formulary watch

HIV therapeutics market to reach $28 billion in 2029

Injectables are driving the growth because they can be taken less frequently, and adherence is a problem with oral medications.

Christine Blank

Treatments for the human immunodeficiency virus (HIV) are expected to reach $28 billion in sales in 2029, driven by injectable medications, a recent report says.

The total HIV therapeutics market was worth an estimated $22.9 billion across 7 major markets globally in 2019, according to GlobalData's 'HIV Therapeutics: Global Drug Forecast and Market Analysis to 2029' report.

The 7 markets include the U.S., France, Germany, Italy, Spain, the United Kingdom, and Japan.

Sales of injectable therapies are expected to exceed $1.8 billion in 2029. Injectables provide a viable alternative to oral medications since patients may not remember to take their medications, said Magdalene Crabbe, MA, senior ophthalmology and infectious diseases analyst at GlobalData, in a press release.

"The launch of STRs [single-tablet regimens of combination antiretroviral drugs] revolutionized the treatment landscape of HIV and met major unmet needs by increasing patient compliance and improving the safety and tolerability profiles of antiretroviral drugs," Crabbe said.

However, there are challenges with STRs, according to Crabbe. "A key component of multiple drugs is tenofovir disoproxil fumarate (TDF), which has been linked to osteoporosis and kidney disease. There are also people who don't remember to take their medication, and people who feel embarrassed about living with HIV, which lowers compliance," she said.

Roche's Fuzeon (enfuvirtide) was the first subcutaneously-administrable drug to be approved for the treatment of HIV-infected patients. "However, the fact that the drug is administered multiple times daily has led to difficulties with adherence and the emergence of injection-site related adverse events such as lipohypertrophy, erythema and pruritus," GlobalData said.

By 2029, other injectable therapies such as CytoDyn's leronlimab and Gilead Sciences' Lenacapavir will be available in the market, according to Crabbe.

In addition, TaiMed's Trogarzo (ibalizumab), which is an intravenously administered monoclonal antibody, launched in the U.S. in 2018 and in Europe in 2020.

There is also an increased market for HIV treatments due to the increase in cases of the disease. GlobalData projects that the diagnosed prevalent HIV cases in the seven major markets will increase from 1.87 million in 2019 to 2.1 million in 2029.

The U.S. will have the highest number of diagnosed prevalent cases of HIV in 2029 with more than 1.4 million, according to GlobalData's report, 'Human Immunodeficiency Virus (HIV): Epidemiology Forecast to 2029'. ■

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Blockbuster heart drug Entresto gets expanded indication

The FDA approved the use of Entresto in a broader group of heart failure patients that includes a large percentage of those with preserved ejection fraction.

Christine Blank

FDA's approval of a broader indication for sacubitril/valsartan (Entresto, Novartis) is expected to generate signficant additional sales of the drug that netted $1.7 billion in sales last year.

FDA approved the expanded indication to reduce the risk of cardiovascular death and hospitalization in a specific type of heart failure. The benefits are most clearly evident in patients with left ventricular ejection fraction (LVEF) below normal, Novartis said in a press release.

Entresto is already approved to treat heart failure with reduced ejection fraction (HFrEF).

"For the first time, there is a treatment with benefit for patients diagnosed with guideline-defined heart failure that includes both those with heart failure with reduced ejection fraction (HFrEF) and many with heart failure with preserved ejection fraction (HFpEF)1-3," Novartis said.

Many heart failure patients were not previously eligible for treatment before because "their ejection fraction was above the region we normally considered reduced," said Scott Solomon, MD, professor of medicine at Harvard Medical School and Brigham and Women's Hospital, and PARAGON-HF Executive Committee Co-Chair. "We can now offer a treatment to a wider range of patients who have an LVEF below normal."

The label expansion is based on efficacy and safety results from the PARAGON-HF, which Novartis says is the largest and only Phase 3 active-controlled study to date in patients with guideline-defined HFpEF2,5,6.

In the trial, the greatest benefit was shown in patients with LVEF below normal, Novartis said.

Around 6 million Americans are living with chronic heart failure (CHF). Approximately 3 million have HFrEF, and of the remaining 3 million, about 2 million have HFpEF with LVEF below normal, according to Novartis.

The expanded indication is important because CHF patients often face worsening symptoms that result in frequent heart failure hospitalizations and approximately 1 in 4 patients are re-admitted for heart failure. In addition, 10% may die within 30 days of discharge, Novartis said. ■

Novo Nordisk seeks weight-loss indication for Ozempic

Application to the FDA is based on results from a placebo-controlled trial showing a 15% decrease in body weight among those who are obese or overweight.

Christine Blank

Novo Nordisk has asked the FDA to expand the indication for its type 2 diabetes drug semaglutide (Ozempic) after a study sponsored by the company showed significant weight loss in patients without diabetes.

Overweight and obese people taking Ozempic had a "sustained, clinical relevant reduction in body weight," according to the doule-blind, placebo-controlled study published in the Feb. 10, 2021, issue of the *New England Journal of Medicine*. The results from that study are the basis for the company's application for the expanded indication for Ozempic.

Semaglutide is an glucagon-like peptide-1 (GLP-1) agonist. Other drugs in that class include dulaglutide (Trulicity), liraglutide (Victoza) and exenatide (Byettta).

According to the results reported in *NEJM*, the injection of 2.4 mg of semaglutide once weekly plus lifestyle intervention resulted in a mean loss in body weight of 14.9% from baseline in the study volunteers who were treated with semaglutide group compared with a 2.4% loss of body weight among those who were treated with a placebo.

The study included nearly 2,000 adults who had tried to

lose weight by changing their diets and either had a BMI of 30 or greater (the standard definition of obesity or a BMI of 27 or greater with one or more treated or untreated weight-related conditions, such as high blood pressure, high LDL cholesterol level or obstructive sleep apnea

"Obesity is associated with a wide range of serious complications, yet many healthcare providers still do not have sufficient medical options available to help people with this chronic disease ," said Mads Krogsgaard Thomsen, executive vice president and chief scientific officer of Novo Nordisk, in a press release. "We are excited about the regulatory filing of semaglutide 2.4 mg in the U.S. and we believe once-weekly semaglutide 2.4 mg has the potential to transform the medical management of obesity."

More participants in the semaglutide group than in the placebo group achieved weight reductions of 5% or more (86.4% vs. 31.5%), 10% or more (69.1% vs. 12%), and 15% or more (50.5% vs. 4.9%) at week 68 (P<0.001 for all three comparisons of odds).

Participants who received semaglutide had a greater improvement in cardiometabolic risk factors and a greater increase in participant-reported physical functioning from baseline than those who received placebo.

Nausea and diarrhea were the most common adverse events associated with semaglutide, but they were typically transient and mild-to-moderate in severity, according to the authors.

More participants in the semaglutide group than in the placebo group discontinued treatment due to gastrointestinal events (4.5% vs. 0.8%). ■

FDA authorizes new COVID-19 treatment; more vaccine doses on the way

Christine Blank

The FDA granted emergency authorization to a new monoclonal antibody COVID-19 treatment and millions of additional doses of COVID-19 vaccines will be available this year.

President Joe Biden said last week that his administration had finalized deals for an additional 100 million doses of the Pfizer-BioNTech and the Moderna's vaccines — 200 million doses in total— "giving the country enough vaccine by the end of July to cover every American adult," *The Washington Post* reported.

Today's Bloomberg says that the latest vaccination rate is 1,699,303 doses per day. At that rate, it will take eight months to cover 75% of the population with a two-dose vaccine, according to Bloomberg's calculations.

However, Johnson & Johnson has applied for an emergency use authorization (EUA_ of its single-dose vaccine. if the single-dose vaccine gets an FDA OK (as it is expected to do) then the proportion of vaccinated Americans could increase faster.

The doses that Biden spoke of last week won't be immediately available, but they will serve to prevent a shortfall later in the year by increasing supply by 50%, the *Washington Post* reported

Meanwhile, FDA an issued an EUA on Feb. 9 for Eli Lilly's monoclonal antibody combination, bamlanivimab (LY-CoV555) and etesevimab (LY-CoV016).

The agency's go-ahead is for the treatment of mild to moderate COVID-19 in patients aged 12 and older who are at high risk for progressing to severe COVID-19 and/or hospitalization.

Bamlanivimab alone under emergency use authorization has already provided many people with an early treatment option that could prevent hospitalizations, said Daniel Skovronsky, MD, PhD, Lilly's chief scientific officer and president of Lilly Research Laboratories, in a press release. "We are excited to now add an additional therapeutic option with a similar demonstrated clinical benefit."

With the risk of resistance emerging as various strains of the virus arise, bamlanivimab and etesevimab together could potentially allow efficacy against a broader range of naturally occurring SARS-CoV-2 variants as the new strains spread around the world, Skovronsky added.

The EUA is based on Phase 3 data from the BLAZE-1 trial, which demonstrated bamlanivimab and etesevimab together reduced the risk of COVID-19 hospitalizations and death by 70%.

Bamlanivimab and etesevimab are administered together via a single intravenous infusion as soon as possible after a positive COVID-19 test and within 10 days of symptom onset, according to Lilly.

In addition, the FDA has authorized infusion times for bamlanivimab alone and bamlanivimab and etesevimab together to be as short as 16 or 21 minutes, respectively – a significant reduction from the previously authorized time of 60 minutes, according to the pharma maker.

"This decision has been made in response to feedback received from front-line nurses and doctors administering these infusions and are aimed at reducing the burden on the healthcare system," Lilly said. ■

FDA OKs Cosela, first-in-class therapy to protect bone marrow after chemotherapy

Christine Blank

The FDA has approved trilaciclib (Cosela, G1 Therapeutics) as the first therapy in its class to protect bone marrow in adults receiving certain types of chemotherapy for extensive-stage small cell lung cancer.

Cosela may help protect bone marrow cells from damage caused by chemotherapy by inhibiting the enzyme cyclin-dependent kinase 4/6, drug approval agency said in a press release.

"For patients with extensive-stage small cell lung cancer, protecting bone marrow function may help make their chemotherapy safer and allow them to complete their course of treatment on time and according to plan," said Albert Deisseroth, M.D., Ph.D., supervisory medical officer in the Division of Non-Malignant Hematology in the FDA's Center for Drug Evaluation and Research.

Cosela is expected to be commercially available through G1's specialty distributor partner network in early March, according to a press release issued by the drug's marker, G1 Therapeutics in Research Triangle Park, North Carolina.

The most serious and life-threatening side effect of chemotherapy is myelosuppression, or damage to the bone marrow, resulting in reduced white blood cells, red blood cells and platelets, said Jeffrey Crawford, M,D., Geller Professor for Research in Cancer in the Department of Medicine and Duke Cancer Institute.

"Chemotherapy-induced myelosuppression may lead to increased risks of infection, severe anemia, and/or bleeding. These complications impact patients' quality of life and may also result in chemotherapy dose reductions and delays," Crawford said.

Treatment approaches to date have included the use of growth factor agents to accelerate blood cell recovery after the bone marrow injury has occurred, along with antibiotics and transfusions as needed, according to Crawford.

Cosela is administered intravenously as a 30-minute infusion within four hours prior to the start of chemotherapy.

"Chemotherapy is the most effective and widely used approach to treating people diagnosed with extensive-stage small cell lung cancer; however, standard of care chemotherapy regimens are highly myelosuppressive and can lead to costly hospitalizations and rescue interventions," said Jack Bailey, CEO of G1 Therapeutics, said in a press release. "COSELA will help change the chemotherapy experience for people who are battling ES-SCLC (extensive-stage small cell lung cancer."

The approval of the new treatment is based on data from three randomized, placebo-controlled trials that showed patients receiving Cosela prior to the start of chemotherapy had clinically meaningful and statistically significant reduction in the duration and severity of neutropenia.

The drug also produced a positive impact on red blood cell transfusions and other myeloprotective measures. The trials evaluated Cosela in combination with carboplatin/etoposide (plus or minus the immunotherapy atezolizumab) and topotecan chemotherapy regimens. ■

FDA clears BMS CAR-T cell therapy, Merck MET inhibitor

One of the new treatments available is a CAR-T cell therapy to treat relapsed or refractory large B-cell lymphoma. *Christine Blank*

The FDA cleared two important cancer treatments in the first week of February, including a CAR-T cell therapy for lymphoma,

Lisocabtagene maraleucel; liso-cel (Breyanzi, Bristol Myers Squibb) is a CD19-directed chimeric antigen receptor (CAR-T) cell therapy to treat adults with relapsed or refractory large B-cell lymphoma (LBCL) after two or more lines of systemic therapy.

"Today's approval represents another milestone in the rapidly progressing field of gene therapy by providing

an additional treatment option for adults with certain types of cancer affecting the blood, bone marrow, and lymph nodes," said Peter Marks, M.D., PhD, director of the FDA's Center for Biologics Evaluation and Research, in a press release. "Gene and cell therapies have evolved from promising concepts to practical cancer treatment regimens."

Bristol Myers Squibb plans to manufacture Breyanzi for each individual patient, with a 24-day target turnaround time, and inpatient or outpatient administration options, the company said in a press release.

"Breyanzi…will have an important role in clinical practice, offering people living with relapsed or refractory large B-cell lymphoma the chance for sustained response with an individualized treatment experience," said Samit Hirawat, MD, chief medical officer for the company.

The pharma maker plans to launch Breyanzi across an expansive network of treatment centers. Treatment centers will be Risk Evaluation and Mitigation Strategy (REMS) certified to support the appropriate use of the drug.

The agency also approved tepotinib (Tepmetko, Merck) to treat adults with metastatic non-small cell lung cancer harboring mesenchymalepithelial transition (MET) exon 14 skipping alterations.

The indication was cleared under accelerated approval based on overall response rate and duration of response, FDA said in its *Clinical Pharmacology Corner* e-newsletter.

The recommended dosage of Tepmetko is 450 mg orally once daily with food until disease progression or unacceptable toxicity. ■

FDA issues new warning on Pfizer's Xeljanz

Preliminary results from a safety clinical trial show an increased risk of serious heart-related problems and cancer with the rheumatoid arthritis and ulcerative colitis medicine Xeljanz.

Christine Blank

The FDA is warning about an increased risk of serious heart-related problems and cancer with the arthritis and ulcerative colitis medicine tofacitinib (Xeljanz and Xeljanz XR, Pfizer).

FDA added a Boxed Warning to Xeljanz and Xeljanz XR in 2019 after the agency found that interim trial results showed an increased risk of blood clots and death with the higher dosage of 10 milligrams, twice a day.

At the time, the agency ordered safety clinic trials, which also investigated other potential risks including blood clots in the lungs and death.

The initial results of one of the trials shows a higher occurrence of serious heart-related events and cancer in RA patients compared with those treated with a TNF inhibitor, leading to the new warning, FDA said in a press release.

FDA is awaiting additional results from the trial.

Patients should not stop taking tofacitinib without first consulting with their healthcare professionals, while healthcare professionals should consider the benefits and risks of tofacitinib when deciding whether to prescribe or continue patients on the medicine.

The FDA is also encouraging healthcare professionals and patients to report adverse events or side effects related to the use of tofacitinib to the FDA's MedWatch Safety Information and Adverse Event Reporting Program. ■

FDA clears Lupkynis, first oral treatment for lupus nephritis

Aurinia's Lupkynis, used in combination with a background immunosuppressive therapy regimen, is available now.

Christine Blank

FDA has approved the first oral treatment for lupus nephritis, voclosporin (Lupkynis, Aurinia Pharmaceuticals), used in combination with a background immunosuppressive therapy regimen.

The medication is available immediately to patients in the U.S.

"For years, treating patients with lupus nephritis has been challenging. We have had a very limited number of therapeutic options, and these have been only modestly effective but highly toxic," said Brad H. Rovin, M.D., professor of medicine and director of the Division of Nephrology at Ohio State University Wexler Medical Center and the medication's clinical trial investigator, in a press release.

"The FDA approval of Lupkynis allows us to treat patients safely and more effectively with a rapid-acting therapy which requires

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FDA CLEARS LUPKYNIS
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far less steroids, something our patients will appreciate," Rovin added.

In clinical trials, patients treated with Lupkynis in combination with standard of care were more than twice as likely to achieve renal response and experienced a decline in urine protein creatinine ratio as the patients receiving standard of care without the new drug.

Early intervention and kidney response are linked to better long-term outcomes and prevent irreversible kidney damage, said the press release from Aurinia. Patients treated with Lupkynis showed improved response rates in all parameters across immunologically active classes of lupus nephritis studied.

"The Lupkynis approval marks a turning point for the lupus nephritis community – patients, caregivers, families, and healthcare professionals – all of whom we thank for their partnership in the development of this innovative novel treatment," said Peter Greenleaf, president and CEO of Aurinia Pharmaceuticals. "The approved label supports the efficacy and safety of Lupkynis as well as Aurinia's proprietary and patented eGFR pharmacodynamic dosing protocol."

Aurinia launched Aurinia Alliance™, a patient support program featuring dedicated nurse case managers who provide personalized educational resources and assistance in navigating insurance and Aurinia medication costs. ■

Vizient projects drug prices will increase but moderately

Christine Blank

Due to more expensive medications that treat COVID-19 and other conditions, healthcare systems' face drug price increases starting this summer, a new report reveals. But the price increases are projected to be moderate.

Vizient's Winter 2021 Pharmacy Market Outlook projects a 2.67% increase in the price of pharmaceuticals purchased by health systems, academic medical centers, pediatric hospitals, and nonacute practices for July 1, 2021 – June 30, 2022.

However, the projected price increase continues to trend slightly downward, "reflecting recent generic entrants to the market as well as increasing adoption of biosimilars," Vizient said in a press release.

"The trend toward more moderate drug price increases is a welcome one, given the financial difficulties created by the pandemic," said Dan Kistner, group senior vice president, pharmacy solutions for Vizient. "Even so, without question the pandemic continues to have an impact on clinical and financial outcomes."

Increased use of high-cost drugs vasopressin and tocilizumab as well as many critical care drugs used to treat COVID patients are continuing to impact budgets, the press release said. A new formulation of vasopressin was recently approved by the FDA and granted market exclusivity through 2035, causing its price to spike significantly, according to the Vizient press release.

The press release said substantial price decreases are expected for drugs like injectable acetaminophen; daptomycin, a commonly used antibiotic; and regadenoson, a medication used in cardiac stress testing/..

However, Vizient is projecting that the supply of albumin and other plasma-derived products are likely to tighten up this year and possibly next because the pandemic has led to a decrease in plasma donations. The company is estimating a 3.1% inflation rate for plasma-dervied products.

Meanwhile, a separate report from RAND found that prescription drug prices in the U.S. are significantly higher than in other nations apart from notable exception of generic medications.

Drug prices in the U.S. are on average 2.56 times higher than those in 32 other nations, according to a new RAND Corporation report, International Drug Price Comparisons.

Brand-name drugs, in particular, are priced 3.44 times higher on average in the U.S. than other countries.

However, the RAND report found that prices for unbranded generic drugs — which account for 84% of drugs sold in the U.S. by volume but only 12% of U.S. spending — are slightly lower in the U.S. than in most other nations.

"For the generic drugs that make up a large majority of the prescriptions written in the U.S., our costs are lower," said Andrew Mulcahy, lead author of the study and a senior health policy researcher at RAND, in a press release. "It's just for the brand-name drugs that we pay through the nose."

The study found that among G7 nations, the United Kingdom, France and Italy generally have the lowest prescription drug prices, while Canada, Germany and Japan tend to have higher prices.

RAND researchers compiled their estimates from industry-standard IQVIA MIDAS data on drug sales and volume for 2018.

The study was sponsored by the Office of the Assistant Secretary for Planning and Evaluation in the U.S. Department of Health and Human Services. ■

ViiV Healthcare's Cabenuva will be available in the U.S. in February

FDA approves first complete long-acting HIV-1 treatment

Christine Blank

FDA cleared Cabenuva, the first and only compete long-acting regimen to treat HIV-1 in adults, according to pharma maker ViiV Healthcare.

Cabenuva is provided as a co-pack with two injectable medicines, ViiV Healthcare's cabotegravir and Janssen's rilpivirine. The prescription calls for it to be administered once monthly, and it is an option that can replace the current antiretroviral (ARV) regimen in those who are virologically suppressed on a stable regimen, with no history of treatment failure, and with no known or suspected resistance to either cabotegravir or rilpivirine, ViiV said in a press release.

Notably, Cabenuva reduces the treatment dosing days from 365 days to 12 days per year, according to ViiV's Lynn Baxter. The approval "represents a shift in the way HIV is treated, offering people living with HIV a completely new approach to care," Baxter said in press release.

ViiV Healthcare says it will begin shipping Cabenuva to wholesalers and specialty distributors in the U.S. in February.

Cabenuva's approval was based on a phase 3 studies that included more than 1,100 patients from 16 countries.

The new treatment was preferred by nine out of 10 patients over their previous daily oral therapy, according to ViiV.

In both studies, the most common adverse reactions (Grades 1 to 4) observed in ≥ 2% of clinical trial participants receiving Cabenuva were injection site reactions, pyrexia (fever), fatigue, headache, musculoskeletal pain, nausea, sleep disorders, dizziness and rash. Serious adverse events occurred in 4% of patients taking Cabenuva, and 3% (17/591) of adverse events led to withdrawal from the study. ■

New Cabometyx-Opdivo combo for renal cell carcinoma treatment

FDA cleared cabozantinib (Cabometyx) for patients with advanced renal cell carcinoma as a first-line treatment in combination with nivolumab (Opdivo).

Christine Blank

FDA cleared cabozantinib (Cabometyx, Exelixis) for patients with advanced renal cell carcinoma (RCC) as a first-line treatment in combination with nivolumab (Opdivo, Bristol Myers Squibb).

Cabometyx tablets are already approved for treatment of advanced RCC and hepatocellular carcinoma when patients have been previously treated with sorafenib.

Opdivo and Opdivo-based combinations are approved to treat multiple forms of cancer, including nonsmall cell lung cancer and malignant pleural mesothelioma.

"This combination of cabozantinib and nivolumab significantly improved key efficacy measures compared to sunitinib [Sutent, Pfizer] – progression-free survival, overall survival and objective response rate – while showing a low rate of treatment discontinuations due to side effects," said Toni Choueiri, M.D. director of the Lank Center for Genitourinary Oncology at Dana-Farber Cancer Institute and the Jerome and Nancy Kohlberg Professor of Medicine at Harvard Medical School, in a press release.

The approval is based on results from a phase 3

pivotal trial, which found that the combination regimen significantly improved overall survival (OS) compared with sunitinib. Median progression-free survival (PFS) was doubled at 16.6 months for Cabometyx in combination with Opdivo, compared with 8.3 months for sunitinib.

Objective response rate (ORR) was also doubled: 56% with Cabometyx in combination with Opdivo versus 27% with sunitinib.

"While significant progress has been made in the treatment landscape for advanced kidney cancer over the last several years, patients still need more therapeutic options to treat this disease as we search for a possible cure," said Bryan Lewis, president and co-founder of KidneyCAN. "The findings for the combination of Cabometyx and Opdivo in the CheckMate -9ER trial make the FDA approval of this combination a notable development for the patient community." ■

Top PBMs increase number of formulary exclusions in 2021

CVS Caremark, Express Scripts and OptumRx have increased the number of medications that are excluded from their national formularies.

Christine Blank

The number of formulary exclusions from the nation's three largest pharmacy benefits managers — Caremark (CVS Health), Express Scripts (Cigna), and OptumRx (United Health Group)—increased significantly in 2021, according to a new analysis.

Many exclusions are brand name treatments with generic equivalents but the PBMs are also leaving off more specialty meds, according to the Philadelphia-based Adam J. Fein, the drug pricing expert.

"The practice of formulary exclusion began in 2014. Since then, the number of products excluded from the national preferred formularies of the three largest PBMs has grown dramatically," wrote Fein, Ph.D., whose Drug Channels website is widely read in the industry. "The growth in excluded products shows how competitive many specialty therapy categories have become — and the undisclosed but presumably significant rebates generated by these products."

CVS Caremark removed 57 drugs and added 6 drugs back in its 2021 standard formulary, according to Fein. Express Scripts expanded it exclusion list by 70 medications. OptumRx excluded 27 more medication in its 2021 standard formulary; by Fein's tally, that OptumRx's total exclusion now has 476 products on it.

Express Scripts excluded some major medications in its 2021 standard formulary, including the psoriasis drug secukinumab (Cosentyx, Novartis), the cancer medication Calquence (AstraZeneca), and the PCSK9 inhibitor Praluent (Regeneron, Sanofi).

Among the notable exclusions in CVS Caremark's 2021 standard formulary are: the antidepression blockbuster paroxetine hydrochloride (Paxil, GlaxoSmithKline), pegfilgrastim (Neulasta, Amgen), and the otic anti-inflammatories/anti-infectives ciproflaxin hydrochloride (Cipro HC, Bayer) and (Ciprodex, Novartis).

OptumRx/ United Health excluded the blockbuster insulin Lantus (Sanofi) and anti-infection drug Neupogen (Amgen) in favor of the drugs' biosimilars. The PBM also excluded leukemia treatment Gleevec (Novartis).

The PBMs differ in how they handle formulary exclusions and additions, *Drug Channels* noted. Express Scripts and OptumRx both excluded Cosentyx, but CVS Caremark did not. CVS Caremark excluded etanercept (Enbrel, Wyeth) for psoriasis only, but Express Scripts and OptumRx did not. ■

"The growth in excluded products shows how competitive many specialty therapy categories have become — and the undisclosed but presumably significant rebates generated by these products."