Evidence-Based Drug Therapy Update 2026

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Objectives

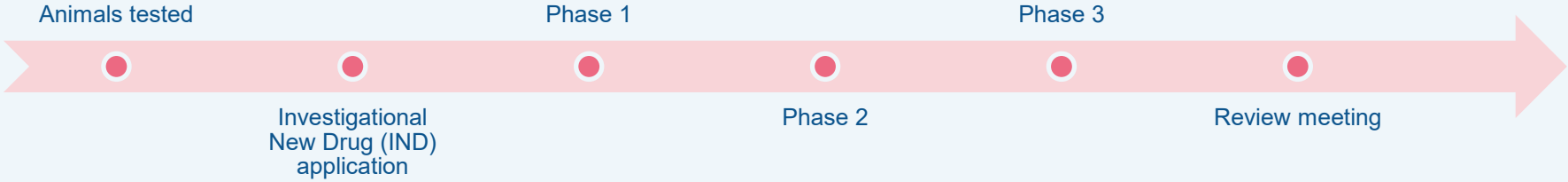
01 Identify indications and key adverse effects of new medications

02 Explain the mechanism of action of new pharmacotherapy agents

03 Evaluate the role of newly approved drugs within current treatment guidleines and evidence-based practice

FDA Approval Process

FDA Approval: What it means



FDA. Drug review process. 2026.

FDA Approval: What it means

FDA. Drug review process. 2026.

Drug Development

Fast Track

- Fulfills an unmet medical need for serious conditions
- Based on promising human or animal data
- Gets new drugs to patients earlier
  - Ex: Keytruda

Breakthrough Therapy

- Treats a serious condition that preliminary clinical evidence shows that drug prove promise over current therapy
- Also available for “fast track”
  - Ex: Farxiga

Priority Review

- FDA is to act in 6 months, compared to a standard 10-month review
- Directs attention and resources to evaluate therapy that can improve serious conditions
  - Ex: Wegovy HD

FDA. Drug development & approval. 2026.

Vaccines

PreHevbrio

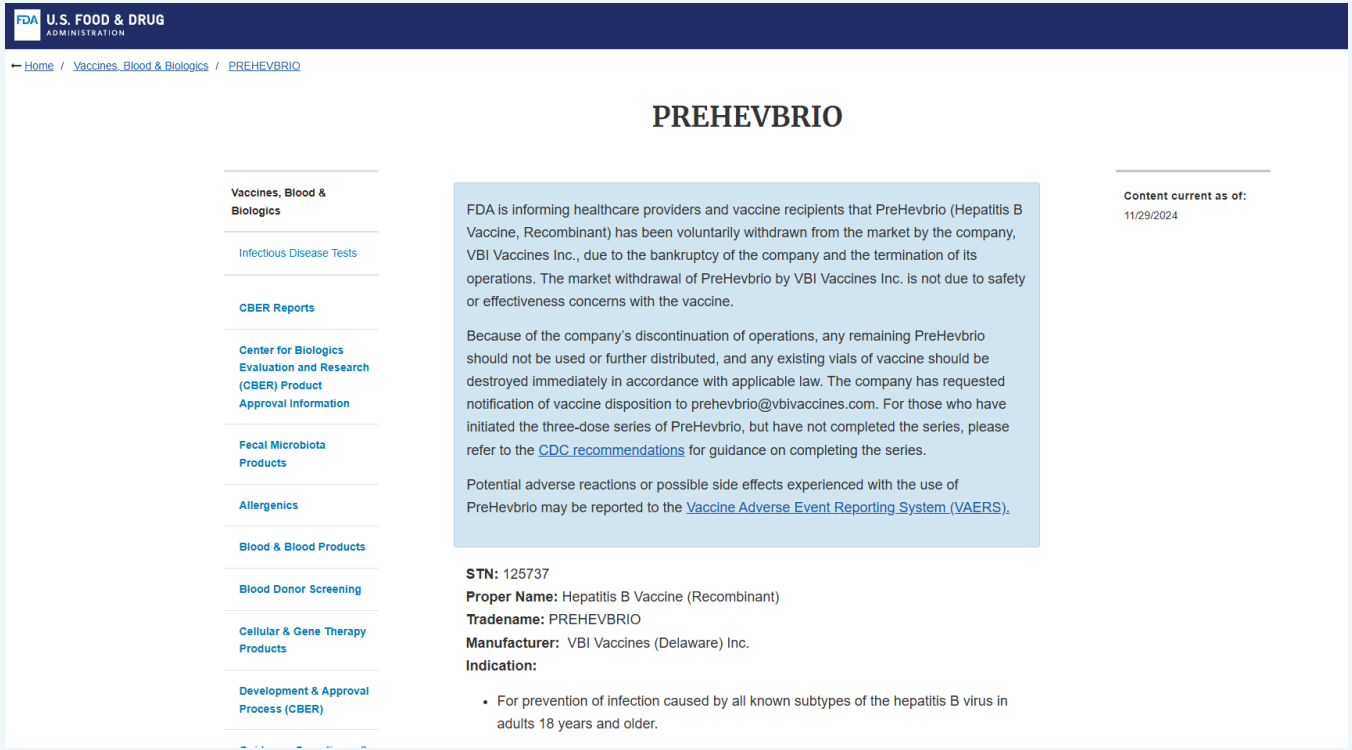
Removed product on AAFP vaccine schedule

HepB vaccines of choice

- Recombivax HB
- Energix-B
- Heplisav-B

FDA. PreHevbrio. 2026.

PreHevbrio



U.S. FOOD & DRUG ADMINISTRATION

← Home / Vaccines, Blood & Biologics / PREHEVBRIO

PREHEVBRIO

Vaccines, Blood & Biologics

- Infectious Disease Tests
- CBER Reports
- Center for Biologics Evaluation and Research (CBER) Product Approval Information
- Fecal Microbiota Products
- Allergenics
- Blood & Blood Products
- Blood Donor Screening
- Cellular & Gene Therapy Products
- Development & Approval Process (CBER)

FDA is informing healthcare providers and vaccine recipients that PreHevbrio (Hepatitis B Vaccine, Recombinant) has been voluntarily withdrawn from the market by the company, VBI Vaccines Inc., due to the bankruptcy of the company and the termination of its operations. The market withdrawal of PreHevbrio by VBI Vaccines Inc. is not due to safety or effectiveness concerns with the vaccine.

Because of the company's discontinuation of operations, any remaining PreHevbrio should not be used or further distributed, and any existing vials of vaccine should be destroyed immediately in accordance with applicable law. The company has requested notification of vaccine disposition to prehevbrio@vbivaccines.com. For those who have initiated the three-dose series of PreHevbrio, but have not completed the series, please refer to the CDC recommendations for guidance on completing the series.

Potential adverse reactions or possible side effects experienced with the use of PreHevbrio may be reported to the Vaccine Adverse Event Reporting System (VAERS).

Content current as of:
11/29/2024

STN: 125737
Proper Name: Hepatitis B Vaccine (Recombinant)
Tradename: PREHEVBRIO
Manufacturer: VBI Vaccines (Delaware) Inc.
Indication:

- For prevention of infection caused by all known subtypes of the hepatitis B virus in adults 18 years and older.

FDA. PreHevbrio. 2026.

MenACWY

Pentavalent meningococcal vaccines

- Penbraya
- Penmenvy

Indication

- 10 years and older when MenAcWY and MenB recommended at the same visit

Campos-Outcalt D. Meningococcal vaccines. *AFP*. 2025.

Complexity Behind 5-in-1

TABLE 2

Pentavalent Meningococcal Vaccines Approved in the United States

Manufacturer	Brand name	ACWY component	B component	Schedule	Age
Pfizer	Penbraya	Nimenrix* (not licensed in the United States)	Trumenba	2 doses, 6 months apart	10-25 years
GlaxoSmithKline	Penmenvy	Menveo	Bexsero	2 doses, 6 months apart	10-25 years

*—Pfizer does not produce a MenACWY product. They used a quadrivalent product licensed in other countries to combine with their MenB product.

Campos-Outcalt D. *Am Fam Physician.* 2025;112(2). Meningococcal vaccines.

Flu- Protection Without Injection

Flumist

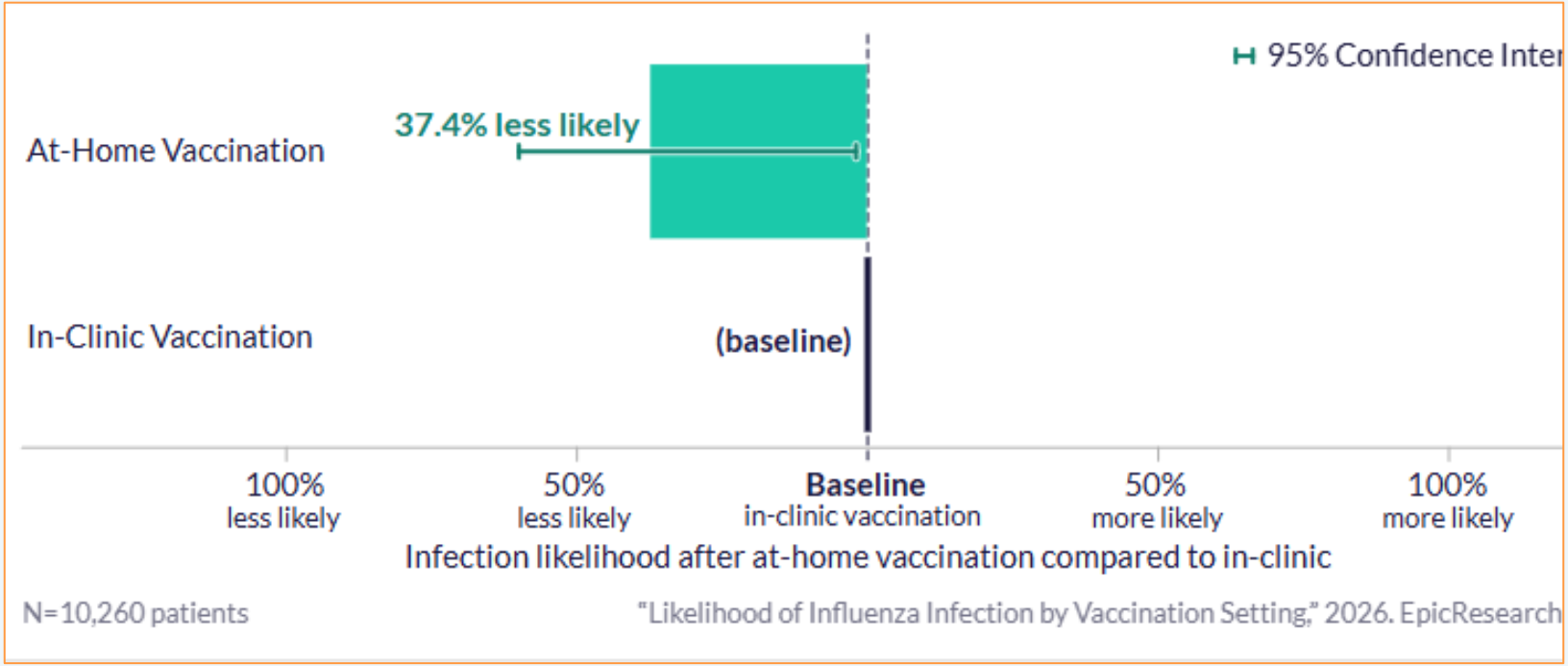
- At home administration now available as of August 2025

Available for ages 2-49

- Live vaccine

NYT. FluMist image. 2014.
FluMist. MedImmune. 2026.

Flumist Effectiveness



EPIC Research. At-home nasal flu vaccine study. 2026.

Respiratory Syncytial Virus (RSV)

Recommended for	All adults 75+	
	Pregnancy	1 dose at 36 weeks and 6 days gestation
	Adults ages 50-74 at increased risk	New

- Chronic cardiovascular disease
- Chronic lung disease
- End stage renal disease
- Diabetes complicated by CKD or other end organ damage
- Neurologic or neuromuscular conditions causing impaired airway clearance
- Chronic liver disease
- Chronic hematologic conditions
- Severe obesity (> 40 kg/m2)
- Residing in a nursing home

Adult-AAFP Updated Charts

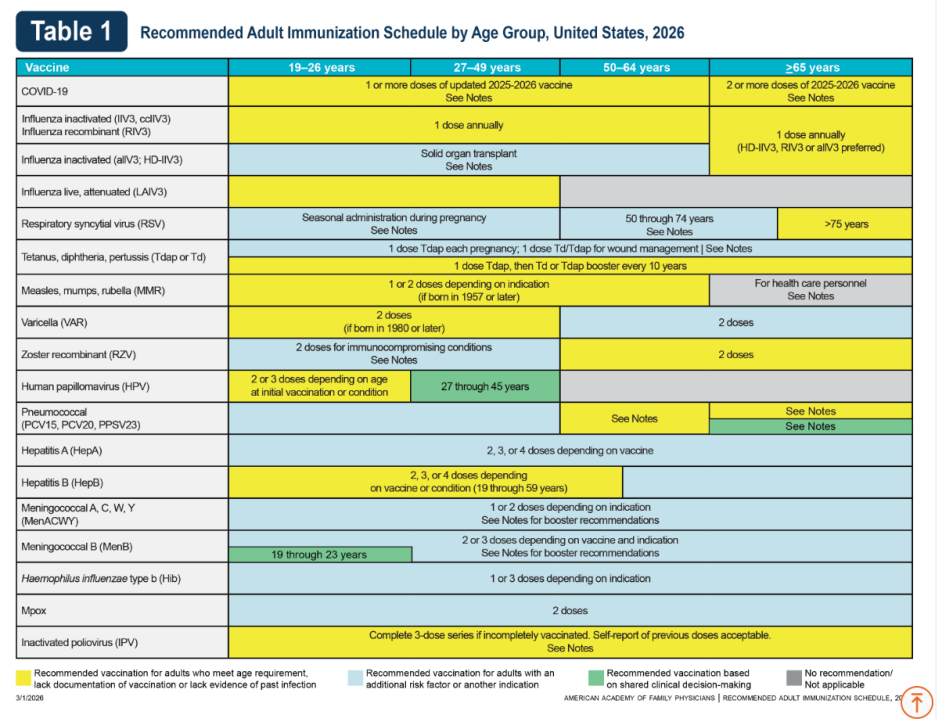


Table 1 Recommended Adult Immunization Schedule by Age Group, United States, 2026

Vaccine	19–26 years	27–49 years	50–64 years	≥65 years
COVID-19	1 or more doses of updated 2025-2026 vaccine See Notes			2 or more doses of 2025-2026 vaccine See Notes
Influenza inactivated (IIV3, cIIV3) Influenza recombinant (RIV3)	1 dose annually			1 dose annually (HD-IIV3, RIV3 or aIIV3 preferred)
Influenza inactivated (aIIV3; HD-IIV3)	Solid organ transplant See Notes			
Influenza live, attenuated (LAIV3)				
Respiratory syncytial virus (RSV)	Seasonal administration during pregnancy See Notes		50 through 74 years See Notes	>75 years
Tetanus, diphtheria, pertussis (Tdap or Td)	1 dose Tdap each pregnancy; 1 dose Td/Tdap for wound management | See Notes			
	1 dose Tdap, then Td or Tdap booster every 10 years			
Measles, mumps, rubella (MMR)	1 or 2 doses depending on indication (if born in 1957 or later)			For health care personnel See Notes
Varicella (VAR)	2 doses (if born in 1980 or later)		2 doses	
Zoster recombinant (RZV)	2 doses for immunocompromising conditions See Notes		2 doses	
Human papillomavirus (HPV)	2 or 3 doses depending on age at initial vaccination or condition	27 through 45 years		
Pneumococcal (PCV15, PCV20, PPSV23)			See Notes	See Notes See Notes
Hepatitis A (HepA)	2, 3, or 4 doses depending on vaccine			
Hepatitis B (HepB)	2, 3, or 4 doses depending on vaccine or condition (19 through 59 years)			
Meningococcal A, C, W, Y (MenACWY)	1 or 2 doses depending on indication See Notes for booster recommendations			
Meningococcal B (MenB)	19 through 23 years	2 or 3 doses depending on vaccine and indication See Notes for booster recommendations		
Haemophilus influenzae type b (Hib)	1 or 3 doses depending on indication			
Mpox	2 doses			
Inactivated poliovirus (IPV)	Complete 3-dose series if incompletely vaccinated. Self-report of previous doses acceptable. See Notes			

Recommended vaccination for adults who meet age requirement, lack documentation of vaccination or lack evidence of past infection

Recommended vaccination for adults with an additional risk factor or another indication

Recommended vaccination based on shared clinical decision-making

No recommendation/ Not applicable

3/1/2026

AMERICAN ACADEMY OF FAMILY PHYSICIANS | RECOMMENDED ADULT IMMUNIZATION SCHEDULE, 20

AAFP Adult Immunization Schedule, 2026

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Adult–AAFP Updated Charts

Pneumococcal

Routine vaccination

Age 50 years or older who have:

- Not previously received a PCV13, PCV15, PCV20, or PCV21 or whose previous vaccination history is unknown: 1 dose PCV15 or 1 dose PCV20 or 1 dose PCV21.
  - If PCV15 is used: administer 1 dose PPSV23 1 year after the PCV15 dose (may use minimum interval of 8 weeks for adults with an immunocompromising condition,* cochlear implant, or cerebrospinal fluid leak).
    - If PPSV23 is not available: 1 dose PCV20 or 1 dose PCV21 may be given 1 year later (only if 1 dose of PPSV23 is indicated).
    - If PCV20 or PCV21 is used: a dose of PPSV23 isn't indicated; pneumococcal vaccinations are complete.

Shared Clinical Decision-Making

Based on shared clinical decision-making, adults age 65 years or older who have previously received ***both*** PCV13 (received at any age) and PPSV23 (received at age 65 years or older) may receive 1 dose PCV20 or 1 dose PCV21 (or no additional pneumococcal vaccine).

Special situations

- **Age 19–49 years with certain underlying medical conditions or other risk factors** who have:**
  - **Not previously received a PCV13, PCV15, PCV20, or PCV21 or whose previous vaccination history is unknown:** 1 dose PCV15 or 1 dose PCV20 or 1 dose PCV21. If PCV15 is used, administer 1 dose PPSV23 at least 1 year after the PCV15 dose (may use minimum interval of 8 weeks for adults with an immunocompromising condition,* cochlear implant, or cerebrospinal fluid leak).
  - **Previously received only PCV7:** follow the recommendation above.
  - **Previously received only PCV13:** 1 dose PCV20 or 1 dose PCV21 at least 1 year after the last PCV13 dose
  - **Previously received only PPSV23:** 1 dose PCV15 or 1 dose PCV20 or 1 dose PCV21, at least 1 year after the last PPSV23 dose. If PCV15 is used, no additional PPSV23 doses are recommended.
  - Previously received PCV13 and 1 dose of PPSV23: 1 dose PCV20 or 1 dose PCV21 at least 5 years after the last pneumococcal vaccine dose.
- **Adults aged 19 years and older who have received PCV20 or PCV21:** no additional pneumococcal vaccine dose recommended.
- **Pregnancy:** no recommendation for PCV or PPSV23 due to limited data.
  - **PPSV23 not available:** adults aged 19 years or older who received PCV15 but have not yet completed PPSV23 series, can complete the series with either 1 dose of PCV20 or 1 dose of PCV21 if they no longer have access to PPSV23.

AAFP. Adult immunization schedule. 2026.

Pediatric Vaccines

	CDC updated schedule (2025/2026)	AAFP/AAP supported schedule (2025/2026)
Overall strategy	Shared clinical decision making (SCDM)	Maintains routine recommendations
Total routine vaccines	Reduced from 17 to 11	17 vaccinations
Covid	SCDM	6-23 months
Flu	SCDM	6 months and older
Rotavirus Hep A/B Meningococcal	SCDM	Routine recommendations
HPV	Reduced to a single dose	Routine recommendations
RSV	High risk only or SCDM	32 weeks and 6 days gestation OR monoclonal antibody

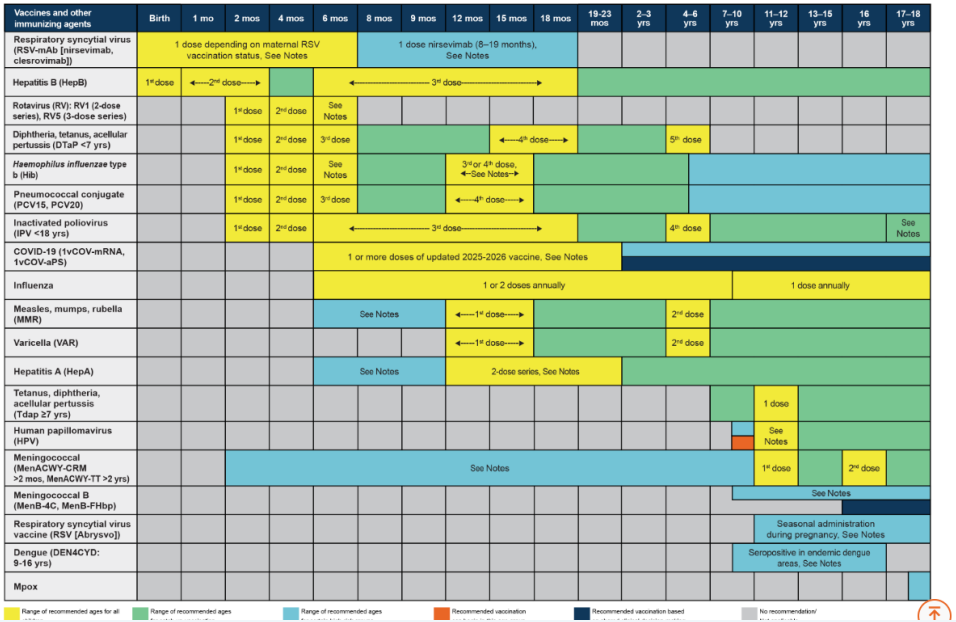
AAFP. Childhood immunization schedule (birth–18). 2026.

Pediatric Vaccines

Schedule Based on Age Group

Table 1 Recommended Child and Adolescent Immunization Schedule for Ages 18 Years or Younger, United States, 2026

These recommendations must be read with the Notes that follow. For those who fall behind or start late, provide catch-up vaccination at the earliest opportunity as indicated by the green bars. To determine minimum intervals between doses, see the catch-up schedule (Table 2).



AAFP. Childhood immunization schedule (birth–18). 2026.

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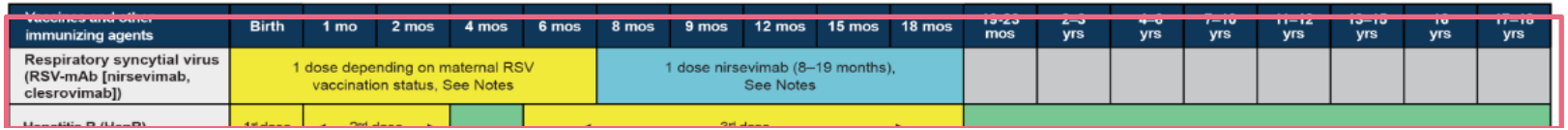
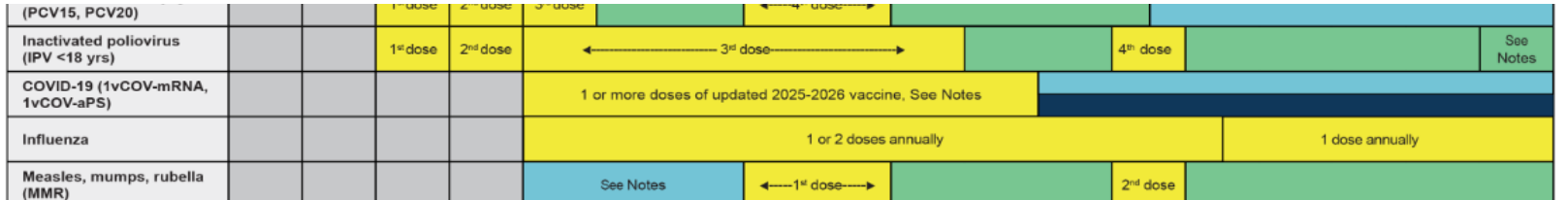


Respiratory syncytial virus

Minimum age: birth (monoclonal antibody) ***Note: "RSV monoclonol antibody" refers to either Nirsevimab or Clesrovimab.**



Enflonsia (Clesrovimab)

Enflonisia (Clesrovimab)

Mechanism of action

- Long-acting monoclonal antibody
- Targets the extracellular domain of the RSV fusion protein to prevent viral entry

Dose

- 105 mg IM regardless of infant weight

Infectious Disease

Bluejepa (gepotidacin)

Mechanism of action

- Triazaacenaphthylene antibiotic

Use

- Treating uncomplicated urinary tract infections and urogenital gonorrhea in females

Dose

- 1500 mg (2 tabs) twice daily x 5 days

Pearls

- Qtc prolongation
- Avoid in severe renal and hepatic impairment

GSK. Blujepa. 2026.

EAGLE-2 and EAGLE-3

	EAGLE-2/3
Study Design	Phase 3, randomized, double-blind, non-inferiority trial
Participants	Females ages 12 years and older with uUTI symptoms
Treatment	Gepotidacin 1500mg BID vs. Nitrofurantoin 100mg BID for 5 days
Primary Endpoint	Therapeutic response at day 10-13

GSK. Blujepa trial design. 2026.

EAGLE-2 and EAGLE-3

Outcome	Gepotidacin	Nitrofurantoin	Difference (95% CI)	Result
Therapeutic success (primary)	50.6%	47.0%	+4.3% (-3.6% to 12.1%)	Met non-inferiority
Clinical success	65.6%	65.2%	+1.2% (-6.3% to 8.7%)	Similar
Microbiological success	72.5%	67.6%	+5.2% (-2.1% to 12.5%)	Similar

GSK. Blujepa trial design. 2026.

EAGLE-2 and EAGLE-3

GoodRx. Nitrofurantoin. 2026.
GoodRx. Blujepa. 2026.

Bottom Line

Bluejepa (gepotidacin) gives a unique option in patients with uUTIs to provide coverage for ESBL and fluroquinolone resistant E. coli

Fills the gap in between drug resistance while still allowing for more narrow coverage

Nuzolvence (zoliflodacin)

Mechanism of action

- Spiropyrimidinetrione bacterial type II topoisomerase inhibitor

Use

- Uncomplicated urogenital gonorrhea

Dose

- Single dose granule packet

Pearls

- Impaired male fertility
- Patients who weigh 50 kg or more take with food

Lexicomp Online, Zoliflodacin (Nuzolvance) drug monograph. Wolters Kluwer Health; accessed 2026

Nuzolvence

	Zoliflodacin versus ceftriaxone plus azithromycin for treatment of uncomplicated urogenital gonorrhea
Study Design	Phase 3, multinational, randomized, double-blind, non-inferiority
Participants	Patients with uncomplicated urogenital gonorrhea
Treatment	Zoliflodacin vs. IM ceftriaxone + oral azithromycin
Primary Endpoint	Microbiologic cure

Luckey A, et al. *Lancet.* 2026

Nuzolvence

Study Endpoint	Gepotidacin (n = 202)	Ceftriaxone + Azithromycin (n = 204)	Treatment Difference (95% CI)
Microbiological success (primary)	92.6%	91.2%	-0.1% (-5.6 to 5.5)

Luckey A, et al. *Lancet*. 2026

Déjà vu?

Bluejepa (gepotidacin)

Mechanism of action

- Triazaacenaphthylene antibiotic

Use

- Treating uncomplicated urinary tract infections and urogenital gonorrhea in females

Dose

- 1500 mg (2 tabs) twice daily x 5 days

Pearls

- Qtc prolongation
- Avoid in severe renal and hepatic impairment

Two Indications: One Drug

FDA Approves Two Oral Therapies to Treat Gonorrhea

Approvals Are for Uncomplicated Urogenital Gonorrhea

More Press Announcements

For Immediate Release: December 12, 2025

The U.S. Food and Drug Administration recently approved two new oral medicines to treat a common sexually transmitted infection called gonorrhea.

The FDA today approved Nuzolvence (zoliflodacin) granules that dissolve in water. This medicine can treat uncomplicated urogenital gonorrhea in adults and children 12 years and older who weigh at least 77 pounds. Yesterday, the FDA approved Blujepa (gepotidacin) oral tablets for the same condition in patients 12 years and older who weigh at least 99 pounds. This medicine is for patients who have few or no other treatment choices because of limited clinical safety data. Blujepa was first approved in March 2025 to treat urinary tract infections.

"These approvals mark a significant milestone for treatment options for patients with uncomplicated urogenital gonorrhea," **said Adam Sherwat, M.D., director of the Office of Infectious Diseases in the FDA's Center for Drug Evaluation and Research (CDER)**

Content current as of:
12/12/2025

Follow FDA
Follow @US_FDA
Follow FDA
Follow @FDAMedia

FDA. Two oral therapies for gonorrhea approved. 2025.

Neurology

Bysanti (milsaperidone)

Mechanism of action

- D2 and 5-HT2 antagonism

Use

- Treatment of schizophrenia in adults
- Acute treatment of manic or mixed episodes

Dose

- Schizophrenia: 6 mg to 12 mg twice daily
- Manic or mixed episodes: 12 mg twice daily

Pearls

- Must be titrated daily until recommended maintenance dose reached
- Similar to Fanapt (iloperidone)
- Possible expansion to treat MDD in the upcoming future

Vanda Pharmaceuticals. Bysanti prescribing information. 2026.

Bysanti (milsaperidone)

Population	Titration Schedule							Recommended Maintenance Dosage
	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	
Schizophrenia	1mg twice daily	2 mg twice daily	4 mg twice daily	6 mg twice daily	8 mg twice daily*	10 mg twice daily*	12 mg twice daily*	6 mg to 12 mg twice daily
Manic or Mixed Episodes Associated with Bipolar I Disorder	1 mg twice daily	3 mg twice daily	6 mg twice daily	9 mg twice daily	12 mg twice daily	Titration complete		12 mg twice daily

* Patients with schizophrenia may either (1) follow the recommended titration schedule, OR (2) starting on Day 5, continue 6 mg twice daily BYSANTI dosing. As needed, titrate subsequent doses based on tolerability and response within the recommended maintenance dosing range of 6 mg to 12 mg twice daily.

Vanda Pharmaceuticals. Bysanti prescribing information. 2026.

Nereus (tradipitant)

Mechanism of action

- Inhibits substance P/ neurokinin-1 receptor

Use

- Prevention of vomiting induced by motion in adults

Dose

- 85 mg or 170 mg as a single dose
- Single dose = max dose

Pearls

- Nereus in Greek mythology is a sea god
- Being investifated for nausea and vomiting induced by GLP-1s

FDA. NDA 220152 prescribing information. 2025.

Endocrine

Awiqli (insulin icodec-abae)

Mechanism of action

- Binds to albumin to create a depot in circulation

Use

- Type 2 diabetes (T2DM)

Dose

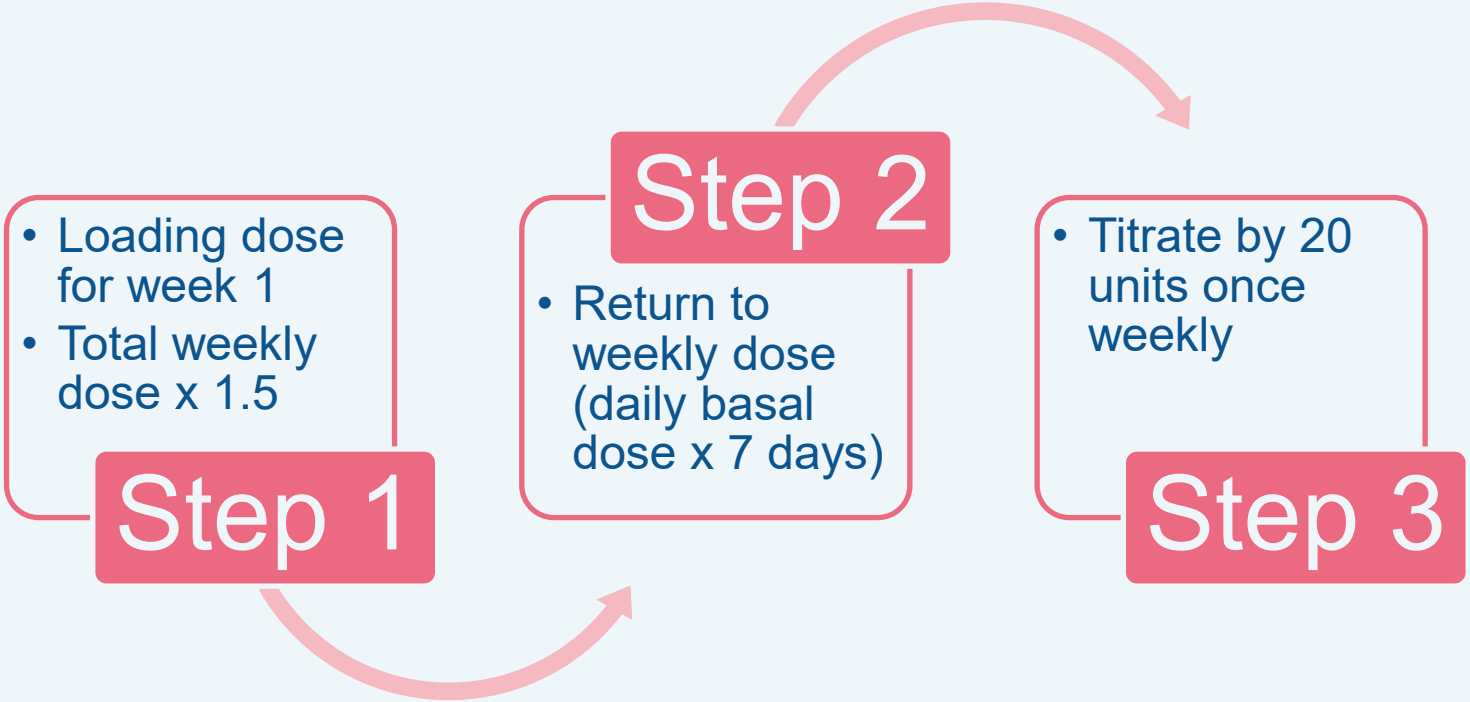
- Once weekly basal insulin

Pearls

- Dosing
  - Insulin naïve: 70 units once weekly
- Hypoglycemia risk most common 2-4 days post injeciton

Holt et al., Lancet Diabetes Endocrinol 2023 (ONWARDS)

Starting Awiqli



Holt et al., Lancet Diabetes Endocrinol 2023 (ONWARDS)

ONWARDS Trials

Glycemic control

- Non-inferior to superior HbA1c reduction
- Greater time in range on CGM reports

Hypoglycemia

- Rates of clinically significant and severe hypoglycemia are low
- Some ONWARDs trials showed numerically higher hypoglycemic events
  - Most noted in early titration periods

ONWARDS-1–6: Holt et al., Lancet Diabetes Endocrinol 2023–2024

Obesity

Semaglutide (PO)

Mechanism of action

- Selective glucagon-like peptide (GLP-1) receptor agonist that increases glucose dependent insulin secretion, decreases inappropriate glucagon secretion, slows gastric emptying

Use

- Weight loss
- Major Adverse Cardiovascular Event (MACE) risk reduction

Dose

- 1.5 mg daily → 4 mg daily → 9 mg daily → 25 mg daily

Pearls

- Formerly known as Rybelsus
- Counseling
  - Patients should take the pill first thing when they wake up on an empty stomach with a small sip of water (4 oz)
  - Wait 30 minutes before eating, drinking, or taking other oral medications

Novo Nordisk. Wegovy pill dosing guide. 2026.

Oral vs. Subqutaneous Weight Loss

Endpoint	Injectable Wegovy (2.4 mg weekly)	Oral Wegovy (25 mg daily)	Key Difference
Mean % weight loss	−14.9% to −16% (68 weeks)	−13.6% to −15.1% (64–68 weeks)	Injectable: 1–2 percentage points greater
≥5% weight loss	83–85% of patients	76–85% of patients	Comparable
≥10% weight loss	66–73% of patients	60–69% of patients	Injectable slightly higher
≥15% weight loss	48–53% of patients	47–54% of patients	Comparable
Gastrointestinal adverse events	82% (mild–moderate)	74–80% (mild–moderate)	Oral: slightly lower GI AE rate
Treatment discontinuation	6–11% due to AEs	5–6% due to AEs	Comparable

Wilding et al., NEJM 2021 (STEP 1)
Wharton et al., NEJM 2025 (OASIS-4)

Oral Wegovy for MACE

Trial	PIONEER-6 (2019)	SOUL (2025)
N	3,183	9,650
Follow-up	≈1.3 years (~16 months)	47.5 months (~4 years)
Design	Non-inferiority CV safety trial	Superiority CV outcomes trial
Primary Result	HR 0.79 (0.57–1.11) **Non-inferior**, not superior	HR 0.86 (0.77–0.96) **Superior**
Power	~122 events (rule out harm)	~1225 events (prove benefit)
Conclusion	CV safe	CV risk reduction confirmed

Husain M, et al. *N Engl J Med*. 2019; PIONEER-6; oral semaglutide CV safety.
SOUL HF analysis. *JAMA Intern Med*. 2026; oral semaglutide reduced HF events.

Semaglutide (HD)

STEP UP Trial Results (at 72 weeks[1], [2])				
		Wegovy® injection 7.2 mg	Wegovy® injection 2.4 mg	Placebo
Average weight reduction[1]	If all patients stayed on treatment (Efficacy estimand*)	~21% (20.7%)	~18% (17.5%)	~2% (2.4%)
	Analysis of all patients regardless of if they stayed on treatment[2] (Treatment regimen estimand**)	~19% (18.8%)	~16% (15.5%)	~4% (3.9%)
	Percent of patients who achieved 25% or more weight loss**	31.2%	15.3%	0%

Novo Nordisk. Wegovy pen results. Accessed April 20, 2026.

Wegovy Cost and Coverage

Wegovy® pill | Wegovy® pen

WITH COMMERCIAL INSURANCE
Pay as little as

$25

per month*

SELF PAY
Starting at

$149

per month
for the 1.5 mg dose*†

Wegovy PO can be ordered through Novocare or any retail pharmacy. Not all retail pharmacy's may accept the manufacturer coupon

Novo Nordisk. Wegovy cost and coverage. 2026.

Wegovy Cost and Coverage

Wegovy® pen

COMMERCIAL INSURANCE

Pay as little as

$25

per month*

SELF PAY

Starting at

$199

per month*

Limited time intro offer, $199 per month for the first 2 months, 0.25 mg or 0.5 mg doses, then $349 per month.

Wegovy® HD 7.2 mg pen is $399 per month‡

Wegovy PO can be ordered through Novocare or any retail pharmacy. Not all retail pharmacy's may accept the manufacturer coupon

Novo Nordisk. Wegovy cost and coverage. 2026.

Foundayo (orforglipron)

Mechanism of action

- Selective glucagon-like peptide (GLP-1) receptor agonist that increases glucose dependent insulin secretion, decreases inappropriate glucagon secretion, slows gastric emptying

Use

- Weight loss

Dose

- 0.8 mg daily →2.5 mg daily → 5.5 mg daily →9 mg daily → 14.5 mg daily → 17.2 mg daily

Pearls

- Can be taken without regard to food or water

Lilly. Foundayo (orforglipron). 2026.

Foundayo Cost

Foundayo is available for self-pay through **LillyDirect**

Self-pay price:
Starting at $149/month^

0.8 mg dose [starting dosage]

Self-pay price:
Starting at $199/month^

2.5 mg dose

Self-pay price:
Starting at $299/month^

5.5 mg dose

At this time Foundayo can only be ordered through LillyDirect Pharmacy

LillyDirect. Foundayo. Accessed April 20, 2026.

Comparison Chart

Medication (at max dose)	Average Estimated Weight Loss
Tirzepatide	21%
Injectable Wegovy	20%
Orforglipron	15%
Oral Wegovy	14%

Aronne LJ, et al. *N Engl J Med*. 2022
Wilding JPH, et al. *N Engl J Med*. 2021
Wharton S, et al. *N Engl J Med*. 2025
O'Neil PM, et al. *Lancet*. 2023

Womens Health

Lynkuet (elinzanetant)

Mechanism of action

- Neurokinin 1 (NK1) and neurokinin 3 (NK3) receptor antagonist the blocks Substance P and Neurokinin B (NKB) to modulate neuronal activity in the thermoregulatory center associated with hot flashes

Use

- Vasomotor symptoms associated with menopause

Dose

- 120 mg once daily at bedtime

Pearls

- LFTs prior to initiation; do not initiate if AST/ALT and/or total bilirubin 2x ULN

Lexicomp Online. Lynkeut. Accessed April 20, 2026.

Biosimilars

Biosimilars in 2026

Biosimilar definition

- A product approved by the FDA based on data showing it is highly similar to an already approved product
- No clinically meaningful differences in safety or effectiveness

Purpose

- Developed to increase patient access to therapies and reduce cost through competition

Prevelence

- As of March 2026, the FDA has approved 82 biosimilars
- Nearly 25 new biosimilars are expected to be approved between 2026-2027

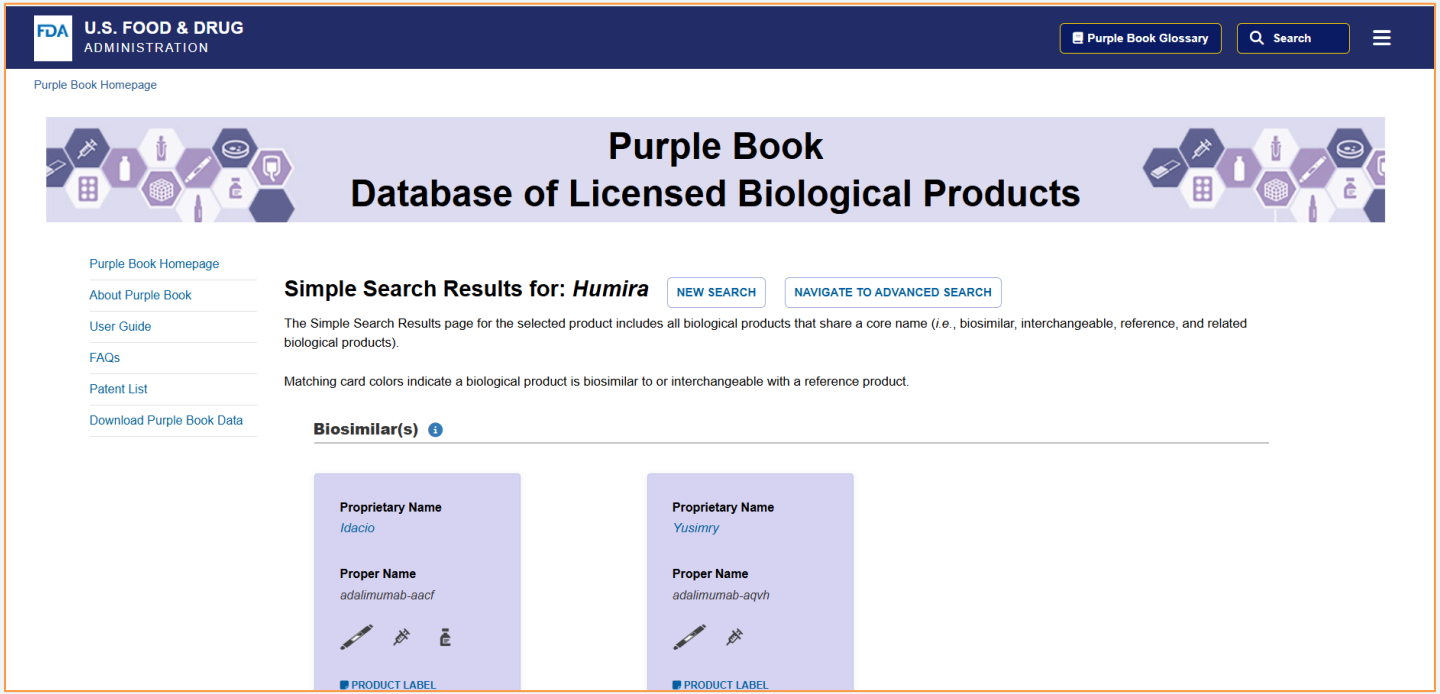
US FDA. *What Is a Biosimilar?* Accessed April 20, 2026

Biosimilars in 2026

Key 2025-2026 Biosimilar Approvals			
Denosumab (Prolia)	• Jubbonti • Ospomyv • Stoboclo	• Conexxence • Bildyos • Enoby	• Osvyrti • Boncresa
Insulin Aspart (Novolog)	• Merilog • Kirsty		
Omalizumab (Xolair)	• Omlyclo		
Adalimumab (Humira)	• Amjevita • Cyltezo • Abrilada • Hadlima	• Simlandi • Hyrimoz • Idacio • Halimatoz	• Yusimry • Selarsdi

US Food and Drug Administration. Purple Book: Database of Licensed Biological Products. Accessed April 20, 2026.

Biosimilars in 2026



US Food and Drug Administration. Purple Book: Database of Licensed Biological Products. Accessed April 20, 2026.

Key Takeaways

With combination vaccines emerging, careful attention to updated guidance on dosing intervals and subsequent doses will be essential to ensure appropriate series completion and optimal protection

With rising antimicrobial resistance, expanded treatment options for gonorrhea are becoming increasingly important.

First new antinausea medication in over 40 years released

Increasing indications for weight loss medications, and new oral weight loss medications now being added to market

Increasing use of biosimilars to help with high-cost medications

THANKS!

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