Pipeline Drugs to Watch Report

Q4 2023

Notable Upcoming Launches

CVS Health®

Specialty

THERAPEUTIC CATEGORY	PRODUCT NAME, ROUTE OF ADMINISTRATION AND MANUFACTURER[1]	PROPOSED INDICATION[1]	PHASE OF STUDY[1]	SELECT AVAILABLE FDA-APPROVED THERAPIES*	COMMENTS
Alzheimer's Disease	**donanemab** intravenous (IV) Eli Lilly	The treatment of early symptomatic Alzheimer's disease	Pending FDA approval 12/15/2023	Aduhelm (aducanumab) IV, Leqembi (lecanemab) IV	Donanemab would provide additional disease-modifying therapy for early Alzheimer's disease. It requires less frequent administration than Leqembi and is more effective than Aduhelm at clearing amyloid plaque. Like Aduhelm and Leqembi, donanemab would require brain MRI prior to, and during, therapy. **Anticipated impact:** Replacement spend, medical benefit
Inflammatory Bowel Disease	**Entyvio** (vedolizumab) subcutaneous (SC) (new formulation) Takeda Pharmaceutical	The treatment of moderate-to-severe ulcerative colitis	Pending FDA approval 10/13/2023	**IV:** Entyvio (vedolizumab), infliximab (Remicade and biosimilar products Avsola, Inflectra, Renflexis), Stelara (ustekinumab) **SC:** adalimumab (e.g., Humira and biosimilars), Simponi (golimumab) Stelara (ustekinumab) **Oral:** Rinvoq (upadacitinib), Xeljanz/Xeljanz XR (tofacitinib), Zeposia (ozanimod)	Entyvio SC would provide an alternative, self-administered option to Entyvio IV, although it is administered more frequently (every 2 weeks SC vs every 8 weeks IV). **Anticipated impact:** Replacement spend, shift from medical benefit
	etrasimod oral Pfizer		Pending FDA approval 10/21/2023		Etrasimod would provide an additional oral option for moderate-to-severe ulcerative colitis. **Anticipated impact:** Replacement spend, pharmacy benefit
	mirikizumab IV & SC Eli Lilly		Pending FDA approval 12/15/2023		Mirikizumab would provide an alternative SC option (following an IV induction period) for patients with moderate-to-severe ulcerative colitis. **Anticipated impact:** Replacement spend, pharmacy benefit

Specialty (continued)

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Muscular Dystrophy	**givinostat** oral Italfarmaco	The treatment of Duchenne muscular dystrophy (DMD), in combination with corticosteroids	Pending FDA approval 12/21/2023	**Exon-Skipping Therapy:** Amondys 45 (casimersen) IV, Exondys 51 (eteplirsen) IV, Viltepso (viltolarsen), Vyondys 53 (golodirsen) IV **Gene Therapy:** Elevidys (delandistrogene moxeparvovec-rokl) IV	Givinostat would provide an additional therapeutic option for DMD with a novel mechanism of action. **Anticipated impact:** Incremental spend, pharmacy benefit
	vamorolone oral Catalyst Pharmaceuticals/ ReveraGen/Santhera Pharmaceuticals	The treatment of DMD	Pending FDA approval 10/26/2023	Emflaza (deflazacort) oral, prednisone oral	Vamorolone would provide an alternative to current corticosteroids. Vamorolone has similar efficacy on motor outcomes as prednisone but causes less impairment in bone growth and height. **Anticipated impact:** Replacement spend, pharmacy benefit
Myasthenia Gravis	**zilucoplan** SC UCB	The treatment of generalized myasthenia gravis in adults who are acetylcholine receptor antibody positive	Pending FDA approval 10/01/2023	**IV:** Soliris (eculizumab), Ultomiris (ravulizumab-cwvz), Vyvgart (efgartigimod alfa) **SC:** Rystiggo (rozanolixizumab-noli) SC infusion, Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc) SC	Zilucoplan would be the first self-administered injectable agent for myasthenia gravis. **Anticipated impact:** Replacement spend, shift to pharmacy benefit
Oncology – Injectable	**lifileucel** IV Iovance Biotherapeutics	The treatment of unresectable or metastatic melanoma in adults who progressed on or after prior PD-1/L1 inhibitor therapy	Pending FDA approval 11/25/2023	**Second-line or later regimens:** Keytruda (pembrolizumab) IV or Opdivo (nivolumab) IV + Yervoy (ipilimumab) IV, Yervoy IV, high-dose Proleukin (aldesleukin) IV Oral combination regimens may be considered for patients with BRAF V600 mutations	Lifileucel is a novel cellular therapy that received Regenerative Medicine Advanced Therapy designation. It would provide a second-line or later therapy for metastatic disease after failure of checkpoint and BRAF/MEK inhibitors, if applicable. **Anticipated impact:** Replacement spend, medical benefit

Specialty (continued)

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Oncology – Oral	**capivasertib** oral AstraZeneca	The treatment of HR-positive, HER2-negative locally advanced or metastatic breast cancer following treatment with an aromatase inhibitor, in combination with fulvestrant	Pending FDA approval 12/12/2023	**Second-line and later options:** exemestane oral, everolimus oral + endocrine therapy, fulvestrant IM +/- CDK4/6 inhibitor oral (Ibrance [palbociclib], Kisqali [ribociclib], Verzenio [abemaciclib]), tamoxifen oral If applicable, targeted therapies can be considered for patients with certain mutations	Capivasertib would provide an additional second-line or later therapy used after progression on an aromatase inhibitor. **Anticipated impact:** Replacement spend, pharmacy benefit
	fruquintinib oral Hutchison MediPharma Limited/Takeda	The treatment of refractory metastatic colorectal cancer	Pending FDA approval 11/30/2023	**IV:** Avastin (bevacizumab), Cyramza (ramucirumab), Erbitux (cetuximab), Vectibix (panitumamb) IV, Zaltrap (ziv-aflibercept) **Oral:** Lonsurf (trifluridine/ tipiracil), Stivarga (regorafenib)	Fruquintinib would provide an additional oral third-line or later therapy option. **Anticipated impact:** Replacement spend, pharmacy benefit
	repotrectinib oral Bristol-Myers Squibb	The treatment of locally advanced or metastatic ROS1-positive non-small cell lung cancer (NSCLC) in patients ages 12 years and older	Pending FDA approval 11/27/2023	Rozlytrek (entrectinib) oral, Xalkori (crizotinib) oral	Repotrectinib was granted Breakthrough Therapy designation and would provide an additional first-line or later line therapy option for ROS1-positive NSCLC. **Anticipated impact:** Replacement spend, pharmacy benefit
	Xtandi (enzalutamide) oral Astellas Pharma/ Pfizer	The treatment of non-metastatic castration-sensitive prostate cancer (also known as non-metastatic hormone-sensitive prostate cancer) with high-risk biochemical recurrence (supplemental indication)	Pending FDA approval 12/23/2023	Androgen deprivation therapy (e.g., Lupron (leuprolide) IM/SC, Zoladex (gosserelin) SC	Xtandi would be the first FDA-approved therapy for non-metastatic castration-sensitive prostate cancer as add-on to pharmacologic or surgical androgen deprivation therapy. **Anticipated impact:** Incremental spend, pharmacy benefit

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Paroxysmal Nocturnal Hemoglobinuria (PNH)	**iptacopan** oral Novartis	The treatment of paroxysmal nocturnal hemoglobinuria (PNH) in adults	Pending FDA approval 12/20/2023	Empaveli (pegcetacoplan) SC, Soliris (eculizumab) IV, Ultomiris (ravulizumab) IV/SC	Iptacopan would be the first oral agent for PNH. It is effective for treatment-naïve patients, as well as those who have had residual anemia after treatment with Soliris or Ultomiris. **Anticipated impact:** Replacement spend, potential shift from medical benefit
Sickle Cell Disease	**exagamglogene autotemcel** IV CRISPR Therapeutics/ Vertex Pharmaceuticals	The treatment of sickle cell disease in patients ages 12 years and older	Pending FDA approval 12/08/2023	Endari (L-glutamine) oral, hydroxyurea (e.g., generic, Droxia, Siklos) oral, Oxbryta (voxelotor) oral HLA-matched sibling allogeneic hematopoietic stem cell transplantation (HSCT)	Exagamglogene autotemcel and lovotibeglogene autotemcel would be the first gene therapies approved for sickle cell disease. They would represent potentially curative options for patients who have severe disease despite treatment with hydroxyurea and do not have a matched donor for HSCT. **Anticipated impact:** Incremental spend, medical benefit
	lovotibeglogene autotemcel IV Bluebird Bio		Pending FDA approval 12/20/2023		
Transthyretin-Mediated Amyloidosis	**eplontersen** SC AstraZeneca/Ionis Pharmaceuticals	The treatment of hereditary transthyretin amyloidosis with polyneuropathy in adults	Pending FDA approval 12/22/2023	Amvuttra (vutrisiran) SC, Onpattro (patisiran) IV, Tegsedi (inotersen) SC	Eplontersen would provide an additional, self-administered, SC option for amyloidosis with polyneuropathy and allows for an every 4-week administration schedule. **Anticipated impact:** Replacement spend, potential shift from medical benefit
	Onpattro (patisiran) IV Alnylam Pharmaceuticals	The treatment of transthyretin-mediated amyloidosis with cardiomyopathy (supplemental indication)	Pending FDA approval 10/08/2023	Vyndamax/Vyndaqel (tafamidis) oral	Onpattro would be the only agent approved for both polyneuropathy and cardiomyopathy due to transthyretin-mediated amyloidosis. It would have an every 3-week administration schedule. **Anticipated impact:** Replacement spend, potential shift from pharmacy benefit

Non-Specialty

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Anti-Obesity	**tirzepatide** SC (new formulation) Eli Lilly	The treatment of obesity in adults	Pending FDA approval 12/01/2023	Saxenda (liraglutide) SC, Wegovy (semaglutide) SC Multiple oral agents also approved for obesity	Tirzepatide would provide an additional SC alternative for obesity. It is approved as Mounjaro for type 2 diabetes. **Anticipated impact:** Replacement spend, pharmacy benefit
Hypertension	**aprocitentan** oral Idorsia/ Janssen Pharmaceuticals/ Johnson & Johnson	The treatment of resistant hypertension	Pending FDA approval 12/19/2023	Multiple oral agents used off-label including: spironolactone, hydralazine, minoxidil, chlorthalidone, clonidine, eplerenone, amiloride	Aprocitentan would provide a new drug class for patients that have failed to achieve blood pressure control on 3 or more classes of antihypertensive medications. **Anticipated impact:** Incremental spend; pharmacy benefit
Mental Health Disorders	**Zurzuvae** (zuranolone) oral Biogen/Sage Therapeutics	The treatment of postpartum depression in adults	Approved 08/04/2023	Zulresso (brexanolone) IV	Zurzuvae would provide an oral, rapid-acting, limited-duration treatment option specifically indicated for postpartum depression. It is awaiting controlled substance designation. **Anticipated impact:** Incremental spend, potential shift from medical benefit

Visit our website for more insights on the active drug pipeline.

1. RxPipeline, August 2023.

*U.S. Food and Drug Administration

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