Pipeline Drugs to Watch Report

Notable upcoming launches

Q3 2026

CVS caremark®

Specialty

Therapeutic category	**Alzheimer's disease**
Product name	Leqembi Iqlik (lecanemab-irmb)
Route of administration	Subcutaneous (SC) injection
Manufacturer	Biogen/Eisai
Proposed indication	The treatment of early Alzheimer's disease in the initiation phase of therapy (supplemental indication)
Phase of study	Pending FDA approval 8/24/26
Select available FDA-approved therapies	**Disease-modifying therapies:** • Kisunla (donanemab-azbt) IV • Leqembi (lecanemab-irmb) IV
Anticipated impact	Incremental spend, shift to pharmacy benefit
Comments	Leqembi Iqlik is currently FDA-approved for SC maintenance treatment of early Alzheimer's disease after an initial 18-month course of IV Leqembi administered every 2 weeks. If approved in this setting, Leqembi will be the first anti-amyloid therapy available for at-home, weekly SC administration from the onset of treatment, potentially shifting some spend from the medical to pharmacy benefit.

Specialty

Therapeutic category	**Dermatological disorders – other**
Product name	brepocitinib
Route of administration	Oral
Manufacturer	Pfizer/Roivant Sciences/Priovant Therapeutics
Proposed indication	The treatment of dermatomyositis in adults
Phase of study	Pending FDA approval 9/3/26
Select available FDA-approved therapies	Immunoglobulin IV (IVIG [e.g., Octagam 10%])
Anticipated impact	Replacement spend, shift to pharmacy benefit
Comments	Brepocitinib is a first-in-class agent for dermatomyositis and could be the first oral therapy for the disorder. It may reduce reliance on IVIG. If approved, it would partially shift spend from the medical to pharmacy benefit.

Specialty

Therapeutic category	**Hemophilia, Von Willebrand disease and related bleeding disorders**
Product name	denecimig
Route of administration	Subcutaneous (SC) injection
Manufacturer	Genmab/Novo Nordisk Pharmaceuticals
Proposed indication	The treatment of hemophilia A, with or without inhibitors, in patients ages 12 years and older
Phase of study	Pending FDA approval 9/29/26
Select available FDA-approved therapies	**Factor replacement products:** • Factor VIII products IV • FEIBA IV **Monoclonal antibody therapies:** • Alhemo (concizumab-mtci) SC • Hemlibra (emicizumab-kxwh) SC • Hympavzi (marstacimab-hncq) SC [without inhibitors only] • Qfitlia (fitusiran) SC
Anticipated impact	Replacement spend, pharmacy benefit
Comments	Denecimig is a non-factor therapy with a similar mechanism of action to Hemlibra, designed to mimic factor VIII activity. It provides an additional therapy option for hemophilia A with or without inhibitors.

Specialty

Therapeutic category	**Human immunodeficiency virus**
Product name	bictegravir/ lenacapavir
Route of administration	Oral
Manufacturer	Gilead Sciences
Proposed indication	The maintenance treatment of human immunodeficiency type-1 (HIV-1) infection in virologically suppressed adults
Phase of study	Pending FDA approval 8/27/26
Select available FDA-approved therapies	**Complete regimen 3-drug fixed-dose combinations (FDCs):** • Biktarvy (BIC/FTC/TAF) • Delstrigo (DOR/3TC/TDF) • EFV/3TC/TDF (i.e., Symfi) • EFV/FTC/TDF (i.e., Atripla) • FTC/RPV/TDF (i.e., Complera) • Genvoya (EVG/COBI/FTC/ TAF) • Odefsey (FTC/RPV/TAF) • Stribild (EVG/COBI/ FTC/TDF) • Symtuza (DRV/FTC/TAF) • Triumeq (ABC/DTG/3TC) **Complete regimen 2-drug FDCs:** • Cabenuva (CAB/RPV) • Dovato (DTG/3TC) • Idvynso (DOR/islatravir) • Juluca (DTG/RPV) **HIV Medication Abbreviations:** abacavir (ABC); bictegravir: (BIC); cabotegravir (CAB); cobicistat (COBI); darunavir (DRV); dolutegravir (DTG); doravirine (DOR); efavirenz: (EFV); elvitegravir (EVG); emtricitabine (FTC); lamivudine (3TC); rilpivirine (RPV); tenofovir alafenamide (TAF); tenofovir disoproxil fumarate (TDF)

Specialty

Anticipated impact	Replacement spend, pharmacy benefit
Comments	The combination of bictegravir and lenacapavir may provide an additional two-drug regimen for the maintenance treatment of HIV. It does not contain a protease inhibitor or nucleoside reverse transcriptase inhibitor, which are common classes of HIV therapy present in current FDCs. It would be the first complete oral fixed-dose combination formulation to contain a capsid inhibitor.

Specialty

Therapeutic category	**Ocular disorders**
Product name	veligrotug
Route of administration	Intravenous (IV) injection
Manufacturer	Viridian Therapeutics
Proposed indication	The treatment of thyroid eye disease in adults
Phase of study	Pending FDA approval 6/30/26
Select available FDA-approved therapies	Tepezza (teprotumumab-trbw) IV
Anticipated impact	Replacement spend, medical benefit
Comments	It requires a finite course consisting of five 30-minute infusions, offering shorter infusion duration and potential for fewer total infusions than Tepezza.

Specialty

Therapeutic category	**Oncology – injectable**
Product name	rusfertide
Route of administration	Subcutaneous (SC) injection
Manufacturer	Protagonist Therapeutics/Takeda
Proposed indication	The treatment of polycythemia vera in adults
Phase of study	Pending FDA approval 9/2/26
Select available FDA-approved therapies	• Besremi (ropeginterferon alfa-2b-njft) SC; • Jakafi (ruxolitinib) oral [limited to later-line use after hydroxyurea] **Additional NCCN supported cytoreductive therapies:** • hydroxyurea oral • Pegasys (peginterferon alfa-2a) SC
Anticipated impact	Incremental spend, pharmacy benefit
Comments	Rusfertide is a first-in-class agent for polycythemia vera that may reduce reliance on routine phlebotomy, offering an additional therapy option for patients who remain phlebotomy-dependent despite standard-of-care treatment.

Specialty

Therapeutic category	**Oncology – oral**
Product name	iberdomide
Route of administration	Oral
Manufacturer	Bristol-Myers Squibb/Celgene
Proposed indication	The treatment of relapsed or refractory multiple myeloma in adults, in combination with dexamethasone and daratumumab (i.e., Darzalex, Darzalex Faspro)
Phase of study	Pending FDA approval 8/17/26
Select available FDA-approved therapies	**NCCN preferred regimens include:** • Darzalex IV or Darzalex Faspro SC + dexamethasone oral plus one of the following: - bortezomib (i.e., Velcade) SC - Kyprolis (carfilzomib) IV - pomalidomide (i. e., Pomalyst) oral • pomalidomide oral + dexamethasone oral plus one of the following: - bortezomib IV/SC - Empliciti (elotuzumab) IV - Kyprolis IV - Ninlaro (ixazomib) oral - Sarclisa (isatuximab irfc) IV • Sarclisa IV + Kyprolis IV + dexamethasone oral • Darzalex IV or Darzalex Faspro SC + Tecvayli (teclistamab-cqyv) SC • CAR-T cell therapies: - Abecma (idecabtagene vicleucel IV [after ≥2 prior lines of therapy] - Carvykti (ciltacabtagene autoleucel IV [after ≥ 1 prior line of therapy]
Anticipated impact	Replacement spend, pharmacy benefit

Specialty

Comments	Iberdomide is a first-in-class agent for relapsed or refractory multiple myeloma that offers an additional treatment option when used in combination with Darzalex or Darzalex Faspro and dexamethasone in later lines of therapy.

Specialty

Therapeutic category	**Oncology – oral**
Product name	daraxonrasib
Route of administration	Oral
Manufacturer	Revolution Medicines
Proposed indication	The treatment of previously treated metastatic pancreatic ductal adenocarcinoma in adults
Phase of study	Phase III, 3Q 2026
Select available FDA-approved therapies	**NCCN preferred treatments include:** gemcitabine IV or fluoropyrimidine IV-based chemotherapy regimens **Additional mutation-directed therapies include:** • KRAS G12C mutations: - Krazati (adagrasib) oral - Lumakras (sotorasib) oral • BRAF v600E mutations: - Tafinlar (dabrafenib) oral - Mekinist (trametinib) oral • FGFR alterations: - Balversa (erdafitinib) oral • HER2 mutations - Enhertu (fam-trastuzumab deruxtecan-nxki) IV • RET gene fusions: - Retevmo (selpercatinib) oral • NRG1 gene fusions: - Bizengri (zenocutuzumab-zbco) IV

Specialty

Anticipated impact	Incremental spend, partial shift to pharmacy benefit
Comments	Daraxonrasib would be the first pan-RAS inhibitor therapy and provide the first oral alternative to chemotherapy for second-line or later treatment of pancreatic ductal adenocarcinoma, that can be used regardless of mutation status. It will be reviewed through the National Priority Voucher pilot program, aimed to shorten the FDA review process to 1–2 months.

Specialty

Therapeutic category	**Oncology – oral**
Product name	Truqap (capivasertib)
Route of administration	Oral
Manufacturer	AstraZeneca
Proposed indication	The treatment of metastatic hormone-sensitive prostate cancer with PTEN deficiency, in combination with abiraterone, prednisone and androgen deprivation therapy (Supplemental indication)
Phase of study	Pending FDA approval 9/1/26
Select available FDA-approved therapies	**NCCN preferred treatments include:** • Androgen deprivation therapy with or without docetaxel and one of the following: - abiraterone (e.g., Zytiga) oral - Nubeqa (daroluatmide) oral - Erleada (apalutamide) oral - Xtandi (enzalutamide) oral
Anticipated impact	Incremental spend, pharmacy benefit
Comments	Truqap would provide the first potential targeted therapy for patients with metastatic hormone-sensitive prostate cancer with PTEN deficiency. PTEN deficiency is present in up to a quarter of patients with metastatic hormone-sensitive prostate cancer and is associated with poorer outcomes.

Specialty

Therapeutic category	**Renal disease**
Product name	atacicept
Route of administration	Subcutaneous (SC) injection
Manufacturer	Vera Therapeutics
Proposed indication	The treatment of immunoglobulin A nephropathy in adults at risk for disease progression
Phase of study	Pending FDA approval 7/7/26
Select available FDA-approved therapies	• Voyxact (sibeprenlimab-szsi) SC • Tarpeyo (budesonide) oral
Anticipated impact	Replacement spend, pharmacy benefit
Comments	Atacicept is a first-in-class agent for immunoglobulin A nephropathy that would provide an additional treatment option for preventing or reducing the formation of kidney-injuring immunoglobulin A complexes.

Specialty

Therapeutic category	**Sleep disorders**
Product name	oveporexton
Route of administration	Oral
Manufacturer	Takeda
Proposed indication	The treatment of narcolepsy with cataplexy (narcolepsy type 1) in patients ages 16 years and older
Phase of study	Pending FDA approval 8/10/26
Select available FDA-approved therapies	**Stimulant medications:** • amphetamines (e.g., Adderall) oral • armodafinil (i.e., Nuvigil) oral • modafinil (i.e., Provigil) oral **Oxybates:** • sodium oxybate immediate-release solution (i.e., Xyrem) oral • Lumryz (sodium oxybate extended-release suspension) oral • Xywav (oxybate salts) oral **Other agents:** • Sunosi (solriamfetol) oral • Wakix (pitolisant) oral
Anticipated impact	Incremental spend, pharmacy benefit
Comments	Oveporexton is a first-in-class agent that targets the underlying orexin deficiency in narcolepsy type 1. It represents a potential disease-modifying approach, rather than symptomatic treatment.

Non-Specialty

Therapeutic category	**Cardiovascular**
Product name	enlicitide decanoate
Route of administration	Oral
Manufacturer	Merck
Proposed indication	The treatment of hypercholesterolemia in adults
Phase of study	Phase III, 3Q 2026
Select available FDA-approved therapies	PCSK9 inhibitors: • Leqvio (inclisiran) SC • Lerochol (lerodalcibep-liga) SC • Praluent (alirocumab) SC • Repatha (evolocumab) SC
Anticipated impact	Incremental spend, pharmacy benefit
Comments	Enlicitide may be the first oral therapy in the PCSK9 inhibitor class. It requires a fasted state for administration. It will be reviewed through the National Priority Voucher pilot program, aimed to shorten the FDA review process to 1– 2 months.

Non-Specialty

Therapeutic category	**Central nervous system**
Product name	centanafadine
Route of administration	Oral
Manufacturer	Otsuka America Pharmaceutical
Proposed indication	The treatment of attention deficit hyperactivity disorder in patients ages 4 years and older
Phase of study	Pending FDA approval 7/24/26
Select available FDA-approved therapies	**Stimulant medications:** • methylphenidate (e.g., Concerta) oral • dexmethylphenidate (e.g., Focalin) oral • amphetamines (e.g., Adderall) oral **Non-stimulant medications:** • atomoxetine (e.g., Strattera) • guanfacine (e.g., Intuniv) • Onyda XR (clonidine) oral • Qelbree (viloxazine) oral
Anticipated impact	Incremental spend, pharmacy benefit
Comments	Centanafadine is a first-in-class, extended-release, triple reuptake inhibitor therapy for attention deficit hyperactivity disorder in pediatric and adult patients. It may provide an additional non-stimulant therapy option.

Non-Specialty

Therapeutic category	**Central nervous system**
Product name	Juvmo (tavapadon)
Route of administration	Oral
Manufacturer	AbbVie
Proposed indication	The treatment of motor fluctuations in adults with Parkinson's disease
Phase of study	Pending FDA approval 9/26/26
Select available FDA-approved therapies	**Dopamine agonists:** • Neupro (rotigotine) transdermal patch • pramipexole (e.g., Mirapex ER) oral ropinirole (e.g., Requip) oral
Anticipated impact	Incremental spend, pharmacy benefit
Comments	Juvmo is the first dopamine agonist to target two specific dopamine receptors, D1 and D5. It does not activate D2 and D3 receptors, activation of which has been associated with many adverse effects seen with some dopamine agonists, including daytime sleepiness, impulse-control disorders, and other psychiatric symptoms. Juvmo may provide an additional dopamine agonist therapy to be used with or without dopamine precursor therapies (e.g., levodopa) for patients with Parkinson's disease.

Non-Specialty

Therapeutic category	**Endocrine and metabolic**
Product name	Awiqli (insulin icodec-abae)
Route of administration	Subcutaneous (SC) injection
Manufacturer	Novo Nordisk Pharmaceuticals
Proposed indication	The treatment of type 2 diabetes mellitus to improve glycemic control in adults, as an adjunct to diet and exercise
Phase of study	Approved, launch anticipated 3Q 2026
Select available FDA-approved therapies	**Once-daily, long-acting insulins:** • insulin glargine (i.e., Lantus, Basaglar, Toujeo, biosimilars) • Tresiba (insulin degludec)
Anticipated impact	Replacement spend, pharmacy benefit
Comments	Awiqli is the first approved once-weekly ultra-long-acting basal insulin product for the treatment of type 2 diabetes mellitus.

Non-Specialty

Therapeutic category	**Endocrine and metabolic**
Product name	insulin efsitora alfa
Route of administration	Subcutaneous (SC) injection
Manufacturer	Eli Lilly
Proposed indication	The treatment of type 2 diabetes mellitus to improve glycemic control in adults, as an adjunct to diet and exercise
Phase of study	Pending FDA approval 9/1/26
Select available FDA-approved therapies	**Once-daily, long-acting insulins:** • insulin glargine (i.e., Lantus, Basaglar, Toujeo, biosimilars) • Tresiba (insulin degludec)
Anticipated impact	Replacement spend, pharmacy benefit
Comments	Insulin efsitora alfa may provide the second once-weekly ultra-long-acting basal insulin product for the treatment of type 2 diabetes mellitus.

Non-Specialty

Therapeutic category	**Endocrine and metabolic**
Product name	Foundayo (orforglipron)
Route of administration	Oral
Manufacturer	Eli Lilly
Proposed indication	The treatment of type 2 diabetes mellitus to improve glycemic control in adults, as an adjunct to diet and exercise (Supplemental indication)
Phase of study	Phase III, 3Q 2026
Select available FDA-approved therapies	**GLP-1 agonists approved for type 2 diabetes:** • exenatide (e.g., Byetta) SC • liraglutide (e.g., Victoza) SC • Mounjaro (tirzepatide) SC • Ozempic (semaglutide) SC/oral • Rybelsus (semaglutide) oral • Trulicity (dulaglutide) SC
Anticipated impact	Replacement spend, pharmacy benefit
Comments	Orforglipron may be the second oral GLP-1 agonist for the treatment of type 2 diabetes mellitus. It does not require a fasting state for administration. It will be reviewed through the National Priority Voucher pilot program, aimed to shorten the FDA review process to 1–2 months.

First-time Biosimilars

Therapeutic category	**Allergen immunotherapy and asthma**
Product name, route of administration and manufacturer(s)	Omlyclo (omalizumab-igec) Celltrion Subcutanous injection
Reference product and manufacturer	Xolair (omalizumab) [Genentech/ Roche/Novartis]
Reference brand indications	• Asthma • Chronic rhinosinusitis with nasal polyps • IgE-mediated food allergy • Chronic spontaneous urticaria
Proposed biosimilar indication(s)	• Asthma • Chronic rhinosinusitis with nasal polyps • IgE-mediated food allergy • Chronic spontaneous urticaria
Anticipated biosimilar launch	2H 2026
Comments	Omlyclo was approved 3/7/25 with an interchangeability designation. It is anticipated to be the first Xolair biosimilar to launch as early as 3Q 2026. At least two additional Xolair biosimilars may be approved and/or launched in 2027. Specialty product Anticipated impact: Replacement spend (potential for decreased spend), pharmacy benefit

Abbreviations

FDA – U.S. Food and Drug Administration
IM – Intramuscular
IV – Intravenous
NCCN – National Comprehensive Cancer Network
SC – Subcutaneous

Source: RxPipeline, CVS Health Clinical Affairs. Information current as of May 2026.

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