Drug Update 2025: Newest medication approvals

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Disclosures

- Speaker Bureau
  - Sanofi-Pasteur, Merck, Pfizer, Seqirus, Moderna – Vaccines
  - Exact Sciences – Colorectal Cancer Screening
  - AstraZeneca – Asthma and COPD
- Consultant
  - Sanofi-Pasteur, Merck, Pfizer, Moderna, and Seqirus – Vaccines
  - GSK: OA/Pain
  - AstraZeneca – Asthma and COPD
- All relevant financial relationships have been mitigated.

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Objectives

- At the end of this presentation, the participant will be able to:

1. Identify 10 – 20 new medications
2. Discuss the use, adverse effects, drug-drug interactions, and benefits of each of the medications.
3. Discuss updates related to labeling, indications, and risks associated with various medications.

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Tips

- References
  - Listed throughout and at the end of the presentation

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New Drugs

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Center for Drug Evaluation and Research (CDER) 2024 Data[2]

Fifty novel medications were approved in 2024

https://www.nature.com/articles/d41573-025-00001-5

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Center for Drug Evaluation and Research (CDER) 2025 Data

16 new drug approvals as of June 17, 2025

https://www.fda.gov/drugs/novel-drug-approvals-fda/novel-drug-approvals-2025 accessed 06-17-2025

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Pain

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Suzetrigine (Journavx)

- Indication:
  - Acute moderate – severe pain in adults
- Dosing:
  - 100 mg orally x 1 dose followed by 50 mg every 12 hours – beginning 12 hours after the 100 mg dose
    - First dose should be given 1 hour before or two hours after food
    - Use for shortest effective treatment (studied up to 14 days)
- Mechanism of Action
  - Selective blocker of the NaV1.8 voltage-gated sodium channel
  - Suzetrigine inhibits transmission of pain signals to the spinal cord and brain

https://pi.vrtx.com/files/uspi_suzetrigine.pdf accessed 06-17-2025

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Suzetrigine

- Efficacy:
  - 874 patients with moderate – severe pain following full abdominoplasty
    - Allowed to use rescue medications such as ibuprofen or acetaminophen
    - Comparator group: placebo, hydrocodone bitartrate/APAP
    - Statistically superior to placebo and as effective as Hydrocodone (not SS)
  - 256 adults with moderate – severe acute pain conditions
  - 1073 adults with moderate – severe pain following bunionectomy
    - Statistically superior to placebo and slightly less effective than hydrocodone

https://pi.vrtx.com/files/uspi_suzetrigine.pdf accessed 06-17-2025

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Suzetrigine

- Contraindications
  - Moderate – severe liver disease
- Precautions
  - Has not been studies in patients with GFR < 15 mL/min
  - Childbearing age women

https://pi.vrtx.com/files/uspi_suzetrigine.pdf accessed 06-17-2025

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Suzetrigine

- Pregnancy concern:
  - Patients of childbearing age using oral contraceptives w/o progestins (levonorgestrel or norethindrone), avoid pregnancy by using effective non-hormonal contraceptive option or switch to COC containing estradiol with levonorgestrel or norethindrone or an IUD during treatment and 28 days after d/c of suzetrigine

https://pi.vrtx.com/files/uspi_suzetrigine.pdf accessed 06-17-2025

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Suzetrigine

- Drug interactions:
  - CYP 3A4 Substrate
    - Avoid strong CYP 3A4 inhibitors
    - Avoid grapefruit juice (need to reduce dose of Suzetrigine with moderate inhibitors)
    - Avoid moderate – strong CYP 3A4 inducers

https://pi.vrtx.com/files/uspi_suzetrigine.pdf accessed 06-17-2025

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Suzetrigine

- Adverse events (low rates of adverse events):
  - Pruritus
  - Muscle spasms
  - Rash
- Benefits
  - First new pain medication in a decade
  - Non-opioid
  - Not a controlled substance
- Cost:
  - $30.00 copay card Good RX
  - $15.50 per pill

https://pi.vrtx.com/files/uspi_suzetrigine.pdf accessed 06-17-2025

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What are the medication targets?

- Wisdom teeth surgery
- Bunionectomy
- Acute back/neck/ortho pain
- Urgent care and ER providers
- Any place you would consider using an opioid for acute pain

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Neurology

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Donanemab - azbt

- Name: Kisunla
- Approval: July 2, 2024
- Class: amyloid beta-directed antibody
- Indications:
  - Mild Cognitive Impairment (Mild Neurocognitive Disorder) and Mild Alzheimer's disease (Major Neurocognitive Disorder)
- Dosage:
  - 700 mg administered as an intravenous infusion over approximately 30 minutes every four weeks for the first three doses, followed by 1400 mg every four weeks

https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/761248s000lbl.pdf accessed 08-01-2024

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Donanemab

- Special monitoring:
  - MRI prior to initiating medication
  - MRI prior to 2nd, 3rd, 4th, and 7th infusion
  - Monitoring for ARIA (given severity, medication will be held, continued, or discontinued)
  - Most of these abnormalities appear early in treatment and as such, vigilance in the first 24 weeks of the medication is imperative
  - Also important as medication may be able to be stopped if amyloid plaque levels drop to minimal levels on amyloid PET scanning
    - This occurred within the clinical trials

https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/761248s000lbl.pdf accessed 08-01-2024

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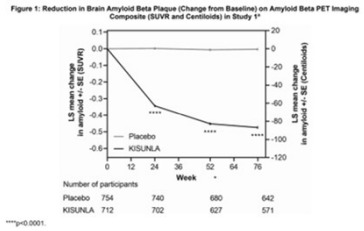
Donanemab

- Efficacy:



https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/761248s000lbl.pdf accessed 08-01-2024

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Functional Assessment

https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/761248s000lbl.pdf accessed 08-01-2024

- ADAS-Cog13 (Baseline and Week 79)
  - Placebo vs. Drug Baseline
    - 29.16 v. 28.53
  - Adjusted mean from baseline
    - 6.79 v. 5.46
    - p = 0.0006

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Donanemab

- Adverse Events:
  - Symptomatic ARIA occurred in 6% (52/853) of patients treated with KISUNLA in Study 1.
    - Clinical symptoms associated with ARIA resolved in approximately 85% (44/52) of patients.
  - Including asymptomatic radiographic events, ARIA was observed in 36% (307/853) of patients treated with KISUNLA, compared to 14% (122/874) of patients on placebo in Study 1.
  - One fatality: intracerebral hemorrhage: study drug and antithrombotic
- Cost:
  - 12 months: approximately $32,000.

https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/761248s000lbl.pdf accessed 08-01-2024

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Research studies ongoing…

- Slower titration dose (ramp up) schedule
- What happens when medication is stopped?

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Meloxicam/rizatriptan (Symbravo)

- Indication: Acute treatment of migraine with and without aura in adults
- Dosage: 1 tablet daily as needed for migraine
  - 20 mg of meloxicam/10 mg of rizatriptan
  - Safety of treating more than 7 migraines in 30 days not established
  - With or without food
- MOA:
  - NSAID/triptan: acute impact of the triptan with the longer action of the NSAID

https://www.axsome.com/wp-content/uploads/2025/02/SYM-USPI-001.001-20250224.pdf accessed 06-26-2025

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Meloxicam/rizatriptan

- Contraindications:
  - CAD
  - History of CVA/TIA/Cerebrovascular disease
  - Poorly controlled hypertension
  - Hemiplegic/basilar migraine
  - PVD
  - Concomitant use of propranolol
  - Allergy to NSAIDs/asthma triad
  - Moderate – severe renal insufficiency
  - History of PUB

https://www.axsome.com/wp-content/uploads/2025/02/SYM-USPI-001.001-20250224.pdf
accessed 06-26-2025

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Meloxicam/rizatriptan

- Warnings:
  - Monitor blood pressure
  - Hepatotoxicity
  - Chest tightness/jaw tightness
  - Worsening heart failure
  - Worsening renal function
  - Serious skin reactions

https://www.axsome.com/wp-content/uploads/2025/02/SYM-USPI-001.001-20250224.pdf
accessed 06-26-2025

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Meloxicam/rizatriptan

- Warnings:
  - Do not use in pregnancy or lactation
  - Medication overuse headache
  - Serotonin syndrome
- Adverse reactions (drug/placebo):
  - Somnolence: 2% vs. 1%
  - Dizziness: 2% vs. 1%

https://www.axsome.com/wp-content/uploads/2025/02/SYM-USPI-001.001-20250224.pdf
accessed 06-26-2025

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Meloxicam/rizatriptan

- Drug Interactions:
  - Warfarin and anticoagulants
  - SSRIs/SNRIs
  - Diuretics
  - Lithium: can increase lithium levels
  - MTX: can increase MTX levels
  - MAOIs
  - Propranolol: 70% increase in AUC of rizatriptan with co-administration

https://www.axsome.com/wp-content/uploads/2025/02/SYM-USPI-001.001-20250224.pdf
accessed 06-26-2025

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Meloxicam/rizatriptan

- Efficacy (drug vs. placebo):
  - Coprimary end points
    - Pain freedom at 2 hours: 19.9% vs. 6.7%
    - Freedom from most bothersome symptom at 2 hours (36.9% vs. 24.4%)
  - Key secondary end points
    - Sustained pain freedom at 24 hours: 16.1% vs. 5.3%
  - Other secondary end points
    - Pain relief at 2 hours and return to function at 2 hours
  - All above statistically significant

https://www.axsome.com/wp-content/uploads/2025/02/SYM-USPI-001.001-20250224.pdf
accessed 06-26-2025

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Meloxicam/rizatriptan

- Available in June 2025
- Dispensed: 9 pills per month
- Cost: $1238.00 for 9 pills
  - Copay card: $30.00

https://www.axsome.com/wp-content/uploads/2025/02/SYM-USPI-001.001-20250224.pdf
accessed 06-26-2025

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Infectious Disease

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Pivmecillinam (Pivya)

- Pivmecillinam (Pivya)
  - Works to bind to peptidoglycan, which inhibits cell wall synthesis of the bacteria
  - Indication: treatment of adult females (18 years and older) with an uncomplicated UTI (*E. Coli, Proteus Mirabilis, S. Saprophyticus*).
  - 185 mg 1 pill three times daily x 3 – 7 days (with or without food)
  - Side effects: GI (n/v/diarrhea)

https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/216483s000lbl.pdf accessed 05-01-2025

Wright, 2025 32

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Pivmecillinam

- Contraindications:
  - Serious hypersensitivity reaction to PCN or beta-lactams
  - Primary or secondary carnitine deficiency resulting from inherited disorders of mitochondrial fatty acid oxidation and carnitine metabolism, and other inborn errors of metabolism (methylmalonic aciduria, or propionic acidemia)
  - Acute porphyria
- Warnings/Precautions
  - *C. difficile*
  - Avoid in pregnancy: can cause false positive newborn test for isovaleric acidemia yet no fetal abnormalities identified

https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/216483s000lbl.pdf accessed 06-01-2025 33

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Pivmecillinam

- Efficacy:
  - 579 females with uUTI
  - Treated with pivmecillinam vs. placebo for 3 – 10 days
  - Ages 18-91 years
  - 62% - 72% efficacy over 4 trials (placebo, cephalexin comparators)

https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/216483s000lbl.pdf accessed 06-01-2025

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Pivmecillinam

- Adverse reactions (drug vs. placebo):
  - Nausea (4.3% vs. 2.1%)
  - Diarrhea (2.1% vs. 0.7%)
  - Vulvovaginal candidiasis (1.8% vs. 0%)
  - Headache (1.4% vs. 0.3%)
- Drug interactions:
  - Valproic acid (muscle aches, confusion, fatigue)
  - MTX (increased levels of MTX)
- Cost: unknown as not yet commercially available

https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/216483s000lbl.pdf accessed 06-01-2025

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Gepotidacin (Blujepa)

- Gepotidacin:
  - Indication: Uncomplicated UTIs
    - Approved for adults (40 kg and greater) and adolescents 12 years of age and older (and at least 40 kg)
  - Approval: May 2025
  - MOA: First-in-class triazaacenaphthylene antibiotic with a novel mechanism, inhibiting bacterial DNA replication at a distinct binding site
    - Targets: Escherichia coli, Klebsiella pneumoniae, Citrobacter freundii complex, Staphylococcus saprophyticus, and Enterococcus faecalis
    - Superiority to nitrofurantoin in uncomplicated UTIs

https://blujepahcp.com/?cc=ps_K46EK7X8TD2689271&mtrc=500369&mcm=500369&gclid=f426272affaf121e52aa4f3d555aa354&gclsrc=3p.ds&msclkid=f426272affaf121e52aa4f3d555aa354 accessed 05-01-2025

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Gepotidacin

- Dosage: 1500 mg (two 750 mg tablets) dosed two times daily x 5 days
- Warnings and Precautions:
  - QT prolongation: avoid in those with known history or QT prolonging medications
  - Acute hypersensitivity reaction
  - *C. difficile*
  - Avoid using in those with eGFR < 30 mL/min and those on dialysis
  - Avoid using in those with moderate – severe hepatic disease

https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/218230s000lbl.pdf accessed 06-01-2025

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Gepotidacin

- CYP 450 Substrate
  - *Avoid strong 3A4 inhibitors*
  - *Avoid strong 3A4 inducers*
- Digoxin:
  - If added to digoxin: monitor digoxin levels closely (can increase levels of digoxin)
- Acetylcholinesterase inhibition
  - In trials, acts as a reversible acetylcholinesterase inhibitor
  - Avoid with other medications (acetylcholinesterase inhibitors)

https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/218230s000lbl.pdf accessed 06-01-2025

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Gepotidacin

- Adverse reactions (drug vs. placebo)
  - Diarrhea (16% vs. 3%)
  - Nausea (9% vs. 4%)
  - Abdominal pain (4% vs. 2%)
  - Flatulence (3% vs. < 1%)
- Avoid in pregnancy and lactation (pregnancy registry established)
  - Mice and rats: increased fetal mortality and decreased fetal weights

https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/218230s000lbl.pdf accessed 06-01-2025

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Gepotidacin

- Efficacy:
  - 22% were 65 years and older: no dosage adjustment needed
  - 51.8% - 72.9% efficacy compared with nitrofurantoin (44% - 66.8%)
- Cost:
  - Plan is to launch 2nd half of 2025
  - TBD

https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/218230s000lbl.pdf accessed 06-01-2025

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Clesrovimab-cfor (Enflonsia)

- To prevent respiratory syncytial virus (RSV) lower respiratory tract disease in neonates and infants who are born during or entering their first RSV season*** 1st season approval only
- Monoclonal antibody
- Approved and available to order July 2025
- 105 mg single dose administered IM to infants prior to their first RSV season
- Warnings and Precautions:
  - Acute hypersensitivity reactions

https://www.merck.com/product/usa/pi_circulars/e/enflonsia/enflonsia_pi.pdf 06-29-2025

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Clesrovimab-cfor

- Adverse events:
  - Injection site redness (3.8%)
  - Injection site swelling (2.7%)
  - Rash (2.3%)
- Education:
  - Remove from refrigerator and allow to warm to room temperature (15 minutes)
  - May co-administer with other pediatric vaccines (different injection site)
- Cost: $250.00 per dose

https://www.merck.com/product/usa/pi_circulars/e/enflonsia/enflonsia_pi.pdf **06-29-2025**

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Respiratory

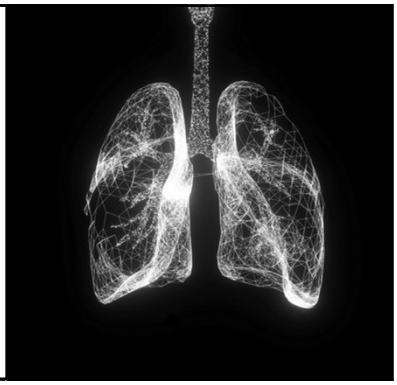

Image source: Microsoft stock image

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Ensifentrine (Ohtuvayre)

- Class:
  - Phosphodiesterase 3 (PDE3) inhibitor and phosphodiesterase 4 (PDE4) inhibitor
    - Causes relaxation of airway muscles and reduces inflammation
    - PDE3: bronchodilates
    - PDE4: reduces inflammation (similar to roflumilast)
  - Molecule was discovered more than 50 years ago
- Indication:
  - Maintenance treatment of chronic obstructive pulmonary disease (COPD) in adult patients.
    - Improve FEV1 and reduce exacerbations

https://ohtuvayre.com/files/Ohtuvayre-US-Prescribing-Information.pdf accessed 08-15-2024

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Ensifentrine (Ohtuvayre)

- Class:
  - Phosphodiesterase 3 (PDE3) inhibitor and phosphodiesterase 4 (PDE4) inhibitor
    - Causes relaxation of airway muscles and reduces inflammation
  - Molecule was discovered more than 50 years ago
- Indication:
  - Maintenance treatment of chronic obstructive pulmonary disease (COPD) in adult patients.
    - Improve FEV1 and reduce exacerbations
- Dosage:
  - 3 mg (one ampule) twice daily administered by oral inhalation using a standard nebulizer.

https://ohtuvayre.com/files/Ohtuvayre-US-Prescribing-Information.pdf accessed 08-15-2024

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Ensifentrine

- Efficacy:
  - Two 24-week trials (Enhance 1 and Enhance 2)
  - 1553 adults with moderate – severe COPD
  - Multiple measures for evaluation
    - Mean FEV1 (mL) Change from Baseline over 12 hours at Week 12
      - 35 mL and 49 mL improvement in morning FEV1 from placebo
      - Statistically significant only in Enhance 1
    - St. George's Respiratory Questionnaire (improvement of 4 or more) at week 24
      - 58.2% for drug vs. 45.9% for placebo

https://ohtuvayre.com/files/Ohtuvayre-US-Prescribing-Information.pdf accessed 08-15-2024

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Ensifentrine

- Adverse events (drug vs. placebo)
  - Back pain 18 (1.8%) vs. 6 (1.0%)
  - Hypertension 17 (1.7%) vs. 5 (0.9%)
  - Urinary tract infection 13 (1.3%) vs. 6 (1.0%)
  - Diarrhea 10 (1.0%) vs. 4 (0.7%)
- Psychiatric events
  - One patient receiving drug in 24-week trial experienced a suicide-related adverse reaction (suicide attempt), and in another controlled study, one patient who received ensifentrine experienced a suicide-related adverse reaction (suicide).

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Ensifentrine

- Warnings and precautions
  - Should not use to treat acute symptoms of bronchospasm
  - If paradoxical bronchospasm occurs, discontinue treatment
  - An increase in psychiatric adverse reactions, including suicidality, were reported during clinical trials
    - Carefully weigh the risks and benefits of treatment in patients with a history of depression and/or suicidality
  - Drug interactions:
    - No significant interactions
  - Cost: $2,950.00 per month

https://ohtuvayre.com/files/Ohtuvayre-US-Prescribing-Information.pdf accessed 08-15-2024

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Additional studies under way

- LAMA (glycopyrrolate) with ensifentrine

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Cardiology

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Aprocitentan (Tryvio)

- Name: aprocitentan (Tryvio)
- Class:
  - Endothelin receptor antagonist (ERA) which inhibits the binding of endothelin (ET)-1 to ETA and ETB receptors.
    - ET-1, via its receptors (ETA and ETB), causes a variety of effects such as vasoconstriction, fibrosis, cell proliferation, and inflammation.
    - In hypertension, ET-1 can cause endothelial dysfunction, vascular hypertrophy and remodeling, sympathetic activation, and increased aldosterone synthesis.
  - This medication will inhibit the effect of ET-1

https://www.idorsia.us/dam/jcr:d834ee09-2e6c-443d-b3ac-c111e38f0990/tryvio_pi.pdf accessed 08-01-2024

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Aprocitentan

- Indication:
  - Endothelin receptor antagonist indicated for the treatment of hypertension in combination with other antihypertensive drugs, to lower blood pressure in adult patients who are not adequately controlled on other drugs.
- Dosage: 12.5 mg once daily with or without food
  - 25 mg dose WAS STUDIED BUT NOT APPROVED
    - No benefit over the 12.5 mg dose; but did show higher edema and fluid retention

https://www.idorsia.us/dam/jcr:d834ee09-2e6c-443d-b3ac-c111e38f0990/tryvio_pi.pdf accessed 08-01-2024

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Aprocitentan

- Efficacy
  - Precision trial
  - Inclusion criteria: Adults with SBP ≥140 mmHg who were prescribed at least three antihypertensive medications
  - 15.4 mm drop in systolic blood pressure at week 4
  - 10.4 mm drop in diastolic blood pressure at week 4
- Drug/drug interactions:
  - No significant drug/drug interactions were seen nor expected

https://www.idorsia.us/dam/jcr:d834ee09-2e6c-443d-b3ac-c111e38f0990/tryvio_pi.pdf accessed 08-01-2024

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Aprocitentan

- Warnings and Precautions
  - ERAs cause hepatotoxicity and liver failure
    - Measure serum aminotransferase levels and total bilirubin prior to initiation of treatment and repeat periodically during treatment
  - Fluid retention may require intervention
  - Decreases in hemoglobin
  - Decreased sperm counts
  - Avoid in end stage liver and kidney disease (has not been studied)

https://www.idorsia.us/dam/jcr:d834ee09-2e6c-443d-b3ac-c111e38f0990/tryvio_pi.pdf accessed 08-01-2024

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Aprocitentan

- Contraindications
  - Pregnancy: can cause major birth defects
    - If capable of pregnancy, obtain negative pregnancy test before initiating medication
    - Should be on a very reliable form of contraception
    - Female rats given macitentan (for which aprocitentan is a major metabolite) from late pregnancy through lactation showed reduced pup survival and impairment of the male fertility of the offspring at all doses
  - REMS PROGRAM HAS BEEN REMOVED
  - PACKAGE INSERT IS COMPREHENSIVE ENOUGH FOR PRESCRIBERS

https://www.idorsia.us/dam/jcr:d834ee09-2e6c-443d-b3ac-c111e38f0990/tryvio_pi.pdf accessed 08-01-2024[55]

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Aprocitentan

- Adverse reactions
  - Edema and fluid retention (drug vs. placebo)
    - 9.1% vs. 2.1%
  - Anemia:
    - 3.7% vs. 0%
- Cost:
  - 775.00 for 30 pills

https://www.idorsia.us/dam/jcr:d834ee09-2e6c-443d-b3ac-c111e38f0990/tryvio_pi.pdf accessed 08-01-2024[56]

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Quick Updates and Additional Approvals

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New Approvals

- Triple drug combination (Widaplik) was approved for treating hypertension in adults.
  - This medication combines telmisartan, amlodipine, and indapamide
  - Available – end of 2025
- Xifrym:
  - Injectable meloxicam for acute moderate – severe pain
  - 30 mg/mL injection once daily via IV injection

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New Warning

- Fezolinetant (Veozah)
  - Black box warning for the risk of serious liver injury
  - Indications: vasomotor symptoms (moderate – severe) associated with menopause
  - Protocol:
    - Monitor LFTs before initiation (do not start if ALT or AST or Bilirubin are two times upper limits of normal or higher)
    - Monitor LFTs monthly x 3 months
    - Recheck at 6 months and 9 months after initiation

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Norgestrel (Opill®)

- FDA voted in favor: RX – OTC switch
  - Progestin only, once daily oral contraceptive
  - Indication: Prevention of pregnancy
  - **Available in all pharmacies April 2024**

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Doxycycline PEP

- According to the CDC, MSM and transgender women who have been diagnosed with a bacterial STI (eg, syphilis, chlamydia, or gonorrhea) in the past 12 months should receive counseling about doxycycline PEP.
- Patients who are prescribed doxycycline PEP should undergo STI testing at baseline and every 3 to 6 months thereafter. Providers should assess whether there is still a need for doxycycline PEP every 3 to 6 months
- 200 mg dose: within 72 hours after exposure; no more than 200 mg per every 24 hours

https://www.empr.com/home/news/cdc-recommends-doxycycline-pep-for-sti-prevention-in-certain-populations accessed 06-16-2024

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New Indication: Linaclotide

- **Linaclotide (Linzess®)**
- Indication: Approved for children ages 6 years and older with functional constipation
- 72 mg once daily dose
- Contraindicated in children ages 2 years and younger

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New Indication

- **Remdesivir (Veklury®)**[19]
  - FDA approved for the acute treatment of COVID-19 in children and adults
  - Now approved for treatment of individuals with severe renal impairment including those on dialysis

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New Indications

- Intranasal flu vaccine (Flumist)
  - Self administration
- Dupilumab:
  - Eosinophilic esophagitis (1 year of age and older)
  - COPD (elevated eosinophils)

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New Indication:

- Ritonavir/nirmatrelvir (Paxlovid):
  - New indication
  - Able to be used in individuals with eGFR < 30 mL/minute per 1.73 m^2.
  - Available April 2025
  - Lower dosage for this population
  - There are now three different dosages so caution when prescribing

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New Indication: Semaglutide (Ozempic)

- Chronic kidney disease in individuals with diabetes

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Lenacapavir (Yeztugo)

- PrEP for HIV-1 (capsid inhibitor)
- Initiated as a tablet and then continued with twice yearly subcutaneous injections
- Administered every 6 months by a health care provider
- Indicated for men and women
- Approved June 18, 2025

https://www.gilead.com/news/news-details/2025/yeztugo-lenacapavir-is-now-the-first-and-only-fda-approved-hiv-prevention-option-offering-6-months-of-protection accessed 06-29-2025

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Immunization Updates

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NEW (October 2024)

- Universal age-based recommendation
  - 50 years of age and older
  - All vaccine naïve individuals
  - PCV20 ***or*** PCV21 ***or*** PCV 15 followed one-year later by PPSV23
- Risk-based recommendation
  - Age 18–49 years
  - PCV20 ***or*** PCV21 ***or*** PCV 15 followed one-year later by PPSV23

Source: CDC. (2024). Advisory Committee on Immunization Practices (ACIP). ACIP Recommendations. https://www.cdc.gov/acip/vaccine-recommendations/index.html

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Update

- When PCV15 is used, the recommended interval between administration of PCV15 and PPSV23 is ≥1-year.
  - A minimum interval of 8 weeks can be considered for adults with an immunocompromising condition, cochlear implant, or cerebrospinal fluid leak.
- Adults who have only received PPSV23 may receive a PCV (either PCV20, PCV 21, ***or*** PCV15) ≥1-year after their last PPSV23 dose.
- When PCV15 is used in those with history of PPSV23 receipt, it need not be followed by another dose of PPSV23.

Source: CDC. (2022). Use of 15-Valent Pneumococcal Conjugate Vaccine and 20-Valent Pneumococcal Conjugate Vaccine Among U.S. Adults: Updated Recommendations of the Advisory Committee on Immunization Practices-United States, 2022. *MMWR*. 71(4);109–117 https://www.cdc.gov/mmwr/volumes/71/wr/mm7104a1.htm

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Newest Vaccine

- PCV 21
  - FDA-approval
    - Indicated for prevention of invasive pneumococcal disease caused by 22 serotypes in individuals 18 years of age and older; ***and***
    - Prevention of pneumonia caused by 21 serotypes in individuals 18 years of age and older
  - Why 22 serotypes when there is only 21 serotypes in the vaccine?
- CDC: Voted for this vaccine wherever PCV 20 would be used
  - PCV 20 or PCV 21

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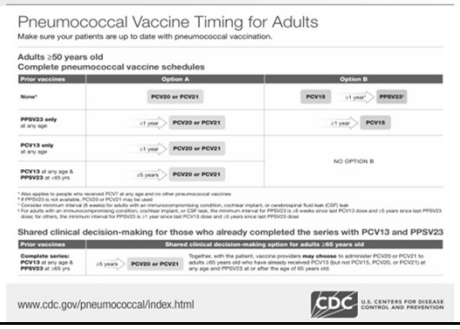
CDC.gov



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PneumoRecs App

Has now been updated
to include PCV 21

Image source: CDC. (2024). Pneumococcal Disease. PneumoRecs VaxAdvisor App for Vaccine Providers. (https://www.cdc.gov/pneumococcal/hcp/vaccine-recommendations/app.html). In the public domain.

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Shingles Vaccination

- New studies:
  - Shingles vaccine may lower heart disease risk by 23% and a 26% lower risk of a major cardiovascular event (CHF, MI, CVA)
    - This benefit may last 8 years or more following vaccination
    - Claims study analyzing 1.2 million adults living in Korea
  - May provide benefit in reducing risk of dementia
- What is the mechanism?
  - Shingles can trigger inflammation in blood vessels

https://www.medicalnewstoday.com/articles/shingles-vaccine-can-lower-heart-disease-risk-23-new-study accessed 05-10-2025

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June 2025

- Next generation mRNA COVID vaccine approved (mNexspike)
- 0.2 mL (10 mcg dose) compared to previous 50 mcg dose
  - Should be administered at least 3 months after previous covid vaccine
  - Expected to be available in the 2025 – 2026 season
- 12 – 64 years of age with at least one underlying condition or 65 years and older
- Noninferiority study: showed 9.3% higher efficacy than comparator in 65 years and older with a similar adverse event profile

https://www.clinicaladvisor.com/news/fda-approves-modernas-next-generation-covid-19-vaccine-mnexspike/ accessed 07-01-2025

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Chikungunya Vaccines

- Two approved:
  - Live – attenuated: Ixchiq (approved 18 and older)
    - Precautions due to live-attenuated vaccine
  - Virus like particle: Vimkunya (approved 12 and older)
- Indications:
  - Traveling to areas where outbreak is occurring
  - If moving to location and staying for extended period of time (6 months) where rates are high
  - Single dose vaccine:

https://www.cdc.gov/chikungunya/vaccines/index.html accessed 07-01-2025

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Chikungunya Vaccines

- 2024: CDC and FDA investigated five hospitalizations for cardiac (heart) or neurologic (nervous system) events following vaccination with the live attenuated vaccine (IXCHIQ) among older people.
  - April 2025: Led to suspension of the live attenuated vaccine for individuals 60 and older
    - Live attenuated should no longer be used in individuals 60 and older

https://www.cdc.gov/chikungunya/vaccines/index.html accessed 07-01-2025

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RSV vaccines (Arexvy and Abrysvo)

- July 2025:
  - Approved for 50 – 74 years of age with risk factors
  - Universal recommendation: 75 years and older
  - Paid under Part D
  - Wait for MMWR publication before administering in individuals 50-59 years as it may not be paid.

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Thank you!

I would be happy to entertain any questions or comments

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End of Presentation!
Thank you for your time, attention.

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