension, 12.5 mg and 25 mg	Annora Pharma Private Limited	Promacta (Eltrombopag) for Oral Suspension	4/18/2024	For the treatment of thrombocytopenia in adult and pediatric patients 1 year and older with persistent or chronic immune thrombocytopenia who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy; for the treatment of thrombocytopenia in patients with chronic hepatitis C to allow the initiation and maintenance of interferon-based therapy; for the treatment of patients with severe aplastic anemia who have had an insufficient response to immunosuppressive therapy
Eribulin Mesylate Injection, 1 mg/2 mL (0.5 mg/mL) Single-dose Vial	Gland Pharma Limited	Halaven (Eribulin Mesylate) Injection	4/5/2024	For the treatment of patients with metastatic breast cancer who have previously received at least two chemotherapeutic regimens for the treatment of metastatic disease; unresectable or metastatic liposarcoma who have received a prior anthracycline-containing regimen

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New Generics

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Generic Name	ANDA Applicant	Brand Name	ANDA Approval Date	ANDA Indications
Valbenazine Capsules, 40 mg, 60 mg, 80 mg	Lupin Limited	Ingrezza (Valbenazine) Capsules	4/5/2024	For the treatment of adults with tardive dyskinesia
Finasteride and Tadalafil Capsules, 5 mg/5 mg	Zydus Worldwide DMCC	Entadfi (Finasteride and Tadalafil) Capsules	3/15/2024	To initiate treatment of the signs and symptoms of benign prostatic hyperplasia (BPH) in men with an enlarged prostate for up to 26 weeks
Ospemifene Tablets, 60 mg	Hetero Labs Limited Unit V	Osphena (Ospemifene) Tablets	2/13/2024	For the treatment of moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy, due to menopause; for the treatment of moderate to severe vaginal dryness, a symptom of vulvar and vaginal atrophy, due to menopause
Cobicistat Tablets, 150 mg	Mylan Laboratories Limited	Tybost (Cobicistat) Tablets	2/4/2024	For the treatment of HIV-1 infection in adults and in pediatric patients
Dronedarone Tablets USP, 400 mg	Lupin Inc.	Multaq (Dronedarone) Tablets	1/31/2024	To reduce the risk of hospitalization for atrial fibrillation (AF) in patients in sinus rhythm with a history of paroxysmal or persistent AF
Pimavanserin Capsules, 34 mg	MSN Laboratories Private Limited	Nuplazid (Pimavanserin) Capsules	1/16/2024	For the treatment of hallucinations and delusions associated with Parkinson's disease psychosis
Pimavanserin Tablets, 10 mg	Zydus Pharmaceuticals (USA) Inc.	Nuplazid (Pimavanserin) Capsules	1/16/2024	For the treatment of hallucinations and delusions associated with Parkinson's disease psychosis
Fidaxomicin Tablets, 200 mg	Actavis Laboratories FL, Inc.	Dificid (Fidaxomicin) Tablets	1/16/2024	For the treatment of C. difficile-associated diarrhea

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New Generics

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Generic Name	ANDA Applicant	Brand Name	ANDA Approval Date	ANDA Indications
Nilotinib Capsules, 50 mg, 150 mg, 200 mg	Apotex, Inc.	Tasigna (Nilotinib) Capsules	1/5/2024	For the treatment of adult and pediatric patients greater than or equal to 1 year of age with newly diagnosed Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) in chronic phase; adult patients with chronic phase (CP) and accelerated phase (AP) Ph+ CML resistant to or intolerant to prior therapy that included imatinib; pediatric patients greater than or equal to 1 year of age with Ph+ CML-CP and CML-AP resistant or intolerant to prior tyrosine-kinase inhibitor therapy

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Recall Notifications

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Date	Drug Name	Reason for Recall	Company name
05/29/2024	Docetaxel Injection, USP	Potential presence of particulate matter	Sagent Pharmaceuticals
05/22/2024	Buprenorphine Hydrochloride Injection Carpuject Units and Labetalol Hydrochloride Injection, USP Carpuject Units	Device & Drug Safety – Potential Packaging Defect	Hospira Inc.
04/23/2024	Sapropterin Dihydrochloride Powder for Oral Solution 100 mg	Decreased Potency	Dr. Reddy's Laboratories Inc
04/01/2024	Atovaquone Oral Suspension, USP 750mg/5mL	Potential Bacillus cereus contamination	AvKARE, LLC
03/28/2024	Methocarbamol Injection, USP 1000 mg/10 mL (100mg/mL) (Single Dose Vial)	Device & Drug Safety – Presence of Particulate Matter	Eugia US LLC
03/27/2024	Vancomycin Hydrochloride for Oral Solution, USP, 250 mg/5mL	Super potent due to bottles being overfilled	Amneal Pharmaceuticals, LLC.
03/12/2024	Treprostinil 20mg/20mL Injection	Potential Presence of Silicone Particulate Matter	Endo International, Par Pharmaceutical
02/26/2024	Eye ointment products	Due to Potential Lack of Sterility Assurance.	Brassica Pharma Pvt. Ltd.
02/02/2024	1% Tolnaftate Athlete's Foot Spray Antifungal Spray Liquid	Presence of benzene	Insight Pharmaceuticals

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Safety Notifications

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December 21, 2023

- FDA announced they continue to investigate counterfeit Ozempic (semaglutide) injection 1 milligram (mg) in the legitimate U.S. drug supply chain and has seized thousands of units of the product. The agency advises wholesalers, retail pharmacies, health care practitioners and patients to check the product they have received and not distribute, use, or sell products labeled with lot number NAR0074 and serial number 430834149057. Some counterfeit products may still be available for purchase.

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Shortages (New)

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Generic name (Brand Name)	Presentation	Posting Date	Related Information
Mefloquine Hydrochloride Tablet	Tablet, 250 mg (NDC 0555-0171-78)	5/14/2024	Estimated recovery August 2024

References:

- FDA Approved Drugs. Food and Drug Administration (FDA). Retrieved from https://www.access.fda.gov/
- FDA: Drug Shortages. https://www.fda.gov/drugs/drug-safety-and-availability/drug-shortages
- FDA: First Generic Drug Approvals. https://www.fda.gov/drugs/drug-and-biologic-approval-and-ind-activity-reports/first-generic-drug-approvals
- FDA: Recalls, Market Withdrawals, & Safety Alerts. https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts

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