JUNE 2021

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.

INCLUDED IN THIS EDITION:

- Clinical Pipeline
- Key New Drug Approvals
- New Indications
- Upcoming and Recent Generic and Biosimilar Launches
- FDA Safety Update
- Drug Shortages, Discontinuations and Recalls

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CRAFTED Rx SOLUTIONS

Clinical Pipeline

PIPELINE STAGE

Korsuva™ *difelikefalin*

Manufacturer: Cara Therapeutics; Vifor Pharma
Indication/Use: Uremic pruritus
Dosage Form: Intravenous (IV) Injection
Pipeline Stage: PDUFA 8/23/2021

Uremic pruritus is a common symptom of end-stage kidney disease. It is multifactorial, but may be attributed to uremia-related abnormalities or toxicities from a buildup of urea in the blood or systemic inflammation. It impacts nearly 50% of chronic kidney disease (CKD) patients, with up to 40% reporting chronic pruritus. Uremic pruritus can greatly reduce the patients' quality of life and lead to restlessness, ulcerations and other skin disturbances.[1,2]

Current therapeutic options for uremic pruritus are limited and may include topical or systemic treatment with off-label medications, such as tacrolimus ointment, gabapentin, naltrexone, anti-inflammatory drugs, phototherapy and acupuncture.[2] Difelikefalin is a peripherally restricted, selective agonist of kappa opioid receptors, recently granted Priority Review from the FDA, that would be the first FDA-approved product for the treatment of uremic pruritus in the United States, if approved.

In a phase III clinical trial, approximately 323 participants randomly received IV difelikefalin or placebo during dialysis three times weekly for 12 weeks. Doses were based on body weight. Patients used the Worst Itch Numeric Rating Scale (WI-NRS) to report their itching intensity. The WI-NRS is a patient-reported, single-item scale that measures the severity of the symptom at its most intense during the previous 24-hour period.[3] Quality of life was a secondary outcome. The primary endpoint was defined as patients with improvement of at least three points from baseline of the WI-NRS score and was met in 49.1% of participants receiving difelikefalin versus 27.9% receiving placebo ($P<0.001$). Quality of life secondary outcomes also showed improvement in the difelikefalin versus the placebo group. The adverse event profile appears to be similar to placebo at this time, and no adverse events related to withdrawal at cessation were reported.[4]

Difelikefalin is under New Drug Application (NDA) review as an IV infusion for the treatment of uremic pruritus; however, there is an oral formulation in the pipeline as well. Difelikefalin is also being studied for the treatment of atopic dermatitis, chronic liver disease pruritus and notalgia paresthetica pruritus (neuropathic itching).[5] Initially, difelikefalin may be administered after dialysis, possibly part of a dialysis payment bundle. However, the oral formulation and additional indications may increase use on the prescription drug spend. Prior authorization may be appropriate to prevent unstudied, off-label use at this time.

Glossary of Terms **BLA** - Biologics License Application **NDA** - New Drug Application **PDUFA** - Prescription Drug User Fee Act

Clinical Pipeline

OC-01 *varenicline nasal spray*

Manufacturer: Oyster Point
Indication/Use: Dry eye disease
Dosage Form: Nasal inhalation
Pipeline Stage: PDUFA 10/17/2021

According to data from the 2013 National Health and Wellness Survey, 6.8%, or 16.4 million adults in the United States have been diagnosed with dry eye disease (DED). The prevalence of DED increases with age and is higher in women.[6] While DED has available treatments, it can have significant impact on visual acuity, daily activities and workplace productivity. First-line therapy is over-the-counter artificial tears. Over time, patients move to prescription options, like topical cyclosporine (Restatsis®, Cequa™) or topical lifitegrast (Xiidra®). These products are effective, but can take up to six weeks to see improvement.[7-8] Ophthalmic glucocorticoids, such as Eysuvis™, can be used on a short-term basis.

Drug manufacturers continue to explore alternative products to help better manage DED. Varenicline was originally FDA-approved in May 2006 as Chantix® for smoking cessation.[9] OC-01 (varenicline nasal spray) has been reformulated from an oral tablet to a nasal spray with the proposed indication for the reduction of signs and symptoms of DED. The action of inhaling varenicline via the nostrils stimulates the trigeminal nerve, which is responsible for sensation to the face and mucous membranes, causing the eyes to tear up. This unique mechanism would be the first nasal spray approved for DED.[10]

ONSET-2 was a phase III clinical trial that enrolled approximately 750 participants to receive one of two doses of varenicline or placebo over the course of four weeks. The primary endpoint included improvement in ocular surface disease index and eye dryness score. Participants in the varenicline group had statistically significant improvement over those in the placebo group. Patients also had relief of symptoms within two weeks of starting this therapy. Participants did not report stinging or burning in the eyes, which is common with other dry eye therapies. Discontinuation rates were minimal and similar amongst the participants.[11-12]

The timing of the approval of varenicline may occur with the generic launch of Restasis, at some time in 2021. The drug pipeline is bustling for DED, with 11 products in phase III trials. Varenicline will offer a new mechanism of action and potential symptom relief sooner than previously marketed topical cyclosporine.

Clinical Pipeline

OMS721 *narsoplimab*

Manufacturer: Omeros
Indication/Use: Thrombotic microangiopathy (TMA)
Dosage Form: Intravenous
Pipeline Stage: PDUFA 10/17/2021

TMA is a rare, but serious medical condition where a pattern of damage occurs in the smallest blood vessels inside the body's organs, particularly the kidneys.[13] It is associated with significant mortality and morbidity and is often characterized by thrombocytopenia, microangiopathic hemolytic anemia and organ injury.[14] TMAs can be inherited or acquired as a primary or secondary condition caused by medication, connective tissue disease, cancer, infection or be transplant associated.

Transplant-associated TMA (TA-TMA) can occur in 0.5% to 76% of the approximately 10,000 U.S. patients receiving haematopoietic stem cell transplants (HSCT) yearly to potentially rid malignancies. TA-TMA has a mortality rate of 60% - 90%, despite treatment.[15] Current treatments for TA-TMA are plasma exchange, corticosteroids and rituximab. Soliris® (eculizumab) may also be used off label. Plasma exchange may not always be effective for these patients.

Narsoplimab has been granted FDA breakthrough therapy for TA-TMA. It is in the pipeline for many other indications as well, such as nephropathies (IgA nephropathy) and atypical hemolytic uremic syndrome (aHUS).[16] Notably, narsoplimab uses a mechanism of action that is hypothesized not to interfere with the body's immune response to fight off infection.[16]

A phase II single-arm, open-label trial was conducted in 23 adult TA-TMA patients that met protocol. Participants received IV narsoplimab 4 mg/kg or 370 mg once weekly for four or eight weeks and were observed for six weeks. Endpoints included laboratory markers of TMA, such as platelet count and lactate dehydrogenase (LDH), and organ function, or freedom from blood or platelet transfusion. Narsoplimab met the primary endpoint in 74% (17/23) of participants based on improvements in both laboratory TMA markers and clinical status (organ function and transfusion burden). Omeros notes there was a sustained improvement in platelet count and LDH change from baseline as well.[17] Prevalence of TMA in HSCT is relatively rare with a high mortality rate, which may limit trial enrollment size and explain the small study population.

Narsoplimab may be the first FDA-approved product for TA-TMA. It will have a very specific indication and utilization management may be needed. As an infused monoclonal antibody, it most likely will be a specialty product. Subsequent indications that may be approved shortly will be crucial to monitor, as these indication expansions could be even more impactful. If expanded to aHUS, narsoplimab would join Ultomiris® and Soliris® as another compliment inhibitor. Of note, narsoplimab is also being studied in critically ill COVID-19 patients.

Key New Drug Approvals

Abecma® *idecabtagene vicleucel*

Manufacturer: Bristol Myers Squibb/bluebird bio
Indication/Use: Adults with relapsed or refractory multiple myeloma
Dosage Form: Intravenous infusion
Traditional or Specialty: Specialty

Abecma was approved by the FDA on March 30, 2021, and is the first chimeric antigen receptor T-cell (CAR-T) immunotherapy approved for multiple myeloma. Like many CAR-T therapies it demonstrated a high overall response rate in clinical studies, but also carries a hefty side effect profile, including nearly 85% of patients experiencing cytokine release syndrome and nearly a quarter experiencing neurotoxicity (most of which resolved). The FDA granted approval for it to be used as a fifth-line therapy, after four or more prior lines of therapy, including an immunomodulatory agent, a proteasome inhibitor and an anti-CD38 monoclonal antibody.

For more information: https://www.fda.gov/vaccines-blood-biologics/abecma-idecabtagene-vicleucel

Aduhelm™ *aducanumab-avwa*

Manufacturer: Biogen Inc.
Indication/Use: Alzheimer's disease
Dosage Form: Intravenous injectable
Traditional or Specialty: Specialty

On June 7, 2021, Aduhelm was FDA-approved for the treatment of Alzheimer's disease. This was the first approval of a treatment for Alzheimer's disease in almost 20 years. The FDA granted Aduhelm an accelerated approval pathway that included clinical trials limited to very specific populations and will require a new randomized controlled trial to verify drug efficacy. In November 2020, the FDA's Peripheral and Central Nervous System Drug Advisory Committee met and discussed this product. Of the 11 committee members, only one member voted in support of approving Aduhelm (eight members voted no and two were uncertain).[18-19] There was some speculation that this product would not be FDA approved based on the advisory committee findings.

For more information: https://www.fda.gov/news-events/press-announcements/fda-grants-accelerated-approval-alzheimers-drug

Key New Drug Approvals

Kloxxado™ *naloxone hydrochloride*

Manufacturer: Hikma
Indication/Use: Emergency treatment of known or suspected opioid overdose
Dosage Form: Nasal spray
Traditional or Specialty: Traditional

Kloxxado was approved by the FDA on April 29, 2021 for the treatment of opioid overdose, as manifested by respiratory and/or central nervous system depression in adult and pediatric patients. During the height of the COVID-19 pandemic, an increase in opioid and fentanyl overdoses occurred, with one U.S. urban location seeing opioid overdose emergency department admissions more than double.[20] Kloxxado was reviewed through the 505b-2 pathway using the FDA's finding of safety and effectiveness for naloxone hydrochloride (NARCAN® injection) to support approval. Kloxxado is a nasal spray, much like Narcan, but delivers a higher dose of naloxone at 8 mg. The need for Kloxxado may be largely attributed to potent, illicit fentanyl, which may be leading to more overdose deaths and require an increased amount of naloxone administrations to treat the overdose.[21]

For more information: https://www.fda.gov/news-events/press-announcements/fda-approves-higher-dosage-naloxone-nasal-spray-treat-opioid-overdose

Nextstellis® *drospirenone; estetrol*

Manufacturer: Mayne Pharma
Indication/Use: Contraception
Dosage Form: Oral tablets
Traditional or Specialty: Traditional

Nextstellis was approved by the FDA on April 15, 2021 as a daily oral contraceptive for pregnancy prevention. Nextstellis contains estetrol (E4), a unique, natural estrogen made exclusively during pregnancy. It is proposed that E4 has less interaction with the liver and does not bind to the carrier protein sex-hormone binding globulin (SHBG), which potentially could offer an improved oral contraceptive side effect profile.

For more information: https://www.maynepharma.com/media/2506/fda-approval-of-novel-oral-contraceptive-nextstellis.pdf

Key New Drug Approvals

Qelbree™ *viloxazine hydrochloride*

Manufacturer: Supernus Pharmaceuticals, Inc.
Indication/Use: Attention-Deficit Hyperactivity Disorder (ADHD)
Dosage Form: Oral capsule
Traditional or Specialty: Traditional

On April 2, 2021, Qelbree was approved by the FDA for pediatric patients aged six to 17 years with ADHD. Stimulants are often the most effective ADHD treatment and considered the gold standard for efficacy, but some patients and parents are in search of non-stimulant options. Qelbree is a non-stimulant alternative, similar to atomoxetine, but can be opened up and sprinkled on apple sauce for administration. It has been described as a serotonin norepinephrine modulating agent.[22] Unlike atomoxetine, Qelbree dose does not need to be adjusted for those that are poor metabolizers of CYP2D6. Qelbree is also known for having a tolerable side effect profile, as it has been approved in the United Kingdom for depression treatment for many years prior to FDA approval.

For more information: https://www.qelbree.com/

Rybrevant™ *amivantamab-vmjw*

Manufacturer: Janssen Pharmaceutical Companies
Indication/Use: Locally advanced or metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 20 insertion mutations
Dosage Form: Intravenous infusion
Traditional or Specialty: Specialty

Rybrevant received FDA approval on May 21, 2021 for adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 20. This is the first targeted treatment option available for this patient population. NSCLC with this specific mutation has a worse prognosis and a shorter survival rate compared with lung cancer driven by more common EGFR mutations.

For more information: https://www.janssen.com/rybrevant-amivantamab-vmjw-receives-fda-approval-first-targeted-treatment-patients-non-small-cell

New Indications

Humira® *adalimumab*

Manufacturer: AbbVie
Indication/Use: Rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, Crohn's disease, psoriasis, juvenile idiopathic arthritis, ulcerative colitis, hidradenitis suppurativa, and certain types of uveitis
Dosage Form: Subcutaneous injectable
Traditional or Specialty: Specialty
Date of Original Approval: December 31, 2002

On February 24, 2021, the FDA approved an age reduction for Humira's labeling for treatment of ulcerative colitis (UC) to five years of age. UC has a large impact on children with limited biologic treatment options. Humira will offer a subcutaneous injectable biologic that can be administered at home. There are several approved biosimilars for Humira, but none of these products have launched due to being held up in litigation. It could be quite some time before we see a biosimilar with a pediatric label.

For more information: https://www.humira.com/

Evekeo® *amphetamine sulfate*

Manufacturer: Arbor Pharmaceuticals
Indication/Use: Attention-Deficit Hyperactivity Disorder (ADHD)
Dosage Form: Oral disintegrating tablet (ODT)
Traditional or Specialty: Traditional
Date of Original Approval: January 30, 2019

Evekeo ODT age labeling was expanded to include children as young as three years of age on April 21, 2021. Previously this product was approved for children six to 17 years of age, making this the only amphetamine product to have approval for use in three year olds. Treatment with Evekeo should be in conjunction with cognitive behavioral therapy.

For more information: https://www.evekeoodt.com/

New Indications

Farxiga® *dapagliflozin*

Manufacturer: AstraZeneca
Indication/Use: Type 2 diabetes, heart failure, chronic kidney disease
Dosage Form: Oral tablet
Traditional or Specialty: Traditional
Date of Original Approval: July 25, 2013

On April 30, 2021 the Farxiga label was expanded, adding reduced risk of sustained estimated glomerular filtration rate decline, end-stage kidney disease, cardiovascular death and hospitalization for heart failure in adults with chronic kidney disease (CKD) at risk of progression with or without diabetes. Previous FDA approval for Farxiga included treatment of type 2 diabetes and reduction of risk of cardiovascular death in heart failure. Additional labeling for use in chronic kidney disease is a significant advancement in the treatment of CKD.

For more information: https://www.farxiga.com/

Nurtec® ODT *rimegepant*

Manufacturer: Biohaven Pharmaceuticals
Indication/Use: Acute migraine
Dosage Form: Oral disintegrating tablet
Traditional or Specialty: Traditional
Date of Original Approval: February 27, 2020

Nurtec ODT received an expanded indication for preventive treatment of episodic migraine in adults on May 27, 2021. Nurtec ODT is the first oral calcitonin gene-related peptide (CGRP) receptor antagonist indicated for both the treatment of acute and prevention of migraines. This product is dosed every other day for prevention. Direct competition for Nurtec ODT will be the other subcutaneous CGRP injectables, Aimovig®, Ajovy® and Emgality®, with monthly or every three month dosing schedules.

For more information: https://www.nurtec.com/

New Indications

Zeposia® *ozanimod*

Manufacturer: Bristol Myers Squibb
Indication/Use: Multiple sclerosis
Dosage Form: Oral capsule
Traditional or Specialty: Specialty
Date of Original Approval: March 25, 2020

Zeposia is the first sphingosine 1-phosphate receptor modulator to receive FDA approval for moderately to severely active ulcerative colitis (UC) in adults, adding an additional once daily oral treatment option with a unique mechanism of action for UC. It is important to note that Zeposia has significant contraindications in patients who have experienced myocardial infarction, unstable angina, stroke or transient ischemic attack, heart failure in the last six months.

For more information: https://www.zeposia.com/

Upcoming and Recent Generic and Biosimilar Launches

Brand Name	Generic or Biosimilar	Generic Name	# of Mfg Entrants	Indication	Launched or Potential Launch Date
Thiola®	Generic	tiopronin	1	Kidney stone prevention	Launched
Absorica®	Generic	isotretinoin	2	Acne, severe recalcitrant nodular	Launched
Lyrica® CR	Generic	pregabalin	3	Neuropathic pain associated with diabetic peripheral neuropathy, postherpetic neuralgia	Launched
Azopt	Generic	brinzolamide	1	Elevated intraocular pressure	Launched
Hysingla® ER	Generic	hydrocodone bitartrate	1	Pain management	Launched
Xulane®	Generic	estradiol; norelgestromin	1	Contraception	Launched
Intelence®	Generic	etravirine	TBD	HIV-1 infection, treatment	06/14/2021
Perforomist®	Generic	formoterol fumarate	TBD	Chronic obstructive pulmonary disease	06/22/2021
Chantix®	Generic	varenicline tartrate	4	Aid to smoking cessation	1H 2021
Sutent®	Generic	sunitinib malate	TBD	Multiple cancer indications	08/16/2021
Bystolic®	Generic	nebivolol hydrochloride	5+	Hypertension	09/17/2021
Gilenya® (0.25 mg)	Generic	fingolimod hydrochloride	1	Multiple sclerosis	11/11/2021
Bepreve®	Generic	bepotastine besilate	4	Allergic conjunctivitis	2021

Upcoming and Recent Generic and Biosimilar Launches

Brand Name	Generic or Biosimilar	Generic Name	# of Mfg Entrants	Indication	Launched or Potential Launch Date
Byetta	Generic	exenatide synthetic	TBD	Diabetes mellitus	2021
Daliresp®	Generic	roflumilast	5+	Chronic obstructive pulmonary disease exacerbation risk reduction	2021
Emend (oral suspension)	Generic	aprepitant	1	Chemotherapy-induced nausea and vomiting	2021
Epiduo® Forte	Generic	adapalene; benzoyl peroxide	1	Acne	2021
Kaletra® (tablets)	Generic	lopinavir; ritonavir	5+	HIV-1 infection, treatment	2021
Narcan® (nasal spray)	Generic	naloxone hydrochloride	1	Opioid overdose	2021
Norvir® (capsules)	Generic	ritonavir	2	HIV-1 infection, treatment	2021
Noxafil® (oral suspension)	Generic	posaconazole	3	Fungal infections	2021
Rescula	Generic	unoprostone isopropyl	2	Open-angle glaucoma or ocular hypertension	2021
Toviaz®	Generic	fesoterodine fumarate	5+	Overactive bladder symptoms	2021
Ulesfia®	Generic	benzyl alcohol	2	Head lice infection	2021

FDA Safety Updates

Drug Safety Communication

Potential Risk of Heart Rhythm Problems for Patients with Heart Disease Taking Lamictal (lamotrigine)

On March 31, 2021, the FDA released an announcement that lamotrigine may have a potential to increase heart rhythm problems, such as arrhythmias, in patients with concurrent heart disease. The FDA is also examining if other medications in the same drug class exhibit similar effects on the heart. Patients should not stop taking lamotrigine until speaking to their healthcare professional to discuss next steps. If patients experience symptoms such as shortness of breath, dizziness or fainting, slow or racing heartbeat, or a skipped heartbeat, a healthcare professional should be contacted right away or go to the emergency room.

For more information:
https://www.fda.gov/drugs/drug-safety-and-availability/studies-show-increased-risk-heart-rhythm-problems-seizure-and-mental-health-medicine-lamotrigine

FDA Restricts Use of Ocaliva® in Primary Biliary Cholangitis Patients with Advanced Cirrhosis

The FDA is adding a contraindication to the labeling for Ocaliva (obeticholic acid) in patients that have a rare, chronic liver disease known as primary biliary cholangitis (PBC) with advanced cirrhosis of the liver because patients developed liver failure and sometimes required liver transplantation. This additional labeling is based on five years of post-approval data identifying 25 cases of serious liver injury. Of note, many of these patients had advanced liver disease prior to starting Ocaliva.

Patients that are currently taking this medication are encouraged to talk to their healthcare provider about this new contraindication and receive education on signs/symptoms of worsening liver injury or development of advanced cirrhosis.

For more information:
https://www.fda.gov/drugs/drug-safety-and-availability/due-risk-serious-liver-injury-fda-restricts-use-ocaliva-obeticholic-acid-primary-biliary-cholangitis

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Clinical efficacy and safety, balanced with a drug's value, are always at the forefront in the Elixir formulary decisions and pipeline planning. The rationale for those decisions may go beyond the use of the FDA's labeled indication. Our clinical reviews may utilize, but are not limited to, recognized consensus guidelines, the Institute for Clinical and Economic Review (ICER), and compendium such as the National Comprehensive Cancer Network (NCCN Guidelines®) and DRUGDEX®. Elixir monitors FDA updates and safety announcements daily, as well as follows guidance from the Center of Disease Control and Prevention (CDC) and the U.S. Preventive Service Task Force (USPSTF®).

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.

Kel Riley, MD
Chief Medical Officer

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