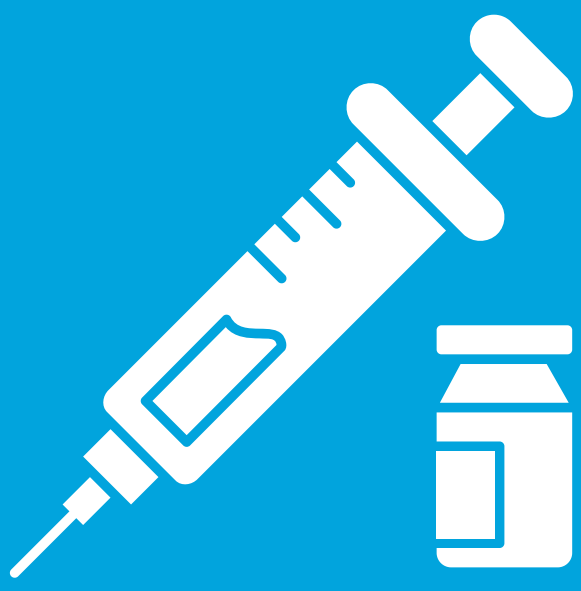


# 1H 2025:
# FDA APPROVALS

*Select Highlights*

Anchor Point Insights

April 29, 2025

# IMAAVY

## *(Nipocalimab)*

For the treatment of **generalized myasthenia gravis (gMG)** in adult & pediatric patients ≥12 years of age who are **anti-acetylcholine receptor or anti-muscle-specific tyrosine kinase antibody positive**

**30mg/kg IV initial dose followed by 15mg/kg IV Q2W**

- IMAAVY is a **neonatal Fc receptor (FcRn) blocking mAb that recudes overall IgG levels,** including the autoantibodies respsonsible for gMG symptoms
- Data from the ongoing **P3 Vivacity-MG3 study** showed Imaavy + SOC **provided supeior disease control throughout 24 weeks vs placebo** as measured by improvement in daily living skills
- **gMG is a chronic disease with significant unmet need** for novel therapies with improved safety & efficacy to help patients manage symptoms while reducing side effects

**API Take:** IMAAVY becomes the **3rd FcRn mAb approved in gMG**, & will face **significant competition** from other in-class assets (led by Argenx's VYVGART HYTRULO [subcutaneous, at-home delivery]). J&J likely views gMG as a foothold in the broader autoimmune space, where it is currently **testing nipocalimab in multiple Ph3 trials.**

Anchor Point Insights

teal health

May 9, 2025

# TEAL WAND

***(vaginal sample at-home self-collection device)***

The first FDA approved device for **at-home cervical cancer screening,** with virtual medical provider support

**5/8” diameter, soft sponge for collection, atraumatic insertion profile**

- The Teal screening kit is **mailed to the user for self-collection**, who then **mails a sample to a lab for high-risk HPV testing**. Results are delivered via a secure portal, with virtual follow-up care available
- Approval based on nationwide trial results: **96% sensitivity** (matching clinician collection with a speculum), 95% positive percent agreement vs clinician-collected results, **94% patient preference**
- The study also found that across racial and ethnic groups, the Teal Wand could **increase screening engagement by up to 20% from current levels**

**API Take:** By enabling self-collection, telehealth support, & a **less invasive alternative to traditional Pap smears**, this innovation **addresses screening barriers while maintaining accuracy.** Its full impact hinges on **ensuring affordability, insurance coverage, and accessible in-person follow-up care.**

Anchor Point Insights

May 16, 2025

# NOVAXOVID

***(protein-based COVID-19 vaccine)***

For the treatment of adults 65 years & older, or those between the ages of 12 - 64 who have at least one underlying condition that puts them at **high risk for severe outcomes from COVID-19**

- Targets the **JN.1 variant** & creates copies of the SARS-CoV-2 surface spike protein
- Full approval based on **Phase 3 clinical data** showing **efficacy and safety in North American populations** (*previously available in the US under Emergency Use Authorization since July 2022*)

**Intramuscular; 2 doses if no prior vaccination, 1 if previously vaccinated**

- The FDA also requested a new postmarketing commitment to conduct a **Phase 4 placebo-controlled trial** in individuals aged 50-64 without high-risk conditions for severe COVID-19

**API Take:** With new **placebo trial requirements** & **high-risk patient population restrictions,** this approval reflects an ongoing, i**ncreasingly cautious approach by the FDA.** Questions remain as to whether evolving U.S vaccine policy adequately weighs risks & benefits.

Anchor Point Insights

azurity pharmaceuticals

June 10, 2025

# XIFRYM

## *(meloxicam injection)*

For the management of **moderate-to-severe pain** in adult patients

**30 mg/mL IV bolus in 15 seconds, once daily**

- Meloxicam is a **non-steroidal anti-inflammatory (NSAID)** that can be **administered alone or in combination with other analgesics** that are not NSAIDs, particularly for rapid relief
- Meloxicam has **been available** in the U.S as an oral tablet since its initial approval & development by Boehringer Ingelheim in **2000** (MOBIC). In 2020, Baudax Bio received **FDA approval for an I.V. formulation** (ANJESO).
- The approval is part of an **ongoing shift away from opioid-based analgesics** in attempts to address the ongoing opioid pandemic & increases in opioid-related deaths

**API Take:** While **neither a novel drug nor formulation**, this generic approval signals **encouraging developments in expanding access to non-addictive, non-opioid analgesics**. While the approval will not shift the market, expanded access is a positive step in fighting the opioid crisis.

Anchor Point Insights

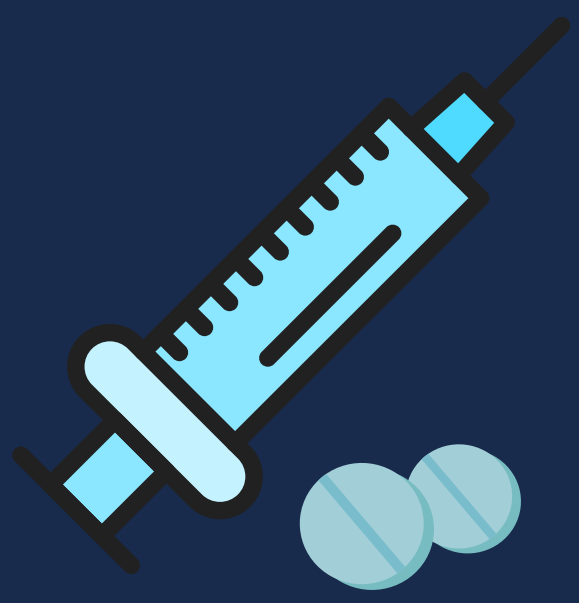
GILEAD

June 18, 2025

# YEZTUGO

## *(lenacapavir injectable HIV-1 capsid inhibitor)*

For **pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV** in adults and adolescents



**twice yearly injections + two oral tablets**

- The medication **reduces the risk of HIV infection** by blocking viral DNA from entering host cells & interrupting the formation of viral capsids
- The approval is based on data from two Phase 3 trials PURPOSE 1 and PURPOSE 2 showed that **99% of patients remained HIV free (2 cases in 4,313 patients)** compared to once-daily oral medications
- The first PrEP medication (a once daily pill, TRUVADA also developed by Gilead) **did not have significant enough uptake to reduce transmission rates**. A twice yearly injection of YEZTUGO aims to increase uptake among high risk individuals.

**API Take:** While PrEP medications are crucial in eliminating HIV/AIDS worldwide, **YEZTUGO faces intense competition with oral generics & price scrutiny** from insurers in the U.S & medical aid organizations in developing countries. It remains to be seen whether the twice yearly injection will succeed in improving patient uptake and expanding access.

Anchor Point Insights