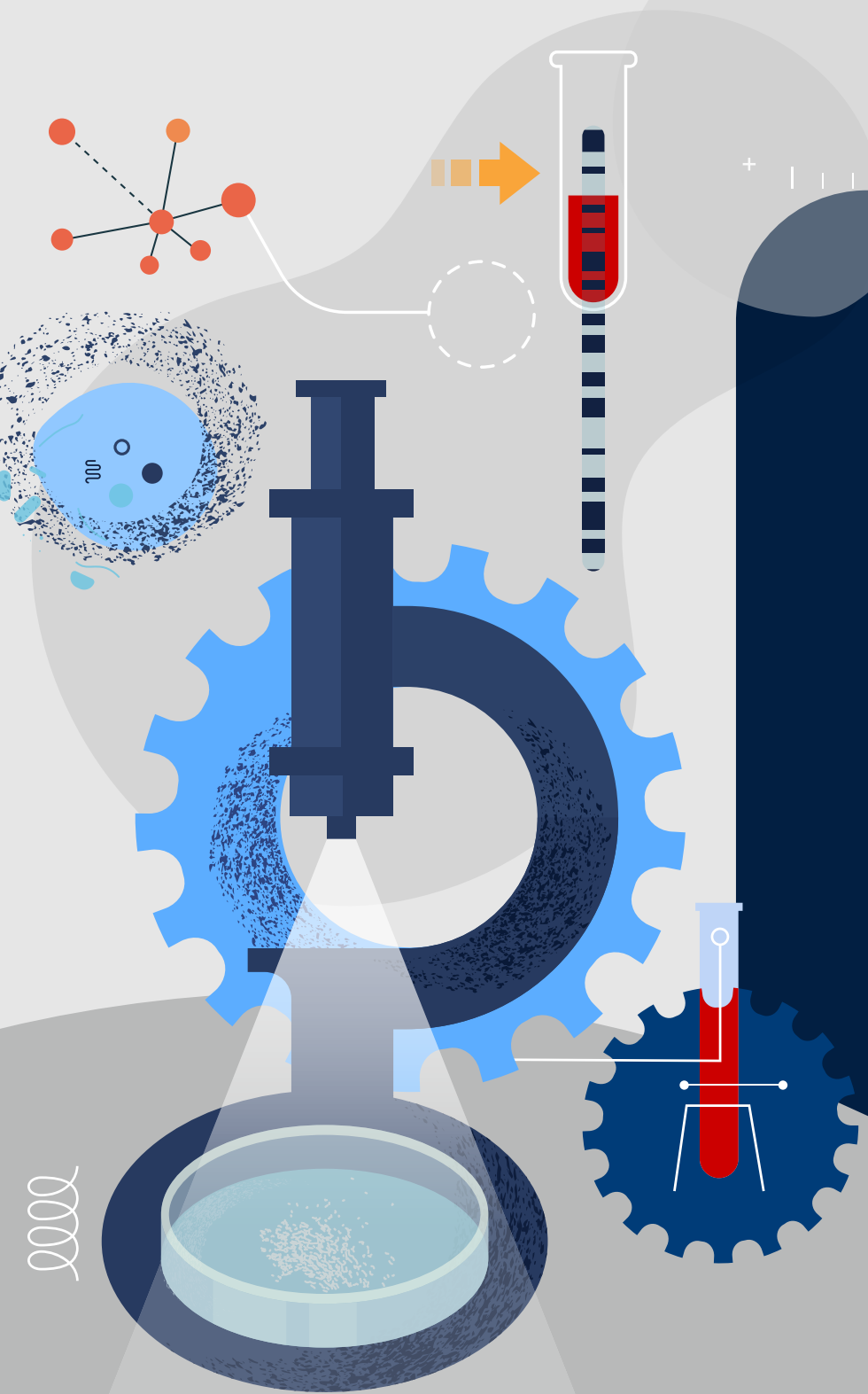

Pipeline Drugs to Watch Report

Q3 2025

Notable Upcoming Launches

CVS caremark®

Specialty

THERAPEUTIC CATEGORY	PRODUCT NAME, ROUTE OF ADMINISTRATION & MANUFACTURER	PROPOSED INDICATION	PHASE OF STUDY	SELECT AVAILABLE FDA-APPROVED THERAPIES	COMMENTS
Hereditary angioedema (HAE)	**donidalorsen** SC Ionis Pharmaceuticals	The prevention of HAE attacks in patients ages 12 years and older	Pending FDA approval 8/21/2025	Andembry (garadacimab) SC, Cinryze (C1 esterase inhibitor [human]) IV, Haegarda (C1 esterase inhibitor SC [human]) SC, Orladeyo (berotralstat) oral, Takhzyro (lanadelumab-flyo)	Donidalorsen would provide an additional treatment option for the prevention of HAE attacks that offers both monthly and bimonthly dosing frequency options. **Anticipated impact:** Replacement spend, pharmacy benefit
Inflammatory bowel disease	**Tremfya (guselkumab)** SC Janssen Pharmaceuticals/ Johnson & Johnson	The treatment of moderate-to-severe ulcerative colitis (UC) in adults as induction therapy (supplemental indication)	Pending FDA approval 9/22/2025	**IL-23 antagonist induction therapy options for UC (all IV administered):** Omvoh (mirikizumab-mrkz), Skyrizi (risankizumab-rzaa), Tremfya, ustekinumab (e.g., Stelara, biosimilars)	Tremfya SC would replace IV infusion induction doses for UC administered at weeks 0, 4 and 8 with a self-administered SC option. This would be the only IL-23 antagonist that offers a SC induction regimen option for UC. **Anticipated impact:** Replacement spend, shift from medical to pharmacy benefit
Multiple sclerosis	**tolebrutinib** Oral Principia Biopharma/ Sanofi	The treatment of non-relapsing secondary progressive multiple sclerosis (SPMS) in adults	Pending FDA approval 9/28/2025	None for non-relapsing SPMS Current therapies approved for treating SPMS are only for patients with active, relapsing disease. Some patients may continue using disease-modifying therapies that were initiated during relapsing phase of disease despite transitioning to non-relapsing SPMS.	Tolebrutinib was granted Breakthrough Therapy designation and would be the first approved treatment specifically for patients in the non-relapsing SPMS stage of MS. **Anticipated impact:** Incremental spend, pharmacy benefit

Specialty (continued)

THERAPEUTIC CATEGORY	PRODUCT NAME, ROUTE OF ADMINISTRATION & MANUFACTURER	PROPOSED INDICATION	PHASE OF STUDY	SELECT AVAILABLE FDA-APPROVED THERAPIES	COMMENTS
Neurological disorders	**Leqembi (lecanemab-irmb)** SC (new formulation) Eisai/Biogen	The treatment of early Alzheimer's disease	Pending FDA approval 8/31/2025	Kisunla (donanemab-azbt) IV, Leqembi (lecanemab-irmb) IV	Leqembi would be the first SC, self- or caregiver-administered, disease-modifying treatment option for early Alzheimer's disease. Similar to Leqembi IV and Kisunla IV, SC-administered Leqembi will still require brain imaging prior to and during therapy to monitor for adverse events (e.g., MRI scans). **Anticipated impact:** Incremental spend, shift from medical to pharmacy benefit
Neuromuscular disorders	**apitegromab** IV Scholar Rock	The treatment of type 2 or type 3 spinal muscular atrophy (SMA) in patients ages 2–21 years receiving Spinraza (nusinersen) or Evrysdi (risdiplam)	Pending FDA approval 9/22/2025	None **Pipeline:** Zolgensma (onasemnogene abeparvovec-xioi)–intrathecal injection–Phase III for type 2 SMA (1Q 2026)	Apitegromab would provide an additional SMA treatment option and be the first muscle-targeting therapy for the condition. It would be used as an add-on treatment to standard of care therapies (Spinraza or Evrysdi) in non-ambulatory type 2 and type 3 SMA patients. **Anticipated impact:** Incremental spend, medical benefit
Oncology-Oral	**sunvozertinib** Oral Dizal Pharmaceutical	The treatment of locally advanced or metastatic non-small cell lung cancer (NSCLC) with EGFR exon 20 insertion mutations in patients who have progressed on or after platinum-based chemotherapy	Pending FDA approval 7/7/2025	Rybrevant (amivantamab-vmjw) IV **Additional guideline-supported therapies:** Enhertu (fam-trastuzumab deruxtecan-nxki if HER2-positive) IV, Keytruda (pembrolizumab) IV, Opdivo (nivolumab) IV, Opdivo Qvantig (nivolumab & hyaluronidase-nvhy) SC, Tecentriq (atezolizumab) IV, Tecentriq Hybreza (atezolizumab & hyaluronidase-tqjs) SC, conventional IV chemotherapy **Pipeline:** zipalertinib oral (1H 2026	Sunvozertinib was granted Breakthrough Therapy designation and would provide the first oral option for second-line or later treatment of NSCLC in patients with EGFR exon 20 insertion mutations. **Anticipated impact:** Incremental spend, shift from medical to pharmacy benefit

Specialty (continued)

THERAPEUTIC CATEGORY	PRODUCT NAME, ROUTE OF ADMINISTRATION & MANUFACTURER	PROPOSED INDICATION	PHASE OF STUDY	SELECT AVAILABLE FDA-APPROVED THERAPIES	COMMENTS
Oncology-Oral	**zongertinib** Oral Boehringer Ingelheim	The treatment of unresectable or metastatic NSCLC tumors with HER2 mutations in adults who have received prior systemic therapy	Pending FDA approval 8/18/2025	Enhertu (fam-trastuzumab deruxtecan-nxki) IV **Additional guideline-supported therapies:** Kadcyla (ado-trastuzumab emtansine) IV **Pipeline:** sevabertinib oral (Nov 2025)	Zongertinib was granted Breakthrough Therapy designation and would provide the first oral targeted therapy for second-line or later treatment of HER2-mutant NSCLC. **Anticipated impact:** Incremental spend, shift from medical to pharmacy benefit
Phenylketonuria (PKU)	**sepiapterin** Oral PTC Therapeutics	The treatment of PKU	Pending FDA approval 7/29/2025	Palynziq (pegvaliase-pqpz) SC, sapropterin (e.g., Kuvan, Javygtor) oral	Sepiapterin would provide an additional oral PKU treatment option for patients unable to achieve sufficient disease control through a phenylalanine-restricted diet alone. **Anticipated impact:** Incremental spend (due to generic competition), pharmacy benefit

Non-Specialty

THERAPEUTIC CATEGORY	PRODUCT NAME, ROUTE OF ADMINISTRATION & MANUFACTURER	PROPOSED INDICATION	PHASE OF STUDY	SELECT AVAILABLE FDA-APPROVED THERAPIES	COMMENTS
Cardiovascular disorders	**Kerendia (finerenone)** Oral Bayer HealthCare	The treatment of heart failure with a mildly reduced or preserved left ventricular ejection fraction in adults (supplemental indication)	Pending FDA approval 7/17/2025	**Guideline supported mineralocorticoid receptor antagonist (MRA) therapies:** eplerenone (e.g., Inspra) oral, spironolactone (e.g., Aldactone) oral	Kerendia would provide an alternative, non-steroidal MRA treatment option that may be associated with lower rates of hyperkalemia relative to existing MRAs. **Anticipated impact:** Incremental spend (due to generic competition), pharmacy benefit
Gastrointestinal disorders – other	**Wegovy (semaglutide)** SC Novo Nordisk	The treatment of adults with metabolic dysfunction-associated steatohepatitis (MASH) with moderate-to-advanced liver fibrosis (stages F2 to F3 fibrosis) (supplemental indication)	Pending FDA approval 9/1/2025	Rezdiffra (resmetirom)	Wegovy was granted Breakthrough Therapy designation. It would provide an additional MASH therapy option and would be the first GLP-1 receptor agonist approved to treat this condition. **Anticipated impact:** Incremental spend, pharmacy benefit
Obesity	**Saxenda (liraglutide)** SC Novo Nordisk	The treatment of obesity in patients ages 6–11 years (supplemental indication)	Pending FDA approval 7/10/2025	None	This expanded use of Saxenda would represent the first GLP-1 receptor agonist approved to treat obesity in patients younger than 12 years of age. **Anticipated impact:** Incremental spend, pharmacy benefit
Pulmonary disorders – other	**brensocatib** Oral Insmed/ AstraZeneca	The treatment of non-cystic fibrosis bronchiectasis (NCFB) in patients ages 12 years and older	Pending FDA approval 8/12/2025	None Current standard of care primarily focuses on acute treatment of pulmonary (lung) exacerbations with antibiotic therapy as well as enhancing airway clearance.	Brensocatib was granted Breakthrough Therapy designation and would become the first approved chronic maintenance treatment for NCFB. **Anticipated impact:** New spend, pharmacy benefit

Non-Specialty (continued)

THERAPEUTIC CATEGORY	PRODUCT NAME, ROUTE OF ADMINISTRATION & MANUFACTURER	PROPOSED INDICATION	PHASE OF STUDY	SELECT AVAILABLE FDA-APPROVED THERAPIES	COMMENTS
Women's health	**elinzanetant** Oral Bayer HealthCare	The treatment of moderate-to-severe vasomotor symptoms associated with menopause	Pending FDA approval 8/1/2025	**Non-hormonal therapy options:** Brisdelle (paroxetine) oral, Veozah (fezolinetant) oral	Elinzanetant would become an additional non-hormonal therapy option for the treatment of vasomotor symptoms (e.g., hot flashes) associated with menopause. **Anticipated impact:** Replacement spend, pharmacy benefit

Proactive surveillance of the drug pipeline can help inform your pharmacy benefits strategy. Learn more and access our latest pipeline reports on our website at **Business.Caremark.com**

FDA (U.S. Food and Drug Administration), SC (subcutaneous), IV (intravenous).

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Source: RxPipeline, CVS Health Clinical Affairs. Information current as of June 12, 2025.

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