Drug Update 2019:
What's Hot and What's Not?

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Disclosures

- Speaker Bureau: Sanofi-Pasteur, Merck, Pfizer
- Consultant: Sanofi-Pasteur, Pfizer, Merck, GlaxoSmithKline

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Objectives

- Upon completion of this learning activity, the participant will be able to:
  - Identify 5 – 10 new medications
  - Discuss the use, side effects, drug-drug interactions, and benefits of each of the medications
  - Discuss updates related to labeling, indications, risks associated with various medications

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New Drugs

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2018: What Happened?

61 medications approved by the FDA in 2018
(Rare diseases: 51%)
Average: 28 between 2006 – 2014
Only 7 – 8 medications for primary care

https://www.fda.gov/Drugs/DevelopmentApprovalProcess/DrugInnovation/ucm537040.htm accessed 1-4-2019

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Respiratory

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Revefenacin (Yupelri)

- Indication:
  - Maintenance of patient with chronic obstructive pulmonary disease (COPD)
- Class:
  - Anticholinergic (Long-acting muscarinic antagonist - LAMA)
  - Inhibits M3 receptor at the smooth muscle leading to bronchodilation
- Dosage:
  - 175 mcg/3 mL solution
  - Inhalation solution via nebulizer

https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=6dfebf04-7c90-436a-9b16-750d3c1ee0a6&type=display accessed 01-02-2019

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Revefenacin

- Warnings and precautions:
  - Not indicated for acute symptoms
  - Paradoxical bronchospasms
  - Worsening of narrow angle glaucoma
  - Worsening of urinary retention
  - Hepatic impairment: Avoid use in these patients
  - Not studied in pregnancy or lactation
- Contraindications:
  - Known allergy or hypersensitivity to ingredients

https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=6dfebf04-7c90-436a-9b16-750d3c1ee0a6&type=display accessed 01-02-2019

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Revefenacin

- Efficacy:
  - 2,285 subjects with COPD in two 12-week efficacy studies
  - One 52-week long-term safety study
  - Demonstrated significant change in FEV1 and an improvement in St. Georges Respiratory Questionnaire compared with placebo

https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=6dfebf04-7c90-436a-9b16-750d3c1ee0a6&type=display accessed 01-02-2019

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Revefenacin

- Drug – Drug Interactions:
  - Anticholinergics
  - Coadministration of revefenacin with OATP1B1 and OATP1B3 inhibitors (e.g. rifampin, cyclosporine, etc.) may lead to an increase in exposure of the active metabolite
    - Increased side effects from revefenacin

https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=6dfebf04-7c90-436a-9b16-750d3c1ee0a6&type=display accessed 01-02-2019

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Revefenacin

- Side effects:
  - Cough (4% vs. 4%), nasopharyngitis (4% vs. 2%), upper respiratory tract infection (3% vs. 2%), headache (4% vs. 3%), and back pain (2% vs. 1%)
- Advantages
  - No dosing adjustment needed for older adults
  - No dosing adjustment needed for individuals with renal impairment

https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=6dfebf04-7c90-436a-9b16-750d3c1ee0a6&type=display accessed 01-02-2019

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Revefenacin

- Competition:
  - Glycopyrrolate inhaled (Lonhala Magnair)
  - All other LAMAs (different delivery mechanism)

https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=6dfebf04-7c90-436a-9b16-750d3c1ee0a6&type=display accessed 01-02-2019

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Women's Health

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Segesterone acetate and ethinyl estradiol vaginal system (Annovera)

- Indication:
  - Prevention of pregnancy for up to one year
  - Soft, reusable flexible silicone ring (2 ¼ inches diameter) that can be inserted and removed by a woman
  - Left in place for 21 days and removed for 7 days
- Class:
  - Progesterone/estrogen vaginal contraceptive system

http://www.annovera.com/pi.pdf accessed 01-02-2019

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Segesterone acetate and ethinyl estradiol vaginal system

- Warnings and precautions:
  - Carries all of the same warnings and precautions as estrogen/progesterone containing hormonal contraception
  - Not adequately evaluated for efficacy in women with BMI > 29 kg/m^2

http://www.annovera.com/pi.pdf accessed 01-02-2019

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Segesterone acetate and ethinyl estradiol vaginal system

- Contraindications:
  - Women over age 35 who smoke or have migraine with or without aura
  - Women who have migraine with aura (any age)
  - Women with breast cancer or history of breast cancer
  - Women with history of DVT
  - Unexplained vaginal bleeding
  - Pregnancy
  - Liver tumors and / or decompensated cirrhosis

http://www.annovera.com/pi.pdf accessed 01-02-2019

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Segesterone acetate and ethinyl estradiol vaginal system

- Efficacy:
  - 17 clinical trials, including two pivotal Phase 3 safety and efficacy trials
  - 2,308 women across 27 study sites
  - 97.3% effective in preventing pregnancy when used as directed
- Drug – Drug Interactions:
  - Certain Hepatitis C medications (rare elevated liver enzymes) – examples - ombitasvir/ritonavir

http://www.annovera.com/pi.pdf accessed 01-02-2019

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Segesterone acetate and ethinyl estradiol vaginal system

- Side effects:
  - Headache (38.6%)
  - Nausea (25.0%)
- Advantages:
  - One year of efficacy
  - Female controlled
  - Not implanted but easily removable

http://www.annovera.com/pi.pdf accessed 01-02-2019

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Segesterone acetate and ethinyl estradiol vaginal system

- Competition:
  - No similar products
- Education:
  - Insert on day 2 – 5 of menstrual cycle; no back-up method needed
  - If more than 5 days from LMP, back-up method for 7 days is recommended
  - If already on CHC, can change to this on any day of her cycle (day 0 – 28) with no back-up required

http://www.annovera.com/pi.pdf accessed 01-02-2019

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Availability

- 3rd quarter of 2019
- Pricing is not yet available for this product

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Levonorgestrel-releasing Intrauterine system (Liletta)

- 52 mg
- Prevention of pregnancy for up to 5 years
- Was 4 years previously and has been on the market since February 2015
- Competition: Skyla, Mirena, Kyleena

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Gastroenterology

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Prucalopride (Motegrity)

- Indication:
  - Treatment of chronic idiopathic constipation (CIC) in adults
- Class:
  - Serotonin-4 (5-HT4) receptor agonist
  - Gastrointestinal prokinetic agent that stimulates colonic peristalsis and increases bowel motility

https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/210166s000lbl.pdf
Accessed 01-04-2019

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Prucalopride

- Dosage:
  - 2 mg once daily
  - With or without food
- Warnings and precautions:
  - Renal dosing (CCl < 30 mL/min) : 1 mg once daily
  - Monitor patients for persistent worsening of depression and emergence of suicidal thoughts and behavior
  - Pregnancy, Lactation, and Children
- Contraindications:
  - Intestinal perforation or obstruction due to structural or functional disorder of the gut wall, obstructive ileus, severe inflammatory conditions of the intestinal tract such as Crohn's disease, ulcerative colitis, and toxic megacolon/megarectum

https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/210166s000lbl.pdf
Accessed 01-04-2019

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Prucalopride

- Efficacy:
  - 2530 patients enrolled in clinical trials
    - 1251 received drug/1279 placebo
  - Responder was defined as a patient with an average of 3 or more CSBMs per week, over the 12-week treatment period
    - 33% vs. 10% and 38% vs. 18% (5 of 6 studies stat. significant)
- Drug – Drug Interactions:
  - No significant drug-drug interactions

https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/210166s000lbl.pdf
Accessed 01-04-2019

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Prucalopride

- Side effects (Drug/placebo):
  - Headache (19% vs. 9%)
  - Abdominal pain (16% vs. 11%)
  - Nausea (14% vs. 7%)
  - Diarrhea (13% vs. 5%)
  - Dizziness (4% vs. 2%)
  - Vomiting (3% vs. 2%)
- Advantages:
  - Another option to the market
  - No QT prolongation

https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/210166s000lbl.pdf
Accessed 01-04-2019

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Prucalopride

- Competition:
  - No direct competition
  - Tegaserod (Zelnorm) – 5-HT4 receptor agonist withdrawn from the market in 2007
  - Cisapride (also withdrawn from the market)

https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/210166s000lbl.pdf
Accessed 01-04-2019

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Infectious Disease

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Baloxavir marboxil (Xofluza)

- Indication:
  - Treatment of acute, uncomplicated influenza in patients aged ≥ 12 years who have been symptomatic for no more than 48 hours
- Class:
  - Polymerase acidic (PA) endonuclease inhibitor
    - Inhibits influenza virus replication

https://www.gene.com/download/pdf/xofluza_prescribing.pdf accessed 01-02-2019

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Baloxavir marboxil

- Dosage:
  - 20 mg and 40 mg dosages available
  - Weight based:
    - 40 kg to < 80 kg: Single dose of 40 mg
    - ≥ 80 kg: 80 mg dose
  - With or without food
  - Avoid co-administration with dairy products, calcium-fortified beverages, polyvalent cation-containing laxatives, antacids, or oral supplements

https://www.gene.com/download/pdf/xofluza_prescribing.pdf accessed 01-02-2019

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Efficacy

- Primary endpoint of both trials was:
  - Time to alleviation of symptoms,
    - Time when all seven symptoms (cough, sore throat, nasal congestion, headache, feverishness, myalgia, and fatigue) had been assessed by the subject as none or mild for a duration of at least 21.5 hours
  - Results Trial 1: 50 hours vs. 78 hours (placebo)
  - Results Trial 2: 54 hours vs. 80 hours (placebo)
  - Also looked at oseltamivir comparison: No difference between oseltamivir and baloxavir marboxil

https://www.gene.com/download/pdf/xofluza_prescribing.pdf accessed 01-02-2019

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Baloxavir marboxil

- Warnings and precautions:
  - Limited data on pregnancy and lactation
- Contraindications:
  - Known hypersensitivity to one of the ingredients

https://www.gene.com/download/pdf/xofluza_prescribing.pdf accessed 01-02-2019

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Baloxavir marboxil

- Side effects:
  - Diarrhea (3%), bronchitis (2%), nasopharyngitis (1%), headache (1%) and nausea (1%)
- Advantages
  - Unique mechanism of action
  - Single dose, oral medication
  - Targets influenza A and B, including those resistant to oseltamivir and avian strains
  - Well-tolerated

https://www.gene.com/download/pdf/xofluza_prescribing.pdf accessed 01-02-2019

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Baloxavir marboxil

- Competition:
  - Oseltamivir
- Cost:
  - $150.00
  - Have found coupons on-line for no more than $30.00

https://www.gene.com/download/pdf/xofluza_prescribing.pdf accessed 01-02-2019

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Omadacycline (Nuzyra)

- Indication:
  - Community-acquired bacterial pneumonia (CABP)
  - Acute bacterial skin and skin structure infections
- Class:
  - Tetracycline class antibacterial

https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/209816_209817lbl.pdf accessed 01-04-2019

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Omadacycline

- Dosage:
  - 150 mg tablets
  - CABP: 300 mg once daily
  - ABSSSI: 450 mg once daily x 2 days; then 300 mg thereafter
  - Treat x 7 – 14 days
  - Fast for at least 4 hours and then take tablets with water.
  - After oral dosing, no food or drink (except water) is to be consumed for 2 hours

https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/209816_209817lbl.pdf accessed 01-04-2019

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Omadacycline

- Warnings and precautions:
  - Mortality Imbalance in Patients with CABP: In the CABP trial, mortality rate of 2% was observed in omadacycline-treated patients compared to 1% in moxifloxacin-treated patients.
  - The cause of the mortality imbalance has not been established. Closely monitor clinical response to therapy
- Contraindications:
  - Known hypersensitivity or allergy to one or more of the ingredients
  - Pregnancy and lactation

https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/209816_209817lbl.pdf accessed 01-04-2019

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Omadacycline

- Efficacy:
  - Clinical success at the early clinical response (ECR) timepoint, 72 to 120 hours after the first dose, was defined as
    - Survival with improvement in at least two of four symptoms (cough, sputum production, chest pain, dyspnea) without deterioration in any of these four symptoms
  - CABP: 81.1% vs. 82.7% (moxifloxacin)
  - ABSSSI: 84.8% vs. 85.5% linezolid (Zyvox)
    - 20% decrease in lesion area/size, no other treatments needed

https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/209816_209817lbl.pdf accessed 01-04-2019

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Omadacycline

- Drug – Drug Interactions:
  - Patients who are on anticoagulant therapy may require downward adjustment of their anticoagulant dosage while taking omadacycline
  - No dairy products, antacids, or multivitamins for 4 hours

https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/209816_209817lbl.pdf accessed 01-04-2019

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Omadacycline

- Side effects (2% – 4%)
  - Nausea (21.9%), vomiting (11.4%), alanine aminotransferase increased, aspartate aminotransferase increased, gamma-glutamyl transferase increased, hypertension, headache, diarrhea, insomnia, and constipation
- Advantages:
  - Once daily oral tetracycline
  - Also available in an IV formulation

https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/209816_209817lbl.pdf accessed 01-04-2019

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Omadacycline

- Competition:
  - Doxycyline hyclate
- Availability:
  - First quarter of 2019
  - Awaiting pricing

https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/209816_209817lbl.pdf accessed 01-04-2019

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Rifamycin (Aemcolo)

- Indication:
  - Treatment of adult patients with Travelers' Diarrhea caused by non-invasive strains of *Escherichia coli*
- Class:
  - Rifamycin antibacterial
  - Inhibits DNA replication and therefore inhibits new bacterial growth

https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/210910s000lbl.pdf Accessed 01-04-2019

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Rifamycin

- Dosage:
  - Available in 194mg delayed-release tablets
  - 388 mg (two tablets) orally twice daily for three days
  - Take each dose with a glass of liquid
  - With or without food
- Warnings and precautions:
  - Do NOT take concomitantly with alcohol
  - Do no crush or cut tablets
  - Not studied in pregnancy or lactation
- Contraindications:
  - Known allergy to any of the ingredients

https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/210910s000lbl.pdf
Accessed 01-04-2019

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Rifamycin

- Efficacy:
  - The endpoint of clinical cure was defined as two or fewer soft stools and minimal enteric symptoms at the beginning of a 24-hour period or no unformed stools at the beginning of a 48-hour period
    - Clinical cure: 81.4% vs. 56.9% (Placebo)
  - 22-hour difference in duration of the symptoms with the drug compared to placebo
  - Was not shown to be effective in patients with diarrhea complicated by fever and/or bloody stool or diarrhea due to pathogens other than noninvasive strains of E. coli and is not recommended for use in such patients

https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/210910s000lbl.pdf
Accessed 01-04-2019

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Rifamycin

- Drug – Drug Interactions:
  - Not studied but none anticipated
- Side effects:
  - Headache (3.3%)
  - Constipation (3.5%)
- Advantages:
  - Only product approved to treat travelers diarrhea in more than 10 years

https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/210910s000lbl.pdf
Accessed 01-04-2019

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Rifamycin

- Competition:
  - Rifaximin (Xifaxin - 600.00 for 30 days)
  - Azithromycin
  - Ciprofloxacin
- Availability:
  - PRICING NOW AVAILABLE: $144 - $145.00
  - Likely to be priced less than rifaximin

https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/210910s000lbl.pdf Accessed 01-04-2019

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Miscellaneous

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Galcanezumab (Emgality)

- Indication:
  - Once monthly preventive treatment for adults with migraine
- Class:
  - CGRP inhibitor
  - Humanized IgG4 monoclonal antibody
  - Galcanezumab-gnlm is produced in Chinese Hamster Ovary (CHO) cells by recombinant DNA technology

http://uspl.lilly.com/emgality/emgality.html#section-2 accessed 01-04-2018

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Galcanezumab

- Dosage:
  - 120 mg/ML prefilled pen
  - Subcutaneous, self-administration
  - 240 mg (2 injections given at same time) x 1 followed by 120 mg once monthly
- Warnings and precautions:
  - Has not been studied in pregnancy and lactation
- Contraindications:
  - Known hypersensitivity to any of the ingredients

http://uspl.lilly.com/emgality/emgality.html#section-2 accessed 01-04-2018

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Galcanezumab

- Efficacy:
  - 2586 patients with migraine
  - Studied for 6 and 12 months
  - Primary efficacy endpoint was the mean change from baseline in the number of monthly migraine headache days over the 6-month treatment period
    - Mean headache days per month: 9.2 days – decreased by 4.7 days (placebo 9.1 decreased by 2.8 days)

http://uspl.lilly.com/emgality/emgality.html#section-2 accessed 01-04-2018

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Galcanezumab

- Additional Efficacy vs. placebo:

≥50% Migraine Headache Days Responders (over Months 1 to 6)				
% Responders*	62%	39%	59%	36%
≥75% Migraine Headache Days Responders (over Months 1 to 6)				
% Responders*	39%	19%	34%	18%

http://uspl.lilly.com/emgality/emgality.html#section-2 accessed 01-04-2018

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Galcanezumab

- Drug – Drug Interactions:
  - No drug-drug interaction studies but significant interactions are not expected
- Side effects:
  - Injection site reactions: (18% vs. 13%)
- Advantages:
  - Another option to the market

http://uspl.lilly.com/emgality/emgality.html#section-2 accessed 01-04-2018

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Galcanezumab

- Competition:
  - Fremanezumab (Ajovy)
  - Erenumab (Aimovig)
- Needs to be stored in refrigerator
- Once out, may be kept out of the refrigerator for up to 7 days

http://uspl.lilly.com/emgality/emgality.html#section-2 accessed 01-04-2018

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Migraines

- Fremanezumab (Ajovy)
  - Approved for the prevention of migraine
  - Subcutaneous injection
  - Once monthly or once every 3 month option (Provider or patient administered)
  - 225mg/1.5mL strength
  - Dosage: 675mg every 3 months or 225mg monthly

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Lofexidine (Lucemyra)

- Indication:
  - Mitigation of opioid withdrawal symptoms to facilitate abrupt discontinuation in adults
- Class:
  - Central alpha-2 agonist that binds to adrenergic receptors
  - Reduces release of norepinephrine and sympathetic tone

https://lucemyra.com/LUCEMYRA-PI.pdf accessed 01-04-2019

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Lofexidine

- Dosage:
  - Initially: 3 tablets 4 x per day; up to 14 days
  - May increase to 4 tablets 4x per day
  - Maximum daily dosage: 2.88 mg (16 tabs)
  - Discontinue gradually by tapering 1 tab/dose every 1-2 days
  - Dose adjustments are recommended for both moderate – severe liver and kidney disease

https://lucemyra.com/LUCEMYRA-PI.pdf accessed 01-04-2019

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Lofexidine

- Warnings and precautions
  - Bradycardia, hypotension, syncope
  - Avoid in severe CAD, recent MI, CVD, Chronic renal failure, those with bradycardia, or prolonged QT
- Contraindications:
  - NONE

https://lucemyra.com/LUCEMYRA-PI.pdf accessed 01-04-2019

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Lofexidine

- Efficacy:
  - Two clinical trials (n = 866 patients total)
  - Two endpoints were: mean Short Opiate Withdrawal Scale of Gossop (SOWS-Gossop) total score on Days 1 – 7 of treatment and the proportion of patients that completed 7 days of treatment
    - 28% of placebo patients, 41% on 2.16 mg, and 40% on 2.88 mg patients completed 7 days of treatment
    - Statistically significant difference in SOWS-Gossop scales between medication and placebo

https://lucemyra.com/LUCEMYRA-PI.pdf accessed 01-04-2019

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Lofexidine

- Drug – Drug Interactions:
  - Concomitant Methadone: increased QT prolongation
  - Benzodiazepines: can potentiate CNS depressant effects
  - CYP2D6 inhibitors: lofexidine is potentiated by these medications (i.e. paroxetine)
  - Oral naltrexone: concomitant use may reduce efficacy of oral naltrexone

https://lucemyra.com/LUCEMYRA-PI.pdf accessed 01-04-2019

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Lofexidine

- Side effects (2.16 mg vs. 2.88 mg vs. placebo):
  - Hypotension (29% vs. 42% vs. 5% placebo)
  - Bradycardia (24% vs. 32% vs. 5% placebo)
  - Syncope (0.9% vs. 1.4% vs. 0% placebo)
  - Dry mouth
  - Sedation
  - Diarrhea
- Advantages

https://lucemyra.com/LUCEMYRA-PI.pdf accessed 01-04-2019

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Lofexidine

- Competition:
  - Clonidine
  - Guanfacine
- 96 tablets (18 mg)
  - $1980.00

https://lucemyra.com/LUCEMYRA-PI.pdf accessed 01-04-2019

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Quick Updates

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Aspirin

- Three studies in healthy older adults did NOT show benefit from 100 mg of aspirin daily
- Was associated with an increased risk of bleeding

New England Journal of Medicine; September 16, 2018
https://www.nejm.org/doi/full/10.1056/NEJMoa1800722

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Prazosin

- Dosage: 4 mg in the morning, 4 mg in the afternoon, and 8 mg at bedtime may decrease alcohol consumption in alcohol abusers
- Prazosin may reduce the likelihood of heavy drinking and the number of drinks per week over time but not the number of drinking days per week
- 3.5 mmHg blood pressure reduction in the treatment group across the 12-week study

https://www.medscape.com/viewarticle/901690?nlid=124744_2048&src=WNL_mdplsnews_180914_mscpedit_imed&uac=45241HZ&spon=18&impID=1739247&faf=1

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Important Updates

- Rivaroxaban (Xarelto)
  - Reduce risks of major CV events in patient with PAD or CAD
- Canagliflozin (Invokana)
  - Indication: reduce risk of major CV events in patients with Type 2 diabetes who have established CV disease

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Glucopyrronium (Qbrexza)

- Treatment of primary axillary hyperhidrosis in children 9 years of age and older and adults
- Single-use cloth
- Anti-cholinergic
- Apply once every 24 hours to axillary regions

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Warnings

- Additional warnings attached to fluoroquinolones:
  - Severe hypoglycemia; fifty-six reports of hypoglycemic coma associated with fluoroquinolone use were identified in FAERS from October 1987 to April 2017
  - Increased risk of aortic aneurysm and dissection
  - Use is associated with a non-negligible increased risk of gastrointestinal (GI) perforation

https://www.empr.com/news/fluoroquinolone-gastrointestinal-perforation-gi/article/689196/ accessed 01-04-2019

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New Combination Medications

- Dapagliflozin & Saxagliptin (Qtern)
  - SGLT2 (Faxiga)
  - DPP4 (Onglyza)
- Ertugliflozin & sitaliptin (Seglujan)
  - SGLT2 (Steglatro)
  - DPP4 (Januvia)

wwww.eMPR.com/news accessed January 2019

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Warnings

- SGLT2s
  - Fourniers gangrene:
  - Extremely rare but life-threatening bacterial infection of the tissue under the skin that surrounds muscles, nerves, fat, and blood vessels of the perineum.
  - In the five years from March 2013 to May 2018, 12 cases in patients taking an **SGLT2** inhibitor reported to the FDA.

https://www.google.com/search?q=SGLT2+fourniers+gangrene&oq=SGLT2+fourniers+gangrene&aqs=chrome..69i57j0.5723j0j8&sourceid=chrome&ie=UTF-8

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OTC Option

- Epinephrine inhalation aerosol bronchodilator suspension (Primatine MIST) for the temporary relief of mild symptoms of intermittent asthma (eg, wheezing, tightness of chest, shortness of breath) in patients aged ≥12 years
- Launch: first quarter of 2019

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Additional Pediatric Indication

- Sweet Vernal, Orchard, Perennial Rye, Timothy, Kentucky Blue Grass Mixed Pollens Extract (Oralair)
  - Indication previously: 10 – 65 years
  - Additional indication: 5 – 9 years
- Sublingual tablet:
  - 100 and 300 mg

wwww.eMPR.com/news accessed January 2019

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Available

- Desmopressin acetate (Nocdurna)
  - Sublingual tablets
  - Indication: Nocturia due to nocturnal polyuria
  - Class: vasopressin analog
  - Dose: 27.7 or 53.3 mcg sublingual tablets

wwww.eMPR.com/news accessed January 2019

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Immunizations

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HPV9

- Expanded indication:
  - Men and women ages 27 – 45 years
  - Three dose series
  - Day 0, day 2 months, and day 6 months
  - Awaiting February 2019 ACIP meeting for recommendations

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Hexavalent Pediatric Vaccine Approved

- Vaxelis:
  - diphtheria and tetanus toxoids and acellular pertussis adsorbed, inactivated poliovirus, haemophilus b conjugate [meningococcal protein conjugate] and hepatitis B [recombinant] vaccine
    - Active immunization in children aged 6 weeks through 4 years (prior to the 5th birthday)
    - 3-dose series given at 2, 4, and 6 months of age
  - It may be used to complete the hepatitis B series
  - The 3-dose series does not constitute a primary immunization series against pertussis; an additional dose of pertussis-containing vaccine is needed to complete the primary series

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RZV (Shingrix)

- Vaccine
  - Herpes zoster vaccine Ages 50 years and older
  - Non-live vaccination
  - 90% efficacy (independent of age 50 - > 80 years)
  - Sustained efficacy over 4 years
  - Two dose vaccine
  - Day zero and day 2 months – 6 months

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October 2017

- Herpes zoster
  - Available but on back order
  - Now preferred over previous herpes zoster vaccine (Zostavax)
  - All individuals who have received previous vaccine should receive this vaccine
  - Age dropped to 50 years of age to align with the FDA approval for vaccination

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October 2018

- All persons aged 1 year and older who experience homelessness should be routinely immunized against Hepatitis A

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ACIP Vote

- Live intranasal influenza vaccine (Flumist quadrivalent) has been approved for use and will return for the 2018 – 2019 influenza season

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Thank you!
I would be happy to entertain any questions or comments

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