Optum Rx®

RxHighlights

April 2023

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New drugs

Drug name manufacturer(s)	Therapeutic category	Indication(s)	Launch information
Abilify Asimtufii® (aripiprazole) extended-release injectable suspension Otsuka, Lundbeck	Atypical antipsychotic	Treatment of schizophrenia in adults and for maintenance monotherapy treatment of bipolar I disorder in adults	May 3, 2023
Liqrev® (sildenafil) oral suspension CMP Pharma	Phosphodiesterase-5 inhibitor	Treatment of pulmonary arterial hypertension (World Health Organization Group I) in adults to improve exercise ability and delay clinical worsening	TBD
Lumryz™ (sodium oxybate)† Avadel	Dopamine receptor agonist	The treatment of cataplexy or excessive daytime sleepiness in adults with narcolepsy	Early June 2023
Lupron Depot-Ped (leuprolide acetate for depot suspension) AbbVie Endocrinology	Gonadotropin-releasing hormone agonist	Treatment of pediatric patients with central precocious puberty	TBD
Omisirge® (omidubicel-onlv)† Gamida Cell	Stem cell therapy	Use in adults and pediatric patients 12 years and older with hematologic malignancies who are planned for umbilical cord blood transplantation following myeloablative conditioning to reduce the time to neutrophil recovery and the incidence of infection	April 27, 2023
Qalsody™ (tofersen)†* Biogen	Antisense oligonucleotide targeting SOD1	Treatment of amyotrophic lateral sclerosis in adults who have a mutation in the superoxide dismutase 1 gene	April 27, 2023

Drug name manufacturer(s)	Therapeutic category	Indication(s)	Launch information
RizaFilm® (rizatriptan) IntelGenx, Gensco	Triptan	Acute treatment of migraine with or without aura in adults and in pediatric patients 12 to 17 years of age weighing 40 kg or more	TBD
Uzedy™ (risperidone) subcutaneous injection Teva Neuroscience	Atypical antipsychotic	Treatment of schizophrenia in adults	May 2023
Vowst™ (fecal microbiota spores, live-brpk)† Seres Therapeutics	Microbiome therapeutic	Prevent the recurrence of *Clostridioides difficile* infection (CDI) in individuals 18 years of age and older following antibacterial treatment for recurrent CDI	May 5, 2023
Zejula® (niraparib) tablets GSK	Poly polymerase inhibitor	Maintenance treatment of adult patients with advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to first-line platinum-based chemotherapy; and deleterious or suspected deleterious germline *BRCA*-mutated recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy	August 2023

*New molecular entity; †Orphan drug; ±New prescription to over-the-counter approval; TBD: To be determined

New generics

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Drug name manufacturer(s)	Generic manufacturer(s)	Strength(s) & dosage form(s)	Therapeutic use	Launch information
Naftin® (naftifine) Sebela	Taro†	2% topical gel	Treatment of interdigital tinea pedis	April 12, 2023
Uceris® (budesonide) Bausch Health	Padagis†±	2 mg rectal foam	Induction of remission in patients with active mild to moderate distal ulcerative colitis	April 28 2023

†A-rated generic manufacturer; 180-days of competitive generic therapy exclusivity.

New authorized brand alternatives

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Drug name manufacturer(s)	Authorized brand alternative manufacturer(s)	Strength(s) & dosage form(s)	Therapeutic use	Launch information
Fleqsuvy® (baclofen) Azurity	Wilshire	5 mg/ mL oral suspension	Treatment of spasticity resulting from multiple sclerosis, particularly for the relief of flexor spasms and concomitant pain, clonus, and muscular rigidity	April 19, 2023

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Indications/Label updates

Drug name manufacturer(s)	Type	Description
Coagadex® (coagulation Factor X [human]) Bio Products Laboratory	Expanded indication	In adults and children with hereditary Factor X deficiency for perioperative management of bleeding in patients with mild, moderate, and severe hereditary Factor X deficiency
COVID-19 bivalent booster vaccines Moderna, Pfizer/BioNTech	Updates	The FDA amended the EUAs of the Moderna COVID-19 bivalent mRNA vaccine and Pfizer/BioNTech COVID-19 bivalent mRNA vaccine to simplify the vaccination schedule. Both bivalent (original and omicron BA.4/BA.5 strains) vaccines are now authorized for active immunization to prevent COVID-19 caused by SARS-CoV-2 in individuals 6 months of age and older. The monovalent Moderna and Pfizer/BioNTech COVID-19 vaccines are no longer authorized for use in the U.S. The FDA authorized the following uses of the Pfizer/BioNTech COVID-19 vaccine, bivalent for individuals 6 months through 4 years of age with certain types of immunocompromise who have previously received three doses : A fourth dose administered at least 1 month following the most recent dose; Additional doses that may be administered at the discretion of the healthcare provider, taking into consideration the individual's clinical circumstances.
Gohibic™ (vilobelimab) InflaRx	New EAU	Treatment of COVID-19 in hospitalized adults when initiated within 48 hours of receiving invasive mechanical ventilation, or extracorporeal membrane oxygenation
Hyqvia® (immune globulin infusion 10% [human] with recombinant human hyaluronidase) Takeda	Expanded Indication	Treatment of primary immunodeficiency in adults and pediatric patients two years of age and older. This includes, but is not limited to, common variable immunodeficiency, X-linked agammaglobulinemia, congenital agammaglobulinemia, Wiskott-Aldrich syndrome, and severe combined immunodeficiencies
Imbruvica® (ibrutinib) Janssen, AbbVie	Indication withdrawals	Janssen and AbbVie announced that they intend to voluntarily withdraw the indications for Imbruvica for the treatment of adult patients with mantle cell lymphoma who have received at least one prior therapy and adult patients with marginal zone lymphoma who require systemic therapy and have received at least one prior anti-CD20-based therapy.

Drug name manufacturer(s)	Type	Description
		This decision was made in consultation with the FDA, consistent with FDA procedural guidance on accelerated approvals.
Keytruda® (pembrolizumab) plus **Padcev®** (enfortumab vedotin-ejfv) Merck, Astellas	New indication	Treatment of adult patients with locally advanced or metastatic urothelial carcinoma who are not eligible for cisplatin-containing chemotherapy
Polivy® (polatuzumab vedotin-piiq) Genentech	New indication	In combination with a rituximab product, cyclophosphamide, doxorubicin and prednisone, for the treatment of adult patients who have previously untreated diffuse large B-cell lymphoma, not otherwise specified or high-grade B-cell lymphoma and who have an International Prognostic Index score of two or greater
Prevnar 20® (pneumococcal 20-valent conjugate vaccine) Pfizer	New indications	Active immunization for the prevention of invasive disease caused by *Streptococcus pneumoniae* (*S. pneumoniae*) serotypes 1, 3, 4, 5, 6A, 6B, 7F, 8, 9V, 10A, 11A, 12F, 14, 15B, 18C, 19A, 19F, 22F, 23F, and 33F in individuals 6 weeks of age and older; or otitis media caused by *S. pneumoniae* serotypes 4, 6B, 9V, 14, 18C, 19F, and 23F in individuals 6 weeks through 5 years of age
Qulipta® (atogepant) AbbVie	Expanded indication	Preventive treatment of migraine in adults
Sogroya® (somapacitan-beco) 10 mg/mL NovoNordisk	Expanded indication, new dosage strength	Treatment of pediatric patients aged 2.5 years and older who have growth failure due to inadequate secretion of endogenous growth hormone The FDA also approved a new dosage strength, 15 mg/1.5 mL (10 mg/mL) in a single-patient-use prefilled pen.
Tepezza® (teprotumumab-trbw) Horizon Therapeutics	Updated indication	Treatment of thyroid eye disease regardless of thyroid eye disease activity or duration
Trikafta® (elexacaftor/tezacaftor/ivacaftor; ivacaftor) Vertex	Expanded indication, new formulation	Treatment of cystic fibrosis in patients aged 2 years and older who have at least one *F508del* mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene or a mutation in the CFTR gene that is responsive based on *in vitro* data

Drug name manufacturer(s)	Type	Description
		The FDA also approved a new oral granule formulation of Trikafta.

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Drug recalls/Withdrawals/Shortages/Discontinuations

Drug name manufacturer(s)	Strength(s) and dosage form(s)	Type	Description
Various drug products Akorn	Various drug products	Recall	Akorn announced a voluntary consumer-level recall of multiple drug products as a result of the company declaring bankruptcy in February 2023 and ceasing all operations. The recall involves over 70 drugs, the majority of which are generics
Fentanyl Teva	100 mcg, 200 mcg, 400 mcg, 600 mcg and 800 mcg buccal tablets	Recall	The FDA announced a consumer level recall of certain lots of Teva's fentanyl buccal tablets because safety updates were omitted in the Product Insert/Medication Guide that are provided with these recalled lots. Fentanyl buccal tablet is indicated for the management of breakthrough pain in cancer patients 18 years of age and older who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain.
FreeStyle Libre® Glucose Monitoring System Readers Abbott	FreeStyle Libre Flash Glucose Monitoring System FreeStyle Libre 14 day Flash Glucose Monitoring System FreeStyle Libre 2 Flash Glucose Monitoring System	Recall	The FDA announced a consumer-level recall of Abbott's FreeStyle Libre, Libre 14 day, and Libre 2 Flash Glucose Management Systems' reader devices, which use rechargeable lithium-ion batteries. The batteries may get extremely hot, spark, or catch on fire if not properly stored, charged, or used with its Abbott provided USB cable and power adapter. The recall does not affect any of the FreeStyle Libre family of sensors. The FreeStyle Libre Glucose Monitoring Systems are intended to provide continuous monitoring of glucose levels.

Drug name manufacturer(s)	Strength(s) and dosage form(s)	Type	Description
Fyremadel® (ganirelix acetate) Sun	250 mcg/0.5 mL injection	Recall	Sun announced a consumer-level recall of one lot of Fyremadel injection because glass particulate was observed in one syringe. Fyremadel injection is indicated for the inhibition of premature luteinizing hormone surges in women undergoing controlled ovarian hyperstimulation.
Makena® (hydroxyprogesterone caproate) AMAG	250 mg/mL single dose vial and 275 mg/1.1 mL auto-injector	Withdrawal	The FDA announced the final decision to withdraw approval of Makena. Makena and its generics are not shown to be effective for reducing the risk of preterm birth in women with singleton pregnancy who have a history of singleton spontaneous preterm birth. Additionally, Makena and its generics have not been shown to be effective for any subgroup of this population, including in women at high risk of preterm birth. The benefits of Makena do not outweigh the risks.

Key guideline/Literature updates

Topic	Reference
American Psychiatric Association – Treatment of Patients with Eating Disorders	*American Journal of Psychiatry*. February 2023
National Institutes of Health – COVID-19 Treatment	*COVID-19 Treatment Guidelines*. April 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Acute Myeloid Leukemia Version - 3.2023	*NCCN Clinical Practice Guidelines in Oncology: Acute Myeloid Leukemia*. April 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Ampullary Adenocarcinoma Version - 1.2023	*NCCN Clinical Practice Guidelines in Oncology: Ampullary Adenocarcinoma*. April 2023

Topic	Reference
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Anal Carcinoma Version - 2.2023	*NCCN Clinical Practice Guidelines in Oncology: Anal Carcinoma*. April 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Bladder Cancer Version - 2.2023	*NCCN Clinical Practice Guidelines in Oncology: Bladder Cancer*. April 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Bone Cancer Version - 3.2023	*NCCN Clinical Practice Guidelines in Oncology: Bone Cancer*. April 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Chronic Myeloid Leukemia Version - 2.2023	*NCCN Clinical Practice Guidelines in Oncology: Chronic Myeloid Leukemia*. April 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Colon Cancer Version - 2.2023	*NCCN Clinical Practice Guidelines in Oncology: Colon Cancer*. April 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Merkel Cell Carcinoma Version - 1.2023	*NCCN Clinical Practice Guidelines in Oncology: Merkel Cell Carcinoma*. April 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Non-Small Cell Lung Cancer Version - 3.2023	*NCCN Clinical Practice Guidelines in Oncology: Non-Small Cell Lung Cancer*. April 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Pediatric Aggressive Mature B-Cell Lymphomas Version - 1.2023	*NCCN Clinical Practice Guidelines in Oncology: Pediatric Aggressive Mature B-Cell Lymphomas*. April 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Rectal Cancer Version - 2.2023	*NCCN Clinical Practice Guidelines in Oncology: Rectal Cancer*. April 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Soft Tissue Sarcoma Version - 2.2023	*NCCN Clinical Practice Guidelines in Oncology: Soft Tissue Sarcoma*. April 2023

Topic	Reference
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Uterine Neoplasms Version - 2.2023	*NCCN Clinical Practice Guidelines in Oncology: Uterine Neoplasms*. April 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Palliative Care Version - 2.2023	*NCCN Clinical Practice Guidelines in Oncology: Palliative Care*. April 2023

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