Maxor®

PHARMACY BENEFIT MANAGEMENT SERVICES

MAXOR PIPELINE Q1 2025

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

January 2025

SPOTLIGHT | PIPELINE NEWS

Stelara® biosimilar products expected to launch in early 2025

As of the close of December 2024, there have been seven biosimilar products approved for the reference drug Stelara®. These products have all gained approval for the same indications as the branded drug. Amgen's biosimilar product, Wezlana™, the first product to gain interchangeable status, **launched in early January 2025** while multiple other approved Stelara biosimilars have estimated launch dates through May 2025. The changing landscape of biosimilar acceptance may drive a quick uptake of Stelara biosimilar adoption by providers, payers, and patients. Many industry forecasts have predicted biosimilar market share reaching 25% within the first year of launch.

Pneumonia vaccination recommendation age lowered

The Centers for Disease Control and Prevention (CDC) has updated its recommendation for pneumococcal vaccination to include **adults 50 years of age and older**. The previous recommendation was for adults 65 and older. The update was based in part on economic data that showed an increase in burden of pneumococcal disease in the 50-64 age group, along with a push to improve health equity for this group. There are currently four FDA-approved pneumococcal vaccines available in the U.S. As a provision of the Affordable Care Act, payers are required to cover CDC-recommended vaccines at $0 cost share.

Manufacturers focusing on proving efficacy in head-to-head trials

In an effort to prove relative efficacy between therapy options, multiple head-to-head trials between weight loss therapy medications are ongoing. Topline results from SURMOUNT-5, the **first ever head-to-head obesity study**, were released in early December 2024. In the study, Eli Lilly's Zepbound® led to an average weight loss of 20.2% of body weight in adults with obesity or overweight, compared to Novo Nordisk's Wegovy®, which showed an average 13.7% weight loss in the same type of population. Other pertinent trials are:

Trial products	Pipeline insights
CagriSema vs. Zepbound	**CagriSema**-pipeline product that combines an amylin analog and GLP-1 agonist. Potential approval 2H 2026
Retatrutide vs. Zepbound	**Retatrutide**-pipeline product combining GLP-1/GIP/glucagon receptor agonist. Potential approval 2027

Prescribing of controlled substances via telemedicine updates

Under the Ryan Haight Online Pharmacy Consumer Protection Act of 2008, a prescribing practitioner may prescribe controlled medications to a patient only after conducting an in-person evaluation of the patient. In response to the COVID-19 public health emergency, temporary exceptions that allowed for the prescribing of controlled medications via telemedicine encounters were implemented. These exceptions were extended through November 2023 and then extended a second time through December 2024. With the deadline quickly approaching, the Drug Enforcement Agency (DEA) and the U.S. Department of Health and Human Services (HSS) issued a third extension of the telemedicine flexibilities to be **effective through December 2025**. The additional time was granted to allow for providers to come into compliance with any final updates to prescribing regulations.

NOW APPROVED | NEW BRAND DRUGS TO MARKET

Brand name	Generic name	Indication	ROA	Approval month
AQNEURSA™	Levacetylleucine	Niemann-Pick Disease Type C	OR	Oct-24
COBENFY™	Xanomeline-Trospium	Schizophrenia	OR	Oct-24
EBGLYSS™	Lebrikizumab	Atopic dermatitis	SC	Oct-24
MIPLYFFA™	Arimoclomol	Niemann-Pick Disease Type C	OR	Oct-24
OCREVUS ZUNOVO™	Ocrelizumab-Hyaluronidase	Multiple sclerosis	SC	Oct-24
TECENTRIQ HYBREZA™	Atezolizumab-Hyaluronidase	Non-small cell lung cancer	SC	Oct-24
VYALEV™	Foslevodopa-Foscarbidopa	Parkinson's disease	SC	Oct-24
HYMPAVZI™	Marstacimab	Hemophilia A; Hemophilia B	SC	Nov-24
ITOVEBI™	Inavolisib	Breast cancer	OR	Nov-24
PAVBLU™	Aflibercept	Neovascular (wet) age-related macular degeneration	IZ	Nov-24
VYLOY®	Zolbetuximab	Gastric or gastroesophageal junction cancer	IV	Nov-24
ATTRUBY™	Acoramidis	Cardiomyopathy of wild-type or variant transthyretin-mediated amyloidosis	OR	Dec-24
AUCATZYL®	Obecabtagene	Acute lymphocytic leukemia	IV	Dec-24
AXTLE®	Pemetrexed	Non-squamous non-small cell lung cancer	IV	Dec-24
BORUZU™	Bortezomib	Multiple myeloma	IJ	Dec-24
DANZITEN™	Nilotinib	Chronic myeloid leukemia	OR	Dec-24
NYPOZI™	Filgrastim	Acute myeloid leukemia	IJ	Dec-24
OPIPZA™	Aripiprazole	Schizophrenia	OR	Dec-24
REVUFORJ®	Revumenib	Acute leukemia	OR	Dec-24
ZIIHERA®	Zanidatamab	Biliary tract cancer	IV	Dec-24

NOW APPROVED | NEW GENERIC DRUGS TO MARKET

Brand name	Generic name	Indication	Launch month
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 cell 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
SANDOSTATIN LAR®	Octreotide	Acromegalic, carcinoid rumors, vasoactive intestinal peptide tumors	Oct-24
TAZORAC®	Tazarotene	Plaque psoriasis	Oct-24
STENDRA®	Avanafil	Avanafil	Nov-24
BYETTA®	Exenatide	Type 2 diabetes	Nov-24
BETIMOL®	Timolol	Elevated intraocular pressure	Dec-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

CLINICAL PIPELINE

Acute pain

Suzetrigine [Vertex]

This medication is an oral non-opioid pain reliever being evaluated for treatment of moderate to severe acute pain. It works in the peripheral nervous system, avoiding central nervous system effects and the potential for addiction that is associated with opioids. If approved, suzetrigine would be the first novel treatment option for this diagnosis in many years and could provide a safer option than opioids for acute pain. Studies did not show superiority when compared to hydrocodone/apap therapies but this product may gain market share as a pain therapy option due to the non-addictive benefit it brings. A regulatory decision option is expected by January 30, 2025.

Cystic fibrosis

Alyftrek™ [Vertex]

Alyftrek is a triple combination therapy that was granted Fast Track and Priority Review by the FDA. Study shows potential for improved efficacy over Trikafta®. Vertex looks for the majority of eligible patients to transition from Trikafta to new therapy within the first couple of years after launch. Due to once daily dosing and increased efficacy, the pricing is expected to be 5% to 10% higher than Trikafta ($346,000 annual WAC). This therapy was approved on December 20, 2024.

Duchenne muscular dystrophy

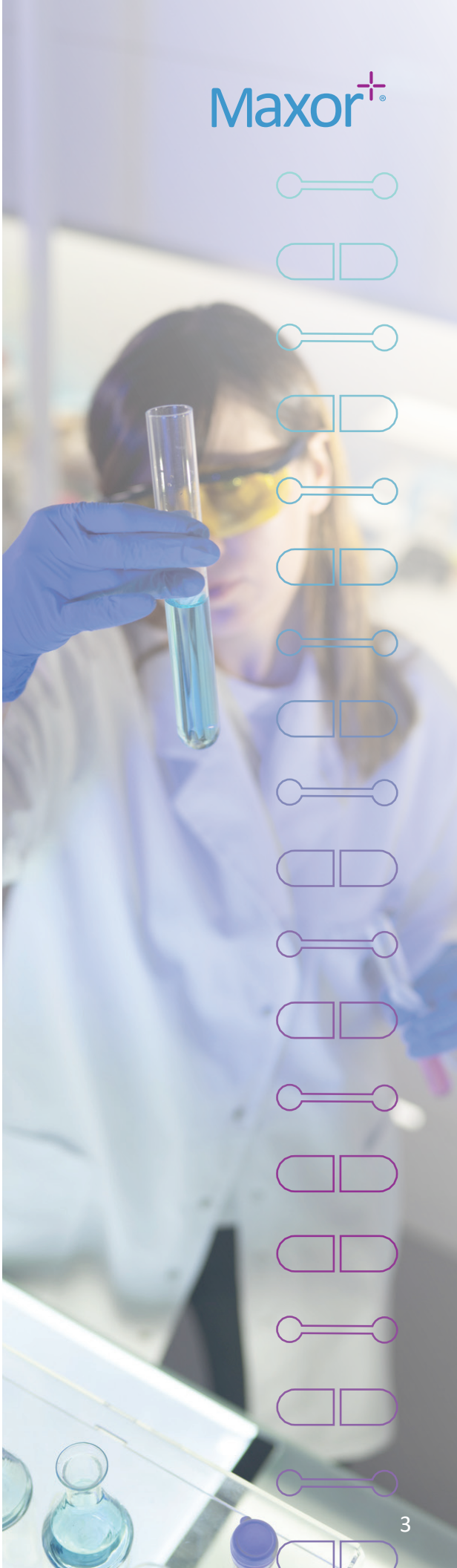
Translarna [PTC Therapeutics]

Translarna is a protein restoration therapy designed to enable the formation of a functioning protein in patients with genetic disorders caused by a nonsense mutation. Around 13% of DMD are caused by this type of mutation. If approved, this drug would be the first in its class indicated for treatment of DMD. The annual treatment cost is estimated to be between $750,000-$1,000,000. A regulatory decision is expected by March 31, 2025.

Parkinson’s disease

Apomorphine [Supernus Pharmaceuticals]

This is a subcutaneous injection pump that provides continuous dopamine agonist therapy for OFF episodes in Parkinson’s disease. The infusion pump is designed to be a more convenient and less invasive way to deliver the company’s apomorphine (Apokyn®), which is administered via subcutaneous injection. The annual price is estimated to be $50,000-$100,000, including both the drug and the device compared to around $76,000 for the generic subcutaneous option. A regulatory decision is expected by February 1, 2025.



SPOTLIGHT
ONCOLOGY PIPELINE

Oncology therapies continue to drive drug pipeline

Oncology therapies continue to drive a major part of the 2025 pipeline, evidenced by the 10 products that are on track for approval in the first half of the year. Many of the anticipated approvals are for novel therapies that may set new standards of care for their respective indication and have the potential to significantly impact the cancer treatment landscape throughout the year. The early 2025 oncology pipeline highlights the continued innovation within this treatment category and includes therapies that target specific genetic mutations and areas where exiting treatment options are limited and span both pharmacy and medical benefit coverage.

2023 oncology spend* in U.S. reached

$99 billion

More than

30

pending approval dates in 2025*

Anticipated approval of novel oncology agents

Novel drugs are new drugs that have never been approved or marketed in the United States. These innovative therapies often bring new treatment options for patients and represent advancement in healthcare overall.

Novel drugs in pipeline			
Drug name	**Indication**	**Pipeline insights**	**Pending approval date**
Vimseltinib [Deciphera]	Solid tumors-Non-malignant	Improved safety profile compared to currently approved option	2/17/2025
Mirdametinib [Pfizer]	NF1-PNs	Preferred dosing schedule offers promising benefit	2/28/2025
Teliso-V [AbbVie]	c-Met overexpressing NSCLC	First therapy targeting c-Met overexpression	2Q 2025
Sunvozertinib [Dizal Pharmaceuticals]	Non-small cell lung cancer	Oral alternative to Rybrevant®, only other therapy targeting EGFR exon 20 insertions	3Q 2025

*IPD Analytics, December 2024
Abbreviations:NF1-PNs, neurofibromatosis type 1-associated plexiform neurofibromas; c-Met, c-mesenchymal-epithelial transition factor; NSCLC, non-small cell lung cancer; EGFR, epidermal growth factor receptor