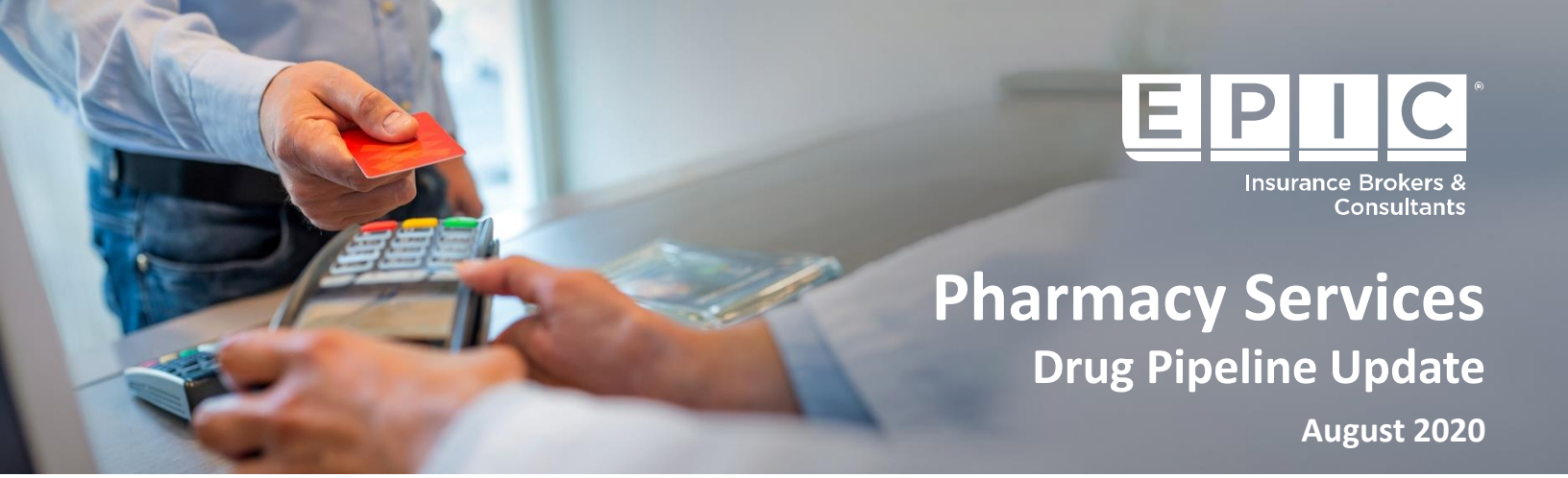

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FDA REJECTIONS

The Food and Drug Administration (FDA) recently rejected Gilead's filing for approval of **filgotinib for rheumatoid arthritis**. With the FDA asking to see data from an ongoing clinical trial, Gilead is unlikely to be able to refile until mid-2021, pushing it further behind its competitors for the Janus Kinase (JAK) inhibitor market. These drugs suppress the immune system to prevent damage to the joints.

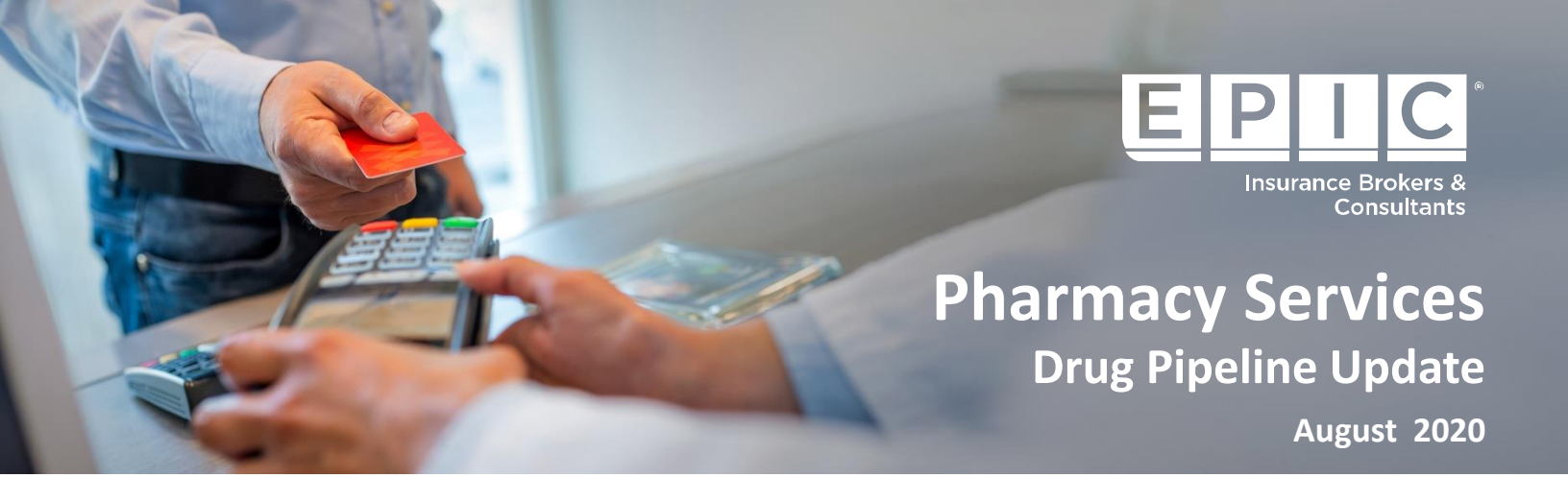
The FDA rejected BioMarin's **Roctavian for hemophilia A**. This expensive gene therapy was expected to revolutionize the treatment of this disease. However, the manufacturer will be required to complete an ongoing late-stage patient study which means it won't likely be approved before late 2022.

The FDA denied the approval of the new **peanut allergy treatment, Viaskin Peanut**, due to concerns related to "the impact of patch-site adhesion on efficacy and indicated the need for patch modifications, and subsequently a new human factor study." This means that Palforzia will be the only FDA treatment available for patients requiring desensitization.

NEW GENERIC APPROVALS

- Generic **Effexor** (antidepressant) is available in 37.5mg, 75mg and 150mg
- Generic **Robaxin** 750mg (muscle relaxant) is available
- Generic **K-Tab** and potassium chloride extended release are available
- The FDA recently approved the generic for AstraZeneca's **Nolvadex (Tamoxifen citrate)** tablets, 10 mg and 20 mg. Tamoxifen citrate is used for the treatment of metastatic breast cancer.
- Generic **Prolixin** was approved in 1mg, 2.5mg, 5mg and 10mg for the treatment of schizophrenia.
- Cipla received final approval from the FDA for generic **Firazyr**, used to treat acute attacks in adults with hereditary angioedema (HAE).
- The FDA has approved **Hulio**, **a biosimilar of Humira** to treat a variety chronic inflammatory disorders i.e. rheumatoid arthritis. Hulio will not be available in the U.S. until mid-2023 due to a patent agreement with the manufacturer of Humira.

RX Team Tip: *We strongly recommend generic dispensing rules so when a generic equivalent is available, the plan only pays the cost of the generic, even if a physician signs a prescription "dispense as written".*



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NEW FDA DRUG APPROVALS

Upneeq™ (oxymetazoline) solution For the treatment of acquired blepharoptosis (drooping upper eyelid) in adults. Upneeq contains the same active ingredient as the nasal spray Afrin, oxymetazoline, which is an alpha adrenoceptor agonist believed to target Mueller's muscle that raises the upper eyelid.

> **RX Team Tip:** *We strongly recommend exclusion from the pharmacy benefit*

Wynzora™ (calcipotriene and betamethasone) cream For the treatment of plaque psoriasis in adults. Wynzora contains the same active ingredients and strengths as Taclonex, but is formulated into a cream versus the currently available suspension and ointment.

> **RX Team Tip:** *We recommend step therapy and prior authorization for this product*

Xywav™ (calcium/magnesium/potassium and sodium oxybates) solution For the treatment of cataplexy (sudden muscle weakness) or excessive daytime sleepiness in narcolepsy patients 7 years of age and older.

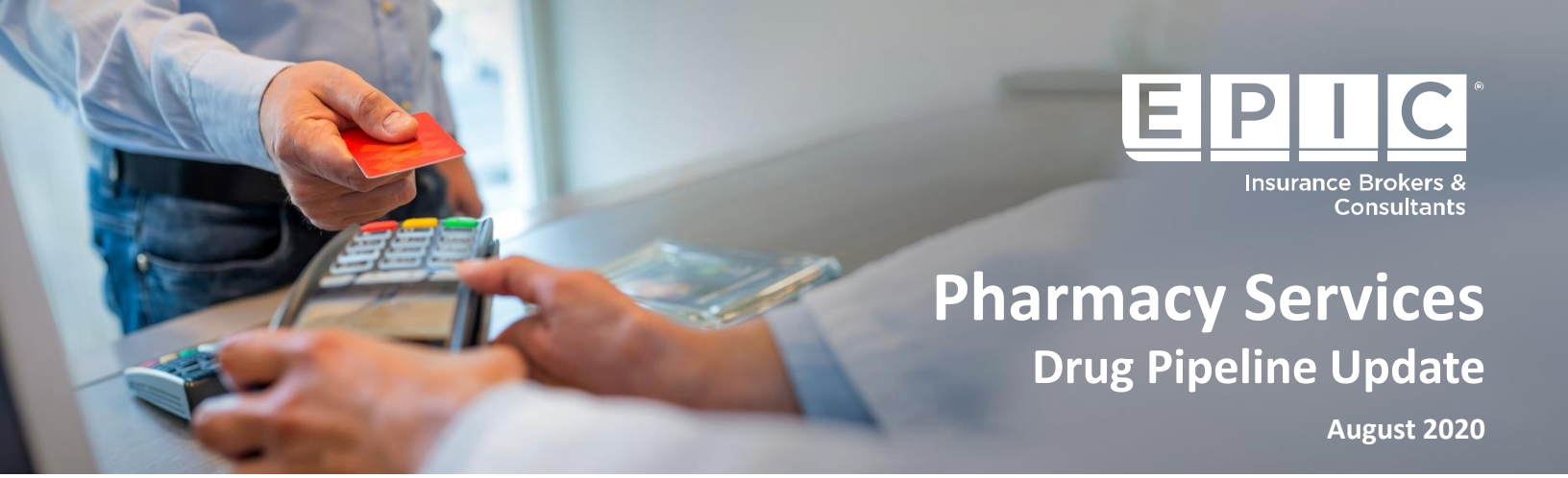
Breztri Aerosphere™ (budesonide, glycopyrrolate, formoterol) inhaler Approved as maintenance therapy for patients with chronic obstructive pulmonary disease (COPD).

Xeglyze™ (abametapir) lotion For the treatment of head lice infestation in patients aged 6 months or older.

Evrysdi® (risdiplam) oral solution For the treatment of spinal muscular atrophy (SMA) patients two months of age and older. Will be limited distribution through Accredo specialty pharmacy. Evrysdi's annual cost will range from $100k-$344k (based on dosage and weight) but it will compete with Zolgensma and Spinraza. As a reminder, Zolgensma is a one-time gene therapy treatment and is priced at $2.1 million. Spinraza is priced at $750,000 for the first year and $375,000 for treatment in subsequent years. Analysts expect that Evrysdi will mostly take market share away from Spinraza as Zolgensma has strong data and is a one-time therapy that will likely be the treatment of choice for very young SMA patients.

Olinvyk™ (oliceridine) injection An opioid for moderate to severe acute pain in a controlled clinical setting i.e. hospital.

> **RX Team Tip:** *Make sure your pharmacy benefit manager (PBM) blocks new drugs until appropriate reviews are conducted to ensure each product is managed with strict clinical programs.*



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APPROVALS FOR NEW INDICATIONS

Spravato® (esketamine) nasal spray
For the treatment of depressive symptoms in adults with major depressive disorder (MDD) with acute suicidal ideation or behavior in conjunction with an oral antidepressant.

Epidiolex® (cannabidiol or CBD) solution
For the treatment of seizures associated with tuberous sclerosis complex in patients one year of age and older.

Epidiolex was previously approved for the treatment of seizures associated with two rare and severe forms of epilepsy, Lennox-Gastaut syndrome and Dravet syndrome.