



# Pipeline Drugs to Watch Report

Notable upcoming launches

Q2 2026

 **CVS** caremark<sup>®</sup>



## Specialty

|                                         |                                                                                                                                                                                                                                                                                                                                                                                                                           |
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| Therapeutic category                    | <b>Alzheimer's disease</b>                                                                                                                                                                                                                                                                                                                                                                                                |
| Product name                            | Leqembi Iqlik (lecanemab-irmb)                                                                                                                                                                                                                                                                                                                                                                                            |
| Route of administration                 | SC                                                                                                                                                                                                                                                                                                                                                                                                                        |
| 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 5/24/26                                                                                                                                                                                                                                                                                                                                                                                              |
| Select available FDA approved therapies | <b>Disease-modifying therapies:</b><br>Kisunla (donanemab-azbt) IV, Leqembi (lecanemab-irmb) IV                                                                                                                                                                                                                                                                                                                           |
| Anticipated impact                      | Incremental spend; shift to pharmacy benefit                                                                                                                                                                                                                                                                                                                                                                              |
| Comments                                | <p>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.</p> <p>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.</p> |



## Specialty

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| Therapeutic category                    | <b>Hepatitis D (HDV)</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| Product name                            | Hepcludex (bulevirtide)                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| Route of administration                 | SC                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| Manufacturer                            | Gilead                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| Proposed indication                     | The treatment of chronic HDV in adults with compensated liver disease                                                                                                                                                                                                                                                                                                                                                                                                        |
| Phase of study                          | Pending FDA approval 5/22/26                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| Select available FDA approved therapies | <b>Off-label agents:</b><br>pegylated interferon alfa-2a (i.e., Pegasys) or alfa-2b (i.e., Pegintron, Sylatron) SC                                                                                                                                                                                                                                                                                                                                                           |
| Anticipated impact                      | Incremental spend; pharmacy benefit                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Comments                                | Hepcludex will offer the first FDA-approved treatment for HDV. Chronic HDV infection typically occurs only in individuals who have established chronic hepatitis B virus infection. While monotherapy with Hepcludex may enable a sustained off-treatment response in some patients, sustained response rates are notably higher when it's combined with pegylated interferon. In patients with sustained off-treatment responses, a finite dosing course may be considered. |



## Specialty

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| Therapeutic category                    | <b>Human immunodeficiency virus (HIV)</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| Product name                            | doravirine/islatravir                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| Route of administration                 | Oral                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| Manufacturer                            | Merck                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| Proposed indication                     | The maintenance treatment of HIV in virologically suppressed adults                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| Phase of study                          | Pending FDA approval 4/28/26                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| Select available FDA approved therapies | <b>Complete Fixed-Dose Combination HIV Regimens:</b> Biktarvy (bictegravir/emtricitabine/tenofovir alafenamide fumarate), Cabenuva (cabotegravir/rilpivirine), Delstrigo (doravirine/lamivudine/tenofovir disoproxil fumarate), Dovato (dolutegravir/lamivudine), Complera (emtricitabine/rilpivirine/tenofovir disoproxil fumarate), efavirenz/emtricitabine/tenofovir disoproxil fumarate (e.g., Atripla), efavirenz/lamivudine/tenofovir disoproxil fumarate (e.g., Symfi/Lo), Genvoya (cobicistat/elvitegravir/emtricitabine/tenofovir alafenamide fumarate), Juluca (dolutegravir/rilpivirine), Odefsey (emtricitabine/rilpivirine/tenofovir alafenamide fumarate), Stribild (cobicistat/elvitegravir/emtricitabine/tenofovir disoproxil fumarate), Symtuza (cobicistat/darunavir/emtricitabine/tenofovir alafenamide), Triumeq/PD (abacavir/dolutegravir/lamivudine) |
| Anticipated impact                      | Replacement spend; pharmacy benefit                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| Comments                                | Doravirine/islatravir will offer an additional two-drug regimen for maintenance therapy in virologically suppressed, treatment-experienced HIV patients. Islatravir, a nucleoside reverse transcriptase translocation inhibitor, will represent a novel mechanism of action for treating HIV.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |



## Specialty

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| Therapeutic category                    | <b>Lipid disorders</b>                                                                                                                                                                                                                                   |
| Product name                            | Tryngolza (olezarsen)                                                                                                                                                                                                                                    |
| Route of administration                 | SC                                                                                                                                                                                                                                                       |
| Manufacturer                            | Akcea Therapeutics/Ionis Pharmaceuticals                                                                                                                                                                                                                 |
| Proposed indication                     | The treatment of severe hypertriglyceridemia (sHTG) (supplemental indication)                                                                                                                                                                            |
| Phase of study                          | Pending FDA approval 6/30/26                                                                                                                                                                                                                             |
| Select available FDA approved therapies | fibrates (e.g., fenofibrate [i.e., Antara, Lipofen]), niacin, omega-3 fatty acids (e.g., icosapent ethyl [i.e., Vascepa], omega-3 ethyl esters, [i.e., Lovaza])                                                                                          |
| Anticipated impact                      | Incremental spend; pharmacy benefit                                                                                                                                                                                                                      |
| Comments                                | Tryngolza will provide the first FDA-approved therapy shown to reduce the risk of acute pancreatitis in patients with sHTG. It will also offer an add-on option for patients whose conditions are inadequately controlled on existing treatment options. |



## Specialty

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| Therapeutic category                    | <b>Renal disorders</b>                                                                                                                                                                                                                                                                                                                                                                                                      |
| Product name                            | Filspari (sparsentan)                                                                                                                                                                                                                                                                                                                                                                                                       |
| Route of administration                 | Oral                                                                                                                                                                                                                                                                                                                                                                                                                        |
| Manufacturer                            | Traverse Therapeutics                                                                                                                                                                                                                                                                                                                                                                                                       |
| Proposed indication                     | The treatment of focal segmental glomerulosclerosis (FSGS) (supplemental indication)                                                                                                                                                                                                                                                                                                                                        |
| Phase of study                          | Pending FDA approval 4/13/26                                                                                                                                                                                                                                                                                                                                                                                                |
| Select available FDA approved therapies | <b>Off-label immunosuppressive agents:</b><br>Oral: systemic corticosteroids, mycophenolate mofetil, cyclosporine, tacrolimus, cyclophosphamide<br>IV: rituximab (e.g., Rituxan, biosimilars), cyclophosphamide<br><br><b>Off-label, oral non-immunosuppressive agents:</b><br>Angiotensin-converting enzyme inhibitors (ACEIs), angiotensin II receptor blockers (ARBs), sodium-glucose cotransporter 2 (SGLT2) inhibitors |
| Anticipated impact                      | Incremental spend; pharmacy benefit                                                                                                                                                                                                                                                                                                                                                                                         |
| Comments                                | Filspari will offer a non-immunosuppressive agent to reduce proteinuria and slow kidney function decline in patients with FSGS. It will be used as an adjunct to standard therapies (e.g., ACEIs/ARBs, corticosteroids) and may be the first FDA-approved agent indicated for FSGS.                                                                                                                                         |



## Non-specialty

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| Therapeutic category                       | <b>Asthma</b>                                                                                                                                                                                                                                                                      |
| Product name                               | beclomethasone dipropionate/formoterol fumarate/<br>glycopyrrolate                                                                                                                                                                                                                 |
| Route of administration                    | Inhalation                                                                                                                                                                                                                                                                         |
| Manufacturer                               | Chiesi USA                                                                                                                                                                                                                                                                         |
| Proposed indication                        | The maintenance treatment of asthma in adults                                                                                                                                                                                                                                      |
| Phase of study                             | Pending FDA approval 6/15/26                                                                                                                                                                                                                                                       |
| Select available<br>FDA approved therapies | <b>Single-inhaler triple therapy combinations:</b><br>Trelegy Ellipta (fluticasone furoate/umeclidinium/<br>vilanterol)                                                                                                                                                            |
| Anticipated impact                         | Replacement spend; pharmacy benefit                                                                                                                                                                                                                                                |
| Comments                                   | Beclomethasone dipropionate/formoterol fumarate/<br>glycopyrrolate offers an additional single-inhaler triple<br>therapy option for asthma maintenance treatment,<br>combining an inhaled corticosteroid, a long-acting beta-2<br>agonist and a long-acting muscarinic antagonist. |



## Non-specialty

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| Therapeutic category                    | <b>Endocrine and metabolic</b>                                                                                                                                                                                                               |
| Product name                            | orforglipron                                                                                                                                                                                                                                 |
| Route of administration                 | Oral                                                                                                                                                                                                                                         |
| Manufacturer                            | Eli Lilly                                                                                                                                                                                                                                    |
| Proposed indication                     | The treatment of obesity in adults                                                                                                                                                                                                           |
| Phase of study                          | Pending FDA approval 4/10/26                                                                                                                                                                                                                 |
| Select available FDA approved therapies | <b>GLP-1 agonists for obesity:</b><br>liraglutide (i.e., Saxenda) SC, Wegovy (semaglutide) oral and SC, Zepbound (tirzepatide) SC                                                                                                            |
| Anticipated impact                      | Replacement spend; pharmacy benefit                                                                                                                                                                                                          |
| Comments                                | Orforglipron may be the second available oral GLP-1 agonist for the treatment of obesity. The review will be through the Commissioner's National Priority Voucher pilot program, which aims to shorten the FDA review process to 1–2 months. |



## Non-specialty

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| Therapeutic category                    | <b>Hypertension</b>                                                                                                                                                                                                                                                                                                                                                                                                        |
| Product name                            | baxdrostat                                                                                                                                                                                                                                                                                                                                                                                                                 |
| Route of administration                 | Oral                                                                                                                                                                                                                                                                                                                                                                                                                       |
| Manufacturer                            | AstraZeneca                                                                                                                                                                                                                                                                                                                                                                                                                |
| Proposed indication                     | The treatment of uncontrolled or treatment-resistant hypertension (TRH) in adults as add-on to other antihypertensive therapies when blood pressure isn't adequately controlled by these agents                                                                                                                                                                                                                            |
| Phase of study                          | Pending FDA approval 6/2/26                                                                                                                                                                                                                                                                                                                                                                                                |
| Select available FDA approved therapies | <b>TRH therapies:</b><br>Tryvio (aproцитentan)<br><br><b>Primary off-label TRH therapies:</b> amiloride (e.g., Midamore), bisoprolol, carvedilol (e.g., Coreg), clonidine (e.g., Catapres-TTS), diltiazem (e.g., Cardizem), doxazosin (e.g., Cardura), eplerenone (e.g., Inspra), guanfacine, hydralazine, metoprolol (e.g., Lopressor, Toprol XL), minoxidil, spironolactone (e.g., Aldactone), verapamil (e.g., Verelan) |
| Anticipated impact                      | Incremental spend; pharmacy benefit                                                                                                                                                                                                                                                                                                                                                                                        |
| Comments                                | Baxdrostat will provide a novel mechanism of action for treating TRH (aldosterone synthase inhibitor). We anticipate this will be a later-line add-on therapy for patients whose blood pressure remains uncontrolled despite multiple antihypertensive medications.                                                                                                                                                        |



## Non-specialty

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| Therapeutic category                    | <b>Smoking cessation</b>                                                                                                                                                                    |
| Product name                            | cytisinicline                                                                                                                                                                               |
| Route of administration                 | Oral                                                                                                                                                                                        |
| Manufacturer                            | Achieve Life Sciences                                                                                                                                                                       |
| Proposed indication                     | The treatment of nicotine dependence for smoking cessation in adults                                                                                                                        |
| Phase of study                          | Pending FDA approval 6/20/26                                                                                                                                                                |
| Select available FDA approved therapies | bupropion (e.g., Zyban), nicotine replacement therapies (NRTs), varenicline (e.g., Chantix)                                                                                                 |
| Anticipated impact                      | Incremental spend; pharmacy benefit                                                                                                                                                         |
| Comments                                | Cytisinicline will provide an alternative non-NRT pharmacologic option for smoking cessation in adults. It will be administered as part of either a 6- or 12-week initial treatment course. |



## First-time biosimilars

|                                                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
|--------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Therapeutic category                                   | <b>Autoimmune disorders</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| Product name, route of administration and manufacturer | golimumab SC<br>Accord Healthcare/Bio-Thera Solutions/Intas Pharmaceuticals                                                                                                                                                                                                                                                                                                                                                                                                                       |
| Reference product and manufacturer                     | Simponi (golimumab)<br>[Janssen Pharmaceuticals/Johnson & Johnson]                                                                                                                                                                                                                                                                                                                                                                                                                                |
| Reference brand indications                            | <ul style="list-style-type: none"><li>• Adults with moderately to severely active rheumatoid arthritis in combination with methotrexate</li><li>• Adults with active psoriatic arthritis alone, or in combination with methotrexate</li><li>• Adults with active ankylosing spondylitis</li><li>• Adults and pediatrics weighing at least 15 kg with moderately to severely active ulcerative colitis</li></ul>                                                                                   |
| Proposed biosimilar indications                        | <ul style="list-style-type: none"><li>• Adults with moderately to severely active rheumatoid arthritis in combination with methotrexate</li><li>• Adults with active psoriatic arthritis alone, or in combination with methotrexate</li><li>• Adults with active ankylosing spondylitis</li><li>• Adult and pediatric patients weighing at least 15 kg with moderately to severely active ulcerative colitis</li></ul>                                                                            |
| Anticipated biosimilar launch                          | Q2 2026                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| Comments                                               | <ul style="list-style-type: none"><li>• Anticipated to be the first Simponi biosimilar to launch as early as Q2 2026 (not including Simponi Aria).</li><li>• The manufacturer is pursuing an interchangeability designation upon approval.</li><li>• At least one additional Simponi biosimilar may get approval and launch by the end of Q4 2026.</li><li>• Specialty product</li><li>• <b>Anticipated impact:</b> Replacement spend (potential for decreased spend), pharmacy benefit</li></ul> |

# Abbreviations

**FDA** - U.S. Food and Drug Administration

**IM** - Intramuscular

**IV** - Intravenous

**SC** - Subcutaneous

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