Drug Update 2024: Newest medication approvals

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Disclosure

- Speaker Bureau
  - Sanofi-Pasteur, Merck, Pfizer, Seqirus, Moderna – Vaccines
  - AbbVie and Biohaven – Migraines
  - Idorsia – Insomnia
  - Exact Sciences – Colorectal Cancer Screening
  - AstraZeneca – Asthma and COPD
- Consultant
  - Sanofi-Pasteur, Merck, Pfizer, Moderna, and Seqirus – Vaccines
  - Idorsia – Insomnia
  - Shield Therapeutics – Iron Deficiency Anemia
- 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) 2023 Data[2]	Fifty-five novel medications were approved in 2023

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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

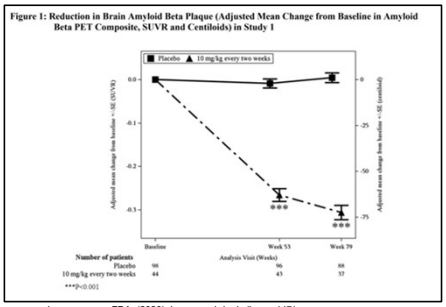

Image source: FDA. (2023). Lecanemab-irmb (Leqembi®). https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/761269Orig1s000lbl.pdf

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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.

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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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Zavegepant (Zavzpret™)[6]

- **Name: Zavegepant**
- Class: gepant (CGRP antagonist)
- Indication
  - Adults with acute migraine with and without aura
- Dose
  - 10 mg via a single spray into one nostril at the onset of migraine (Maximum dose in 24-hour period is 10 mg.)

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Zavegepant (Zavzpret™)[6] (continued)

- Efficacy
  - Two, double-blind, placebo-controlled trials
  - Study 1
    - N=623 (drug) and N=624 (placebo)
    - Pain free at two hours: 23.6% vs. 14.9% (p<0.001)
    - Most bothersome symptom free at 2 hours: 39.6% vs. 31.1% (p 0.001)
- Similar findings in Study 2
- Also looked at return to normal function, pain relief, sustained pain freedom at 48 hours

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Zavegepant (Zavzpret™)[6] (continued)

- Adverse events (drug vs. placebo)
  - Taste disorders (18% vs. 4%)
  - Nausea (4% vs. 1%)
  - Nasal discomfort (3% vs. 1%)
  - Vomiting (2% vs. <1%)

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Zavegepant (Zavzpret™)[6] (continued)

Drug Interactions

- Zavegepant is a 3A4 substrate but no significant interactions with 3A4 inhibitors or were inducers seen.

- OATP1B3 inhibitors
  - Coadministration with rifampin
    - Strong OATP1B3 inhibitor ***and***
    - 3A inducer resulted in an increase in AUC of Zavegepant 2.3-fold.

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Zavegepant (Zavzpret™)[6] (continued)

Drug Interactions (cont.)

- OATP1B3 inducers
  - Has not been studied however, may decrease AUC of Zavegepant
- Intranasal decongestants
  - May decrease the efficacy of Zavegepant
  - If absolutely needed, use 1-hour or more after Zavegepant.

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Zavegepant (Zavzpret™)[6] (continued)

- Precautions/contraindications
  - Avoid use in pregnancy and lactation.
    - Animal models did not demonstrate any issues, but inadequate safety data.
  - No indication in children
  - Avoid use in patients with severe hepatic impairment (no studies).
  - Avoid use in patients with creatinine clearance of <30 mL/min.
- Cost
  - $1,168.00 for 6 sprays (devices) per drugs.com

23

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Respiratory

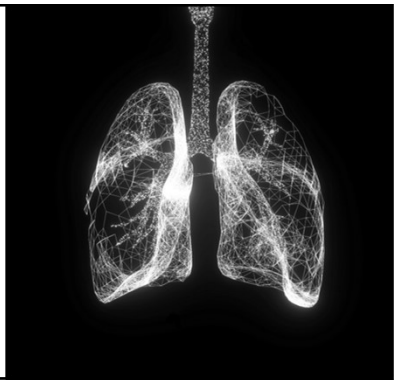

Image source: Microsoft stock image

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Albuterol and Budesonide Inhaler[7]

- Name: **Albuterol and budesonide (Airsupra™)**
- Class: SABA/ICS
- Indication: As needed treatment for acute bronchospasm or prevention of bronchospasm and to reduce the risk of acute asthma exacerbations in adults 18 years of age and older
- Dosage: 180 mcg of albuterol and 160 mcg of budesonide
  - Dosed: 2 puffs every 4 hours as needed
  - Do not exceed 6 doses (12 puffs) in 24 hours.

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Albuterol and Budesonide Inhaler[7] (continued)

- Adverse effects
  - Oral candidiasis: Should instruct to rinse mouth out.
  - Caution: DPI – Acute paradoxical bronchospasm
- Why a combination?
  - GINA and EPR4 recommend use of ICS whenever SABA is needed to prevent/reduce exacerbations and the need for systemic corticosteroids.
  - Provides ICS/SABA in one inhaler thus decreasing copays

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Albuterol and Budesonide Inhaler[7] (continued)

- Drug interactions
  - Budesonide
    - CYP450 3A4 substrate
    - Avoid strong 3A4 inhibitors as they may increase systemic exposure of budesonide.
- Not currently approved for children
- Will not be available until early 2024
- Canister will have a dosing counter on it to enable patient to see how many doses remain.
- Cost: Has not been announced

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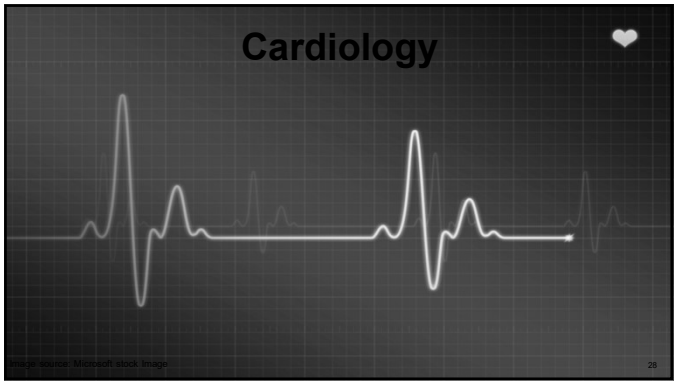

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Newest Agent

- **Inclisiran (Leqvio®)**[8]
  - Indication: Add on to maximally tolerated statin to lower LDL-C for adults with…
    - Heterozygous familial hypercholesterolemia
    - Atherosclerotic cardiovascular disease
    - Primary hyperlipidemia

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Inclisiran (continued)

LDQ

- Mechanism of action[8]
  - A small interfering RNA (siRNA) directed to PCSK9 mRNA
    - Works by increasing LDL-C receptor recycling and expression on the hepatocyte cell surface, which increases LDL-C uptake and lowers LDL-C levels in the circulation

- Dosage: 284 mg subcutaneous injection
  - Administered day 0, then day 3 months, then every 6 months
  - Administered by healthcare provider

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Slide 30

LD0 Wendy, on first pink bullet, left hand side- would it make sense to add 'chemically synthesized small" so that it reads "A chemically synthesized small interfering RNA..."?
Larlene Dunsmuir, 2023-07-26T17:21:02.208

Inclisiran[8] (continued)

- Efficacy (Study 1): Patients with hyperlipidemia and ASCVD already on maximally tolerated statin
  - Change from baseline was evaluated
    - LDL: 51% reduction
    - Total cholesterol: 34% reduction
    - Non-HDL-C: 47% reduction
    - ApoB: 45% reduction

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Inclisiran[8] (continued)

- Studies
  - 1,833 patients treated with inclisiran in clinical studies
    - 981 (54%) patients were 65 years of age and older
    - 239 (13%) patients were 75 years of age and older
    - No overall differences in safety or effectiveness were observed between patients 65 years of age and older and younger adult patients.

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Inclisiran[8] (continued)

- Adverse events (drug vs. placebo)
  - Injection site reaction (8% vs. 2%)
  - Arthralgia (5% vs. 4%)
  - Bronchitis (4% vs. 3%)

- Precautions/contraindications
  - Avoid in pregnant women (may cause fetal harm)
  - Avoid in lactation (no safety information available)
  - Avoid in pediatric patients
  - Has not been studied in severe liver or kidney disease
- Cost: $3,250.00 per dose

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Endocrinology

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Bexagliflozin (Brenzavvy™)[9]

- Class: SGLT2-I
- Indication: Adults with type 2 diabetes
  - No additional indication beyond diabetes currently
  - In pivotal trials: 10.1% receiving placebo experience Major Adverse Cardiovascular Events (MACE) vs. 7.9% receiving bexagliflozin

- Dosage: 20 mg once daily taken in the morning
  - Check GFR prior to starting medication.
  - Do not initiate in individuals with GFR <30 mL/min.

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Bexagliflozin (Brenzavvy™)[9] (continued)

- Efficacy (23 clinical trials performed)
  - Decrease in A1C from baseline (0.5% vs. placebo of 0.1%)
    - 31% of patients achieved A1C of <7% (0.07 proportion).
  - Trial 2: A1C decrease 1.0% vs. placebo of 0.5%
    - 26% achieved A1C of <7.0% (0.07 proportion)

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Slide 35

LD0 Wendy, do you want to spell out Major Adverse Cardiac Effects (MACE)?
Larlene Dunsmuir, 2023-07-26T19:09:54.777

WW0 0 done
Wendy Wright, 2023-07-26T21:03:14.857

Bexagliflozin (Brenzavvy™)[9] (continued)

- Adverse events (drug vs. placebo)
  - Increased urination: 7% vs. 3%
  - UTI: 6% vs. 4%
  - Female genital mycotic infections: 6% vs. 0%
  - Thirst: 3% vs. 2%

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Bexagliflozin (Brenzavvy™)[9] (continued)

- Precautions/warnings
  - Carries same warnings and precautions as all other SGLT2Is
  - Euglycemic DKA, genital mycotic infections, UTI/urosepsis, Fournier's gangrene, lower extremity amputations
  - Avoid use in pregnancy/lactation
  - Discontinue 3 days before any surgery.

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Bexagliflozin (Brenzavvy™)[9] (continued)

- Drug-drug interactions
  - No evidence of significant drug-drug interactions
- Cost: $47.85 for 30 days ***This will be the marketing tool.
- FYI: This will be the first SGLT2I approved for cats with diabetes.

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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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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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Tirzepatide (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

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

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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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Tirzepatide (continued)

- Adverse reactions (placebo, 5 mg, 10 mg, and 15 mg)
  - Nausea: (8%, 25%, 29%, 28%)
  - Diarrhea: (8%, 19%, 21%, 23%)
  - Vomiting: (2%, 8%, 11%, 13%)
  - Constipation: (5%, 17%, 14%, 11%)
- Cost: Approximately 1,400 for 4 weeks
  - Numerous copay cards are available online.

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

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Quick Updates and Additional Approvals

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Newer Agents

- gepirone ER (Exxua)
- Dosed once daily and indicated for MDD in adults only
  - 18.2 mg is starting dose with food; may increase to 36.3 mg on day 7
  - Maximum: 72.6 mg
- Perform ECG first and assess QT - do not initiate if QTc is > 450 msec
- Target of medication: serotonin 1A receptor
  - MOA: triggers release of serotonin and dopamine
  - Many of current medications do not engage the serotonin 1A receptor
- Drug interactions:
  - Reduce dose of gepirone by 50% if on a moderate CYP 3A4 inhibitor
  - Avoid in strong CYP 3A4 inhibitors

https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/021164s000lbl.pdf accessed 10-11-2023

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Newer Agents

- gepirone ER
- Efficacy:
  - Clinical trials involved 5000 patients
  - Statistically significant improvement on HAM-D; separation from placebo began approximately 2 weeks after starting medication
- Benefits:
  - Label does not include sexual dysfunction or weight gain
- Adverse events:
  - Nausea (35% vs. 13%) and dizziness (49% vs. 10%)
  - Carries same boxed warning as other antidepressants

https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/021164s000lbl.pdf accessed 10-11-2023

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What's Coming

- Zuranolone (Zurzuvae)
  - Postpartum depression
  - Class: neuroactive steroid (NAS) GABA-A receptor positive allosteric modulator (PAM)
  - 50 mg dose: once daily capsule for 14 days in the evening with a fatty meal
  - Waiting on DEA schedule
  - Improvement day 3 and lasted to day 42 of studies
  - Monitor for suicidality and sedation

https://www.drugs.com/zuranolone.html accessed 10/6/2023

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Norgestrel (Opill®)

- FDA voted in favor: RX – OTC switch
  - Progestin only, once daily oral contraceptive
  - Indication: Prevention of pregnancy
  - Awaiting final approval summer 2023 making pill available by end of 2023
    - **July 14, 2023: Approved by FDA. No released date of availability or cost.**

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Naloxone Nasal Spray (Narcan®)[12]

- Approved for OTC switch
- Available by end of summer 2023 in all states
- 4 mg nasal spray
- Safe to administer to adults, adolescents, and children

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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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Boxed Warning[13]

- All ADHD drugs
  - FDA statement: "Patients should never share their prescription stimulants with anyone, and the boxed warning will describe the risks of misuse, abuse, addiction, and overdose consistently for all medicines in the class."

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New Indication

- **Brexpiprazole (Rexulti®)**[14]
  - Agitation associated with Alzheimer's disease
  - Dosing
    - 0.5 mg on day 1–7
    - 1 mg on day 8–14
    - Recommended target dose: 2 mg
    - Maximum dose: 3 mg
    - Adverse effects: Headache, dizziness, sleep disturbances
    - Boxed warning remains in effect

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New Indications

- **Semaglutide (Wegovy®)**[15]
  - Approved 2.4 mg once weekly dosage for use in adolescents 12 years of age and older with obesity
  - Defined as
    - BMI at or above the 95th percentile for age and sex

- **Phentermine/topiramate (Qsymia®)**
  - Approved for 12 years of age and older with obesity

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Latest Updates[17]

- FDA has removed EUA for tixagevimab/cilgavimab (Evusheld™)
  - Previously used for individuals who were immunocompromised to prevent COVID-19

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Latest Updates[18] (continued)

- 2/2/2023: **Daprodustat (Jesduvroq®)** was approved for anemia of chronic kidney disease in patients on dialysis.
  - Hypoxia-inducible factor prolyl hydroxylase inhibitor (often referred to as HIF-PHI); increases intrinsic erythropoietin (EPO)
  - Oral agent
  - Competes with EPO products
  - Boxed warning: Thrombotic events

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Updated Indication

- **Atogepant (Qulipta™)**
  - New indication: Chronic migraine (15 or more migraine days per month)
  - Dose: 60 mg once daily
  - Class: CGRP antagonist
  - Efficacy begins within 1-week of starting medication.

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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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Immunizations

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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
- 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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Slide 65

RK0 Larlene/Sally: FYI, I cannot find if Arexvy is registered and/or trademarked. I am going to leave as is unless you can find. It maybe too new.
Renee Kirshner, 2023-07-24T16:16:33.722

LD0 0 Trademark application has been filed but not authorized yet.
Larlene Dunsmuir, 2023-07-26T20:37:44.521

Slide 66

RK0 What is C/I and should it be written out?
Renee Kirshner, 2023-07-24T18:54:48.016

LD0 0 Contraindications
Larlene Dunsmuir, 2023-07-26T20:38:22.701

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

- Additional information: CDC – Fully approved
  - Medicare Part D payment
  - One and done for now (2 years)…studies ongoing
- Additional studies underway
  - Influenza coadministration
  - 50–59 years of age
  - 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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RKO

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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Slide 69

RK0 Please see comment on slide 73 regarding C/I. Whatever decision there, I will include/not include here. Thanks
Renee Kirshner, 2023-07-24T18:56:21.527

Respiratory Syncytial Virus Vaccine[21] (continued)

- Additional information: FDA-approved
- Additional studies underway
  - ? Need for annual revaccination
  - Continued monitoring for Guillain-Barre
- Information
  - Medicare Part D payment
  - One and done for now

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RZV

- **Recombinant Zoster Vaccine (Shingrix®)**
- Approved by FDA for 18 years of age and older; immunocompromised
- Two dose series: Day 0 and day 1–2 months
- CDC: Now ages 19 years and up; immunocompromised

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New

- Universal hepatitis B vaccination for all unvaccinated adults aged 19–59 years
  - **Those with risk factors and aged 60 years and older should also be immunized against Hepatitis B.**
- PCV 15 may now be substituted in children for PCV 13.
- MCV4 (Menactra®) is being replaced by MenQuadFi®.

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PCV 20

- FDA has approved PCV 20 for children.
  - To be used in infants and children

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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.

Wendy L. Wright,
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WendyARNP@aol.com

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