Pipeline Drugs to Watch Report

Q3 2024

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
Alopecia Areata	**deuruxolitinib** Oral Sun Pharma	The treatment of moderate-to-severe alopecia areata in adults	Pending FDA approval 07/06/2024	Litfulo (ritlecitinib) oral (approved for ages 12 years+), Olumiant (baricitinb) oral (approved for adults)	Deuruxolitinib was granted Breakthrough Therapy designation and would provide an additional therapy option for extensive alopecia areata in adults. **Anticipated impact:** Replacement spend, pharmacy benefit
Atopic Dermatitis	**lebrikizumab** SC Eli Lilly	The treatment of moderate-to-severe atopic dermatitis in patients ages 12 years and older	Pending FDA approval 09/15/2024	**SC:** Adbry (tralokinumab-ldrm), Dupixent (dupilumab) **Oral:** Cibinqo (abrocitinib), Rinvoq (upadacitinib) Numerous topical therapies may be used **Pipeline agent:** nemolizumab SC (pending FDA approval 12/14/2024)	Lebrikizumab would provide an additional SC therapy option with the potential for less frequent maintenance dosing as compared to Dupixent. **Anticipated impact:** Replacement spend, pharmacy benefit
Dermatological Disorders - Other	**nemolizumab** SC Galderma Laboratories	The treatment of severe pruritus (itching) associated with moderate-to-severe prurigo nodularis in adults	Pending FDA approval 08/14/2024	Dupixent (dupilumab) SC Numerous topical and oral therapies may be used off-label.	Nemolizumab was granted Breakthrough Therapy designation and would provide an alternative SC therapy option with less frequent dosing as compared to Dupixent. Nemolizumab is also pending FDA approval (12/14/2024) for the treatment of moderate-to-severe atopic dermatitis in patients ages 12 years and older. **Anticipated impact:** Replacement spend, pharmacy benefit

Specialty (continued)

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Gastrointestinal Disorders - Other	**seladelpar** Oral CymaBay Therapeutics/ Gilead Sciences	The treatment of primary biliary cholangitis in adults with inadequate response or intolerance to ursodiol	Pending FDA approval 08/14/2024	Iqirvo (elafibranor) oral Ocaliva (obeticholic acid) oral **Off-label:** oral fibrates (e.g., fenofibrate)	Seladelpar was granted Breakthrough Therapy designation and would provide an alternative second-line treatment option for primary biliary cholangitis, with a favorable adverse effect profile. **Anticipated impact:** Incremental spend, pharmacy benefit
Hormonal Therapies	**TransCon PTH** (palopegteriparatide) SC Acendis Pharma	The treatment of hypoparathyroidism in adults	Pending FDA approval 08/14/2024	Oral calcium + vitamin D Natpara SC (parathyroid hormone): Only available through a special use program that will be permanently discontinued by the end 2024 due to ongoing manufacturing issues.	If approved, TransCon PTH would be the only exogenous parathyroid hormone product, and would provide a treatment option for patients who fail to achieve an adequate response to calcium and vitamin D supplementation. **Anticipated impact:** Incremental spend, pharmacy benefit
Multiple Sclerosis	**Ocrevus** (ocrelizumab) SC (new formulation) Biogen/Genentech/ Roche	The treatment of relapsing forms of multiple sclerosis and the treatment of primary progressive multiple sclerosis	Pending FDA approval 09/13/2024	**Injectable/Infused:** Avonex IM/Rebif SC (interferon beta-1a), Betaseron/Extavia (interferon beta-1b) SC, Briumvi (ublituximab-xiiy) IV, glatiramer (e.g., Copaxone) SC, Kesimpta (ofatumumab) SC, Lemtrada (alemtuzumab) IV, mitoxantrone (e.g., Novantrone) IV, Ocrevus IV, Plegridy (peginterferon beta 1a) IM/SC, Tysabri (natalizumab) IV **Oral:** Bafiertam (monomethyl fumarate), dimethyl fumarate (e.g., Tecfidera), fingolimod (e.g., Gilenya), Mavenclad (cladribine), Mayzent (siponimod), Ponvory (ponesimod), Tascenso ODT (fingolimod), teriflunomide (e.g., Aubagio), Vumerity (diroximel fumarate), Zeposia (ozanimod)	Ocrevus SC would provide an additional therapy option to available oral and injectable agents. It is anticipated to be administered by a healthcare provider every 6 months over 10 minutes. **Anticipated impact:** Replacement spend, medical benefit

Specialty (continued)

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Muscular Dystrophy	**Duvyzat** (givinostat) Oral Italfarmaco	The treatment of Duchenne muscular dystrophy in patients ages 6 years and older	FDA approved 03/21/2024 Pending launch Q3 2024	**Exon-Skipping Therapy:** Amondys 45 (casimersen) IV, Exondys 51 (eteplirsen) IV, Viltepso (viltolarsen), Vyondys 53 (golodirsen) IV **Gene Therapy:** Elevidys (delandistrogene moxeparvovec-rokl) IV	Duvyzat would provide an additional therapy option for Duchenne muscular dystrophy with a novel mechanism of action. Duvyzat may be used as an add-on therapy to corticosteroids and its use is not limited to specific mutations. **Anticipated impact:** Incremental spend, pharmacy benefit
Neurological Disorders	donanemab IV Eli Lilly	The treatment of early symptomatic Alzheimer's disease	Pending FDA approval 07/08/2024	Aduhelm (aducanumab-avwa) IV – will be discontinued 11/2024, Leqembi (lecanemab-irmb) IV	Donanemab was granted Breakthrough Therapy designation and would provide an alternative disease-modifying therapy for early Alzheimer's disease, with the potential for finite dosing. Donanemab requires less frequent administration (every 4 weeks) as compared to Leqembi (every 2 weeks) and demonstrated improved plaque clearing as compared to Aduhelm. Like Aduhelm and Leqembi, donanemab would require brain imaging prior to, and during, therapy. **Anticipated impact:** Replacement spend, medical benefit
Oncology - Injectable	**Rybrevant** (amivantamab-vmjw) IV Genmab/Janssen Pharmaceuticals/ Johnson & Johnson	The treatment of locally advanced or metastatic non-small cell lung cancer with EGFR exon 19 deletions or L858R substitution mutations after disease progression on, or after, Tagrisso (osimertinib), in combination with chemotherapy (supplemental indication)	Pending FDA approval 09/20/2024	Third-line and later therapies include successive rounds of Tagrisso oral, immunotherapy (e.g., Keytruda [pembrolizumab] IV, Opdivo [nivolumab] IV), and platinum-based chemotherapy **Pipeline agent:** patritumab deruxtecan IV (pending FDA approval 06/26/2024)	Rybrevant is currently FDA approved for the treatment of non-small cell lung cancer with EGFR exon 20 insertion mutations. If approved, Rybrevant, in combination with chemotherapy, would provide a third-line or later therapy option for non-small cell lung cancer with EGFR exon 19 deletions or L858R substitution mutations. There is currently no FDA-approved standardized treatment after progression on or after Tagrisso. **Anticipated impact:** Replacement spend, medical benefit

Specialty (continued)

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Pulmonary Disorders	**Dupixent** (dupilumab) SC Regeneron Pharmaceuticals/ Sanofi	The treatment of moderate-to-severe chronic obstructive pulmonary disease with type 2 inflammation (supplemental indication)	Pending FDA approval 09/27/2024	Daliresp (roflumilast) oral, azithromycin (e.g., Zithromax) oral	Dupixent was granted Breakthrough Therapy designation and would be the first biologic approved for chronic obstructive pulmonary disease. It would be used as an add-on to triple (or max-tolerated) controller therapy. The manufacturer estimates ~300,000 individuals in the US have uncontrolled chronic obstructive pulmonary disease with type 2 inflammation. **Anticipated impact:** Incremental spend, pharmacy benefit
Renal Disease	**Fabhalta** (iptacopan) Oral Novartis	The treatment of immunoglobulin A nephropathy (supplemental indication)	Pending FDA approval 08/15/2024	**Immunosuppressive agents:** Tarpeyo (budesonide) oral **Non-immunosuppressive agents:** Filspari (sparsentan) oral **Off-label, immunosuppressive agents:** Oral: systemic glucocorticoids, mycophenolate mofetil, cyclosporine, tacrolimus, azathioprine, cyclophosphamide, leflunomide, hydroxychloroquine IV: rituximab, cyclophosphamide, other cytotoxic agents **Off-label, non-immunosuppressive agents**: Oral: angiotensin-converting enzyme inhibitors, angiotensin receptor blockers, mineralocorticoid receptor antagonists, sodium-glucose cotransporter-2 inhibitors	Fabhalta is currently FDA approved for the treatment of paroxysmal nocturnal hemoglobinuria. If approved, Fabhalta would provide an additional, later-line therapy option in a novel drug class for the treatment of immunoglobulin A nephropathy. **Anticipated impact:** Incremental spend, pharmacy benefit

Non-Specialty

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Antidiabetics, Insulin	**insulin icodec** SC Novo Nordisk Pharmaceuticals	The treatment of type 1 and type 2 diabetes mellitus	Pending FDA approval 07/14/2024	Basal insulin products	Insulin icodec would provide an alternative basal insulin therapy option and would be the first once-weekly administered insulin product. Currently available basal insulin products are administered at least daily. On May 24, 2024, the FDA Endocrinologic and Metabolic Drugs Advisory Committee voted 7 to 4 that the benefits of insulin icodec did not outweigh its risks in adults with type 1 diabetes mellitus. **Anticipated impact:** Incremental spend, pharmacy benefit
Antipsychotics	**KarXT** (xanomeline/ trospium) Oral Bristol-Myers Squibb/ Karuna Pharmaceuticals	The treatment of schizophrenia in adults	Pending FDA approval 09/26/2024	Multiple first-generation ("typical") and second-generation ("atypical") antipsychotic agents are available in a variety of dosage formulations and routes of administration and with varying administration schedules.	KarXT would provide an alternative, twice-daily administered therapy option for schizophrenia. KarXT has a novel mechanism of action that may have a differentiated safety profile from existing antipsychotics, many of which are available as generic products. **Anticipated impact:** Incremental spend, pharmacy benefit
Gastrointestinal	**Voquezna** (vonoprazan) Oral Phathom Pharmaceuticals	The treatment of non-erosive gastroesophageal reflux disease in adults (supplemental indication)	Pending FDA approval 07/19/2024	Oral histamine-2-receptor antagonists, oral proton pump inhibitors	Voquezna is currently FDA approved for erosive gastroesophageal reflux disease and in combination with antibiotics for the treatment of *Helicobacter pylori* infection. If approved, Voquezna would provide an additional, later-line therapy option with a novel mechanism of action for patients with non-erosive gastroesophageal reflux disease. **Anticipated impact:** Incremental spend, pharmacy benefit

Promising new therapies for schizophrenia, which affects more than 3.5 million Americans, are in development; benefits may include greater tolerability. **Read our *Insights* post to learn more**.

Abbreviations

FDA - U.S. Food and Drug Administration

SC - Subcutaneous

IM - Intramuscular

IV - Intravenous

1. RxPipeline, May 2024.