Maxor®

PHARMACY BENEFIT MANAGEMENT SERVICES

MAXOR PIPELINE Q4 2024

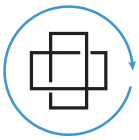
Industry news | New to market brands and generics | Drug pipeline spotlight

November 2024

SPOTLIGHT | INDUSTRY NEWS

FDA approves first nasal spray for anaphylaxis

In August 2024, the Food and Drug Administration (FDA) approved the **first needle-free treatment** for adults and children with severe allergic reactions. Neffy® is a nasal spray that delivers epinephrine and is approved for the emergency treatment of allergic reactions, including anaphylaxis, in adults and children over 66 pounds. According to survey results, ARS Pharmaceuticals says that up to 60% of epinephrine users will make the switch to Neffy. This product is expected to be priced at a slight premium compared to other products. The manufacturer will offer a copay savings program to limit the cost for commercially insured members.



Annual vaccination recommendation updates

Annual vaccination continues to be the best way to reduce the risk of severe illness and death associated with vaccination-preventable viruses. The Centers for Disease Control and Prevention recommends that everyone aged six months and older receive a flu shot. The 2024-2025 influenza vaccines are trivalent, a change from the decade-long history of quadrivalent vaccines. The B/Yamagata strain is no longer detectable and was recommended for removal this season. The FDA recently approved **COVID-19 vaccines (2024-2025 formula).** These updated formulas have been developed to better target the most commonly circulating virus strains.

Humira experiences movement on many formularies

Since the launch of biosimilars for Humira® began in January 2023, 10 products have entered the market. Humira has continued to hold the most market share, but this is expected to change in 2025 as more formularies prefer biosimilar products over the brand name drug. Some of the largest commercial formularies in the U.S. will **no longer include Humira**, opting instead for branded and unbranded biosimilars. AbbVie, the manufacturer of Humira, has been preparing for this shift, and is focusing on its newer medications, Skyrizi® and Rinvoq®, to offset the impact from the declining sales of Humira.

Ongoing drug shortage prompts DEA to increase production

Vyvanse®, produced by Takeda, has been experiencing shortages since June 2023. Shortages were prompted by limited inventory of Adderall®, another commonly prescribed medication for attention-deficit/hyperactivity disorder. Although the generic launched in August 2023, both the brand and generic versions have been in short supply. In an effort to decrease misuse and diversion, Schedule II controlled substances, like Vyvanse, are subject to production limits set by the Drug Enforcement Administration (DEA). In response to a request by the FDA, the DEA has **allowed an increase in the production** of lisdexamfetamine, the active ingredient in Vyvanse and its generics. If they choose to do so, manufacturers can now increase the production of the capsules and chewable tablets to help ease the shortage.

NOW APPROVED | NEW BRAND DRUGS TO MARKET

Brand name	Generic name	Indication	ROA	Approval month
KISUNLA™	Donanemab	Alzheimer's disease	IV	Jul-24
OHTUVAYRE™	Ensifentrine	Pulmonary disease	IN	Jul-24
RYTELO™	Imetelstat	Myelodysplastic syndromes	IV	Jul-24
SOFDRA™	Sofpironium	Axillary hyperhidrosis	EX	Jul-24
ZORYVE®	Roflumilast	Mild to moderate atopic dermatitis	EX	Jul-24
PIASKY®	Crovalimab	Paroxysmal nocturnal hemoglobinuria	IJ	Aug-24
TECELRA®	Afamitresgene	Synovial sarcoma	IV	Aug-24
VAFSEO®	Vadadustat	Anemia due to kidney disease	OR	Aug-24
VIGAFYDE™	Vigabatrin	Infantile spasms	OR	Aug-24
CREXONT®	Carbidopa & Levodopa	Parkinson's disease	OR	Sep-24
LAZCLUZE™	Lazertinib	Non-small cell lung cancer	OR	Sep-24
LIVDELZI®	Seladelpar	Primary biliary cholangitis	OR	Sep-24
NEFFY®	Epinephrine	Allergic reactions	NA	Sep-24
NEMLUVIO®	Nemolizumab	Prurigo nodularis	SC	Sep-24
ONYDA™ XR	Clonidine	Attention deficit hyperactivity disorder	OR	Sep-24
TEVIMBRA®	Tislelizumab	Metastatic esophageal squamous cell carcinoma	IV	Sep-24
TRYVIO™	Aprocitentan	Hypertension	OR	Sep-24
VORANIGO®	Vorasidenib	Grade 2 astrocytoma or oligodendroglioma	OR	Sep-24
YORVIPATH®	Palopegteriparatide	Hypoparathyroidism	SC	Sep-24

NOW APPROVED | NEW GENERIC DRUGS TO MARKET

Brand name	Generic name	Indication	Launch month
ESTROGEL®	Estradiol	Vasomotor symptoms	May-24
HALAVEN®	Eribulin	Breast cancer	May-24
MYRBETRIQ®	Mirabegron	Overactive bladder	May-24
ORACEA®	Doxycycline	Rosacea	May-24
EMFLAZA®	Deflazacort	Duchenne muscular dystrophy	Jun-24
CORLANOR®	Ivabradine	Chronic heart failure	Jul-24
RADICAVA®	Edaravone	Amyotrophic lateral sclerosis	Jul-24
VICTOZA®	Liraglutide	Type 2 diabetes	Jul-24
ENDARI®	L-Glutamine	Sickle aell anemia	Aug-24
ROXYBOND™	Oxycodone	Pain	Aug-24
LUCEMYRA®	Lofexidine	Mitigation of opioid withdrawal	Sep-24
OXTELLAR XR®	Oxcarbazepine	Seizures	Sep-24
SPRYCEL®	Dasatinib	Chronic myeloid leukemia	Sep-24

The report provided is for informational purposes only. This information should not be solely relied upon for formulary decision-making purposes and is subject to change. www.maxorplus.com
Abbreviation: ROA- Route of Administration; EX-External; IJ-Injection; IM-Intramuscular; IV-Intravenous; OR-Oral; SC-Subcutaneous

WHAT'S IN THE **CLINICAL PIPELINE?**

Type 1 diabetes

Sotagliflozin [Lexicon Pharmaceuticals]

This medication is an oral SGLT 1/2 inhibitor currently approved as Inpefa® to reduce the risk of cardiovascular death in people with heart failure or type 2 diabetes (T2D). This was submitted for review as an oral adjunct therapy to insulin for glycemic control in patients with type 1 diabetes (T1D) and chronic kidney disease. If approved, sotagliflozin will be the first SGLT1/2 inhibitor and oral treatment for patients with T1D and chronic kidney disease. The regulatory decision is expected by December 20, 2024.

Short bowel syndrome

Glepaglutide [Zealand Pharma]

Glepaglutide is a subcutaneous twice weekly auto-injectable glucagon-like peptide-2 (GLP-2) analog. A Gattex® (tedglutide) is a once daily GLP-2 analog that is currently approved and has the potential to have an equivalent generic approved late this year. There is also a once weekly GLP-2 (apraglutide) that is in the pipeline with a possible approval in late 2025. The annual treatment cost is estimated to be approximately $540,000. A regulatory decision is expected by December 22, 2024.

Familial chylomicronemia syndrome

Olezarsen [Ionis Pharmaceuticals]

Familial chylomicronemia syndrome (FCS) is a rare genetic disorder that prevents the body from breaking down triglycerides, which can lead to extremely high levels of triglycerides in the blood. If approved, this medication would be the first agent for FCS. Olezarsen is also being studied for the more common diagnosis of hypertriglyceridemia that affects one in five adults in the U.S. Pricing for the rare indication is expected to be close to $350,000 per year. The regulatory decision for FCS is expected in December 2024, while study results for hypertriglyceridemia are expected in the second half of 2025.

Breast cancer

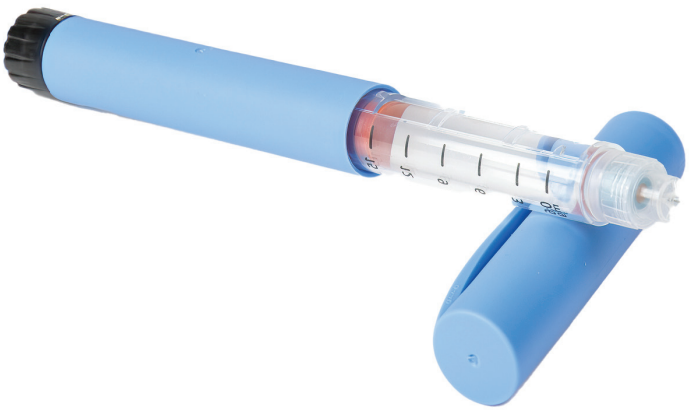
Inavolisib [Roche: Genentech]

This breast cancer treatment is an oral phosphoinositide (PI3K) inhibitor that was granted Breakthrough Therapy designation and Priority Review by the FDA. The PI3K inhibitors are currently second-line therapies after progression on a first-line treatment. Inavolisib may after disease progression shift to first line as triple therapy with Ibrance® (palbociclib) and fulvestrant. Inavolisib was approved on October 10, 2024.

GLP-1 RECEPTOR AGONISTS

Advancements in development fuels future therapies

Glucagon-like peptide-1 (GLP-1) receptor agonist therapies continue to drive a significant portion of the traditional drug pipeline. There are over **30 products** in various stages of development with multiple manufacturers that have various formulations that either single out or combine GLP-1 agonists. Known for treating type 2 diabetes and obesity, this class of medication is also being studied for multiple highly prevalent diagnoses, including Alzheimer's disease, sleep apnea, and metabolic dysfunction-associated steatohepatitis (MASH). The pipeline consists of single, dual, and even triple-mechanism of action therapies. These "enhanced" GLP-1 products can be differentiated by their dosing schedule, impact on diabetes, weight loss outcomes, and development as either an oral or injectable option.



Pending indication approvals		
Drug name	**Indication**	**Pending approval date**
Zepbound® [Eli Lilly]	Obstructive sleep apnea	Dec-24
Ozempic® [Novo Nordisk]	Chronic kidney disease	Jan-25

Tirzepatide shows positive results in pivotal 2024 study

On August 20, Lilly announced topline data from a Phase III study that evaluated the safety and efficacy of once weekly tirzepatide for long-term weight management and progression to diabetes in adults with prediabetes who were also obese or overweight. The results showed that the studied doses **reduced the risk** of progression to type 2 diabetes by 94% when compared to placebo. This is in addition to a sustained weight loss during the trial period. Tirzepatide is marketed under the brand name Mounjaro® to improve blood sugar control in adults with type 2 diabetes and as brand name Zepbound® for chronic weight management.

Decisions on new indications are pending including Zepbound for the treatment of sleep apnea expected in December 2024 and the decision on Ozempic for the treatment of chronic kidney disease expected in January 2025.

SPOTLIGHT
ATOPIC DERMATITIS

Atopic dermatitis in the United States

Atopic dermatitis (AD) is a chronic inflammatory skin condition associated with dry skin, intense itching, rash, and thickening of the skin over time. Symptoms often begin in childhood and may continue into the teen and adult years. AD affects over 26 million people in the U.S. There is **no cure**, but the treatment landscape is changing quickly with many new high-cost approvals for this chronic condition.

Drug pipeline includes 40+ products with AD indication

From 2001 to 2021, only two new therapies (Dupixent® and Eucrisa®) were approved to treat AD. Since September 2021, five new drugs have been approved: Adbry®, Cibinqo®, Rinvoq®, Zoryve®, and Opzelura®. The next three to five years could see more than a dozen new therapies based on the current development pipeline status. Current therapies **range from $20,000 to $50,000+ annually**.

Pipeline therapies will compete with market favorites

The drug pipeline has a heavy focus on both the non-steroidal topical options and systemic biologic therapies. Along with biologics, **phototherapy**, if available and acceptable to the patient, is an alternative first-line option in combination with topical corticosteroids for adults and adolescents with moderate to severe AD.[1]

Ebglyss™, approved in September 2024, is the third approved biologic for AD. Nemluvio®, with pending approval in December 2024, is expected to be promoted as a first-line option. It was approved in August 2024 for treatment of prurigo nodularis.

Atopic dermatitis pipeline products

Drug name	Regulatory status	Notes
Ebglyss [Lilly]	Approved Sept-24	• Third approved biologic for AD behind Dupixent® and Adbry® • May be dosed every 4 weeks vs. every 2 weeks for other biologics
Nemluvio [Galderma]	Pending approval Dec-24	• If approved, expected to be promoted as first-line for AD • Once monthly dosing • Approved in August 2024 for prurigo nodularis (PN)-second to gain approval after Dupixent

1.Dawn M.R. Davis, Aaron M. Drucker, et al. Guidelines of care for the management of atopic dermatitis in adults with phototherapy and systemic therapies, Journal of the American Academy of Dermatology,Volume 90, Issue 2,2024,Pages e43-e56,

PRODUCT SPOTLIGHT
DERMATOLOGICAL SPEND SOLUTION

Creating an impact on reducing medical spend while making clinically proven phototherapy accessible at home

Narrowband Ultraviolet B (NB-UVB) Phototherapy at home

Dermatologic spend solutions are making an impact on reducing medical spend while making clinically proven phototherapy treatment available at home. Narrowband ultraviolet B (NB-UVB) phototherapy is effective on multiple types of skin conditions including psoriasis, vitiligo, and AD. It works to improve skin by calming overactive immune cells, decreasing inflammation, and promoting normal skin barrier growth. It is a fraction of the cost of biologics, biosimilars, and other advanced therapies.

Dermatologic spend solutions can deliver a five times return on investment* and achieve a 53% reduction in annual prescription drug costs per member. Upwards of a treatment adherence rate of 74%, 94% of psoriasis patients experience clearance within 10 weeks.**

Get Started. Reach out to your MaxorPlus account manager. They will support you every step of the way.