2026–2027

Drug Pipeline Report for Hospitals & Health Systems

Evaluating the top look-back and look-forward trends, impacts, and considerations

Amber Skrtic, PharmD, CSP, AAHIVP
CPS Solutions, LLC

Background

The 2026 drug pipeline completely surpassed expectations. Back in January 2026, it seemed like there would be a relatively low number of FDA approvals for novel drugs. However, a new FDA pilot initiative—the Commissioner's National Priority Voucher (CNPV) program—and other agency changes generated an uptick in new market entries.

Accelerated Timeline

The CNPV program aims to accelerate the review and approval process for products that align with a critical national health priority. By receiving a voucher, drugs can potentially complete the entire regulatory process in just 1-2 months, the shortest of any FDA priority review program by far.[1]

> SPOTLIGHT
>
> The first new molecular entity (NME) approved through the CNPV program—Foundayo (orforglipron)—had its decision issued on April 1, 2026. Approval came within just 50 days of filing, the fastest approval of an NME since 2002.[2]

This ultra-fast regulatory pathway can improve patient access to therapies that address unmet medical needs, but the compressed timeline also brings additional operational pressure.

Many therapies may receive FDA approval before manufacturers are ready to go to market. If they already have an established launch strategy, then the strain shifts to health systems, requiring them to prepare earlier and coordinate care with less lead time.

SUMMARY

Key Pipeline Trends

1. Orphan Drug Designation
2. Patient-Centric Administration & Dosing
3. Precision Medicine
4. Generic & Biosimilar Development

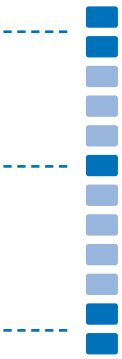
See the **full article** and the accompanying **Novel Drugs of Note breakdown**, which identifies treatments related to those trends

Average FDA Review Timelines[1]

1-2 months
CNPV program

6+ months
other priority review programs

10-12 months
standard



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Record-Breaking Entry

Given the FDA set many target action dates for November and December, the 2026 drug pipeline will remain fluid until it hits that year-end cluster.

If a substantial portion of remaining applications receive decisions, the full-year potential of novel drug approvals is roughly 53-59 in total—representing one of the highest annual counts of the past ten years.



Consequential Specialty Drugs

Many late-year reviews involve high-impact specialty treatments in oncology, endocrinology, and immunology.

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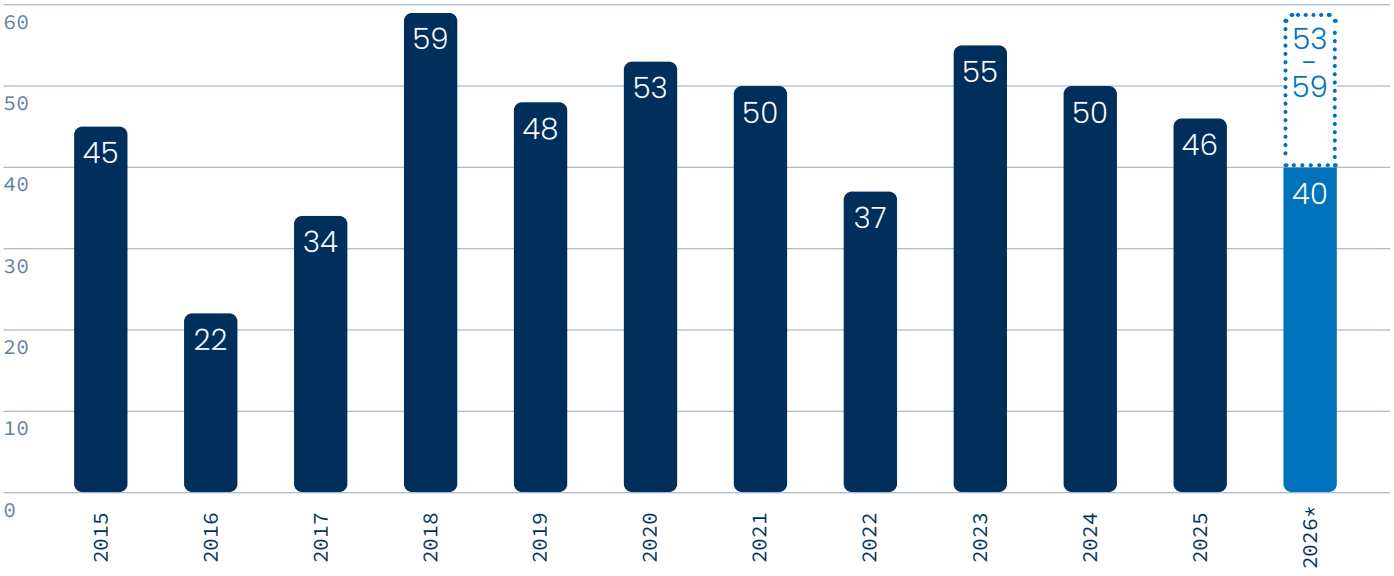
Annual FDA Approvals for New Chemical Entities & Biologics[3]



** As of publication date*

SUMMARY

Health System Considerations

The question is no longer whether new treatment options will come to market soon or not. For health systems, the new call-to-action for 2027 and beyond is a matter of patient identification, effective operationalization, multidisciplinary care coordination, change management for benefit and site-of-care shifts, and outcomes documentation.

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KEY TREND

1. Orphan Drug Designation

Bringing first-ever treatment options to the rare disease space

Consistent with last year, rare disease remains the innovation engine of this year's drug pipeline. The operational intensity is disproportionate to patient volume, but smaller populations can still produce significant financial exposure because of the high per-patient cost.

SPOTLIGHT

Orphan-designated Lisraya (brepocitinib) received FDA approval in late August to treat dermatomyositis, a rare autoimmune disease. Previously, available treatment options only helped manage symptoms, so this disease-specific drug addresses a significant unmet need.[6]



Importantly, several approvals for rare-disease treatments—especially mechanism-driven ones in immunology—show promising potential for future lifecycle growth. Drugs may expand into additional indications, greatly widening the eligible patient population.

Annual FDA Approvals for Novel Orphan-Designated Drugs

1 in 2 2025[4]

1 in 3* 2026[5]

** As of publication date*

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6 FDA approves first oral drug indicated to treat dermatomyositis in adults. News release. US Food & Drug Administration. August 27, 2026. Accessed September 10, 2026. https://www.fda.gov/news-events/press-announcements/fda-approves-first-oral-drug-indicated-treat-dermatomyositis-adults

SUMMARY

Health System Considerations

- Access to limited distribution networks, which often have complex reporting requirements, needed to support dispensing via an in-house specialty pharmacy
- Treatment-specific diagnostic testing for genetic or biomarker confirmation
- Increased need for patient financial navigation support and specialty pharmacy coordination, which can be greater than population size suggests
- Additional patient education for complex administration methods and referral to specialized centers
- Initial and long-term clinical monitoring, which is especially important for therapies with complex safety and monitoring requirements
- Proactive development of clinical understanding and expertise of the patient journey for rare diseases with new orphan therapies not previously managed by care teams

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KEY TREND

2. Patient-Centric Administration & Dosing

Catering to patient preference with oral formulations and longer injection intervals

Administrative burden increasingly influences uptake, persistence, site of care, and patient experience. As a result, manufacturers have prioritized the development of more convenient, patient-centric dosing (i.e., oral pills, self-administered injections, and weekly or monthly intervals) even when their efficacy or safety differences are modest.

The largest shift has been from injections to oral formulations, which not only impacts current patients but also expands the treatment population to include those who prefer not to use needles.

SPOTLIGHT

After receiving FDA approval in April 2026, the Saphnelo Pen (anifrolumab) became a new self-injected systemic treatment option for lupus, an autoimmune disease impacting 1.5 million people in the US.[7,8] Now, patients can receive the same clinical benefit as the intravenous drug but from their own home instead.



Catering to patient preference is a competitive advantage that commercially and clinically differentiates therapy options while also helping more patients achieve their treatment goals.

Scan the QR code below to read the full article.

91%

patients who prefer oral versus injected/infused route of drug administration[9]

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See the **full article** and the accompanying **Novel Drugs of Note breakdown**

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