JANUARY 2022

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 2022:

- Hemophilia Gene Therapy
- COVID-19 Prevention and Treatment Pipeline
- Leading Oncology Medication Revlimid® (lenalidomide) Generic in the Pipeline
- Interchangeable Biosimilars… Still a Ways to Go
- Pipeline PrEP and Pending Update to USPSTF Recommendations

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Clinical Pipeline

Hemophilia Gene Therapy

Hemophilia is a genetic disorder that usually occurs in males and may cause excessive bleeding due to a lack of proteins that help the blood to clot. Hemophilia A occurs in about one in 5,000 and hemophilia B occurs in approximately one in 20,000 live male births. Rates of hemophilia in the U.S. may have been underestimated previously and most recently was projected to be approximately 30,000 to 33,000 males.[1]

The majority of patients will have less than 1% normal blood clotting factor levels (often factor VIII in hemophilia A patients and factor IX in hemophilia B patients).[1] Severity of bleeding varies in hemophilia patients, with mild patients only having episodes after traumatic events and moderate or more severe patients requiring prophylaxis treatment. There is also concern that bleeding within joints can lead to loss of joint function and disability.

Current Treatments: The Centers for Disease Control and Prevention (CDC) estimates four out of 10 hemophilia persons may have a severe form of hemophilia. Prophylaxis treatment for severe hemophilia often consists of costly and inconvenient factor concentrates. Hemlibra® (emicizumab) has been an advancement for many hemophilia A patients needing prophylaxis, but still requires weekly to monthly dosing and is costly. Gene therapy could potentially restore the natural expression of factor VIII or factor IX for hemophiliacs.

How Gene Therapy Treats Hemophilia: Gene therapy provides functional gene replacement to those with a dysfunctional gene. Very small increases in blood factor can lead to significant bleed prevention in severe hemophilia patients, so hemophilia is a good candidate for gene therapy.[2]

Currently, gene therapy for hemophilia uses adeno-associated vectors (AAV), which help transport a genetic code to the recipient.[3] There has been some controversy with potential side effects associated with AAV. Also, antibodies may form against the AAV, making re-administration of that therapy in the future potentially ineffective.

It is unknown how long the effects of current gene therapies in the pipeline will last after dosed, but longer observational periods are starting to bring data. Most current trials are not assessing patients that have inhibitors, which is a big limitation in hemophilia treatment.

Upcoming Hemophilia Gene Therapy Treatments[4-7]

Gene Therapy	Hemophilia Type	Clinical Study Stage	Drug Composition	Clinical Insight
Valoctocogene roxaparvovec (Roctavian)	A	Phase III	AAV - Restore factor VIII	Received a complete response letter (CLR) in 2020 requesting 2 more years of data November 2021 article stated, few adverse events and no factor VIII inhibitors observed; response up to 5 years post treatment FDA decision could occur in late 2022

Hemophilia Gene Therapy Continued

Gene Therapy	Hemophilia Type	Clinical Study Stage	Drug Composition	Clinical Insight
Giroctocogene fitelparvovec (PF-07055480)	A	Phase III	AAV - Restore factor VIII	Pfizer reported Alta Phase 1/2 two-year follow up found that of 11 participants receiving therapy only 2 needed exogenous factor VIII treatment Most common side effects were liver related Phase III study has enrolled >50% of patients No inhibitors development noted
AMT-061 (etranacogene dezaparvovec)	B	Phase III	AAV with Padua variant of factor IX	Similar to AMT-060 54 participants in HOPE-B trial showed statistical reduction in annualized bleed rate at 18 months versus 6 months in standard of care One hepatocellular carcinoma event occurred but concluded as unrelated to treatment
PF-06838435 (fidanacogene elaparvovec)	B	Phase III	AAV with Padua variant of factor IX	Delayed reporting as manufacturer awaits complete analysis

Multiple other gene therapies are in earlier clinical trial stages, with some using AAV technology and others using lentivirus technology. Most trials enrolled participants 18 years of age and older, with a handful including those two years to 65 years of age.

Future Follow Up: In 2020, the FDA recommended long-term follow up of 15 years for those with AAV genome editing and five years for all other AAV gene therapies. Additionally, in September 2021, the FDA Cellular, Tissue and Gene Therapies Advisory Committee held a meeting to discuss toxicities associated with AAV gene therapy products, such as hepatotoxicity, thrombotic microangiopathy and neurotoxicity, as these serious life-threatening toxicities have been reported in patients receiving AAV gene therapy.[8]

Hemophilia gene therapies would not be the first to use AAV gene therapy, as Luxturna®, a gene therapy for the treatment of Leber congenital amaurosis, and Zolgensma®, a gene therapy to treat spinal muscular atrophy, utilize this technology and are FDA approved.

Hemophilia Gene Therapies' Place in the Market: Hemophilia is an extremely costly medical condition where spend can be seen on both the medical and prescription benefit. Reduction in the administration of factor concentrates most likely would provide improvements in patient quality of life and possible cost reduction. However, the safety of gene therapy products is under close scrutiny by the FDA.

Pricing of these products initially has been estimated to be as high as in the millions of dollars, and if their durability isn't found to be many years, it may not provide a financial benefit. The question of subsequent dosing of gene therapy still needs to be determined and could also be a factor in the value of gene therapy for hemophilia.

Expect more conversations about long-term data and the role of gene therapy in hemophilia in 2022, with a possible FDA approval near the end of the year, pending increased scrutiny by the FDA on gene therapy safety.

Clinical Pipeline

COVID-19 Prevention and Treatment Pipeline

Despite multiple current vaccines being available for COVID-19 prevention, as of December 2021, the World Health Organization (WHO) noted 137 vaccines in clinical development.[9] While new COVID-19 vaccination approvals have been relatively quiet in the United States, with the need to vaccinate the world, a search for more vaccine options will continue. The WHO listed the majority of vaccine types as protein subunit viral vectors (non-replicating), DNA, inactivated virus and RNA platforms.

U.S. COVID-19 Vaccines in the Pipeline: Notably in the U.S., Novavax, a recombinant nanoparticle vaccine, is planning to submit its Emergency Use Authorization (EUA) request to the FDA in the upcoming month.[10] Previously, Novavax was held up due manufacturing problems. Additionally, two U.S. scientists recently developed Corbevax™, a traditional recombinant protein-based technology vaccine that can easily be produced large scale.[11] Corbevax was granted approval in India to help vaccinate its population. It is unknown where this product stands compared to U.S. vaccinations in use at this time.

COVID-19 Treatments in the Pipeline: Variants, such as Omicron, have prompted concerns with the efficacy of COVID-19 monoclonal antibodies. Sotrovimab (GSK) was given an EUA in 2021, for the treatment of mild-to-moderate COVID-19 in adults and those 12 years of age and older who are at high risk for progression to severe COVID-19, including hospitalization or death. Sotrovimab may be the most promising antibody against the Omicron variant, but supplies are limited.[12] Sotrovimab has not been studied in hospitalized patients.

COVID-19 Treatment Options[13-19]

Drug	Approval Status	Dosing	Age	Clinical Insight
Molnupiravir (Merck)	EUA - 12/23/21	Four 200 mg capsules taken orally every 12 hours for 5 days	18 years of age and older	Contraceptive precautions for males and females of childbearing age In MOVE-OUT study, 6.8% of molnupiravir patients were hospitalized or died vs. 9.7% of the placebo patients Must be given within 5 days of diagnosis
Paxlovid™ (Pfizer)	EUA - 12/22/21	Orally twice daily as three tablets (two tablets of nirmatrelvir and one tablet of ritonavir) for 5 days	12 years of age and older	Numerous potential drug interactions Caution in liver and renal disease In EPIC-HR study, Paxlovid reduced the portion of people with COVID-19-related hospitalizations or death from any cause by 88% compared to placebo Must be given within 5 days of diagnosis

COVID-19 Prevention and Treatment Pipeline Continued

Drug	Approval Status	Dosing	Age	Clinical Insight
Veklury® (Gilead)	FDA Approved NDA – 10/22/20	200 mg IV as a single dose on day 1, followed by 100 mg IV once daily	12 years of age and older	Currently approved for hospitalized patients Phase III investigational study evaluating a 3-day course for non-hospitalized patients at high risk of disease progression was stopped in April 2021, but recently, a study of Veklury as outpatient use was published in the *New England Journal of Medicine* claiming an 87% lower risk of hospitalization or death versus placebo Gilead believes Veklury will be effective against the Omicron variant as it targets viral RNA polymerase where no mutations were identified
Fluvoxamine	Pending - EUA application filed	100 mg twice daily for 10 days	TBD	Oral antidepressant, selective serotonin reuptake inhibitor, approved for obsessive-compulsive disorder Benfits may include: already available, low cost and may have minimal short-term side effect profile Reduced the need for hospitalization, “defined as retention in COVID-19 emergency setting or transfer to a tertiary hospital” In the per-protocol population there was one death in the fluvoxamine group vs. 12 in the placebo Currently listed as insufficient evidence for treatment by NIH and IDSA clinical guidelines

New Drug Application (NDA)
National Institute of Health (NIH)
Infectious Disease Society of America (IDSA)

Treatment Considerations: The FDA has stated that the treatments above are not a substitute for vaccination and, at this time, are not to be used for post-exposure prophylaxis or prevention of infection.

It is not clear yet how recently approved COVID-19 treatments will classify high-risk patients. The EUA for molnupiravir and Paxlovid left this area open ended, though many may use some form of the CDC high-risk patient qualifiers until further guidance is given (https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html). Availability of Paxlovid and molnupiravir may prove difficult, as the government begins to roll out distribution.

With these treatments, it may be reasonable to anticipate a variation of the complications currently seen with the efficacy of monoclonal antibodies. Questions to consider include:

- How many times the treatments can be used by one patient if contracting COVID-19 multiple times
- Will resistance develop to treatments
- Will vaccinated and unvaccinated patients both use these treatments
- Continued safety profile questions

While the Omicron variant has thrown another loop in the pandemic, with nearly two years in, we have learned a few things about COVID-19 and are seeing progress, yet, there is still a lot to learn. As COVID-19 has brought rapidly authorized new treatments and updated guidelines, Elixir has and will continue to closely monitor developments and modified guidance for oral COVID-19 treatments, keeping clients apprised and reacting promptly when action is needed.

Clinical Pipeline

Leading Oncology Medication Revlimid® (lenalidomide) Generic in the Pipeline

Oncology is consistently one of payers top spend drug classes. New oncology medications are being approved nearly on a monthly basis by the FDA. So when a tried and true oncology treatment has a potential generic launch, it catches stakeholders' eyes.

Revlimid, an immunomodulatory agent that kills abnormal cells in bone marrow, is an oral oncology medication approved in 2015 that has since gathered indications for multiple forms of non-Hodgkin's lymphoma, multiple myeloma, mantel cell lymphoma and myelodysplastic syndromes. It is reported, per Bristol Myers Squibb, as the number one prescribed chemotherapy for multiple myeloma.[20] The National Comprehensive Cancer Network lists Revlimid as first-line therapy for myeloma patients that are both candidates and non-candidates for transplant, as well as maintenance therapy use.[21] Patients may be taking Revlimid as initial treatment, for relapses or for maintenance therapy.

Brand sales of Revlimid were reported at over $8 billion in 2020 for the 5, 10, 15 and 25 mg capsules. If a generic is approved in 2022, lenalidomide would join other generic oncology medications, such as imatinib mesylate, erlotinib and abiraterone acetate. There are multiple generic filers, with the earliest expected launch in March 2022 and others to follow later in the year. However, a recent label expansion for follicular lymphoma (non-Hodgkin) and marginal zone lymphoma may contribute to continued brand growth.

Expect a slow roll out in 2022 of the generic, if approved, due to volume production limitations pending on litigation and legal agreements with manufacturers. Initially, applying utilization management to the branded product may be difficult due to supply; however, even modest financial relief in the oncology class is welcomed.[22]

Clinical Pipeline

Interchangeable Biosimilars... Still a Ways to Go!

While not the same as generic medications, biosimilars are as safe and effective as the original biologic product or originator. Both products are rigorously evaluated by the FDA. Before a biosimilar is FDA approved, experts review the data and determine there is no clinically meaningful difference from the originator. However, biosimilar launches continue to be delayed due to patent ligation in relation to originator products, especially with inflammatory drugs like Humira® and Enbrel®.[23-25]

In addition to biosimilars coming to the market, there are also interchangeable biosimilars that have been long awaited. If pharmacy state law allows, these products may be substituted at the pharmacy level without the healthcare provider writing a new prescription for the biosimilar. This is similar to how generic atorvastatin can be substituted for brand Lipitor®.

The status of a product as an interchangeable biosimilar can be verified in the FDA Purple Book. As of January 2022, there were over 600 unique biologic license agreements (BLAs) in the Purple Book, 29 of these were biosimilar products and only two were interchangeable biosimilars. The two interchangeable biosimilars that are FDA approved are Semglee® (insulin glargine-yfgn) and Cyltezo® (adalimumab-adbm).

Approved Interchangeable Products

Interchangeable Biosimilar	Originator	Availability
Cyltezo (adalimumab-adbm) Biosimilar approval: 8/25/17 Interchangeable approval: 10/15/21	Humira	Based on litigation it looks like Cyltezo could launch after 7/1/2023 First interchangeable biosimilar for Humira
Semglee (insulin glargine-yfgn) Biosimilar approval: 6/11/2020 Interchangeable approval: 7/28/2021	Semglee	Launched October 2021 First interchangeable biosimlar for Lantus

As Elixir tracks the biosimilar pipeline, we will continue to monitor for potential interchangeable biosimilars and perform financial analysis to determine which product is more cost effective for both the member and the plan. The hope is as more interchangeable biosimilars come to market the cost can be decreased in these historically high-cost biologic categories. To learn more about biosimilars and interchangeable products, watch a recording of our webinar Biologics, Biosimilars and Interchangeable Products Oh My!

Pipeline PrEP and Pending Update to USPSTF Recommendations

Pre-exposure prophylaxis (PrEP) is medicine taken to prevent transmission of HIV in people that are at high risk of getting the disease. PrEP reduces the risk of HIV transmission from sex by about 99% and from intravenous drug use by at least 74%.[26] However, adherence to therapy is a key to prevention.

As of June 2019, the United States Preventive Service Task Force (USPSTF) endorsed a 'Grade A' recommendation that 'clinicians offer PrEP with effective antiretroviral therapy to persons who are at high risk of HIV.' At this time, the FDA has approved three products for HIV PrEP: Truvada®, Descovy® and newly approved injectable Apretude.

Apretude is an intramuscular injection, a new route of administration for PrEP therapy. In clinical trials, Apretude achieved superiority in comparison to Truvada in mixed populations that were at high risk for HIV. The superiority may be linked to improved adherence by healthcare-administered injections every eight weeks in comparison to once daily oral administration at home. Prior to each injection, HIV testing was required to continue PrEP therapy. The guidance for oral Truvada and Descovy recommend retesting every three months.[27]

There are a number of PrEP drugs in the pipeline, some with new routes of administration. The USPSTF is currently reviewing their recommendations to consider the newer routes of administration and pipeline drugs for inclusion in guidelines related to Affordable Care Act (ACA) coverage.[27-30]

FDA Approved and Pipeline Products for HIV PrEP[27, 29, 30, 31]

Drug	Manufacturer	Approval Status	Route of Administration	Clinical Insight
Dapivirine	Janssen	1Q 2022	Intravaginal	Flexible ring that is inserted vaginally May be safer during pregnancy due to minimal systemic exposure to dapivirine Potentially fewer side effects
GS-6207 (lenacapavir)	Gilead	1H 2022 for HIV 2024 for PrEP indication	Oral; subcutaneous	Initial approval in 2022 for treatment-resistant HIV Once stable administered every 6 months December 22, 2021 FDA put hold on all trials to evaluate the safety of the injectable product, forecasted not to impact outcome
Truvada	Gilead	Approved	Oral	Broader FDA label for PrEP Available as generic formulation Recommendation of negative HIV test every 3 months

Pipeline PrEP and Pending Update to USPSTF Recommendations Continued

Drug	Manufacturer	Approval Status	Route of Administration	Clinical Insight
Descovy (emtricitabine; tenofovir alafenamide fumarate)	Gilead	Approved	Oral	Specific PrEP indication: at-risk adults and adolescents weighing at least 35 kg for pre-exposure prophylaxis (PrEP) to reduce the risk of HIV-1 infection from sexual acquisition, excluding individuals at risk from receptive vaginal sex Recommendation of negative HIV test every 3 months
Apretude	Viiv	Approved, awaiting Elixir P&T Committee review	Intramuscular injection	Once stable, administered every 8 weeks Healthcare provider administered, negative HIV test required prior to administration

Elixir will continue to track any updates that are released by the USPSTF in regards to PrEP therapy. Apretude and additional pipeline products that are approved will be evaluated by our Pharmacy & Therapeutics Committee to determine appropriateness of formulary placement.

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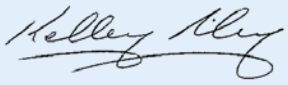
Our Clinical Steering Committee

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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