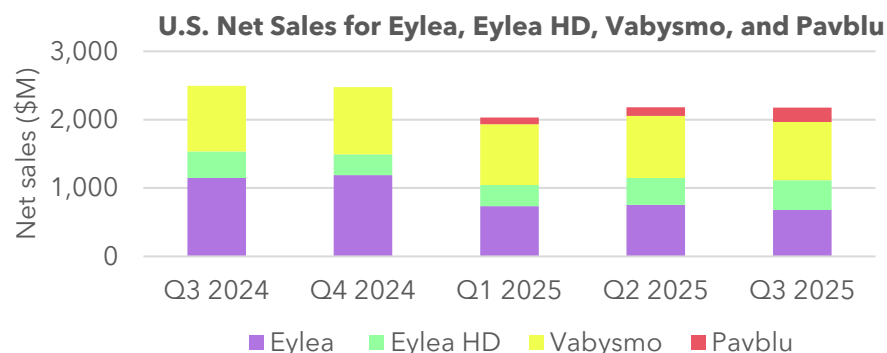


The FDA approves Eylea HD Q4W dosing: a milestone amid market challenges

Market Event Summary

Eylea HD U.S. regulatory timeline: consequences of delayed approvals and CRLs

- June 2023** ● The FDA issued a CRL for Eylea HD’s BLA, citing unresolved observations after an inspection at Catalent, a third-party filling manufacturer.
- August 2023** ● The FDA approved Eylea HD Q8W to Q16W for the treatment of wAMD, DME, and DR.
- December 2024** ● Novo Holdings acquired Catalent, selling three fill-finish sites to Novo Nordisk in anticipation of increased demand for its GLP-1 therapies Wegovy and Ozempic.
- April 2025** ● The FDA issued a CRL for the sBLA seeking to extend dosing intervals up to Q24W.
- August 2025** ● The FDA extended the target action dates for two regulatory submissions—Q4W dosing and PFS form—into Q4 2025, pending completion of the Novo Nordisk / Catalent facilities inspection.
- October 2025** ● The FDA classified the former Catalent facility as “Official Action Indicated” (OAI), a serious compliance designation. The FDA issued a CRL for the Eylea HD PFS sBLA.
- November 2025** ● The FDA approved Eylea HD administered Q4W for wet AMD, DME, DR, and RVO. Regeneron plans to:
 - Resubmit its sBLA by January 2026 with an alternative PFS filling manufacturer
 - Expand its manufacturing footprint with a new facility in NY to mitigate third-party risks



“The 8-week dosing limitation with Eylea HD is a real challenge. Some patients show worsening disease activity before that point. I’ve had to switch many back to Eylea 2 mg or occasionally to Vabysmo.”—**Retinal specialist, United States, September 2025**

Clarivate’s takeaways



Regulatory delays and CRLs

Since Eylea HD launched in 2023, Regeneron has pursued label expansions for Q4W and extended dosing intervals, new indications, and PFS. However, progress has been slowed by ongoing compliance challenges at Catalent.



Competitive advantage of Vabysmo

Vabysmo continues to hold a strong advantage over Eylea HD with its first-to-market advantage (launched in January 2022), differentiated MOA, greater dosing flexibility since launch, and PFS since July 2024. Eylea HD was designed to extend dosing intervals, but before Q4W approval, clinicians faced a critical gap: patients needing shorter intervals than Q8W could not use Eylea HD, which often led to switches to Vabysmo. While Q4W dosing is approved (>1 year after Eylea HD’s initial launch), the PFS form remains unapproved, still constraining adoption.



Impact on sales

Eylea HD sales have increased modestly but have been insufficient to offset the decline in Eylea sales, driven by the launch and uptake of Amgen’s Pavblu, the first and only biosimilar of aflibercept available in the United States since October 2024.

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Clarivate coverage of wet AMD products

- [Disease Landscape & Forecast | Dry and Wet Age-Related Macular Degeneration \(G7\)](#) (November 2025)
- [Current Treatment: Physician Insights | Dry and Wet Age-Related Macular Degeneration \(US\)](#)
- [Treatment Algorithms: Claims Data Analysis | Wet Age-Related Macular Degeneration \(US\)](#)
- [Access & Reimbursement | Age-Related Macular Degeneration \(US\)](#)
- [China In-Depth | Dry and Wet Age-Related Macular Degeneration \(China\)](#)

Clarivate coverage of DME products

- [Disease Landscape & Forecast | Diabetic Macular Edema | Diabetic Retinopathy \(G7\)](#)
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