



Pipeline Drugs to Watch Report

Notable upcoming launches

Q4 2026

 **CVS** caremark[®]



Specialty

Therapeutic category	Anti-infectives
Product name	bepirovirsen
Route of administration	SC
Manufacturer	GSK/Ionis Pharmaceuticals
Proposed indication	The treatment of chronic hepatitis B virus infection in adults as add-on to nucleoside analogue therapy
Phase of study	Pending FDA approval 10/26/26
Select available FDA-approved therapies	Long-term suppressive nucleos(t)ide analogues: entecavir oral, tenofovir disoproxil fumarate oral, Vemlidy (tenofovir alafenamide) oral
Anticipated impact	Incremental spend; pharmacy benefit
Comments	Bepirovirsen would offer a once-weekly treatment option of finite duration designed to achieve a functional cure of chronic hepatitis B. If approved, it would be added on to long-term suppressive nucleos(t)ide analogue therapy and potentially enable treatment discontinuation in the subset of patients who achieve a functional cure.



Specialty

Therapeutic category	Immunologic agents
Product name	Enspryng (satralizumab-mwge)
Route of administration	SC
Manufacturer	Chugai Pharmaceutical/Genentech/Roche
Proposed indication	The treatment of thyroid eye disease in adults (supplemental indication)
Phase of study	Pending FDA approval 10/15/26
Select available FDA-approved therapies	Lumvoa (veligrotug-vvze) IV, Tepezza (teprotumumab-trbw) IV Pipeline: Tepezza SC (Q2 2027), elegrobart SC (Q1 2028)
Anticipated impact	Replacement spend; shift to pharmacy benefit
Comments	Enspryng would provide the first SC self-administered biologic option for thyroid eye disease and would introduce a novel mechanism of action to this treatment space.



Specialty

Therapeutic category	Immunologic agents
Product name	ianalumab
Route of administration	SC
Manufacturer	Novartis
Proposed indication	The treatment of Sjögren's disease in adults
Phase of study	Pending FDA approval 10/15/26
Select available FDA-approved therapies	Off-label immunosuppressive therapies: hydroxychloroquine oral, methotrexate oral, corticosteroids oral, azathioprine oral, rituximab (e.g., Rituxan, biosimilars) IV
Anticipated impact	Incremental spend; pharmacy benefit
Comments	As the first potential therapy specifically approved for Sjögren's disease, ianalumab would establish a new treatment standard in a disease currently managed largely with symptomatic care and off-label immunosuppressive therapies.



Specialty

Therapeutic category	Immunologic agents
Product name	Skyrizi (risankizumab-rzaa)
Route of administration	SC
Manufacturer	AbbVie/Boehringer Ingelheim
Proposed indication	The treatment of moderately-to-severely active Crohn's disease in adults as induction therapy (supplemental indication)
Phase of study	Pending FDA approval 10/27/26
Select available FDA-approved therapies	adalimumab (e.g., Humira, biosimilars) SC, Cimzia (certolizumab pegol) SC, Entyvio (vedolizumab) IV/SC, infliximab (e.g., Remicade, biosimilars) IV, natalizumab (e.g., Tysabri, biosimilars) IV, Omvoh (mirikizumab-mrkz) IV/SC, Rinvoq (upadacitinib) oral, Tremfya (guselkumab) IV/SC, ustekinumab (e.g., Stelara, biosimilars) IV/SC
Anticipated impact	Replacement spend; partial shift to pharmacy benefit
Comments	Approval of induction with SC Skyrizi would make it the second IL-23 inhibitor, after Tremfya, to offer a fully SC treatment pathway in Crohn's disease. If approved, it would allow both induction and maintenance treatment to be administered subcutaneously, eliminating the three IV infusions currently required during induction therapy.



Specialty

Therapeutic category	Immunologic agents
Product name	Rinvoq (upadacitinib)
Route of administration	Oral
Manufacturer	AbbVie
Proposed indication	The treatment of non-segmental vitiligo in patients ages 12 years and older (supplemental indication)
Phase of study	Pending FDA approval 12/03/26
Select available FDA-approved therapies	Topical corticosteroids, topical tacrolimus, topical pimecrolimus, Opzelura (ruxolitinib) topical
Anticipated impact	Incremental spend; pharmacy benefit
Comments	Rinvoq would become the first oral systemic therapy approved for non-segmental vitiligo. It would provide an alternative beyond topical therapies and may expand treatment options for patients with more extensive disease involvement.



Specialty

Therapeutic category	Oncology – oral
Product name	giredestrant
Route of administration	Oral
Manufacturer	Genentech/Roche
Proposed indication	The adjuvant treatment of medium- and high-risk stage I-III ER-positive, HER2-negative breast cancer
Phase of study	Pending FDA approval 11/30/26
Select available FDA-approved therapies	tamoxifen +/- Verzenio (abemaciclib), aromatase inhibitors (e.g., anastrozole, exemestane, letrozole) +/- CDK 4/6 inhibitor (e.g., Verzenio, Kisqali [ribociclib])
Anticipated impact	Incremental spend; pharmacy benefit
Comments	This is the first of two anticipated FDA decisions for giredestrant in Q4 2026. Giredestrant would provide an additional treatment option for certain patients with early-stage hormone receptor-positive breast cancer. If approved, it would expand adjuvant treatment options used after surgery to reduce the risk of breast cancer recurrence in patients at higher risk.



Specialty

Therapeutic category	Oncology – oral
Product name	giredestrant
Route of administration	Oral
Manufacturer	Genentech/Roche
Proposed indication	The treatment of ER-positive, HER2-negative, ESR1-mutated locally advanced or metastatic breast cancer, in combination with everolimus, in adults previously treated with a CDK 4/6 inhibitor and endocrine therapy
Phase of study	Pending FDA approval 12/18/26
Select available FDA-approved therapies	Inluriyo (imlunestrant) oral, Orserdu (elacestrant) oral, Veppanu (vepdegestrant) oral
Anticipated impact	Replacement spend; pharmacy benefit
Comments	This is the second of two anticipated FDA decisions for giredestrant in Q4 2026. Giredestrant would provide an additional targeted treatment option for patients with ESR1-mutated hormone receptor-positive advanced breast cancer following progression on endocrine therapy and a CDK 4/6 inhibitor. If approved, it would expand options in a growing biomarker-guided treatment setting.



Specialty

Therapeutic category	Renal disease
Product name	povetacicept
Route of administration	SC
Manufacturer	Vertex Pharmaceuticals
Proposed indication	The treatment of immunoglobulin A nephropathy in adults at risk for disease progression
Phase of study	Pending FDA approval 11/30/26
Select available FDA-approved therapies	APRIL-targeted therapies: Trutakna (atacicept-vymj) SC, Voyxact (sibeprenlimab-szsi) SC Other approved therapies: Fabhalta (iptacopan) oral, Filspari (sparsentan) oral, Tarpeyo (budesonide) oral, Vanrafia (atrasentan) oral
Anticipated impact	Replacement spend; pharmacy benefit
Comments	Povetacicept would provide an additional APRIL-targeted treatment option for preventing or reducing the formation of kidney-injuring immunoglobulin A complexes in immunoglobulin A nephropathy. Like Trutakna and Voyxact, povetacicept targets upstream immune pathways involved in disease progression. Its every-4-week dosing schedule is less frequent than once-weekly Trutakna and similar to Voyxact.



Specialty

Therapeutic category	Renal disease
Product name	Ultomiris (ravulizumab-cwvz)
Route of administration	IV
Manufacturer	Alexion Pharmaceuticals/AstraZeneca
Proposed indication	The treatment of immunoglobulin A nephropathy in adults at risk for disease progression (supplemental indication)
Phase of study	Pending FDA approval 10/15/26
Select available FDA-approved therapies	Complement-targeted therapy: Fabhalta (iptacopan) oral Other approved therapies: Filspari (sparsentan) oral, Tarpeyo (budesonide) oral, Trutakna (atacicept- vymj) SC, Voyxact, (sibeprenlimab-szsi) SC, Vanrafia (atrasentan) oral
Anticipated impact	Replacement spend; shift to medical benefit
Comments	Ultomiris would represent the first C5 complement inhibitor and the second complement-targeted therapy approved for immunoglobulin A nephropathy, following Fabhalta. Its provider-administered, every-8-week IV dosing schedule could offer a differentiated treatment option.



Specialty

Therapeutic category	Sickle cell disease
Product name	Pyrukynd (mitapivat)
Route of administration	Oral
Manufacturer	Agios Pharmaceuticals
Proposed indication	The treatment of sickle cell disease in patients ages 16 years and older (supplemental indication)
Phase of study	Pending FDA approval 11/01/26
Select available FDA-approved therapies	Current curative therapy for patients ages 16+ years: hematopoietic stem cell transplant, Casgevy (exagamglogene autotemcel) IV, Lyfgenia (lovotibeglogene autotemcel) IV Current disease-modifying therapies for patients ages 16+ years: hydroxyurea oral, Adakveo (crizanlizumab) IV, Endari (L-glutamine) oral Pipeline: etavopivat oral (3Q 2027)
Anticipated impact	Incremental spend; pharmacy benefit
Comments	Pyrukynd would provide an additional oral, disease-modifying treatment option for sickle cell disease. If approved, it would introduce a novel mechanism of action for this condition and could be used with or without hydroxyurea.



Non-specialty

Therapeutic category	Antiobesity
Product name	cagrilintide/semaglutide
Route of administration	SC
Manufacturer	Novo Nordisk Pharmaceuticals
Proposed indication	Use as chronic weight management in adults with initial BMI greater than or equal to 30 kg/m ² (obesity) or greater than or equal to 27 kg/m ² (overweight) with at least 1 weight-related comorbid condition
Phase of study	Pending FDA approval 12/18/26
Select available FDA-approved therapies	GLP-1 RA-based therapies: Foundayo (orforglipron) oral, liraglutide SC, Wegovy (semaglutide) SC and oral, Zepbound (tirzepatide) SC Other approved therapies: Contrave (bupropion/naltrexone) oral, orlistat oral, Qsymia (phentermine/topiramate) oral
Anticipated impact	Replacement spend; pharmacy benefit
Comments	This fixed-dose combination targets both the GLP-1 and amylin pathways, offering a novel approach to weight management. If approved, it would provide an additional once-weekly injectable option for chronic weight management in a category that continues to expand, with several additional obesity therapies expected over the coming years.



Non-specialty

Therapeutic category	Hematologic
Product name	asundexian
Route of administration	Oral
Manufacturer	Bayer
Proposed indication	The prevention of secondary stroke in adults following a non-cardioembolic ischemic stroke or transient ischemic attack
Phase of study	Pending FDA approval 11/19/26
Select available FDA-approved therapies	Antiplatelet therapies: aspirin, clopidogrel, low-dose aspirin + dipyridamole
Anticipated impact	Incremental spend; pharmacy benefit
Comments	Asundexian would introduce a first-in-class factor XIa inhibitor as add-on therapy to standard antiplatelet treatment for secondary stroke prevention following a non-cardioembolic ischemic stroke or transient ischemic attack. If approved, it would provide a novel treatment approach intended to reduce recurrent ischemic events.



Non-specialty

Therapeutic category	Hypertension
Product name	lorundrostat
Route of administration	Oral
Manufacturer	Mineralys Thera-peutics
Proposed indication	The treatment of uncontrolled or treatment-resistant hypertension in adults as add-on to other antihypertensive therapies when blood pressure is not adequately controlled by these agents
Phase of study	Pending FDA approval 12/22/26
Select available FDA-approved therapies	Baxfendry (baxdrostat) oral, Tryvio (aprocitentan) oral Primary off-label oral therapies for treatment-resistant hypertension: amiloride, bisoprolol, carvedilol, clonidine, diltiazem, doxazosin, eplerenone, guanfacine, hydralazine, metoprolol, minoxidil, spironolactone, verapamil
Anticipated impact	Incremental spend; pharmacy benefit
Comments	Lorundrostat may become the second aldosterone synthase inhibitor approved for hypertension, following recently approved Baxfendry. Approval would expand options within this emerging class for patients whose blood pressure remains uncontrolled despite multiple therapies.



First-time biosimilars

Therapeutic category	Immunologic agents
Product name, route of administration and manufacturer	abatacept IV Dr. Reddy's Laboratories
Reference product and manufacturer	Orencia (abatacept) Bristol-Myers Squibb
Reference brand indications	• Rheumatoid arthritis • Polyarticular juvenile idiopathic arthritis • Psoriatic arthritis • Prophylaxis of acute graft versus host disease
Proposed biosimilar indications	• TBD
Anticipated biosimilar launch	Q4 2026
Comments	• Anticipated to be the first Orencia biosimilar to launch as early as Q4 2026. • The manufacturer is pursuing an interchangeability designation upon approval. • Specialty product • Anticipated impact: Replacement spend (potential for decreased spend); medical benefit



First-time biosimilars

Therapeutic category	Immunologic agents	
Product name, route of administration and manufacturer	Immgolis (golimumab-sldi) SC Accord Healthcare/ Bio-Thera Solutions/Intas Pharmaceuticals	golimumab SC Alvotech/ Teva Pharmaceuticals
Reference product and manufacturer	Simponi (golimumab) Janssen Pharmaceuticals/Johnson & Johnson	
Reference brand indications	• Rheumatoid arthritis • Psoriatic arthritis • Ankylosing spondylitis • Ulcerative colitis	
Proposed biosimilar indications	• Rheumatoid arthritis • Ulcerative colitis	• TBD
Anticipated biosimilar launch	Q4 2026	
Comments	• Anticipated to be the first two Simponi biosimilars to launch as early as Q4 2026. • Immgolis was approved on 05/15/26 as an interchangeable biosimilar. • Specialty products • Anticipated impact: Replacement spend (potential for decreased spend); pharmacy benefit	



First-time biosimilars

Therapeutic category	Immunologic agents	
Product name, route of administration and manufacturer	Immgolis Intri (golimumab-sldi) IV Accord Healthcare/ Bio-Thera Solutions/Intas Pharmaceuticals	golimumab IV Alvotech/ Teva Pharmaceuticals
Reference product and manufacturer	Simponi Aria (golimumab) Janssen Pharmaceuticals/Johnson & Johnson	
Reference brand indications	• Rheumatoid arthritis • Psoriatic arthritis • Ankylosing spondylitis • Juvenile idiopathic arthritis	
Proposed biosimilar indications	• Rheumatoid arthritis	• TBD
Anticipated biosimilar launch	Q4 2026	
Comments	• Anticipated to be the first two Simponi Aria biosimilars to launch as early as Q4 2026. • Immgolis Intri was approved on 5/15/26 as an interchangeable biosimilar. • Specialty products • Anticipated impact: Replacement spend (potential for decreased spend); medical benefit	

BMI (body mass index), FDA (U.S. Food and Drug Administration), GLP-1 RA (glucagon-like, peptide-1 receptor agonist), IM (intramuscular), IV (intramuscular), IV (intravenous), SC (subcutaneous), TBD (to be determined).

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