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Pharmacy Solutions

- **COVID-19 therapy updates and expanded EUAs for Pfizer and Moderna vaccines**
- **FDA approvals for agents treating rare conditions and CAR-T therapies for cancer treatment**
- **Gene therapy developments for blood disorders and expected approval of teplizumab for type I diabetes**

Pipeline Report

May 2022

This quarterly publication is developed by our Clinical Pharmacy Drug Information team to increase your understanding of the drug pipeline, ensuring that you are equipped with insights to prepare for shifts in prescription drug management.

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As the SARS-CoV-2 virus evolves, recommendations for treatment and prophylaxis of COVID-19 continue to change. Restrictions on the monoclonal antibody therapies (e.g., **sotrovimab, casirivimab + imdevimab, bamlanivimab + etesevimab**) have been expanded to encompass the entire U.S., due to Omicron becoming the dominant variant across the country. These agents are not currently recommended for use in any setting. The National Institutes of Health (NIH) now recommends **Paxlovid** as the preferred first-line treatment of COVID-19, followed by **Veklury** (remdesivir), with **bebtelovimab** and **molnupiravir** offered as alternative therapies if the two preferred therapies are unavailable for non-hospitalized patients with mild to moderate COVID-19 who are at high risk of disease progression. Additionally, as data supports vaccine boosters, the **Pfizer COVID-19 vaccine** and the **Moderna COVID-19 vaccine** have received expanded Emergency Use Authorizations (EUAs) for use as second booster doses for all individuals ≥ 50 years of age and for certain immunocompromised individuals ≥ 12 years of age (Pfizer) or ≥ 18 years of age (Moderna).

In other news, **Camzyos** (mavacamten) and **Carvykti** (ciltacabtagene autoleucel) are two recent and significant FDA approvals. Camzyos is the first pharmacologic agent approved for the treatment of adults with obstructive hypertrophic cardiomyopathy (HCM) and is the first agent to address the underlying pathophysiology of HCM. Carvykti, meanwhile, is not the first CAR T-cell therapy to be approved for relapsed or refractory multiple myeloma, but its strong efficacy data does bode well for its entry into the market. It is also being studied in earlier lines of multiple myeloma therapy, as are other CAR T-cell therapies for other hematologic cancers. One such example is **Yescarta** (axicabtagene ciloleucel), which recently was FDA-approved for the expanded indication as second-line therapy inadults with relapsed or refractory large B-cell lymphoma. Yescarta had previously been approved for use in the third-line or later setting.

Noteworthy developments in the drug pipeline include an expected FDA decision in August on gene therapy **betibeglogene autotemcel** for transfusion-dependent beta-thalassemia (TDT). At the same time, the FDA is due to decide on **teplizumab**. It is proposed to be the first agent to delay the onset of type I diabetes in patients who do not currently have the disease, but who are at high risk of developing it. The potential for significant impact on the lives of those within the targeted population are striking. We await these and other important FDA decisions, highlighted in the attached report.

Our pipeline report is just one of many ways we are committed to providing helpful tools and resources to our clients and partners. We look forward to sharing more updates with you in the months ahead.

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To provide comments, feedback or requests for report enhancements, please email us at Communications@EnvolveHealth.com.

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FDA-APPROVED AGENTS					
Drug Name	**Manufacturer(s)**	**FDA Approval Date**	**Therapeutic Class**	**Comments**	**Cost (WAC)**
Veklury *remdesivir* intravenous infusion	Gilead	FDA Approval: 10/22/2020 Pediatric EUA replaced with full FDA approval: 4/25/2022	Treatment - antiviral	• 4/25/2022: The FDA expanded the approval of the COVID-19 treatment Veklury (remdesivir) to include pediatric patients 28 days of age and older weighing at least 3 kilograms with positive results of direct SARS-CoV-2 viral testing, who are: • Hospitalized, or • Not hospitalized and have mild-to-moderate COVID-19 and are at high risk for progression to severe COVID-19, including hospitalization or death • This approval is already applied to adults and makes Veklury the first approved COVID-19 treatment for children less than 12 years of age; as a result, the agency also revoked the emergency use authorization for Veklury that previously covered this pediatric population	$520 for a 100 mg single dose vial $2,340 for a 5-day course $5,720 for a 10-day course

***Initially, the federal government will supply the vaccine at no cost.**

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Drug Name	Manufacturer(s)	FDA Approval Date	Therapeutic Class	Comments	Cost (WAC)
Comirnaty *Pfizer COVID-19 vaccine* intramuscular injection	Pfizer	Full FDA approval: 8/23/2021 Original EUA: 12/11/2020 Revised EUA: 3/29/2022	Vaccine	• 5/17/22: The FDA expanded the EUA to authorize a single booster dose for administration to individuals 5 through 11 years of age at least five months after completion of a primary series with the Pfizer-BioNTech COVID-19 Vaccine. The CDC independent advisory committee voted 11-1 (with one abstention) in favor of approval for Pfizer and BioNTech's COVID-19 booster doses to be given to children aged 5 to 11 years • 3/29/2022: The FDA expanded EUA to authorize a second booster dose to individuals ≥ 50 years of age who have received a first booster dose of any authorized or approved COVID-19 vaccine; and a second booster dose to individuals ≥ 12 years of age with certain kinds of immunocompromise and who have received a first booster dose of any authorized or approved COVID-19 vaccine • 1/3/2022: The FDA also amended the EUA to reduce the time between completion of primary vaccination and administration of a booster dose from at least 6 months to at least 5 months • The FDA also amended the EUA to allow for administration of a third primary series dose in certain immunocompromised children 5–11 years of age • Lastly, the FDA amended the EUA of Pfizer-BioNTech's COVID-19 vaccine to include the use of a single booster dose in children 12–15 years of age • Subsequently on 1/5/2022, the CDC also recommended that children 12-17 years of age should get a Pfizer-BioNTech coronavirus vaccine booster • **No cost to patients**	$19.50 per dose*

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Drug Name	Manufacturer(s)	FDA Approval Date	Therapeutic Class	Comments	Cost (WAC)
Spikevax *Moderna COVID-19 vaccine, mRNA* intramuscular injection	Moderna	Full FDA approval: 1/31/2022 Original EUA: 12/18/2020 Revised EUA: 3/29/2022	Vaccine	• 4/28/2022: Moderna initiated an EUA request for the prevention of COVID-19 in children 6 months to < 6 years of age; the requests are based on a 25 µg two-dose primary series of mRNA-1273 • The KidCOVE results included a supportive preliminary efficacy analysis on cases mostly collected during the Omicron wave • When the analysis is limited only to cases confirmed positive for SARS-CoV-2, Spikevax efficacy remained significant at 51% among infants between 6 months to < 2 years of age, and was 37% for the subgroup of children 2 years to < 6 years of age, the company said • 3/29/2022: The FDA expanded the EUA to authorize a second booster dose to individuals ≥ 50 years of age who have received a first booster dose of any authorized or approved COVID-19 vaccine; and a second booster dose to individuals ≥ 18 years of age with certain kinds of immunocompromise and who have received a first booster dose of any authorized or approved COVID-19 vaccine • 1/31/2022: The FDA granted full approval for the COVID-19 vaccine known as Spikevax® (Moderna COVID-19 Vaccine, mRNA) as a two-dose primary vaccination series for the prevention of COVID-19 disease in individuals 18 years of age and older • Moderna COVID-19 Vaccine remains available under Emergency Use Authorization (EUA) for individuals 18 years of age and older for the following: as a two-dose primary series, as a third primary series dose for individuals who have been determined to have certain kinds of immunocompromise, and as a single booster dose (either homologous or heterologous) • 1/7/2022: The EUA revised the authorized dosing interval of the homologous Moderna vaccine booster dose to at least five months after completion of the primary series of this vaccine to individuals 18 years of age or older • **No cost to patients**	$15-$37 per dose*

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Drug Name	Manufacturer(s)	FDA Approval Date	Therapeutic Class	Comments	Cost (WAC)
Olumiant *baricitinib* oral tablet	Eli Lilly	FDA approval: 5/10/2022 Original EUA: 11/19/2020 Revised EUA: 7/28/2021, 5/10/2022	Treatment - ARDS Janus kinase (JAK) inhibitor	• 5/10/2022: Olumiant gained FDA approval for the treatment of COVID-19 in hospitalized adults requiring supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO) • Olumiant remains under EUA status for hospitalized pediatric patients 2 to < 18 years of age requiring supplemental oxygen, non-invasive or invasive mechanical ventilation, or ECMO	$2,553 for 14-day course $91.17 per 2 mg tablet
AGENTS GRANTED FDA EMERGENCY USE AUTHORIZATION (EUA)					
Drug Name	**Manufacturer(s)**	**EUA Approval Date**	**Therapeutic Class**	**Comments**	**Cost (WAC)**
Ad26.COV2-S intramuscular injection	J&J; Janssen	Original: 2/27/2021 Revised: 5/5/2022	Vaccine	• 5/5/2022: The FDA limited the authorized use of the Janssen COVID-19 Vaccine to 1) individuals 18 years of age and older for whom other authorized or approved COVID-19 vaccines are not accessible or clinically appropriate, and 2) individuals 18 years of age and older who elect to receive the Janssen COVID-19 Vaccine because they would otherwise not receive a COVID-19 vaccine • The FDA determined that the risk of thrombosis with thrombocytopenia syndrome (TTS), with the onset of symptoms approximately one to two weeks following administration of the Janssen COVID-19 Vaccine, warrants limiting the authorized use of the vaccine • 4/8/2022: The FDA has extended the shelf life for its COVID-19 vaccine from nine months to 11 months • 3/17/2022: A peer-reviewed study published in JAMA demonstrated vaccine effectiveness was estimated to be 76% for COVID-19 infection and 81% for hospitalizations for at least 180 days after vaccination before and during the Delta variant surge • **No cost to patients**	$10 per dose*

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Drug Name	Manufacturer(s)	EUA Approval Date	Therapeutic Class	Comments	Cost (WAC)
REGEN-COV *casirivimab + imdevimab* intravenous infusion	Regeneron	Original: 11/21/2020 Revised: 1/24/2022	Treatment - monoclonal antibody	· 4/29/2022: The NIH COVID-19 guidelines (as of 4/29/2022) continue to recommend against using casirivimab plus imdevimab for the treatment of COVID-19 because the Omicron variant of concern (VOC) has become the dominant variant in the U.S. · 4/14/2022: FDA extends PDUFA date of BLA review for the treatment of COVID-19 in non-hospitalized patients and as post-exposure prophylaxis in certain individuals to 7/14/2022; this was due to additional time needed for additional data review • **No cost to patients, although healthcare facilities may charge fees related to administration**	$1,500 single dose infusion $450 administration cost
LY-CoV555 + LY-CoV016 *bamlanivimab + etesevimab* intravenous infusion	Eli Lilly	Original: 2/9/2021 Revised: 1/24/2022	Treatment - monoclonal antibody	· 4/29/2022: The National Institute of Health (NIH) COVID-19 guidelines continue to recommend against using bamlanivimab plus etesevimab for the treatment of COVID-19 because the Omicron VOC has become the dominant variant in the U.S. • **Outpatient only - no cost to patients, although healthcare facilities may charge fees related to administration**	N/A
sotrovimab intravenous infusion	GlaxoSmithKline; Vir	EUA: 5/26/2021 Revised EUA: 2/23/2022	Treatment - monoclonal antibody	· 4/5/2022: Sotrovimab is not authorized in any U.S. state or territory at this time – the CDC data estimates that the proportion of COVID-19 cases caused by the Omicron BA.2 variant is above 50% in all Health and Human Services U.S. regions · Data included in the health care provider fact sheet show the authorized dose of sotrovimab is unlikely to be effective against the BA.2 sub-variant · The NIH COVID-19 guidelines (as of 4/29/2022) recommend against using sotrovimab for the treatment of COVID-19 because the Omicron VOC has become the dominant variant in the U.S. · 2/23/2022: The FDA limited the EUA use of sotrovimab when administered for treatment of COVID-19 to exclude geographic regions where, based on available information including variant susceptibility to these drugs and regional variant frequency, infection is likely due to a variant that is non-susceptible to sotrovimab · 1/13/2022: GSK/Vir submitted EUA for intramuscular administration of sotrovimab for the early treatment of COVID-19	$2,100 single dose infusion

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Drug Name	Manufacturer(s)	EUA Approval Date	Therapeutic Class	Comments	Cost (WAC)
Convalescent plasma intravenous infusion	U.S. Dept of Health and Human Services	Original: 8/23/2020 Revised: 12/18/2021	Treatment - blood product	· 4/29/2022: The NIH COVID-19 Guidelines (as of 4/29/2022) were updated to include a recommendation against the use of COVID-19 convalescent plasma (CCP) that was collected prior to the emergence of the Omicron (B.1.1.529) variant for the treatment of COVID-19; the panel also recommended against the use of CCP for the treatment of COVID-19 in hospitalized, immunocompetent patients	Unknown at this time
Actemra *tocilizumab* intravenous infusion	Roche; Genentech	Original: 6/24/2021	Treatment - IL-6 receptor antagonist	· 4/4/2022: The FDA has accepted the company's supplemental BLA for Priority Review for the treatment of COVID-19 in hospitalized adults who are receiving systemic corticosteroids and require supplemental oxygen, mechanical ventilation, or extracorporeal membrane oxygenation – a decision on FDA approval is expected in the second half of 2022 • **8-12 mg/kg single IV infusion; one additional infusion may be administered**	$3,228 for a single infusion for a 70 kg patient
Evusheld *tixagevimab and cilgavimab* intramuscular injections	AstraZeneca	Original: 12/8/2021 Revised: 2/24/2022	Monoclonal antibody	· 2/24/2022: The FDA updated the EUA and authorized a higher dose of AstraZeneca's Evusheld for the pre-exposure prophylaxis (PrEP) of COVID-19, based on the emergence of resistant Omicron subvariants (BA.1 and BA.1.1) · The new dose of 300 mg of tixagevimab and 300 mg of cilgavimab is double that of the initial authorized dose · The FDA recommended that patients who received the initial authorized dose of Evusheld should receive an additional dose as soon as possible to increase their monoclonal antibody levels • **150 mg of tixagevimab and 150 mg of cilgavimab administered as two separate consecutive intramuscular injections** • **No cost to patients**	No projected pricing yet*

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Paxlovid *PF-07321332* oral tablets	Pfizer	Original: 12/22/2021 Revised: 4/14/2022	antiviral protease inhibitor	· 4/14/2022: The FDA updated the EUA to authorize an additional dose presentation with appropriate dosing for patients with moderate renal impairment within the scope of the EUA · 4/1/2022: As of 4/1/2022, the NIH COVID-19 Guidelines recommend Paxlovid as the preferred 1st line therapy prior to Veklury (along with bebtelovimab and molnupiravir as alternative therapies if the preferred therapies are unavailable) for non-hospitalized patients with mild to moderate COVID-19 who are at high risk of disease progression • **No cost to patients**	$530 per course*
Lagevrio *molnupiravir* oral capsules	Merck; Ridgeback	Original: 12/23/2021	antiviral nucleoside analog	· 4/1/2022: The NIH COVID-19 Guidelines recommend molnupiravir as an alternative therapy (with the preferred being Paxlovid and Veklury) for non-hospitalized patients with mild to moderate COVID-19 who are at high risk of disease progression • **No cost to patients**	$700 per course*
bebtelovimab intravenous infusion	Eli Lilly	Original: 2/11/2022	Monoclonal antibody	· 4/1/2022: As of 4/1/2022, the NIH COVID-19 Guidelines recommend bebtelovimab as an alternative therapy (with the preferred being Paxlovid and Veklury) for non-hospitalized patients with mild to moderate COVID-19 who are at high risk of disease progression • **No cost to patients**	$1,200 per dose*

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PIPELINE AGENTS					
Drug Name	**Manufacturer(s)**	**Anticipated Date of EUA or FDA Approval**	**Therapeutic Class**	**Comments**	**Cost (WAC)**
BRII-196 + BRII-198 *amubarvimab + romlusevimab* intravenous infusion	Brii Biosciences	7/14/2022	Monoclonal antibodies	• 5/9/2022: The EUA submission is currently under review by the FDA • This antibody combination is proposed for the treatment of patients with COVID-19 at high risk of severe disease progression, including hospitalization or death • Data showed that this long-acting COVID-19 neutralizing antibody combination therapy retains neutralizing activity against the Omicron BA.2 SARS-CoV-2 subvariant • Based on the final results from the U.S. NIH-sponsored ACTIV-2 Phase 3 clinical trial with 837 enrolled outpatients, the combination demonstrates a statistically significant 80% reduction of hospitalization and death with fewer deaths through 28 days in the treatment arm (0) relative to placebo (9), and improved safety outcome over placebo in non-hospitalized COVID-19 patients at high risk of clinical progression to severe disease • Similar efficacy rates were observed in participants initiating therapy early (0-5 days) and late (6-10 days), following symptom onset, providing critically needed clinical evidence in COVID-19 patients who were late for treatment • Amubarvimab and romlusevimab are non-competing SARS-CoV-2 monoclonal neutralizing antibodies derived from convalesced COVID-19 patients	No projected pricing yet
Vaxzevria *AZD 1222* intramuscular injection	AstraZeneca	Currently unknown	Vaccine	• 9/30/2021: Vaxzevria found to have 74% efficacy in preventing symptomatic disease in the US, according to a report published in the New England Journal of Medicine • Non-replicating chimpanzee adenovirus-vector dsDNA expressing SARS-CoV-2 spike protein • **No cost to patients**	Projected $3-$4 per dose*

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Drug Name	Manufacturer(s)	Anticipated Date of EUA or FDA Approval	Therapeutic Class	Comments	Cost (WAC)
NVX-CoV2373 intramuscular injection	Novavax	1H 2022	Vaccine	· 1/31/22: Novavax formally submitted an EUA request to the FDA — on 6/7/2022, the VRBPAC will discuss the EUA request for Novavax's COVID-19 vaccine for individuals 18 years of age and older · SARS-CoV-2 spike glycoprotein nanoparticle + adjuvant vaccine • **No cost to patients**	Projected $10-$16 per dose*
Covaxin *BBV152* intramuscular injection	Ocugen	2H 2022	Vaccine	· 3/4/2022: The FDA has declined to issue an EUA for Covaxin for active immunization to prevent COVID-19 caused by SARS-CoV-2 in individuals 2-18 years of age · Whole-virion, inactivated vaccine • **No cost to patients**	No projected pricing yet
lenzilumab intravenous infusion	Humanigen, Inc.	2022	Monoclonal antibody	· Lenzilumab is a proprietary first-in-class monoclonal antibody that neutralizes GM-CSF, a cytokine of importance in the hyperinflammatory cascade associated with COVID-19 and other indications	No projected pricing yet
favipiravir oral tablet	Fujifilm; Others	Currently unknown	Antiviral	· Phase 2 - Limited data available to date – small studies have shown virus clearance from airway; contraindicated in pregnant women • **Dose: Loading dose twice daily on Day 1, then twice daily on Days 2-7**	Overseas priced at $1 per tablet
Zyesami *aviptadil* intravenous infusion	NRx Pharmaceuticals	2022	Synthetic vasoactive intestinal peptide	· 1/5/2022 - NRx Pharmaceuticals submitted EUA application for Zyesami to treat patients at immediate risk of death from COVID-19 respiratory failure despite treatment with remdesivir and other approved therapies	No projected pricing yet; available overseas
SNG001 *interferon-beta* inhalation	Synairgen	2022	Broad-spectrum anti-viral protein interferon beta	· 2/21/2022: The Phase 3 study of SNG001 in patients hospitalized with COVID-19 failed to meet its primary or key secondary efficacy endpoints; results from the SPRINTER trial showed that patients who received SNG001 were no more likely to be discharged from hospital than those on placebo · The study also found that people given SNG001 were no more likely to recover to "no limitation of activities" than patients who received placebo	No projected pricing yet

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Drug Name	Manufacturer(s)	Anticipated Date of EUA or FDA Approval	Therapeutic Class	Comments	Cost (WAC)
CoVLP intramuscular injection	Medicago; GlaxoSmithKline	2022	Vaccine	· 12/8/2021 - Phase 3 study demonstrated an overall efficacy rate of 71% against widely circulating SARS-CoV-2 variants; regulatory filing process initiated in the U.S. · Plant-based COVID-19 vaccine composed of recombinant spike glycoprotein expressed as virus-like particles (VLPs) • **Dose: two 3.75 µg doses of antigen in combination with GlaxoSmithKline's pandemic adjuvant given 21 days apart**	No projected pricing yet
ADG20 intravenous infusion	Adagio Therapeutics	2022	Monoclonal antibody	· 4/14/2022: Based on feedback from the FDA regarding adintrevimab's lack of neutralizing activity against the BA.2 variant, Adagio is pausing the submission of an EUA request · 3/30/2022: Adagio reported that the primary endpoints were met with statistical significance for all three indications in the company's ongoing global Phase 2/3 clinical trials evaluating its investigational drug adintrevimab (ADG20) as a pre-and-post-exposure prophylaxis (EVADE) and treatment (STAMP) for COVID-19 · The risk of symptomatic COVID-19 was reduced by 71% compared to placebo in pre-exposure prophylaxis and 75% compared to placebo in post-exposure prophylaxis · The risk of hospitalization or death in participants with mild to moderate COVID-19 was reduced by 66% compared to placebo in the primary efficacy analysis population and by 77% compared to placebo in participants who received treatment within three days of symptom onset · ADG20 is a monoclonal antibody targeting the spike protein of SARS-CoV-2 and related coronaviruses	No projected pricing yet

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Drug Name	Manufacturer(s)	Anticipated Date of EUA or FDA Approval	Therapeutic Class	Comments	Cost (WAC)
MP0420 *ensovibep* intravenous infusion	Novartis; Molecular Partners	2022	Antiviral	• 2/10/2022: EUA for the treatment of COVID-19 submitted to FDA based on the positive results of the phase 2 portion of the EMPATHY study • Ensovibep is a multi-specific DARPin (Designed Ankyrin Repeat Protein), specifically designed to block the receptor binding domains of SARS-CoV-2 spike protein through highly potent and cooperative binding, making it challenging for escape mutants • **Dose: 75 mg IV**	No projected pricing yet
ACB294640 *opaganib* oral therapy	Redhill Biopharma	Currently unknown	Antiviral	• 1/13/2022: In a prespecified analysis of all Phase 2/3 study patients with positive PCR at screening, opaganib improved the median time to viral RNA clearance by at least four days; median of 10 days for viral clearance in the opaganib arm vs. clearance median not reached by end of 14-day treatment in placebo arm (Hazard Ratio 1.34; nominal p-value=0.043, N=437/463) • Results were achieved in a severely ill hospitalized patient population with a median of 11-days from onset of symptoms • Opaganib is a potential first-in-class, orally-administered, sphingosine kinase-2 selective inhibitor, with proposed dual anti-inflammatory and antiviral activity	No projected pricing yet
fluvoxamine oral therapy	Various generic manufacturers	2022	Sigma-1 receptor activator, SSRI	• 5/17/2022: The FDA declined to authorize the EUA request for the antidepressant fluvoxamine to treat COVID-19. "Based on the review of available scientific evidence, the FDA has determined that the data are insufficient to conclude that fluvoxamine may be effective in the treatment of non-hospitalized patients with COVID-19 to prevent progression to severe disease and/or hospitalization," the agency said • 12/21/2021: EUA submitted for the treatment of mild-to-moderate COVID-19 in non-hospitalized adults with confirmed SARS-CoV-2 infection; the TOGETHER trial resulted in 30% reduction in ER visits and hospitalization • Fluvoxamine is a potent activator of the sigma-1 receptor, which decreases inflammation via reducing endoplasmic reticulum stress; it is being studied at doses of 50-100 mg twice daily	Approximately $1 per tablet

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Drug Name	Manufacturer(s)	Anticipated Date of EUA or FDA Approval	Therapeutic Class	Comments	Cost (WAC)
VERU-111 *sabizabulin* oral therapy	Veru	2022	Antiviral, Anti-inflammatory cytoskeleton disruptor	• 4/11/2022: Veru announced positive efficacy and safety results from a planned interim analysis of the double-blind, randomized, placebo-controlled Phase 3 COVID-19 clinical trial evaluating oral sabizabulin 9 mg versus placebo in 150 hospitalized COVID-19 patients at high risk for Acute Respiratory Distress Syndrome (ARDS) • The prespecified primary endpoint was death at or before Day 60 • Sabizabulin treatment resulted in a clinically and statistically meaningful 55% relative reduction in deaths (p=0.0029) in the intent to treat population • Veru plans to meet with the FDA to discuss next steps including the submission of an EUA application • 1/31/2022: FDA granted fast track designation to the Phase 3 registration program for the investigation of sabizabulin to combat COVID-19 infection and the cytokine storm that is responsible for ARDS and death • Sabizabulin is a cytoskeleton disruptor which blocks microtubule trafficking and has the potential to treat both the SARS-CoV-2 viral infection and the cytokine storm and septic shock that leads to ARDS and the high COVID-19 mortality rates	No projected pricing yet

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Drug Name	Manufacturer(s)	Anticipated Date of EUA or FDA Approval	Therapeutic Class	Comments	Cost (WAC)
RHB-107 oral therapy	Redhill Biopharma	Currently unknown	Antiviral	• 3/1/2022: Phase 2 of the Phase 2/3 study of once daily oral RHB-107 in symptomatic COVID-19 demonstrated 100% reduction in hospitalization due to COVID-19 with zero patients (0/41) on the RHB-107 arms versus 15% (3/20) hospitalized on the placebo-controlled arm (though not powered for efficacy assessment) • It also showed 87.8% reduction in reported new severe COVID-19 symptoms after treatment initiation, with only one patient in the RHB-107 treated group 2.4%, (1/41) versus 20% (4/20) of patients in the placebo-controlled arm • RHB-107 is a first-in-class, orally-administered antiviral, that targets human serine proteases involved in preparing the spike protein for viral entry into target cells	No projected pricing yet
Sanofi-GSK vaccine intramuscular injection	Sanofi; GSK	Currently unknown	Vaccine	• 2/23/2022: Sanofi and GlaxoSmithKline announced they will seek regulatory approval for their COVID-19 vaccine to be administered as a two-dose primary series (given 3 weeks apart) as well as for use as a booster dose • In the Phase 3 VAT08 clinical study, the Sanofi-GSK vaccine demonstrated 100% efficacy against severe COVID-19 disease and hospitalizations, and 75% efficacy against moderate or severe COVID-19 • Noting that the trial predominantly included patients infected with SARS-CoV-2 variants of concern, the companies reported 57.9% efficacy against symptomatic COVID-19 • Sanofi-GSK vaccine is a recombinant protein vaccine that uses the SARS-CoV-2 virus spike protein as the vaccine antigen	No projected pricing yet

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Drug Name	Manufacturer(s)	Anticipated Date of EUA or FDA Approval	Therapeutic Class	Comments	Cost (WAC)
Lambda *peginterferon lambda* subcutaneous injection	Eiger BioPharmaceuticals	2022	Antiviral, type III interferon	• 3/17/2022: Eiger announced that peginterferon lambda reduced the risk of COVID-19-related hospitalizations or emergency room visits greater than six hours by 50% (primary endpoint) and death by 60% in the Phase 3 TOGETHER study, a multi-center, randomized, double-blind, placebo-controlled study of non-hospitalized adult patients with COVID-19, who are at high risk of progressing to severe illness • The TOGETHER study is the second largest study to date of a COVID-19 therapeutic; final analyses evaluated data from 1,936 patients, with 84% of patients having received at least a single dose of any COVID-19 vaccine • Lambda is a late-stage, first-in-class, type III interferon that stimulates immune responses that are critical for the development of host protection during viral infections and has been well-tolerated in clinical studies	No projected pricing yet
proxalutamide oral therapy	Kintor Pharmaceutical	2022	ACE2 (angiotensin-converting enzyme 2)	• 4/6/2022: A Phase 3 trial of symptomatic patients with mild-to-moderate COVID-19, regardless of vaccination status or risk factors, showed significantly reduced rates of hospitalizations and death • Top-line results showed that among all randomised patients with at least one day of treatment (N=730), proxalutamide reduced the risk of hospitalisation or death by 50% compared to the control group, while in those with more than one day of treatment (N=721), the drug cut the risk by 71% • Among patients with more than seven days of treatment (N=693), proxalutamide reduced the risk of hospitalization or death by 100% compared to the control group ($p < 0.02$) • Kintor stated that among patients with more than one day of treatment, there were seven hospitalisations in the control group, including one death, whereas two patients in the proxalutamide arm were hospitalised, and there were no deaths; Kintor plans to seek EUA approval from the FDA	No projected pricing yet
ExoFlo intravenous infusion	Direct Biologics	Currently unknown	Acellular human bone marrow mesenchymal stem cell derived extracellular vesicle product	• 4/12/2022: This is proposed for treatment of ARDS associated with COVID-19 • The FDA has awarded ExoFlo a Regenerative Medicine Advanced Therapy (RMAT) designation for the treatment of ARDS associated with COVID-19	No projected pricing yet

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Available at: A AcariaHealth P PANTHERx Rare # Other

Drug Name	Manufacturer(s)	Indication(s)	FDA Approval Date	Comments	Cost (WAC)
CARDIOVASCULAR					
1 2 3 4 5 **Camzyos** *mavacamten* oral capsule	Bristol-Myers Squibb	Hypertrophic cardiomyopathy (HCM)	4/28/2022	· FDA-approved for the treatment of adults with symptomatic New York Heart Association (NYHA) class II-III obstructive HCM to improve functional capacity and symptoms · Camzyos is the first agent to target the cardiac muscle proteins that drive the excessive contractility and impaired relaxation that are hallmarks of HCM with the intent of correcting the abnormal function of the heart · Prescribing Information includes a black box warning regarding an increased risk of heart failure, and distirbution only through a REMS program · Projected impact: incremental cost increase	$89,500/year
ENDOCRINOLOGY					
A **Vijoice** *alpelisib* oral tablet	Novartis	PIK3CA-related overgrowth spectrum (PROS)	4/5/2022	· Approved for the treatment of adult and pediatric patients ≥ 2 years of age with severe manifestations of PROS who require systemic therapy · First FDA-approved treatment for PROS, which is a range of rare conditions characterized by overgrowths and blood vessel anomalies impacting approximately 14 per one million people · Projected impact: cost increase	$423,800/year
6 **Cuvrior** *trientine tetrahydrochloride* oral tablet	Orphalan	Wilson's disease	4/28/2022	· For the treatment of adult patients with stable Wilson's disease who are de-coppered and tolerant to penicillamine · Syprine (trientine hydrochloride) is FDA-aproved for patients with Wilson's disease who are intolerant to d-penicillamine · Projected impact: cost replacement of existing therapies	Pending launch

[1]Accredo, [2]Alivia Health, [3]AllianceRx Walgreens Prime, [4]CVS Caremark, [5]Optum, [6]Pending Launch

 | Data is current as of 05/26/2022

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Available at: A AcariaHealth P PANTHERx Rare # Other

Drug Name	Manufacturer(s)	Indication(s)	FDA Approval Date	Comments	Cost (WAC)
HEMATOLOGY					
4 **Enjaymo** *sutimlimab-jome* intravenous infusion	Sanofi	Cold agglutinin disease (CAD)	2/4/2022	· FDA-approved to decrease the need for red blood cell transfusion due to hemolysis in adults with CAD · Estimated population prevalence: 16 per 1 million, approximately 75% of whom are believed to be in need of treatment · Rituximab alone or in combination with bendamustine, fludarabine, or ibrutinib is used off-label for the treatment of CAD · Projected impact: incremental cost increase	$309,000/year
7 **Pyrukynd** *mitapivat* oral tablets	Agios Pharmaceuticals	Pyruvate kinase deficiency (PKD)	2/17/2022	· First agent to be FDA-approved for the treatment of hemolytic anemia in adults with PKD · The estimated prevalence of PK deficiency with hemolytic anemia is ~3.3-12.2 per million in Western populations · Current management strategies consist of blood transfusions and splenectomy · Projected impact: cost increase	$335,000/year
7 8 **Vonjo** *pacritinib* oral therapy	CTI BioPharma Corp	Myelofibrosis	2/28/2022	· FDA-approved for the treatment of adults with intermediate- or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis with a platelet count below 50 × 109/L · Projected impact: cost replacement of existing therapies	$234,000/year

[4]CVS Caremark, [7]Biologics, [8]Onco 360

 | Data is current as of 05/26/2022

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Drug Name	Manufacturer(s)	Indication(s)	FDA Approval Date	Comments	Cost (WAC)
NEUROLOGY					
[9] **Ztalmy** *ganaxolone* oral therapy	Marinus Pharmaceuticals	Seizures associated with CDKL5 deficiency disorder (CDD)	3/18/2022	· First FDA-approved agent for this indication; approved for use in patients ≥ 2 years of age · CDD is a serious and rare genetic disorder that predominantly affects girls and is characterized by early-onset, difficult-to-control seizures and severe neuro-developmental impairment · Most children affected by CDKL5 cannot walk, talk, or care for themselves; many also suffer from scoliosis, visual impairment, gastrointestinal difficulties, and sleeping disorders · Projected impact: incremental cost increase	$133,000/year
ONCOLOGY					
[10] **Carvykti** *ciltacabtagene autoleucel* intravenous infusion	Janssen	Multiple myeloma	2/28/2022	· Anti-BCMA CAR T-cell therapy approved for the treatment of adult patients with relapsed or refractory multiple myeloma after four or more prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody · Prescribing Information includes a black box warning regarding cytokine release syndrome, neurologic toxicities, hemophagocytic lymphohistiocytosis/macrophage activation syndrome, and prolonged and recurrent cytopenia · CARTITUDE-1 trial data demonstrated a 98% overall response rate and 83% stringent complete response rate after nearly two years of follow-up · Projected impact: cost replacement of existing therapies	$465,000/one-time treatment
[11] **Opdualag** *relatlimab + nivolumab* intravenous infusion	Bristol Myers Squibb	Melanoma	3/18/2022	· Approved for the treatment of adult and pediatric patients 12 years of age or older with unresectable or metastatic melanoma · Projected impact: cost replacement of existing therapies	$328,700/year

[9]Orsini, [10]Hospital Administration, [11]Hospital, Infusion Center, or Doctor's Office Administration

 | Data is current as of 05/26/2022

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Available at: A AcariaHealth P PANTHERx Rare # Other

Drug Name	Manufacturer(s)	Indication(s)	FDA Approval Date	Comments	Cost (WAC)
6 **Hyftor** *sirolimus* topical gel	Nobelpharma	Facial angiofibroma	3/22/2022	· Approved for the treatment of facial angiofibroma associated with tuberous sclerosis in adults and pediatric patients 6 years of age and older · Projected impact: cost replacement of existing therapies	Pending launch
12 **Pluvicto** *lutetium Lu 177 vipivotide tetraxetan* intravenous infusion	Novartis	Metastatic castration-resistant prostate cancer (mCRPC)	3/23/2022	· Approved for the treatment of adult patients with prostate-specific membrane antigen (PSMA)-positive mCRPC who have been treated with androgen receptor pathway inhibition and taxane-based chemotherapy · A radiopharmaceutical agent that requires special handling and training · In the pivotal, Phase 3 VISION study Pluvicto plus standard of care significantly improved overall survival and radiographic progression-free survival for men with progressive PSMA-positive mCRPC compared to standard of care alone · Pluvicto is dosed every six weeks for up to six doses · Projected impact: cost replacement of existing therapies	$255,000/six-dose course of therapy
10 **Yescarta** *axicabtagene ciloleucel* intravenous infusion	Gilead	Large B-cell lymphoma (LBCL)	4/1/2022	· NEW INDICATION FOR AN EXISTING CAR T-CELL THERAPY · Approved for the treatment of adults with LBCL that is refractory to first-line chemoimmunotherapy or relapses within 12 months of first-line chemoimmunotherapy. It is not indicated for the treatment of patients with primary central nervous system lymphoma · Previously FDA-approved for use in relapsed/refractory LBCL in the third-line or later setting · Top-line results from the primary analysis of the pivotal ZUMA-7 study showed superiority of Yescarta compared to standard of care as second-line therapy, with a 60% reduction in risk of event-free survival events vs. standard of care after a median follow-up of two years · Projected impact: cost replacement of existing therapies	$399,000/one-time treatment

[6]Pending Launch, [10]Hospital Administration, [12]Hospital or Infusion Center Administration

 | Data is current as of 05/26/2022

Drug Name	Manufacturer(s)	Indication(s)	FDA Approval Date	Comments	Cost (WAC)
DERMATOLOGY					
Vtama *tapinarof* topical cream	Dermavant	Plaque psoriasis	5/23/22	· "*Approved for use in the adult population *Will compete with multiple existing topical therapy alternatives"	$1,325/60-gram tube
ENDOCRINOLOGY					
Mounjaro *tirzepatide* subcutaneous injection	Eli Lilly	Type 2 diabetes mellitus	5/13/2022	· Approved for use as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus · Is the first agent approved with a dual mechanism of action - glucose-dependent insulinotropic polypeptide (GIP) and glucagon-like peptide-1 (GLP-1) receptor agonist · Will compete with multiple existing GLP-1 agonist therapies (e.g., Byetta, Ozempic, Trulicity)	$11,700/year
GASTROENTEROLOGY					
Voquezna Triple Pak *vonoprazan + amoxicillin + clarithromycin* **Voquezna Dual Pak** *vonoprazan + amoxicillin* oral tablets and capsules	Phathom Pharmaceuticals	*Helicobacter pylori* infection	5/3/2022	FDA-approved for the treatment of *Helicobacter pylori (H. pylori)* infection in adults · Voquezna treatment regimens demonstrated: Non-inferiority to lansoprazole triple therapy in patients without a clarithromycin or amoxicillin resistant strain of *H. pylori* at baseline · Superior eradication rates compared to lansoprazole triple therapy among all patients, including in patients with clarithromycin-resistant strains of *H. pylori*	Pending launch
INFECTIOUS DISEASES					
Vivjoa *oteseconazole* oral capsule	Mycovia Pharmaceuticals	Recurrent vulvovaginal candidiasis (RVVC)	4/26/2022	· Approved to reduce the incidence of RVVC in females with a history of RVVC who are not of reproductive potential · Vivjoa is contraindicated in females of reproductive potential · RVVC is generally defined as three or more yeast infections per year · Oral fluconazole is currently used off-label for RVVC	Pending launch

 | Data is current as of 05/26/2022

Drug Name	Manufacturer(s)	Indication(s)	FDA Approval Date	Comments	Cost (WAC)
PSYCHIATRY					
Igalmi *dexmedetomidine* sublingual film	BioXcel Therapeutics	Schizophrenia or bipolar disorder	4/5/2022	• Approved for the acute treatment of agitation associated with schizophrenia and bipolar disorders I and II under the supervision of a healthcare provider • Expert consensus best-practice guidelines have recommended that agitation should be treated by a combination of behavioral calming techniques, verbal de-escalation, and medications that are voluntarily accepted by patients without coercion • A non-invasive therapy that causes rapid and sustained symptom relief may be helpful to avoid the use of coercive techniques which may result in admission and prolonged hospitalization	$105/sublingual film

 | Data is current as of 05/26/2022

Drug Name	Manufacturer(s)	Indication(s)	Mechanism(s) of Action	Comments	Anticipated Cost	Anticipated Approval Date
AMT-061* *etranacogene dezaparvovec* intravenous infusion	Uniqure; CSL Behring	Hemophilia B	Gene therapy	• Proposed for the treatment of adults with severe disease (~40% of the total hemophilia B population) • Current standard of care is factor IX replacement therapy • Recent data from the Phase 3 HOPE-B study showed continued durable, sustained increases in factor IX activity at 18 months post-infusion with a mean factor IX activity of 36.9% of normal, compared to mean factor IX activity of 39.0% at six months post-infusion • The ABR for all bleeds after stable factor IX expression, assessed at 18 months, was 1.51 compared with the ABR of 4.19 for the six-month lead-in period • AMT-061 was generally well-tolerated with over 80% of adverse events considered mild • A serious adverse event of hepatocellular carcinoma (HCC) was identified in one patient • Independent molecular characterization and vector integration analysis of the HCC and adjacent tissue supported the conclusion that the HCC was unrelated to treatment with AMT-061 • No inhibitors to factor IX were reported • FDA has accepted the BLA for Priority Review	$3.5 million/ one-time treatment	4Q 2022

***Expected to cost > $500,000 per member.**

 | Data is current as of 05/26/2022

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Drug Name	Manufacturer(s)	Indication(s)	Mechanism(s) of Action	Comments	Anticipated Cost	Anticipated Approval Date
COAGULATION DISORDERS						
Roctavian* *valoctocogene roxaparvovec* intravenous infusion	BioMarin	Hemophilia A	Gene therapy	• Proposed for the treatment of adults with severe disease (~60% of the total hemophilia A population) • Current standard of care is factor VIII replacement therapy or Hemlibra • On 8/19/2020, BioMarin received a Complete Response Letter for its BLA for valoctocogene roxaparvovec, citing the need for longer-term durability data • In January 2022, two-year follow-up data for annualized bleeding rate (ABR) from the Phase 3 GENEr8-1 trial were reported: the mean ABR fell from its baseline of 4.8 to 0.9 at one year, then to 0.7 at two years • The mean endogenous factor VIII activity level was 23.0 IU/dL at two years, after a mean value of 42.9 at one year • An analysis of a subset of 17 patients with three years of follow-up suggests that the downward trend may continue, with the three-year mean being 16.8, although the three-year mean ABR remained steady at 0.6, relative to the second year • BLA resubmission is anticipated in 2Q 2022	$2-3 million/ one-time treatment	1H 2023

***Expected to cost > $500,000 per member.**

Drug Name	Manufacturer(s)	Indication(s)	Mechanism(s) of Action	Comments	Anticipated Cost	Anticipated Approval Date
SPK-8011* intravenous infusion	Spark; Roche	Hemophilia A	Gene therapy	· Proposed for the treatment of adults with severe disease (~60% of the total hemophilia A population) · Current standard of care is factor VIII replacement therapy or Hemlibra · In the ongoing Ph I/II trial, factor VIII expression was sustained in 16 of 18 participants with up to four years of follow-up · Across all dose cohorts, there was a 91.2% reduction in annualized bleed rate · There were no deaths and no FVIII inhibitor development in the four years	$1-2 million/ one-time treatment	2023
SB-525* *giroctocogene fitelparvovec* intravenous infusion	Sangamo BioSciences, Inc; Pfizer	Hemophilia A	Gene therapy	· For the treatment of adults with severe disease (~60% of the total hemophilia A population) · Current standard of care is factor VIII replacement therapy or Hemlibra · SB-525 was being studied in the Phase 3 AFFINE trial, which has been voluntarily paused by the manufacturers to address the observation that some patients had factor VIII activity of 150% or more, potentially raising their risk of blood clots; a study protocol amendment is pending · Meanwhile, updated results from the Phase 1/2 Alta trial showed that, among five patients receiving the highest dose of SB-525, mean factor VIII levels were 25.4% at two years · During year two, one patient had eight bleeds, while another had one	$1-2 million/ one-time treatment	2023

***Expected to cost > $500,000 per member.**

 | Data is current as of 05/26/2022

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Drug Name	Manufacturer(s)	Indication(s)	Mechanism(s) of Action	Comments	Anticipated Cost	Anticipated Approval Date
PF-06838435/SPK-9001* *fidanacogene elaparvovec* intravenous infusion	Pfizer; Spark	Hemophilia B	Gene therapy	· Interim analysis of the Phase 3 Benegene-2 trial results has been delayed to 1Q 2023	$1-2 million/ one-time treatment	2024
DERMATOLOGY						
BI 655130 *spesolimab* intravenous infusion	Boehringer Ingelheim	Psoriasis	IL-36 receptor antibody	· Proposed for the treatment of generalized pustular psoriasis (GPP) flares · GPP flares are rare and potentially serious, requiring emergency medical care; they begin with dry, red, and tender skin, and within hours widespread pus-filled blisters appear · Current off-label therapies include oral retinoids and biologic disease-modifying anti-rheumatic drug (DMARD) therapies	$60,000/year	6/16/2022
BMS-986165 *deucravacitinib* oral therapy	Bristol Myers Squibb	Psoriasis	Tyrosine kinase 2 inhibitor	· Proposed for the treatment of adults with moderate to severe plaque psoriasis · In two pivotal trials, deucravacitinib demonstrated significant improvements in skin clearance, symptom burden, and quality of life measures compared to placebo and Otezla	$50,000/year	9/10/2022
ENDOCRINOLOGY						
ALN-TTRsc02 *vutrisiran* subcutaneous infusion	Alnylam	Transthyretin-mediated (hATTR) amyloidosis	TTR-targeting RNA interference agent	· Proposed for the treatment of polyneuropathy of hATTR amyloidosis in adults · Would compete with Onpattro (IV infusions every three weeks) and Tegsedi (weekly subcutaneous injections) for the same indication, with quarterly subcutaneous infusions	$400,000/ year	7/14/2022

***Expected to cost > $500,000 per member.**

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envolve Pharmacy Solutions

Pipeline Report

May 2022

Drug Name	Manufacturer(s)	Indication(s)	Mechanism(s) of Action	Comments	Anticipated Cost	Anticipated Approval Date
AT-GAA* *cipaglucosidase alfa/miglustat* intravenous infusion plus oral therapy	Amicus Therapeutics	Pompe disease	Cipaglucosidase alfa: recombinant human acid alpha-glucosidase enzyme replacement therapy (ERT) Miglustat: pharmacological chaperone	· Proposed for the treatment of late-onset Pompe disease · Estimated U.S prevalence of Pompe disease: ~1 in 40,000 people · Lumizyme and Nexviazyme are available FDA approved ERT alternatives (Nexviazyme for late-onset disease).	$500,000/ year	8/29/2022
GZ402665 *olipudase alfa* intravenous infusion	Sanofi	Acid sphingomyelinase deficiency (ASMD)	Enzyme replacement therapy	· Proposed for the treatment of patients with non-neurological manifestations of ASMD · Would be the first approved treatment for ASMD, which is estimated to affect ~1 in 250,000 individuals	$300,000/ year	7/3/2022
PRV-031 *teplizumab* intravenous infusion	Provention Bio	Delay of type I diabetes	Anti-CD3 monoclonal antibody	· Proposed for the delay of clinical type I diabetes in patients at high-risk of developing the disease · Would be the first-ever agent to delay onset of DM for patients at-risk of advancing to clinical type 1 diabetes · Administered as a single course of therapy consisting of daily intravenous infusions for 14 days	$100,000/14-day course of therapy	8/17/2022

***Expected to cost > $500,000 per member.**

 | Data is current as of 05/26/2022

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Drug Name	Manufacturer(s)	Indication(s)	Mechanism(s) of Action	Comments	Anticipated Cost	Anticipated Approval Date
HEMATOLOGY						
Beti-cel* *betibeglogene autotemcel* intravenous infusion	bluebird bio	Transfusion-dependent beta-thalassemia (TDT)	Gene therapy	· Proposed for the treatment of patients with beta-thalassemia who require regular blood transfusions · Demonstrated ability to dramatically decrease or terminate the need for chronic blood transfusions · Twenty-five of 29 patients (86%) in a Phase 3 trial demonstrated transfusion independence (TI) after treatment, with a median ongoing TI duration of 26.3 months (min-max: 13.1 – 39.4)	$1-2 million/ one-time treatment	8/19/2022
Rolontis *eflapegrastim* subcutaneous injection	Spectrum Pharmaceuticals	Chemotherapy-induced neutropenia	Colony stimulating factor	· Dosed once every three weeks · Would compete with Neulasta, Fulphila, and Udenyca	$5,000/dose	9/9/2022
INFECTIOUS DISEASE						
Myrcludex B *bulevirtide* subcutaneous injection	Myr Pharmaceuticals	Hepatitis delta virus (HDV) infection	Viral entry inhibitor	· Proposed for the treatment of chronic HDV in adults with compensated liver disease · Would be the first FDA-approved agent for this indication; pegylated interferon products have been used off-label · Daily subcutaneous injection	$150,000/ year	4Q 2022

***Expected to cost > $500,000 per member.**

 | Data is current as of 05/26/2022

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Drug Name	Manufacturer(s)	Indication(s)	Mechanism(s) of Action	Comments	Anticipated Cost	Anticipated Approval Date
MUSCULOSKELETAL CONDITIONS						
SRP-9001* *delandistrogene moxeparvovec* intravenous infusion	Sarepta Therapeutics	Duchenne muscular dystrophy (DMD)	Gene therapy	· Targets exons 18 through 58 (~60-75% of DMD patients have mutations in these exons) · In October 2021 the global pivotal Phase 3 EMBARK trial was initiated · Results from Study SRP-9001-101 (n=4, ages 4-7) found that participants improved 8.6 points on the North Star Ambulatory Assessment (NSAA) compared to a matched natural history cohort three years following a single administration of SRP-9001 (p<0.0001) · In Study SRP-9001-102, SRP-9001-treated participants ages 6-7 years (n=12) had a positive 2.9-point difference on NSAA change from baseline compared to a matched natural history control (p=0.0129) · The first functional results were presented from Study SRP-9001-103 (ENDEAVOR), which uses commercially representative SRP-9001 material · Results from the first 11 participants in Cohort 1, ages 4-7 years, demonstrated a 3.0-point improvement from baseline on NSAA six months after treatment · In Part 2 of SRP-9001-102, participants from the placebo crossover group (n=20, aged 5-8) scored 2.0 points higher on the mean NSAA 48 weeks after treatment with SRP-9001 compared to pre-specified matched external control cohort	$1-2 million/ one-time treatment	2023

***Expected to cost > $500,000 per member.**

 | Data is current as of 05/26/2022

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Drug Name	Manufacturer(s)	Indication(s)	Mechanism(s) of Action	Comments	Anticipated Cost	Anticipated Approval Date
SGT-001* intravenous infusion	Solid Biosciences	DMD	Gene therapy	• Two-year interim efficacy and safety data from the first three patients in the high dose (2E14 vg/kg) cohort suggest durable benefit 24-months post-administration of SGT-001, when compared to natural history • Additionally, data from the next three treated patients suggest improved motor function at two years post-infusion, as assessed by 6-Minute Walk Test and NSAA, against expected natural history declines • The data also suggest improved pulmonary function, as measured by forced vital capacity and peak expiratory flow when compared to both baseline and natural history • No new drug-related safety findings have been identified in any of the first nine treated patients in post-dosing periods of 90 days to approximately four years.	$1-2 million/ one-time treatment	2024

***Expected to cost > $500,000 per member.**

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Drug Name	Manufacturer(s)	Indication(s)	Mechanism(s) of Action	Comments	Anticipated Cost	Anticipated Approval Date
PF-06939926* *fordadistrogene movaparvovec* intravenous infusion	Pfizer	Duchenne muscular dystrophy (DMD)	Gene therapy	• One-time treatment • Three serious adverse effects were identified in the Phase 3 CIFFREO trial, muscle weakness including two cases of myocarditis, attributed to the gene therapy • The study protocol was amended to exclude patients with any mutation (exon deletion, exon duplication, insertion, or point mutation) affecting exons 9 through 13, inclusive, or a deletion that affects both exon 29 and exon 30; these mutations are estimated to represent ~15% of patients with DMD • The FDA's clinical hold on the CIFFREO trial has recently been lifted and Pfizer plans to open U.S. trial sites by June 2022 • There are indications that the muscle-related adverse effects associated with specific exon gene mutations may be a class effect across DMD gene therapies	$1-2 million/ one-time treatment	2025
GALGT2* *AAVrh74.MHCK.GALGT2* intra-arterial injection	Sarepta Therapeutics	DMD	Gene therapy	• Would compete with SRP-9001 gene therapy for those with mutations between exons 18-58 • SRP-9001 is further along in the pipeline process, but comparative safety and efficacy are undetermined	$1-2 million/ one-time treatment	2025

***Expected to cost > $500,000 per member.**

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Drug Name	Manufacturer(s)	Indication(s)	Mechanism(s) of Action	Comments	Anticipated Cost	Anticipated Approval Date
NEUROLOGY						
AMX0035 *sodium phenylbutyrate/ taurursodiol* oral therapy	Amylyx Pharmaceuticals	Amyotrophic lateral sclerosis (ALS)	Sodium phenylbutyrate: histone deacetylase inhibitor Taurursodiol: cellular apoptosis inhibitor	• In an interim survival analysis of the Phase 2 CENTAUR trial participants who were followed for up to three years, those who started on AMX0035 showed a 44% lower risk of death compared to those who started on placebo • Median survival duration was 25 months in the AMX0035 group vs. 18.5 months in the placebo group	$200,000/ year	6/29/2022
Lenti-D* *elivaldogene autotemcel* intravenous infusion	bluebird bio	Cerebral adrenoleukodystrophy (cALD)	Gene therapy	• Currently, the only therapeutic option for patients with cALD is allogeneic hematopoietic stem cell transplant (HSCT); beneficial effect has been reported if performed early in the course of cALD progression • On August 9, 2021, bluebird bio announced that one patient in the ALD-104 clinical trial had developed myelodysplastic syndrome, and that it was likely related to Lenti-D therapy; the ALD-104 trial has been placed on clinical hold pending further investigation into this case • In the U.S., newborn screening for ALD has been added to the Recommended Universal Screening Panel and is currently active in 27 states and Washington, D.C., accounting for > 60% of U.S. newborns • The worldwide incidence of ALD is ~1 in 5,000 to 1 in 17,000 newborns (both male and female), and ~1 in 20,000 to 1 in 30,000 newborn males; cALD develops in approximately 40% of affected boys and in a smaller number of adult men	$1-2 million/ one-time treatment	9/16/2022

***Expected to cost > $500,000 per member.**

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Drug Name	Manufacturer(s)	Indication(s)	Mechanism(s) of Action	Comments	Anticipated Cost	Anticipated Approval Date
TG-1101 *ublituximab* intravenous infusion	TG Therapeutics	Multiple sclerosis (MS)	Anti-CD20 monoclonal antibody	• Proposed for the treatment of patients with relapsing forms of MS • Loading doses administered on Day 1 and Day 15, then dosed every six months • Has the same mechanism of action as, and would compete with, Ocrevus, Kesimpta, and Rituxan in the treatment of MS	$75,000/year	9/28/2022

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Drug Name	Manufacturer(s)	Indication(s)	Mechanism(s) of Action	Comments	Anticipated Cost	Anticipated Approval Date
PTC-AADC* *eladocagene exuparvovec* intraputamenal injection	PTC Therapeutics	Aromatic L-amino acid decarboxylase (AADC) deficiency	Gene therapy	· There are no approved therapies for the treatment of AADC deficiency, which is an ultra-rare enzyme deficiency disorder · Estimated prevalence: ~5,000 patients worldwide, with a live-birth incidence of approximately 1 in 40,000 worldwide · Five-year follow-up results from a clinical trial show that motor function improvements after PTC-AADC therapy were sustained, demonstrating that the treatment effect is durable · Across three clinical trials, improvements in motor development were recorded in all children from as early as 3 months of age · Cognitive and language skills were also reported to improve significantly from baseline, as measured by Bayley-III scores, with children able to understand their caregivers and express themselves · The rate of respiratory infection declined from an average of 2.4 episodes per year at 12 months of age to 0.6 episodes per year at 2 years of age and 0.3 episodes per year at 5 years of age · Almost all treated children went from a baseline weight below the third percentile to making age-appropriate weight gains by 12 months following treatment · Planned BLA submission in 3Q 2022	$1-2 million/ one-time treatment	2023

***Expected to cost > $500,000 per member.**

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Drug Name	Manufacturer(s)	Indication(s)	Mechanism(s) of Action	Comments	Anticipated Cost	Anticipated Approval Date
ONCOLOGY						
Kymriah *tisagenlecleucel* intravenous infusion	Novartis	Follicular lymphoma (FL)	CAR-T therapy	· New indication for an existing CAR-T cell therapy · Proposed for the treatment of adults with relapsed or refractory FL after two prior lines of treatment · In the pivotal Phase II ELARA trial, 66% achieved a complete response and the overall response rate was 86% in heavily pretreated patients; no patients experienced grade 3 or higher cytokine release syndrome related to Kymriah within the first eight weeks following infusion · Yescarta is another CAR T-cell therapy that is FDA-approved as 3rd-line treatment for relapsed or refractory FL	$475,000/ one-time treatment	5/27/2022
Breyanzi *lisocabtagene maraleucel* intravenous infusion	Bristol Myers Squibb	LBCL	CAR-T therapy	· Proposed for the treatment of adults with relapsed or refractory LBCL in the second-line setting · Currently FDA-approved for use in relapsed/ refractory LBCL in the third-line or later setting · Would compete with Yescarta for the same indication · In the Phase 3 TRANSFORM trial, Breyanzi demonstrated significant improvements in event-free survival, complete responses, and progression-free survival in patients with LBCL whose disease was primary refractory or relapsed within 12 months after first-line therapy, compared to standard of care	$410,300/ one-time treatment	6/24/2022

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envolve Pharmacy Solutions

Pipeline Report

May 2022

Drug Name	Manufacturer(s)	Indication(s)	Mechanism(s) of Action	Comments	Anticipated Cost	Anticipated Approval Date
BGB-A317 *tislelizumab* intravenous infusion	BeiGene; Novartis	Esophageal carcinoma	Humanized IgG4 anti-PD-1 monoclonal antibody	• Proposed for the treatment of patients with unresectable recurrent locally advanced or metastatic esophageal squamous cell carcinoma after prior systemic therapy	$175,000/year	7/12/2022
Pedmark *sodium thiosulfate* intravenous infusion	Fennec Pharmaceuticals	Chemotherapy-induced ototoxicity		• Proposed for the prevention of ototoxicity induced by cisplatin chemotherapy in patients 1 month to < 18 years of age with localized, non-metastatic, solid tumors	$20,000/year	9/23/2022
TAS-120 *futibatinib* oral therapy	Taiho Oncology	Cholangiocarcinoma	FGFR inhibitor	• Proposed for the treatment of previously treated locally advanced or metastatic cholangiocarcinoma with FGFR2 gene rearrangements, including gene fusions • Would be third to market for this indication, after Pemazyre and Truseltiq	$275,000/ year	9/30/2022
HM78136B *poziotinib* oral tablet	Spectrum Pharmaceuticals	Non-small cell lung cancer (NSCLC)	Tyrosine kinase inhibitor	• Proposed for the treatment of previously treated locally advanced or metastatic NSCLC with HER2 exon 20 insertion mutations • Insertion mutations in exon 20 of HER2 are detected in 2%-5% of NSCLCs and are associated with never-smoker status, female sex, and adenocarcinoma histology	$200,000/ year	11/24/2022
MRTX849 *adagrasib* oral therapy	Mirati Therapeutics	NSCLC	KRASG12C inhibitor	• Proposed for the treatment of patients with NSCLC who harbor the KRASG12C mutation following at least one prior systemic therapy • Would compete with Lumakras for the population with locally advanced or metastatic disease	$200,000/ year	12/14/2022

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Drug Name	Manufacturer(s)	Indication(s)	Mechanism(s) of Action	Comments	Anticipated Cost	Anticipated Approval Date
tremelimumab + durvalumab intravenous infusion	AstraZeneca	Hepatocellular carcinoma (HCC)	Cytotoxic T-lymphocyte antigen (CTLA) 4 inhibitor + programmed death-ligand 1 (PD-L1) inhibitor	· Proposed for the treatment of unresectable HCC	$300,000/ year	4Q 2022
WOMEN'S HEALTH						
Yselty *linzagolix* oral tablet	ObsEva	Uterine fibroids	Gonadotropin-releasing hormone (GnRH) antagonist	· Proposed for use as once daily oral therapy for the treatment of heavy menstrual bleeding associated with uterine fibroids · Oriahnn and Myfembree are FDA-approved for the same indication, although both of these products are combination products which include a GnRH antagonist with hormonal add-back therapy; if approved, Yselty would be the only GnRH antagonist in uterine fibroids with a low dose non-add-back therapy option	$13,000/year	9/13/2022

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Drug Name	Manufacturer(s)	Indication(s)	Mechanism(s) of Action	Comments	Anticipated Approval Date
CARDIOVASCULAR					
AMG 423 *omecamtiv mecarbil* oral tablet	Amgen	Heart failure with reduced ejection fraction (HFrEF)	Cardiac myosin activator	• Would compete with agents already FDA-approved for HFrEF, including Entresto, Farxiga, and Verquvo	11/30/2022
DERMATOLOGY					
ARQ-151 *roflumilast* topical cream	Arcutis Biotherapeutics, Inc.	Plaque psoriasis	Phosphodiesterase type 4 (PDE4) inhibitor	• Proposed for the treatment of mild-to-severe plaque psoriasis in adults and adolescents • Once daily topical administration • Would compete with multiple existing topical therapy alternatives	7/29/2022

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Drug Name	Manufacturer(s)	Indication(s)	Mechanism(s) of Action	Comments	Anticipated Approval Date
NEPHROLOGY					
Duvroq *daprodustat* oral tablet	GlaxoSmithKline	Anemia of chronic kidney disease (CKD)	Selective hypoxia-inducible factor (HIF) inhibitor	• Proposed for the treatment of anemia in patients with dialysis-dependent and non-dialysis dependent CKD • Would be the first HIF inhibitor to be FDA-approved after failure of roxadustat and vadadustat due to safety issues; daprodustat appears to have a more favorable cardiovascular safety profile than the previous two agents • Would compete with erythropoietin-stimulating agents	2/1/2023
PSYCHIATRY					
AXS-05 *bupropion/ dextromethorphan* oral tablet	Axsome	Major depressive disorder	N-methyl-D-aspartate receptor antagonist and sigma-1 receptor agonist + norepinephrine and dopamine reuptake inhibitor	• Would enter a crowded antidepressant market • Bupropion serves to increase the bioavailability of dextromethorphan	2Q 2022

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Drug Name	Manufacturer(s)	Biosimilar Reference Drug	Indication(s)	Status/Estimated Approval	Biosimilar Currently Launched?	Comments
HEMATOLOGY						
Releuko *filgrastim-ayow* subcutaneous injection	Amneal Biosciences	Neupogen	Neutropenia	FDA-approved: 2/25/2022	Yes - Nivestym, Zarxio	· Another biosimilar to Neupogen, after Nivestym and Zarxio · Product launched in early March 2022
Fylnetra *pegfilgrastim-pbbk* subcutaneous injection	Amneal/Kashiv	Neulasta	Neutropenia	FDA-approved: 5/26/2022	Yes - Fulphila, Udenyca, Ziextenzo	· *Another biosimilar to Neulasta, after Fulphila, Udenyca, and Ziextenzo
Lupifil-P *pegfilgrastim* subcutaneous injection	Lupin Pharmaceuticals	Neulasta	Neutropenia	BLA is under FDA review (BsUFA date: 2Q 2022)	Yes - Fulphila, Udenyca, Ziextenzo	· Another biosimilar to Neulasta, after Fulphila, Udenyca, and Ziextenzo
MSB11455 *pegfilgrastim* subcutaneous injection	Fresenius Kabi	Neulasta	Neutropenia	BLA is under FDA review (BsUFA date: 2Q 2022)	Yes - Fulphila, Udenyca, Ziextenzo	· Another biosimilar to Neulasta, after Fulphila, Udenyca, and Ziextenzo · Completion of the FDA review is contingent upon completion of a pre-approval inspection, which has yet to occur
IMMUNOLOGY						
AVT02 *adalimumab* subcutaneous injection	Alvotech	Humira	Rheumatoid arthritis	BLA is under FDA review (BsUFA date: Dec 2022)	No	· FDA is now reviewing the BLA, including the request for interchangeability with Humira · AVT02 would be another biosimilar to Humira, after Abrilada, Amjevita, Cyltezo, Hadlima, Hulio, and Hyrimoz

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Drug Name	Manufacturer(s)	Biosimilar Reference Drug	Indication(s)	Status/Estimated Approval	Biosimilar Currently Launched?	Comments
Abrilada, interchangeability status *adalimumab-afzb* subcutaneous injection	Alvotech	Humira	Rheumatoid arthritis	BLA is under FDA review (BsUFA date: 4Q 2022)	No	· Previously approved biosimilar agent; currently proposed for interchangeability with Humira
ONCOLOGY						
Alymsys *bevacizumab-maly* intravenous infusion	Amneal Pharmaceuticals	Avastin	Colorectal cancer	FDA-approved: 4/13/2022	Yes - Mvasi, Zirabev	· Another biosimilar to Avastin, after Mvasi and Zirabev
BAT1706 *bevacizumab* intravenous infusion	Bio-Thera Solutions, Inc.	Avastin	Colorectal, non-small cell lung, cervical cancers, glioblastoma, renal cell carcinoma	BLA is under FDA review (BsUFA date: 5/28/2022)	Yes - Mvasi, Zirabev	· Another biosimilar to Avastin, after Mvasi and Zirabev
MYL-1402O *bevacizumab* intravenous infusion	Mylan; Biocon	Avastin	Breast cancer	BLA is under FDA review (BsUFA date: 5/22/2022)	Yes - Mvasi, Zirabev	· Another biosimilar to Avastin, after Mvasi and Zirabev · BLA is pending an FDA inspection of a manufacturing facility
OPHTHALMOLOGY						
Cimerli *ranibizumab* intraocular injection	Formycon AG; Bioeq; Coherus	Lucentis	Neovascular (wet) age-related macular degeneration	BLA is under FDA review (BsUFA date: 8/2/2022)	No	· Another biosimilar to Lucentis, after Byooviz

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Recent Approvals			
GENERIC NAME	**BRAND NAME**	**MANUFACTURER(S)**	**MARKET LAUNCH DATE**
maraviroc	Selzentry (tablet)	Hetero	2/7/2022
deferiprone	Ferriprox (1,000 mg)	Hikma	2/14/2022
amphotericin B	Ambisome	Sun	2/15/2022
apomorphine hydrochloride	Apokyn	Sage Chemicals	2/25/2022
lenalidomide	Revlimid (5, 10, 15, 25 mg)	Arrow International Ltd	3/3/2022
paclitaxel	Abraxane	Twi Pharmaceuticals	4/7/2022
bortezomib	Velcade	Fresenium Kabi	5/2/2022
pirfenidone	Esbriet (tablet)	Sandoz	5/4/2022
Pipeline Agents*			
GENERIC NAME	**BRAND NAME**	**MANUFACTURER(S)**	**ANTICIPATED LAUNCH DATE**
pemetrexed disodium	Alimta (100 mg, 500 mg, 750 mg, 1000 mg)	Accord; Apotex; Fresenius; Dr. Reddy's; Hospira; Sun; Wockhardt; Zydus; Amneal; Biocon; Glenmark; Sandoz; Teva	5/25/2022
gefitinib	Iressa	Apotex; Cipla; Natco Pharma; Qilu Pharmaceutical Co.; Synthon	7/13/2022
pralatrexate	Folotyn	Dr. Reddy's; Fresenius; Sandoz; Teva	11/15/2022
bendamustine hydrochloride	Treanda (powder, solution)	Accord ; Breckenridge/Natco Pharma ; Dr. Reddy's; Glenmark; Hospira/Pfizer; InnoPharma/Pfizer ; Mylan/Viatris ; Actavis/ Teva; Hetero; Sandoz; Sun	12/7/2022
prednisone	Rayos	Actavis/Teva	12/23/2022
sodium oxybate	Xyrem	Hikma	2H 2022
lenalidomide	Revlimid (2.5, 20 mg)	Dr. Reddy's	2022
thalidomide	Thalomid	Hikma; Lannett	2022
ritonavir	Norvir (capsule)	Mylan/Viatris	2022
teriflunomide	Aubagio	Accord; Alembic; Breckenridge; Glenmark; Sandoz; Alvogen	3/12/2023

***Includes generic agents with > 50% launch probability**

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Pipeline Agents*			
GENERIC NAME	**BRAND NAME**	**MANUFACTURER(S)**	**ANTICIPATED LAUNCH DATE**
teduglutide recombinant	Gattex	Par/Endo	3/19/2023
fingolimod hydrochloride	Gilenya (0.25 mg)	Teva	2022-2023
darunavir ethanolate	Prezista (75 mg, 150 mg, 300 mg, 400 mg, 600 mg, 800 mg)	Cipla; Hetero; Lupin; Dr. Reddy's; Aurobindo; Teva; Zydus	2022-2023

***Includes generic agents with > 50% launch probability**

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Pipeline Report

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Recent Approvals			
GENERIC NAME	**BRAND NAME**	**MANUFACTURER(S)**	**MARKET LAUNCH DATE**
cyclosporine	Restatsis	Mylan	2/3/2022
baclofen	Ozobax	Palmetto Pharmaceuticals	2/25/2022
lacosamide	Vimpat tablet	Indoco Remedies	3/17/2022
diclofenac potassium	Zipsor	Aurobindo	3/24/2022
nalmefene hydrochloride	Revex	Purdue	3/31/2022
lacosamide	Vimpat injection	Indoco Remedies	4/12/2022
hydralazine hydrochloride/isosorbide dinitrate	Bidil	RinconPharma	4/12/2022
diclofenac sodium	Pennsaid solution 2%	Apotex	5/10/2022
mesalamine	Pentasa	Sun	5/17/2022
Pipeline Agents*			
GENERIC NAME	**BRAND NAME**	**MANUFACTURER(S)**	**ANTICIPATED LAUNCH DATE**
lacosamide	Vimpat oral solution	Amneal, Sandoz	2Q 2022
methylphenidate	Daytrana	Mylan	2Q 2022
dabigatran	Pradaxa	Alkem Labs; Apotex; Aurobindo; Breckenridge; Hetero	2Q 2022
clobetasol propionate	Impoyz	Glenmark	7/27/2022
magnesium sulfate anhydrous/potassium sulfate/sodium sulfate	Suprep Bowel Prep Kit	Lupin	9/2022
vilazodone	Viibryd	Aurobindo; Zydus; Hetero; Impax Labs; Wockhardt	2022
ethinyl estradiol/levonorgestrel	Balcoltra	Unknown	2022
enalapril maleate	Epaned KIT	Bionpharma	2022
fluticasone propionate	Flovent HFA	Teva	2022
rotigotine	Neupro	Actavis/Teva	2022
benzoyl peroxide/clindamycin phosphate	Onexton	Taro	2022
fesoterodine fumarate	Toviaz	Aurobindo ; Zydus ; Apotex; Hetero; Impax Labs; Wockhardt	2022
tafluprost	Zioptan	Micro Labs ; Sandoz	2022
topiramate	Trokendi XR	Zydus; Actavis/Teva	1/1/2023

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GENERIC NAME	BRAND NAME	MANUFACTURER(S)	ANTICIPATED LAUNCH DATE
vancomycin hydrochloride	Firvanq Kit	Alkem Labs	1/8/2023
halobetasol propionate/tazarotene	Duobrii	Perrigo	1/15/2023
diclofenac potassium	Cambia	Wockhardt	1/2023
posaconazole	Noxafil injection	Par/Endo Pharmaceuticals	1/2023
lurasidone hydrochloride	Latuda	Sunovion	2/20/2023
tirofiban hydrochloride	Aggrastat	Gland Pharma; Nexus	3/1/2023
ivabradine hydrochloride	Corlanor tablet	Centaur Pharmaceuticals; Bionpharma; Hetero/Annora; MSN Laboratories; Torrent; Zydus	4/15/2023
pitavastatin calcium	Livalo	Orient Pharma; Sawai; Aurobindo; Zydus	5/2/2023
formoterol fumarate/mometasone furoate	Dulera	Lupin	2022-2023
diclofenac sodium	Dyloject	Mylan/Viatris	2022-2023
cyanocobalamin	Nascobal (spray)	Lupin	2022-2023
tiotropium bromide	Spiriva	Lupin	2022-2023
ceftaroline fosamil	Teflaro	Apotex ; Sandoz	2022-2023

***Includes generic agents with > 50% launch probability**

Term	Definition
AADC	aromatic L-amino acid decarboxylase
ALS	amyotrophic lateral sclerosis
AMD	age-related macular degeneration
ARDS	acute respiratory distress syndrome
ASMD	acid sphingomyelinase deficiency
BCMA	B-cell maturation antigen
BLA	biologics license application
BsUFA	Biosimilar User Fee Act
CAD	cold agglutinin disease
cALD	cerebral adrenoleukodystrophy
CAR T-cell	chimeric antigen receptor T-cell

Term	Definition
CCP	COVID-19 convalescent plasma
CDD	CDKL5 deficiency disorder
CKD	chronic kidney disease
COVID-19	coronavirus disease 2019
CTLA	cytotoxic T-lymphocyte antigen
DMARD	disease-modifying anti-rheumatic drug
DMD	Duchenne muscular dystrophy
ERT	enzyme replacement therapy
EUA	Emergency Use Authorization
FDA	Food and Drug Administration
FL	follicular lymphoma

Term	Definition
GIP	glucose-dependent insulinotropic polypeptide
GLP-1	glucagon-like peptide-1
GnRH	gonadotropin-releasing hormone
GPP	generalized pustular psoriasis
hATTR	hereditary transthyretin-mediated
HCC	hepatocellular carcinoma
HCM	hypertrophic cardiomyopathy
HDV	hepatitis delta virus
HFrEF	heart failure with reduced ejection fraction
HIF	hypoxia-inducible factor
H. pylori	Helicobacter pylori

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Term	Definition
LBCL	large B-cell lymphoma
mCRPC	metastatic castration-resistant prostate cancer
MS	multiple sclerosis
NET	neuroendocrine tumor
NIH	National Institute of Health
NSCLC	non-small cell lung cancer
PDE4	phosphodiesterase type 4
PD-L1	Programmed death-ligand 1
PKD	pyruvate kinase deficiency
PrEP	pre-exposure prophylaxis
PROS	PIK3CA-related overgrowth spectrum

Term	Definition
PV	polycythemia vera
RVVC	recurrent vulvovaginal candidiasis
SARS-CoV-2	severe acute respiratory syndrome coronavirus 2
TDT	transfusion-dependent beta-thalassemia
TI	transfusion independence
VOC	variant of concern
WAC	Wholesale Acquisition Cost
VVC	vulvovaginal candidiasis
WAC	Wholesale Acquisition Cost

Envolve Pharmacy Solutions provides comprehensive pharmacy and specialty pharmacy services. With over two decades of experience, we work with our clients and members to provide exceptional service that improves care, controls cost and produces measurable outcomes. To prepare this report, our team accesses a wide range of clinical resources. This information is then analyzed, resulting in updates across multiple disease states including recent and anticipated drug approvals, key changes in the biosimilar agent landscape, and notes on recent and anticipated generic product launches.

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