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PERSPECTIVE ON THE Rx PIPELINE

Understanding changes in the medication market and their impact on cost and care.

Elixir continuously monitors the drug pipeline. As treatment options change, we evaluate and share our perspective on the clinical benefits, cost effectiveness and overall impact to payers and members. Our Perspective on the Rx Pipeline report provides ongoing actionable insights from our team of clinical experts and the steps we are taking to protect and improve plan performance.

FIVE PIPELINE DEVELOPMENTS TO WATCH IN 2023:

- Humira and Biosimilars
- Long COVID-19
- Hemophilia and Gene Therapy
- Accelerated Approval Pathway
- Microbiome and Pipeline

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CRAFTED Rx SOLUTIONS

Clinical Pipeline

Humira and Biosimilars

Biosimilars are products that are very comparable and have no clinically meaningful difference from an already FDA-approved originator product.[1] Some biosimilar products have interchangeability status. Depending on state laws, interchangeable products may be substituted at the pharmacy without prescriber involvement. The United States originally saw a slow uptake in the utilization of biosimilar products largely due to higher-than-expected prices, prescriber unfamiliarity and patent litigation delaying launch.

Currently, there are FDA-approved biosimilars for several originator products such as Epogen®, Humira®, Lantus®, Neulasta® and Neupogen®.[2] Since the first approval in 2015, biosimilars have been a hot topic, and this year will be no exception due in part to AbbVie's $20 billion drug, Humira, and its expected loss of exclusivity.[3]

Humira was originally approved in 2002 and has since been the front runner in the tumor necrosis factor (TNF) inhibitors market. Humira's high annual sales can be attributed to its expansive FDA-approved indications and provider familiarity with the product. AbbVie originally marketed a low concentration, 50 mg/mL, product. In 2017, the FDA approved a higher concentration, 100 mg/mL, product that was also citrate free. This newer product resulted in less stinging and irritation upon injection and since its launch, accounts for at least 83% of the Humira market.[4]

Currently, there are nine Humira biosimilars that are FDA-approved. Prior to 2022, none of the high concentration products were approved, making a robust Humira biosimilar uptake unlikely. However, in August of 2022, the FDA approved its first high concentration Humira biosimilar and three more are expected within the next quarter. Presently, there is only one interchangeable product though many are currently seeking interchangeability. By mid-2023, it is expected that eight low concentration and four high concentration products will launch. It is anticipated that this expanded competition within the Humira biosimilar space will help drive down pharmacy spend.

TABLE 1: HUMIRA BIOSIMILARS[3,5]

Biosimilar	Manufacturer	Citrate-Free	Interchangeability	Potential / Actual Approval Date	Anticipated Launch Date
Low Concentration (50 mg/mL)					
Amjevita	Amgen	Yes	Unclear	2016	1/31/2023
Hadlima	Samsung Bioepis/Organon	No	Seeking	2019	7/1/2023
Cyltezo	Boehringer Ingelheim	Yes	Yes	2017	7/1/2023
Abrilada	Pfizer	Yes	Seeking	2019	7/1/2023
Yusimry	Coherus	Yes	No	2021	7/1/2023
Hulio	Biocon	Yes	No	2020	July 2023
Hyrimoz	Sandoz	No	No	2018	July 2023
Idacio	Fresenius	Yes	No	December 2022	7/1/2023

Humira and Biosimilars Continued

TABLE 1: HUMIRA BIOSIMILARS[3,5]

Biosimilar	Manufacturer	Citrate-Free	Interchangeability	Potential / Actual Approval Date	Anticipated Launch Date
High Concentration (100 mg/mL)					
Hadlima HC	Samsung Bioepis/Organon	Yes	Seeking	August 2022	7/31/2023
Yuflyma (CT-P17)	Celltrion	Yes	Seeking	Anytime	7/1/2023
AVT02	Alvotech/Teva	Yes	Seeking	Anytime	7/1/2023
Hyrimoz HCF	Sandoz	Yes	Unclear	March 2023	July 2023
Amjevita HC	Amgen	Yes	Seeking	2024 or later	2024 or later
Yusimry HC	Coherus	TBD	TBD	TBD	TBD

Elixir actively promotes evidence-based use of biosimilars to deliver best value for clients. As biosimilars are granted FDA-approval, Elixir reviews each one for safety, efficacy and place in therapy. Elixir believes Humira and biosimilars can coexist as formulary options and will evaluate specific biosimilar placement as they enter the market. This strategy will provide optionality and flexibility for patients and providers and still deliver lowest net cost.

Clinical Pipeline

Long COVID-19

We are now approaching three years since the start of the COVID-19 pandemic. In this time, there have been approximately 650 million confirmed cases resulting in more than 6 million deaths worldwide.[6] Almost half of those who survive experience lingering symptoms.[7] These symptoms are often referred to as long COVID. As the COVID pandemic continues to evolve, long COVID has increasingly become a topic of interest.

The CDC recently released a report stating that more than 3,500 Americans died from long COVID from January 2020 through June 2022.[8] Those at higher risk for long COVID include those who had more severe disease needing hospitalization or intensive care, those with underlying health conditions, the unvaccinated and people who develop multisystem inflammatory syndrome, a rare but serious condition in which the heart, lungs, kidneys, brain, skin, eyes or gastrointestinal organs can become inflamed, during COVID.[9]

Symptoms of long COVID vary widely but some of the most common include extreme fatigue, difficulty thinking or concentrating, shortness of breath, cough and muscle or joint pain. Symptoms typically start four weeks after the acute infection phase and can last for months afterward. It is not yet clear how long COVID develops but some theories include organ damage from the infection itself, complications from an inflammatory state, ongoing viral activity, autoimmunity and inadequate antibody response.[10]

There haven't been as many breakthrough treatments for long COVID discovered yet in comparison to the vaccines to prevent and antivirals to treat acute disease. This can be attributed to the uncertainty of its cause, the likely multimodality of its pathogenesis and the ease to utilize symptom management. There are several common drugs such as famotidine, colchicine and antihistamines that are being studied. RSLV-132 is a novel intravenous product in the pipeline that is designed to remove virus RNA circulating in the blood.[11]

While there may be some promising options being studied, the trials that are underway are in the beginning stages. Researchers are hopeful that the $1 billion dollars the US pledged for long COVID research and treatment can help to expedite this process.[12] Nonetheless, the best treatment is to prevent COVID infection altogether by getting vaccinated and staying up to date with vaccines.[8]

Clinical Pipeline

Hemophilia and Gene Therapy

Many gene therapies are in the pipeline, but the hemophilia gene therapies are capturing a lot of attention due to the recent approval of Hemgenix® for hemophilia B, and its hefty price tag. Specialty spend for hemophilia has been one of highest per-member therapy costs before gene therapy.[13]

Hemophilia patients have impaired coagulation cascades which leads to excessive bleeding. The disease can be mild to severe depending on the patient. Hemophilia is a X-linked genetic disease and therefore seen in males. Hemophilia can be treated through hemophilia treatment centers (HTM) or specialty pharmacies. Some patients may need to be on prophylactic therapy while others may manage using "on-demand" treatment.[14]

TABLE 2: HEMOPHILIA COMPARISON[13,14]

	Factor Deficiency	Prevalence	Treatment	FDA Approved Gene Therapy	Pipeline
Hemophilia A*	VIII	1 in 5,000 male births (about half are severe)	Factor VIII replacement, bypassing agents, Hemlibra® (emicizumab)	None	Roctavian (valoctocogene roxaparvovec) with a PDUFA 3/31/2023 SB-525 (Phase III)
Hemophilia B*	IX	About 4 times less common than hemophilia A	Factor IX replacement, bypassing agents	Hemgenix® (etranacogene dezaparvovec-drlb)	PF-06838435 (Phase III)

*About 15 to 20 percent of those with hemophilia may develop antibodies to clotting factors which may require more clotting factor or different types of clotting factors be used.

In November 2022, ICER (Institute for Clinical and Economic Review) published the *Gene Therapy for Hemophilia B and An Update on Gene Therapy for Hemophilia A: Effectiveness and Value.* Please refer to the Table 3: ICER Hemophilia Report Findings below.

TABLE 3: ICER 2022 HEMOPHILIA REPORT FINDINGS[15]

Gene Therapy Treatment	Comparator	ICER Evidence Rating
Etranacogene Dezaparvovec (Hemgenix)	Factor Prophylaxis	B+
Valoctocogene Roxaparvovec (Roctavian)	Factor Prophylaxis	C++
Valoctocogene Roxaparvovec (Roctavian)	Emicizumab (Hemlibra)	I

- A rating of B+ implies moderate certainty of a small or substantial net health benefit, with high certainty of at least a small net health benefit for Hemgenix vs factor prophylaxis.
- A rating of C++ implies moderate certainty of a comparable, small, or substantial net health benefit, with a high certainty of at least comparable net health benefit for Roctavian vs factor prophylaxis.
- For hemophilia A, there was no direct evidence comparing Roctavian to Hemlibra (low certainty about the net health benefit) which may be the most interesting comparison as Hemlibra has clinical support for reducing the annualized bleeding rate and is used in many hemophilia A patients who requiring prophylaxis.[16, 17]

Hemophilia and Gene Therapy Continued

Hemophilia replacement factors and Hemlibra may be covered under the prescription benefit or medical benefit. In recent years, more payers have moved these products to prescription coverage or through hemophilia treatment centers.[13] The hope is that the recently approved Hemgenix and future gene therapies can significantly reduce use of continued prophylactic treatment and on demand factor replacement situations while showing a favorable safety profile.

Continued long term clinical studies will be needed to make sure that the value of the gene therapies sustains, that patients and payers see a reduction in alternative treatments for hemophilia, and safety is not a concern. Whether products are approved for adults only, or include pediatric patients is also notable. And lastly, if patients have inhibitors, gene therapy trials often exclude this population from clinical trials; this should be considered when implementing therapy or coverage policies.

Gene therapies for hemophilia are currently infused as a onetime dose, and require monitoring while infusion occurs. Elixir considers Hemgenix a medical benefit therapy, and if future products mirror administration requirements, they too will most likely fall into this coverage. Medicare currently covers gene therapy under Part B. Uptake of these products may be initially slow and increase if long term clinical trials continue to show efficacy and safety, especially in the hemophilia A patients that are stable on Hemlibra® (which may be self-administered) with positive results.

Clinical Pipeline

Accelerated Approval Pathway

Accelerated approval may be granted to allow earlier approval of drugs that may treat a serious condition.[18] They may use surrogate endpoints in clinical studies, which can be used in the place of a clinical endpoint and should correlate with clinical benefit. An example may be controlling blood pressure to improve clinical outcomes in a stroke patient.[19]

When granted accelerated approval, drug companies must conduct a phase 4 confirmatory trial to keep approval status. If data is not conclusive or the study isn't conducted, the accelerated approval may be withdrawn from market either voluntarily by the manufacturer or via FDA proceedings.[20] If the data supports accelerated approval, the products are converted to traditional approval. Accelerated approvals may include new drugs/biologics or expanded indications. Accelerated approval pathway applications to the FDA are increasing, and it was reported in 2021, 14 of the 50 drugs (or 28% of approvals) used the accelerated approval pathway.[21]

In recent years, there have been concerns with FDA follow up on drugs or biologics that have received accelerated approval. In many instances, sponsors have had delays in confirmatory clinical trials, which delay FDA's ability to facilitate approval conversion. A report by the Office of Inspector General stated "Of all 278 drug applications granted accelerated approval, 104 have incomplete confirmatory trials. Of those 104, 34 percent (35 of 104) have at least one trial past its original planned completion date."[22]

TABLE 4: ACCELERATED APPROVAL DATA[20]

Summary Data (Years)	2002-2011	2012-2021
FDA Accelerated Approvals Granted	59	167
Converted to Traditional Approval	44	51
Those with Confirmatory Trials Pending	3	102

Adapted from "Analysis of FDA's Accelerated Approval Program Performance December 1992–December 2021" Published July 2022.

Notably, the FDA and sponsors withdrew 13 percent of all accelerated approval drug applications since the pathway began, and the majority of those were withdrawn since January 2021.[22] A recent example of a withdrawn accelerated approval is Blenrep® (belantamab mafodotin-blmf). The manufacturers of Blenrep withdrew the product after advice from the FDA when a follow up trial, DREAMM-3, did not meet FDA requirements for continued approval.[23] An ongoing discussion has continued for Makena® (hydroxyprogesterone caproate) as well. In a recent FDA hearing, it was suggested that Makena should be withdrawn (but pending finalization as the manufacturer is contesting).[24]

Recently, the FDA has proposed to resolve the issue of clinical trial delays. The FDA is considering penalizing companies that don't meet accelerated approval requirements in the future.[25] Future withdrawals and time frames can be expected to be watched closely in 2023, with the increase in accelerated approvals and the long list of products still awaiting final confirmatory trials and evaluation. Elixir continues to monitor FDA reviews and suggested market withdrawals, as well as fully withdrawn products. If necessary, Elixir's National P&T Committee will review these products and update utilization management as needed. As the FDA focuses on their process, we are hopeful that 2023 will bring more scrutiny to drugs and biologics under the accelerated approval pathway.

Clinical Pipeline

Microbiome and Pipeline

At the end of 2022, much conversation about gut health and microbiomes has erupted. A microbiome is a group of microorganisms (all living organisms possibly consisting of fungi, bacteria and virus) that exist in a particular environment together. For our current definition, the environment is the human body.[26] These microorganisms may be helpful, benign, or harmful. Researchers are starting to develop a hypothesis that disruption to microbiomes may cause or worsen disease. Helpful microorganisms are being studied to be used as medical treatments for certain disease states. The microbiome has even been quoted as the "last organ" in research.[27]

A report by Delveinsight noted that over 130 companies and over 175 therapies are in the possible pipeline.[28] The first microbiome product, Rebyota (fecal microbiota, live - jslm), was approved in November 2022. Rebyota was approved under a BLA to prevent recurrence of Clostridioides difficile infection (CDI) in individuals 18 years of age and older, following antibiotic treatment for recurrent CDI. Like in Rebyota, the side effect profile of many microbiome products is limited and usually not severe in most patients.

The FDA regulates some products that are composed of or impact microbes and/or microbial communities, such as fecal microbiota for transplantation, live biotherapeutic products, living microbes in foods, dietary supplements and tobacco products.[29] To be a medical product, microbiome pipeline drugs need to be tested in a controlled human trial. The below microbiome products are seeking BLA or NDA from the FDA in the upcoming future. Examples of other indications that may have microbiome products further down the line may include: ulcerative colitis, Crohn's disease, various malignancies, and even COVID-19 infection.

TABLE 5: MICROBIOME PIPELINE[28, 30-38]

Drug Name	Approval Status	Disease State	Route of Administration	Clinical Pearls
SER-109	PDUFA 04/26/2023	Recurrent C. difficile	Oral	• Purified Firmicutes spores for prevention of C. difficile • Recent study in those with 3 or more C. dificilie infections in a year • Recurrence at 8 weeks after treatment was higher in placebo than those administered SER-109; 40% vs 12%
B244	Phase III	Acne Vulgaris, Allergic Rhinitis, Dermatitis, or Eczema, Hypertension, Migraine or Headache, Rosacea	Topical	• Incorporating a single live strain of ammonia-oxidizing bacteria (AOB) Nitrosomonas eutropha D23 • Repopulate the microbe on skin which may be removed with soap • Recently published immunology data demonstrated that B244 can reduce the inflammatory and pruritic cytokines IL-4, IL-5, IL-13, and IL-31
CP101	Phase III	Recurrent C. difficile	Oral	• Prevention • Possible positive results at 8 AND 24 weeks post treatment

Microbiome and Pipeline Continued

Drug Name	Approval Status	Disease State	Route of Administration	Clinical Pearls
MaaT013	Phase III	Graft Versus Host Disease (GVHD), Melanoma	Enema (rectally)	• Phase 3 trial investigating MaaT013 in patients with acute Graft-versus-Host-Disease with gastrointestinal involvement (GI-aGvHD) who are refractory to both steroids, and multiple standards of care • Studied as a third-line, salvage therapy in GI-acute GvHD patients
US-APR2020	Phase III	Kidney Disease	Oral	• Reduction in uremic toxins • Dietary supplement seeking FDA approval for a drug
PreforPro	Phase III	Vaginal Infections	Oral	• Oral supplement for FDA approval
GV-971 (Sodium Oligomannate)	Phase III	Alzheimer's Disease	Oral	• Study began in 2020 and primary completion in December 2025 • To improve cognition in people with mild to moderate Alzheimer's disease • Active ingredient derived from brown algae may alter the gut microbiome and reduce inflammation in the brain • Approved in China in 2019
Oxabact (Oxalobacter Formigenes)	Phase III	Congenital And Chromosomal Abnormalities (not otherwise classified)	Oral	• Primary Hyperoxaluria • Oxalobacter formigenes, a non-pathogenic, oxalate-degrading commensal bacterium • Oxabact may increase excretion of oxalate by promoting active and passive secretion of oxalate from the plasma into the gut • Urinary oxalate excretion was slightly higher in the Oxabact group vs placebo; 2.10 and 1.76 mmol/day/1.73 m^2, respectively

PDUFA: Prescription Drug User Fee Act
NDA: New Drug Application
BLA: Biologic License Application
Phase III clinical trials are designed to evaluate efficacy and monitor adverse reactions in a larger population and over approximately 1 to 4 years.

Depending on route of administration, microbiome products may find their way on prescription coverage. Some microbiome products may have very specific indications and require utilization management. Others could be medical foods or "nonprescription" products that switch to NDA or BLA approval. Elixir will continue to monitor the pipeline in the microbiome for next steps.

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Our Clinical Steering Committee

The Elixir Clinical Steering Committee brings together leaders from across our national pharmacy care company to monitor the drug landscape, provide recommendations on how to address changes, and to ensure our clients and patients are prepared—in advance.

With any new development, we partner with our Pharmacy & Therapeutics (P&T) committee and consult with our best-in-class specialty pharmacy, to provide a balanced perspective on the clinical effectiveness of all available options, the cost impact to our plan sponsors and patients, and the impact on the overall patient experience.

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