NEW DRUGS: A GERIATRIC UPDATE

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Disclosure Statement

• Programming offered by Auburn University Harrison School of Pharmacy shall exhibit balance, providing the audience information of different perspectives from which to develop an informed professional opinion.
• I, Haley Phillipe, have no actual or potential conflict of interest in relation to this program.

Objectives

1. Describe indications, mechanism of action, dosage and administration, adverse effects, cost, and drug interactions for selected medications recently approved by the FDA
2. Discuss advantages and disadvantages of each agent compared to older medications
3. Review new dosage forms and first time generic medications
Antidiabetic Agents and Insulin

- Empagliflozin (Jardiance®—Boehringer-Ingelheim; Lilly)
- Albiglutide (Tanzeum™—GlaxoSmithKline)
- Dulaglutide (Trulicity™—Eli Lilly)
- Insulin Glargine (Toujeo® Solostar—Sanofi)

Empagliflozin (Jardiance)¹

- **Comparable Agents:** canagliflozin (Invokana), dapagliflozin (Farxiga)
- **Indication:** adjunct to diet and exercise in adults with T2DM
- **MOA:** sodium-glucose cotransporter 2 (SGLT2) inhibitors
  - Reduces the reabsorption of filtered glucose in the kidneys and increases urinary glucose excretion
- **Studied combinations:** metformin, glimepiride, pioglitazone, or insulin

- **Initial Dose:** 10 mg daily
- **Max Dose:** 25 mg daily
- **Renal Dosing:** Do not initiate and use caution if CrCl <45 mL/min; Contraindicated if CrCl <30 mL/min
- **ADRs:** UTIs, yeast infections (F>M), hypotension,
- **Warnings:** controversial risk of bladder cancer with class of drugs, ketoacidosis (FDA warning 5/2015)
- **Available Combination:** empagliflozin and linagliptin (Glyxambi)
Question 1
Which of the following patients would be the best candidate for empagliflozin therapy?
A. A 46 yof with T2DM, HTN, DLD, and renal impairment (CrCl ~ 30 ml/min)
B. A 64 yof with T2DM, HTN, DLD, and h/o of bladder cancer
C. A 32 yof with T2DM, HTN, DLD, and osteoarthritis
D. A 53 yof with T2DM, HTN, DLD, and h/o of UTIs

Albiglutide (Tanzeum)

- Comparable Agents: exenatide (Byetta, Bydureon) and liraglutide (Victoza)
- Indication: adjunct to diet and exercise for adults with T2DM, not first-line
- MOA: glucoagon-like peptide-1 (GLP-1) receptor agonist
  - Augment glucose-dependent insulin secretion and slows gastric emptying

Albiglutide (Tanzeum)

- Initial Dose: 30 mg once weekly SubQ
- Max Dose: 50 mg once weekly SubQ
- Renal Dosing: none available, use caution in renal impairment
- ADRs: GI, injection site reactions
- Warnings: acute pancreatitis, severe gastrointestinal disease (including gastroparesis)
- Contraindications: FH or personal h/o thyroid cancer—Boxed Warning, REMS program
Dulaglutide (Trulicity)³

- **Comparable Agents:** exenatide (Byetta, Bydureon) and liraglutide (Victoza), albiglutide (Tanzeum)
- **Indication:** adjunct to diet and exercise for adults with T2DM, not first-line
- **MOA:** glucagon-like peptide-1 (GLP-1) receptor agonist
  - Augment glucose-dependent insulin secretion and slows gastric emptying

Dulaglutide (Trulicity)³

- **Initial Dose:** 0.75 mg once weekly SubQ
- **Max Dose:** 1.5 mg once weekly SubQ
- **Renal Dosing:** none available, use caution in renal impairment
- **ADRs:** GI, fatigue, tachycardia, prolongation P-R interval
- **Warnings:** acute pancreatitis, severe gastrointestinal disease (including gastroparesis)
- **Contraindications:** FH or personal h/o thyroid cancer—Boxed Warning, REMS program

Question 2

2. Which of the following patients would be the best candidate for dulaglutide therapy?
   A. A 57 yom with T2DM, HTN, and gastroparesis
   B. A 76 yom with T2DM, HTN, DLD, and h/o of thyroid cancer
   C. A 31 yom with T1DM, HTN, DLD, and asthma
   D. A 71 yom with T2DM, HTN, DLD, and erectile dysfunction
### Insulin Glargine (Toujeo®)^

- **Comparable Agents**: insulin glargine (Lantus), insulin detemir (Levemir)
- **Indication**: patients with T1DM or T2DM
- **MOA**: long-acting insulin
- **Formulation**: pen only; contains 300 units/mL compared to 100 units/mL with Lantus or Levemir
- **Dosing**: similar to Lantus or Levemir

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### Bronchodilator

- Umeclidinium Bromide (Incruse Ellipta—GlaxoSmithKline)
- Olodaterol hydrochloride (Striverdi Respimat—Boehringer Ingelheim)

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### Umeclidinium Bromide/Vilanterol (Anoro Ellipta)^

- **Comparable Agents**: first of combination of LAMA and LABA
- **Indication**: long-term, maintenance treatment of COPD
- **MOA**: long-acting muscarinic antagonist (LAMA) plus long-acting beta₂-adrenergic agonist
Umeclidinium Bromide/Vilanterol (Anoro Ellipta)\(^5\)
- **Initial/Max Dose:** 1 inhalation once daily (umeclidinium 62.5 mcg/vilanterol 25 mcg)
- **ADRs:** anticholinergic symptoms, pharyngitis, diarrhea
- **Warnings:** avoid if severe hypersensitivity to milk proteins, concurrent use of beta blocker
- **Umeclidinium Bromide (Incruce Ellipta)—recent FDA approval for single agent (LAMA) inhaler**
  - [https://www.youtube.com/watch?v=Nx_JDTcmSeo](https://www.youtube.com/watch?v=Nx_JDTcmSeo)

Olodaterol hydrochloride (Striverdi Respimat)\(^6\)
- **Comparable Agents:** LABAs: salmeterol (Serevent), formoterol (Foradil), indacaterol (Arcapta)
- **Indication:** long-term, maintenance treatment of COPD
- **MOA:** long-acting \(\beta_2\)-adrenergic agonist

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Olodaterol hydrochloride (Striverdi Respimat)\(^6\)
- **Initial/Max Dose:** 2 inhalation once daily (5 mcg)
- **ADRs:** pharyngitis, skin rash, URTI, bronchitis, cough
- **Boxed Warnings:** increased asthma-related deaths if use LABA as monotherapy
- **Warnings:** paradoxical bronchospasm, may increase pulse rate and BP, prolong QT interval, hypokalemia, exacerbate seizure disorders, thyrotoxicosis
  - [https://www.youtube.com/watch?v=U1NV10RuV6Y](https://www.youtube.com/watch?v=U1NV10RuV6Y)
Question 3

3. Which of the following patients would be the best candidate for olodaterol hydrochloride therapy?
   A. A 54 yof with COPD (Gold Group C), currently taking albuterol PRN and tiotropium daily
   B. A 32 yof with asthma, currently taking albuterol PRN
   C. A 67 yom with COPD (GOLD Group B), currently taking albuterol PRN and salmeterol twice daily
   D. A 72 yom with COPD (Gold Group A), currently taking albuterol PRN

Question 4

4. Which of the following patient groups would umeclidinium bromide/vilanterol be appropriate per the GOLD guidelines?
   A. GOLD patient group A
   B. GOLD patient group B
   C. GOLD patient group C
   D. GOLD patient group D

Antidepressant

• Vortioxetine hydrobromide (Brintellix—Takeda)
Vortioxetine hydrobromide (Brintellix)

- **Indication:** Major depressive disorder
- **MOA:** inhibits serotonin reuptake, agonist/partial agonist for 5-HT1A/5-HT1B, and antagonist at 5-HT3, 5-HT1D/5-HT1D7 receptors
- **DDIs:** linezolid, MAOIs
- **Initial Dose:** 10 mg once daily
- **Max Dose:** 20 mg once daily

Vortioxetine hydrobromide (Brintellix)

- **Renal Dosing:** No adjustment needed
- **ADRs:** GI, sexual dysfunction
- **Boxed Warnings:** increased risk of suicidal thinking and behavior
- **Warnings:** increased bleeding risk, increased CNS depression, increased bone fracture risk, serotonin syndrome, long-term lead to narrow-angle glaucoma

Erectile Dysfunction

- Avanafil (Stendra—Auxilium;Vivus)
**Avanafil (Stendra)**

- **Comparable Agents:** sildenafil (Viagra), tadalafil (Cialis), and vardenafil (Levitra)
- **Indication:** erectile dysfunction
- **MOA:** phosphodiesterase type 5 (PDE5) inhibitor

- **Initial Dose:** 100 mg once every 24 hours as needed
- **Max Dose:** 200 mg once every 24 hours as needed
- **Renal Dosing:** avoid if CrCl < 30 mL/min
- **ADRs:** hypotension, dizziness, headache, flushing, hearing loss, optic neuropathy
- **Warnings:** avoid use with any nitrate (nitroglycerin), avoid alcohol intake, avoid in patients with pre-existing CV disease, hypotension, priapism (>6 hrs), vision loss

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**Menopause-Associated Conditions**

- Estrogens (conjugated/equine) plus bazedoxifene acetate (Duavee—Pfizer)
Estrogens (conjugated/equine) plus bazedoxifene acetate (Duavee)

- **Comparable Agents:** first to include estrogen agonist/antagonist instead of progestin. Bazedoxifene similar to Evista or Osphena.
- **Indication:** women with a uterus for the treatment of moderate-to-severe vasomotor symptoms associated with menopause, and for the prevention of postmenopausal osteoporosis
- **MOA:** estrogen agonist/antagonist, selective estrogen receptor modulator (SERM)

**Dose:** one tablet daily

- **ADRs:** muscle spasms, GI, upper abdominal pain, oropharyngeal pain, neck pain, dizziness
- **Contraindications:** undiagnosed abnormal uterine bleeding, risk or h/o breast cancer, estrogen-dependent neoplasia, h/o thromboembolism, any thrombophilic disorder, known hepatic disease
- **Boxed Warnings:** endometrial cancer, CVD, dementia

Antipsoriatic Agent

- Secukinumab (Cosentyx—Novartis)
Secukinumab (Cosentyx)\textsuperscript{10}

- **Indication:** Plaque psoriasis

- **MOA:** IgG1 monoclonal antibody that selectively binds to the interleukin-17A (IL-17A) cytokine and inhibits its interaction with the IL-17 receptor
  - Inhibits the release of proinflammatory cytokines and chemokines

- **Comparable Agents:** Stelara (ustekinumab)

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**Secukinumab (Cosentyx)**\textsuperscript{10}

- **Dosing:** SubQ 300 mg once weekly at weeks 0, 1, 2, 3, and 4 followed by 300 mg every 4 weeks.

- **Renal Dosing:** not studied in renal impairment

- **ADRs:** Infection, nasopharyngitis, GI

- **Warnings:** Urticaria and anaphylaxis, increased risk of infections, avoid in patients with TB, may exacerbate Crohns, may contain latex, must be up-to-date with all vaccines prior to receiving

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**Cardiology/Vascular Diseases**

- **Ivabradine (Corlanor – Amgen)**
Ivabradine (Corlanor)¹¹

- **Indication:** Heart Failure
- **MOA:** inhibition of the hyperpolarization-activated cyclic nucleotide-gated (HCN) channels (I_{f}-channels) within the SA node
- **Initial Dose:** 2.5 to 5 mg twice daily with food
- **Max Dose:** 7.5 mg twice daily with food

Ivabradine (Corlanor)¹¹

- **Renal Dosing:** avoid if CrCl <15 mL/min
- **Hepatic Dosing:** avoid if Child-Pugh class C
- **ADRs:** HTN, AFIB, bradycardia, visual brightness
- **Contraindications:** ADHF, hypotension, third-degree AV block, HR < 60 bpm, pacemaker dependence, sick sinus syndrome
- **Warnings:** increased risk of AFIB, bradycardia, visual changes

Question 5

- 5. Which of the following patients would be the best candidate for ivabradine therapy?
  - A. A 76 yom with unstable heart failure
  - B. An 83 yom with stable heart failure, EF ~ 20%, resting HR 62 bpm, taking metoprolol succinate 100 mg daily
  - C. A 62 yof with stable heart failure, EF ~25%, resting HR 86 bpm, currently taking metoprolol succinate 100 mg daily
  - D. A 74 yof with stable heart failure, EF ~30%, resting HR 83 bpm, currently taking metoprolol succinate 200 mg daily
### New Dosage Forms
- Duopa (carbidopa/levodopa) – Enteral formulation
- Rytary (carbidopa/levodopa) – New ER capsule
- Prestalia (perindopril/amlodipine) – New combination

### First Time Generics—Now Available
- Celecoxib (Celebrex)
- Amlodipine/valsartan/HCTZ (Exforge HCT)
- Lamotrigine ODT (Lamictal ODT)
- Esomeprazole DR (Nexium)
- Linezolid (Zyvox)
- Testosterone transdermal gel (Testim)

### First Time Generics—upcoming
- Colesevelam (Welchol) – 2nd Quarter 2015
- Aripiprazole (Abilify) – 2nd Quarter 2015
- Oxybutynin transdermal patch (Oxytrol) – 2nd Quarter 2015
- Memantine (Namenda) – 3rd Quarter 2015
- Mesalamine DR (Asacol HD) – Fourth Quarter 2015
- Dutasteride (Avodart) – November 2015
- Dutasteride/tamsulosin (Jalyn) – November 2015
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