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 several 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
- To facilitate your learning
  - Specific tables/images can be viewed full page at the end of your handout.

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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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Neurology

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Eisai's New Medication

Image source: Microsoft stock image

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Lecanemab-irmb (Leqembi®)[4]

- Class
  - An amyloid beta-directed antibody which in clinical trials demonstrated a reduction in amyloid beta plaques
  - Recombinant human immunoglobulin gamma 1 (IgG1) monoclonal antibody directed against aggregated soluble and insoluble forms of amyloid beta
- Indication
  - Initiated in the mild cognitive impairment or mild stage of dementia from Alzheimer's disease

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Reduction in Amyloid Beta PET Composite

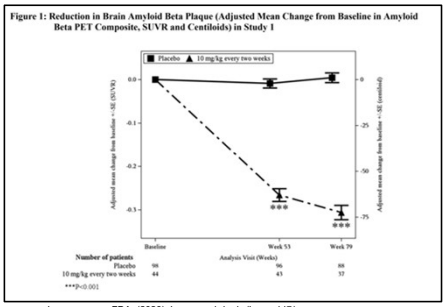

Image source: FDA. (2023). Lecanemab-irmb (Leqembi®). https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/761269Orig1s000lbl.pdf

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ADAS-Cog14[5]

- Baseline to 18 months
  - Baseline: 24.45 (drug arm) vs. 24.37 (placebo)
  - Mean change from placebo at 18 months
    - 4.14 (drug) vs. 5.581 (placebo)
    - Statistical significance: p=0.00065

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Lecanemab-irmb (Leqembi®)[5] (continued)

- Dosage: 10 mg/kg administered via IV solution over 1-hour every 2 weeks
- Testing before and during treatment
  - MRI prior to initiation and…
  - MRI prior to 5th, 7th, and 14th infusions

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Lecanemab-irmb (Leqembi®)[5] (continued)

Adverse related events

- Amyloid related imaging abnormalities (ARIA) including ARIA-E (edema) and ARIA-H (hemosiderin deposition)
- Depending upon severity and symptoms, dosing may be continued, suspended or discontinued.

- Symptomatic ARIA occurred in 3% (29/898) of patients treated with Lecanemab in study 2 with serious symptoms reported in 0.7% (6/898).
- Clinical symptoms associated with ARIA resolved in 79% (23/29) of patients during the period of observation.
- Similar findings were observed in Study 1.

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Learning More About This Class[5]

- We are starting to learn…
  - ApoE ε4 homozygotes patients
    - Those treated with this class of medications have a higher incidence of ARIA, including symptomatic and serious ARIA, compared to heterozygotes and noncarriers.
    - Testing for ApoE ε4 status should be performed prior to initiation of treatment to inform the risk of developing ARIA.
    - Prior to testing, prescribers should discuss with patients the risk of ARIA across genotypes and the implications of genetic testing results.
    - This is approximately 15% of those with AD.

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Laboratory tests

- *APOE* gene test
  - If positive, you have at least one copy of the gene in your DNA
  - Providers need to be well versed in these tests before obtaining
    - Counseling needs to be available
  - Having one of these can increase risk of AD but does not mean someone will inherit
  - 2-5% of individuals have 2 copies
  - Can be done via blood or buccal swab
  - CPT: 82542

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Additional laboratory test

- AD-Detect, Beta-Amyloid 42/40 Ratio, Plasma
  - Offered through major labs
- Purpose: to assess for elevated levels in patients exhibiting symptoms of MCI and AD
- CPT code: 0346U

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Now What…

- Lecanemab is the first product in this class to be fully FDA approved and thus, covered.
- The Centers for Medicare and Medicaid Services (CMS) has announced that it will provide Medicare coverage for new Alzheimer's drugs if they receive traditional approval from the Food and Drug Administration (FDA).

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January 2025

- Lecanemab
- One monthly maintenance dose will be reviewed by FDA

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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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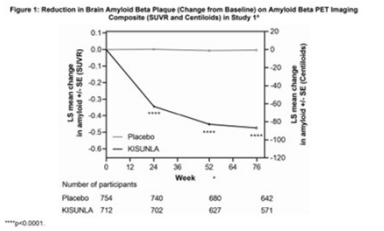
Donanemab

- 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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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[28]

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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[29]

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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
  - TRYVIO is available only through a restricted program under a REMS called the TRYVIO REMS because of the risk of embryo-fetal toxicity
    - Must be REMS certified to prescribe this medication

https://www.idorsia.us/dam/jcr:d834ee09-2e6c-443d-b3ac-c111e38f0990/tryvio_pi.pdf accessed 08-01-2024[30]

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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 31

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Endocrinology

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Sotagliflozin (Inpefa)

- Sotagliflozin
- Class: SGLT inhibitor (inhibitor of SGLT2 and SGLT1)
  - Inhibiting SGLT2 reduces renal reabsorption of glucose and sodium which may lower both pre-and afterload of the heart and downregulate sympathetic activity.
  - Inhibiting SGLT1 reduces intestinal absorption of glucose and sodium
    - This is likely what contributes to the side effect of diarrhea

https://www.lexpharma.com/inpefa-US-PI.pdf accessed 08-10-2024

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Sotagliflozin

- Indications: to reduce the risk of CV death, hospitalization for CHF, or urgent heart failure visit in adults with:
  - Diabetes, CKD and other CV risks
  - Heart failure
  - Considered a first line treatment for HF regardless of EF
- Dosage: 200 – 400 mg once daily
  - Begin with 200 mg once daily; may increase to 400 mg after two weeks
  - Swallow whole: do not crush or chew or cut

https://www.lexpharma.com/inpefa-US-PI.pdf accessed 08-10-2024

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Sotagliflozin

- If initiated for decompensated heart failure, treatment with this medication may begin as soon as the patient is hemodynamically stable
- Can be initiated during hospitalization or immediately upon discharge or during urgent outpatient treatment

https://www.lexpharma.com/inpefa-US-PI.pdf accessed 08-10-2024

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Sotagliflozin

- Efficacy:
  - During clinical trials, this drug was initiated at eGFR of 25 mL/min or higher
    - Studies did not include those with levels < 25 mL/min nor on dialysis
  - Soloist Trial: (Scored trial – similar results)
    - Patients with diabetes and heart failure
      - Total occurrence of cardiovascular death, hospitalization for heart failure, and urgent heart failure visit
        - Drug events per 100 patient years vs. placebo
        - 51.3 vs. 76.4 (p=0.001)

https://www.lexpharma.com/inpefa-US-PI.pdf accessed 08-10-2024

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Sotagliflozin

- Precautions/warnings:
  - DKA (Euglycemic)
  - Volume depletion: correct volume status before initiating
    - Monitor for signs of hypotension during treatment
  - Urosepsis and pyelonephritis
  - Hypoglycemia with concomitant use of insulin and secretagogues
  - Fournier's gangrene
  - Genital mycotic infections
  - Avoid in pregnancy and lactation

https://www.lexpharma.com/inpefa-US-PI.pdf accessed 08-10-2024

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Sotagliflozin

- Adverse events (common events for this class of medication):
  - Urinary tract infections
  - Volume depletion
  - Diarrhea
  - Hypoglycemia
- Drug interactions:
  - Monitor digoxin levels (can increase digoxin levels)
  - Monitor lithium levels (may decrease lithium levels)
- Cost: $658.00 (30 pills on drugs.com)

https://www.lexpharma.com/inpefa-US-PI.pdf accessed 08-10-2024

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All SGLT2Is

- Should be discontinued 3 days prior to surgery if possible, particularly those that require prolonged fasting

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Tirzepatide (Mounjaro™)[10]

- Class: GIP/GLP-1 agonist
  - Works by increasing insulin secretion, decreasing glucagon secretion, increasing insulin sensitivity and delaying gastric emptying
  - Indications
    - Type 2 diabetes (adults only)
    - It is not indicated for type 1 diabetes.

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Tirzepatide[10] **(continued)**

- Class: GIP/GLP-1 agonist (cont.)
  - Dosing
    - 2.5 mg SC once weekly × 4 weeks; then 5 mg once weekly × 4 weeks; then 7.5 mg once weekly × 4 weeks; then 10 mg once weekly × 4 weeks; then 12.5 mg once weekly × 4 weeks
    - Maximum: 15 mg once weekly

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Tirzepatide[10] **(continued)**

- Clinical trials/efficacy
  - 1539 (30.1%) were 65 years of age or older, and 212 (4.1%) were 75 years of age or older

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Tirzepatide[10] (continued)

- Clinical trials/efficacy (cont.)
  - 5 clinical trials to assess efficacy: SURPASS 1–5
    - 40-week monotherapy trial
      - A1C baseline: 8.1%, 8.0%, 7.9%, 7.9% (0.081, 0.08, 0.079, 0.079 proportion)
      - A1C 40 weeks (placebo, 5 mg, 10 mg, and 15 mg)
        - -0.1%, -1.8%, -1.7%, -1.7%
      - Weight baseline
        - -1.0 kg, -6.3 kg, -7.0 kg, -7.8 kg

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Tirzepatide[10] (continued)

- Precautions/warnings
  - No hepatic and renal dosing adjustments
  - Caution: History of gastroparesis or pancreatitis
  - Caution when adding to medications with narrow therapeutic index
  - Do not use in pregnancy; no data on impact in lactation

- Contraindications
  - Patients with medullary thyroid carcinoma or family history of such
  - Patients with multiple endocrine neoplasia syndrome

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Tirzepatide[10] (continued)

- Adverse reactions (placebo, 5 mg, 10 mg, and 15 mg)
  - Nausea: (4%, 12%, 15%, 18%)
  - Diarrhea: (9%, 12%, 13%, 17%)
  - Decreased appetite: (1%, 5%, 10%, 11%)
  - Vomiting: (2%, 5%, 5%, 9%)
  - Constipation: (1%, 6%, 6%, 7%)
- Cost: Approximately $1,000 for 4 weeks
  - Numerous copay cards are available online.

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Contraception

- Advise females using oral contraceptives to switch to a non-oral contraceptive method or add a barrier method of contraception for 4 weeks after initiation and for 4 weeks after each dose escalation

https://uspl.lilly.com/zepbound/zepbound.html#pi **accessed 01-13/2024**

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Newest Approval: Tirzepatide

- Tirzepatide (Zepbound™)
- Glucose-dependent insulinotropic polypeptide (GIP) receptor and glucagon-like peptide-1 (GLP-1) receptor agonist indicated as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adults with an initial body mass index (BMI) of:
  - 30 kg/m2 or greater (obesity) or
  - 27 kg/m2 or greater (overweight) in the presence of at least one weight-related comorbid condition (e.g., hypertension, dyslipidemia, type 2 diabetes mellitus, obstructive sleep apnea or cardiovascular disease)

https://uspl.lilly.com/zepbound/zepbound.html#pi accessed 01-13/2024

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Tirzepatide

- Newest indication:
  - Moderate – severe obstructive sleep apnea in adults with obesity
  - Trial: SURMOUNT-OSA
    - Trial: 65%-70% of participants had severe OSA
    - Average: more than 30 events/h on the apnea-hypopnea index (AHI) and a mean of 51.5 events/h.
    - 52 weeks: tirzepatide patient had 27-30 fewer events/h compared with 4-6 fewer events/h for those taking placebo.
    - Significantly more of those on tirzepatide achieved OSA remission or severity reduction to mild.
    - Tirzepatide: averaged 20% weight loss

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Tirzepatide (continued)

- Class: GIP/GLP-1 agonist (cont.)
  - Dosing
    - 2.5 mg SC once weekly × 4 weeks; then 5 mg once weekly × 4 weeks; then 7.5 mg once weekly × 4 weeks; then 10 mg once weekly × 4 weeks; then 12.5 mg once weekly × 4 weeks
    - Maximum: 15 mg once weekly
    - Administer any time of the day with or without regard to food
    - If dose is missed, patient has up to 96 hours to administer the dose; otherwise, should skip and administer next time the dose is due

https://uspl.lilly.com/zepbound/zepbound.html#pi accessed 01-13/2024

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Tirzepatide (continued)

- Clinical trials/efficacy:
  - Study 1 and Study 2
  - Average baseline weight: 100 – 105 kg
  - Study 1:
    - 5% weight reduction (15 mg): 90.9%
    - 10% weight reduction (15 mg): 83.5%
    - 15% weight reduction (15 mg): 70.6%
    - 20% or more weight reduction (15 mg): 56.7%

https://uspl.lilly.com/zepbound/zepbound.html#pi accessed 01-13/2024

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Tirzepatide (continued)

- Clinical trials/efficacy at 72 weeks:
  - Study 1 and Study 2
  - Average baseline weight: 100 – 105 kg
  - Study 2 (Patients also had diabetes):
    - 5% weight reduction (15 mg): 82.8%
    - 10% weight reduction (15 mg): 64.8%
    - 15% weight reduction (15 mg): 48.0%
    - 20% or more weight reduction (15 mg): 30.8%

https://uspl.lilly.com/zepbound/zepbound.html#pi accessed 01-13/2024

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Respiratory

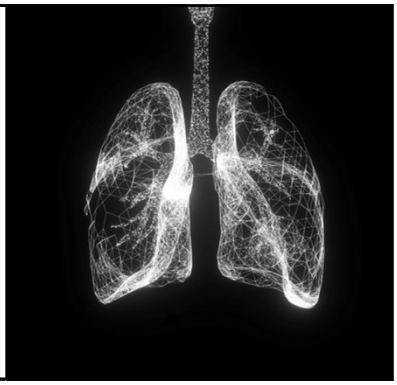

Image source: Microsoft stock image

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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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Gastrointestinal

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Vonoprazan (Voquezna)

- Approval: first approved 2022
- Indication:
  - for healing of all grades of erosive esophagitis and relief of heartburn associated with erosive esophagitis in adults
  - to maintain healing of all grades of erosive esophagitis and relief of heartburn associated with erosive esophagitis in adults
  - for the relief of heartburn associated with non-erosive gastroesophageal reflux disease in adults.
  - in combination with amoxicillin and clarithromycin for the treatment of Helicobacter pylori (H. pylori) infection in adults
  - in combination with amoxicillin for the treatment of H. pylori infection in adults

https://www.phathompharma.com/wp-content/uploads/VOQUEZNA-tablets-Prescriber-Information.pdf accessed 08-30-2024

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Vonoprazan

- Class:
  - Potassium-competitive acid blocker
- MOA:
  - Suppresses basal and stimulated gastric acid secretion at the secretory surface of the gastric parietal cell through inhibition of the H+, K+-ATPase enzyme system in a potassium-competitive manner.
  - This enzyme is regarded as the acid (proton) pump within the parietal cell and as such, vonoprazan has been characterized as a type of gastric proton-pump inhibitor, in that it blocks the final step of acid production.
  - Vonoprazan does not require activation by acid.

https://www.phathompharma.com/wp-content/uploads/VOQUEZNA-tablets-Prescriber-Information.pdf accessed 08-30-2024

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Vonoprazan

- Dosage:
  - Heartburn associated with NERD: 10 mg once daily for 4 weeks
  - Take with or without food
  - Take whole
- Warnings and precautions:
  - Carries same warnings as PPIs (Cdiff, bone fracture, B12 deficiencies, SJS, hypomagnesemia)
  - Fundic gland polyps (reported with vonoprazan and PPIs)
  - Avoid in pregnancy and lactation

https://www.phathompharma.com/wp-content/uploads/VOQUEZNA-tablets-Prescriber-Information.pdf accessed 08-30-2024

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Vonoprazan

- Efficacy:
  - Percentage of 24-Hour Heartburn-Free Days in Patients with Non-Erosive Gastroesophageal Reflux Disease Through Week 4
  - 10 mg Once Daily (drug vs. placebo)
    - 45% vs. 28%
  - Drug interaction:
    - rilpivirine used to treat HIV-1 (decreased efficacy)
  - Cost: 694.00 per month

https://www.phathompharma.com/wp-content/uploads/VOQUEZNA-tablets-Prescriber-Information.pdf accessed 08-30-2024

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Allergy

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Epinephrine nasal spray (Neffy)

- Class:
  - An alpha and beta-adrenergic receptor agonist
- Indication:
  - Emergency treatment of type I allergic reactions, including anaphylaxis, in adult and pediatric patients who weigh 30 kg or greater.
- Dosage:
  - One spray (2 mg of epinephrine) administered into one nostril.
  - If no improvement or worsening, administer a second dose in the same nostril with a new nasal spray starting 5 minutes after the first dose.

https://www.ars-pharma.com/wp-content/uploads/pdf/Prescribing_Information.pdf accessed 08-30-2024

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Epinephrine nasal spray

- Patient education
  - Administer by inserting the nozzle of the nasal spray fully into one nostril until patient's fingers touch their nose
  - Right hand sprays into right nostril and left hand sprays into left nostril
  - Hold device straight into nostril
  - Avoid sniffing during or after administration
- Adverse events:
  - Same as other epinephrine-based products
- Advantage:
  - Needle free epinephrine

https://www.ars-pharma.com/wp-content/uploads/pdf/Prescribing_Information.pdf accessed 08-30-2024

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Epinephrine nasal spray

- Cost:
  - $25 for two, single-use devices.
  - For those without insurance or whose insurance won't cover, pharma company will offer it for a cash price of $199.00

https://www.ars-pharma.com/wp-content/uploads/pdf/Prescribing_Information.pdf accessed 08-30-2024

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Quick Updates and Additional Approvals

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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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Immunizations

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PCV 21

- Pneumococcal 21-valent Conjugate Vaccine (Capvaxive)
- Indications:
  - active immunization for the prevention of invasive disease caused by *Streptococcus pneumoniae* serotypes 3, 6A, 7F, 8, 9N, 10A, 11A, 12F, 15A, 15B, 15C, 16F, 17F, 19A, 20A, 22F, 23A, 23B, 24F, 31, 33F, and 35B in individuals 18 years of age and older.
  - active immunization for the prevention of pneumonia caused by *S. pneumoniae* serotypes 3, 6A, 7F, 8, 9N, 10A, 11A, 12F, 15A, 15C, 16F, 17F, 19A, 20A, 22F, 23A, 23B, 24F, 31, 33F, and 35B in individuals 18 years of age and older

https://www.merck.com/product/usa/pi_circulars/c/capvaxive/capvaxive_pi.pdf accessed 08-10-2024

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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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When and how do I use this vaccine?

- Adults 50 years of age and older who have not previously received a pneumococcal conjugate vaccine or whose previous vaccination history is unknown;
- Adults 19-49 years of age with certain underlying medical conditions or other risk factors who have not previously received a pneumococcal conjugate vaccine or whose previous vaccination history is unknown;
- Adults 19 years of age and older who have started their pneumococcal vaccine series with PCV13 (pneumococcal 13-valent conjugate vaccine) but have not received all recommended PPSV23 (pneumococcal 23-valent polysaccharide vaccine) doses.

https://www.merck.com/news/cdcs-acip-unanimously-recommends-mercks-capvaxive-pneumococcal-21-valent-conjugate-vaccine-for-pneumococcal-vaccination-in-appropriate-adults / accessed 08-10-2024

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65 years and older: 2024-2025 Season

- Give 2nd COVID Vaccine: 6 months after 1st injection

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Respiratory Syncytial Virus Vaccine, Adjuvanted

- Name: **RSV virus vaccine (Arexvy)**[20]
- Class: Vaccine
- Indication: Prevention of RSV in individuals 60 years of age and older
  - Newest indication: 50-59 years at increased risk of LRTD from RSV
- Efficacy: 24,966 participants
  - 82.6% efficacy against RSV-LRTD in adults 60 years and older
  - 94.6% efficacy against RSV-LRTD in adults 60 years and older with at least one comorbidity (i.e., CV or DM)
  - 94.1% efficacy against severe RSV-LRTD

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Respiratory Syncytial Virus Vaccine, Adjuvanted[20] (continued)

- Dose: 0.5 mL single dose; delivered IM; must be reconstituted
- C/I: Any allergies to active ingredient
- Caution: Syncope
- Adverse events
  - Injection site pain (60.9%)
  - Fatigue (33.6%)
  - Myalgia (28.9%)
  - Headache (27.2%)
  - Arthralgia (18.1%)

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Respiratory Syncytial Virus Vaccine, Adjuvanted[20] (continued)

- Additional information: CDC – Fully approved
  - Medicare Part D payment
  - One and done for now (3 years)…studies ongoing
- Additional studies underway
  - Influenza coadministration
  - Continued monitoring for Guillain-Barre and atrial fibrillation per FDA

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Respiratory Syncytial Virus Vaccine

- Name: **RSV virus vaccine (Abrysvo™)**[21]
- Class: Vaccine – Single dose
- Indication: Prevention of RSV in individuals 60 years of age and older
- Efficacy: Study 1: n=17,197 (vaccine) vs. n=17,186 (placebo)
  - First episode of RSV associated LRTD with 2 or more symptoms: 66.7%
  - First episode with 3 or more symptoms: 85.7%

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Respiratory Syncytial Virus Vaccine[21] (continued)

- Dose: 0.5 mL single dose; delivered IM; must be reconstituted
- C/I: Any allergies to active ingredient
- Caution: Syncope
- Adverse events
  - Injection site pain (10.5%)
  - Fatigue (15.5%)
  - Myalgia (10.1%)
  - Headache (12.8%)
  - Arthralgia (7.5%)

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Respiratory Syncytial Virus Vaccine[21] (continued)

- Additional information: FDA-approved
- Additional studies underway
  - When do we revaccinate
  - Continued monitoring for Guillain-Barre
- Information
  - Medicare Part D payment
  - One and done for now

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mRNA RSV vaccine approved

- Manufactured by Moderna
- mResvia is the trade name
- 60 years of age and older at risk of LRTD from RSV
- mRNA vaccine
- Currently available

https://news.modernatx.com/news/news-details/2024/Moderna-Receives-U.S.-FDA-Approval-for-RSV-Vaccine-mRESVIAR/default.aspx accessed 06-16-2024

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Latest CDC Update

- RSV vaccine:
  - Universal recommendation 75 years and older
  - Risk based recommendation: age 60 – 74 years

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What's Coming Soon

- First non-opioid pain reliever
  - Suzetrigine: Acute pain, anticipated in January 2025
- Gepotidacin: Uncomplicated UTIs, anticipated March 2025

https://www.goodrx.com/drugs/news/fda-top-new-approvals?label_override=undefined

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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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