Drug Update 2020: What's Hot and What's Not?

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Disclosures

- Speaker Bureau: Sanofi-Pasteur, Merck, Pfizer, Allergan
- Consultant: Sanofi-Pasteur, Pfizer, Merck, GlaxoSmithKline, Gilead
- I will not discuss off-label medication uses or investigational use in my presentation.

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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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2019: What Happened?

48 medications approved by the FDA in 2019

7 – 8 of these medications will be used in primary care

Average: 28 between 2006 – 2014

https://www.fda.gov/drugs/new-drugs-fda-cders-new-molecular-entities-and-new-therapeutic-biological-products/novel-drug-approvals-2019

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Respiratory

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Aclidinium bromide and Formoterol fumarate (Duaklir Pressair)

- Indication:
  - Maintenance treatment of COPD
  - Not indicated for acute bronchospasm or the treatment of asthma
- Class:
  - Anticholinergic (LAMA) and a long-acting beta-2 agonist (LABA)
- Dosage:
  - 400mg and 12 mcg dry powder
  - 1 inhalation two times daily (max dosing)

https://www.duaklir.com/pdf/duaklir-pressair-prescribing-information.pdf accessed O1-15-2020

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Aclidinium bromide and Formoterol fumarate

- Warnings and precautions:
  - Not recommended for initiation with deteriorating COPD
  - Not indicated for relief of acute symptoms
  - Paradoxical bronchospasms
  - Cardiovascular disorders
  - Worsening of urinary retention, narrow angle glaucoma
- Contraindications:
  - Milk protein sensitivity
  - Use of LABA in patients with asthma without ICS

https://www.duaklir.com/pdf/duaklir-pressair-prescribing-information.pdf accessed O1-15-2020

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Aclidinium bromide and Formoterol fumarate

- Efficacy:
  - 3 randomized, DB, placebo controlled 24-week trials
  - 40 years of age and older with moderate – very severe COPD
  - Co-primary end points of trials: were change from baseline in FEV1 and change from baseline in 1 hour post-dose FEV1 compared with formoterol alone at week 24
    - Statistical significance in both co-primary end points
    - Improvement in FEV1 at 5 minutes after dosing and decreased need for rescue medication
    - In addition, looked at COPD exacerbations at end of year one. Statistically significant reduction in COPD exacerbations by 17%

https://www.duaklir.com/pdf/duaklir-pressair-prescribing-information.pdf accessed O1-15-2020

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Aclidinium bromide and Formoterol fumarate

- Drug – Drug Interactions:
  - Diuretics: Use with caution. Electrocardiographic changes and/or hypokalemia associated with non-potassium sparing diuretics may worsen with concomitant beta2-agonists.
  - Monoamine oxidase inhibitors and tricyclic antidepressants: Use with extreme caution. May potentiate effect of formoterol fumarate on cardiovascular system.
  - Caution with beta blockers

https://www.duaklir.com/pdf/duaklir-pressair-prescribing-information.pdf accessed O1-15-2020

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Aclidinium bromide and Formoterol fumarate

- Side effects:
  - Higher than placebo:
    - Upper respiratory tract infection (8.9% vs. 6.3% placebo)
    - Headache (6.3% vs. 5.1% placebo)
    - Back pain (3.8% vs. 3.4% placebo)
- Advantages:
  - Another option on the market

https://www.duaklir.com/pdf/duaklir-pressair-prescribing-information.pdf accessed O1-15-2020

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Aclidinium bromide and Formoterol fumarate

- Competition:
  - Other LAMA/LABA combinations such as:
    - Umeclidinium/vilanterol (Anoro Ellipta)
    - Glycopyrrolate/formoterol fumarate (Bevespi Aerosphere)
    - Tiotropium/olodaterol (Stiolto respiramat)
    - Indacaterol/glycopyrrolate (Utribron neohaler)
- Cost:
  - $1,000/month – cash paying

https://www.duaklir.com/pdf/duaklir-pressair-prescribing-information.pdf accessed O1-15-2020

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Endocrinology

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Semaglutide (Rybelsus)

- Indication:
  - Adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus
- Class:
  - GLP-1 agonist
- Dosage:
  - 7 mg and 14 mg
  - Start with 3 mg once daily; 30 minutes prior to food or any other oral medications; with water.
    - Take 3 mg x 1 month; then increase to 7 mg daily
    - Take 7 mg x 1 month; then increase to 14 mg daily if needed

https://www.novo-pi.com/rybelsus.pdf accessed 02-01-2020

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Semaglutide

- Warnings and Precautions:
  - Risk of thyroid C-cell tumors like all other GLP-1 agonists
  - Not indicated for patients with Type 1 diabetes or for those with DKA
  - Pancreatitis has been reported with this class
  - Diabetic retinopathy: has been reported in clinical trials
  - Avoid in pregnancy and lactation
- Contraindications:
  - All patients with a personal or family history of multiple endocrine neoplasia syndrome

https://www.novo-pi.com/rybelsus.pdf accessed 02-01-2020

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Semaglutide

- Efficacy:
  - Average A1C entering trials 7.9 – 8.0%
    - Reduction of:
    - −0.9 – 7 mg dosage
    - −1.1% - 14 mg dosage
    - 69% and 77% achieved A1C of < 7.0%
    - Weight reduction: 2.3 kg and 3.7 kg in the 7 and 14 mg groups respectively at 26 weeks
- Drug-drug interactions:
  - Delays gastric emptying; monitor levels for any drug with a narrow therapeutic index

https://www.novo-pi.com/rybelsus.pdf accessed 02-01-2020

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Semaglutide

- Side effects:
  - Nausea (Placebo: 6%, 7 mg: 11%, and 14 mg: 20%
  - Abdominal pain (Placebo: 4%, 7 mg: 10%, and 14 mg: 11%)
  - Diarrhea, decreased appetite, vomiting and constipation
  - Hypoglycemia – possible with sulfonylureas or insulin
- Advantages:
  - First oral GLP-1 agonist for patients who do not want to inject. No other oral products on the market
  - Competitors: injectable GLP-1 agonists including semaglutide (Ozempic)
  - No dosage adjustment and may be use in individuals with renal and liver disease
- Cost:
  - $500.00 per month; $10.00 copay cards available

https://www.novo-pi.com/rybelsus.pdf accessed 02-01-2020

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Romosozumab-aqqg (Evenity)

- Indication:
  - Indicated for the treatment of osteoporosis in postmenopausal women at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other available osteoporosis therapy.
- Class:
  - Sclerostin inhibitor
  - Inhibits the action of sclerostin, a regulatory factor in bone metabolism.
  - Increases bone formation and, to a lesser extent, decreases bone resorption

https://www.pi.amgen.com/~/media/amgen/repositorysites/pi-amgen-com/evenity/evenity_pi_hcp_english.ashx accessed 02-01-2020

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Romosozumab

- Dosage:
  - Two separate subcutaneous injections are needed to administer the total dose of 210mg. Inject two syringes, one after the other
  - Should be administered by a healthcare provider
  - Administer 210 mg subcutaneously once every month for 12 doses in the abdomen, thigh, or upper arm

https://www.pi.amgen.com/~/media/amgen/repositorysites/pi-amgen-com/evenity/evenity_pi_hcp_english.ashx accessed 02-01-2020

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Romosozumab

- Warnings and Precautions:
  - May increase risk of MI, cardiovascular or cerebrovascular death
  - Should not be used in individual who has had MI or CVA in the past 1 year
  - Limit to length of use: 1 year (effect wanes after 1 year)
  - Renal Impairment: Patients with severe renal impairment or receiving dialysis are at greater risk of developing hypocalcemia. Monitor serum calcium and supplement with calcium and vitamin D
- Contraindications:
  - Hypocalcemia
  - Pregnancy and lactation

https://www.pi.amgen.com/~/media/amgen/repositorysites/pi-amgen-com/evenity/evenity_pi_hcp_english.ashx accessed 02-01-2020

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Romosozumab

- Efficacy:
  - Significantly reduced the incidence of new vertebral fractures through month 12 compared to placebo.
  - In addition, the significant reduction in fracture risk persisted through the second year in women who received romosozumab during the first year and transitioned to denosumab compared to those who transitioned from placebo to denosumab
  - Increased BMD at month 12; 12.7% at the lumbar spine, 5.8% at the total hip, and 5.2% at the femoral neck

https://www.pi.amgen.com/~/media/amgen/repositorysites/pi-amgen-com/evenity/evenity_pi_hcp_english.ashx accessed 02-01-2020

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Romosozumab

- Side effects:
  - Arthralgias (0.2%) and headache (0.1%)
  - In a randomized controlled trial in postmenopausal women, there was a higher rate of major adverse cardiac events (MACE), a composite endpoint of cardiovascular death, nonfatal myocardial infarction and nonfatal stroke, in patients treated with EVENITY compared to those treated with alendronate
    - MI: 0.2% placebo, 0.3% Romosozumab
    - CVA: 0.3% placebo, 0.2% Romosozumab
    - MI: 0.8% Romosozumab, 0.2% alendronate
    - CVA: 0.6% Romosozumab, 0.3% alendronate
  - Osteonecrosis of the jaw

https://www.pi.amgen.com/~/media/amgen/repositorysites/pi-amgen-com/evenity/evenity_pi_hcp_english.ashx accessed 02-01-2020

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Romosozumab

- Advantages:
  - First in its class
- Competition:
  - No other product within class
  - Another option for those with osteoporosis
- Cost:
  - Approximately $1825.00 per month

https://www.pi.amgen.com/~/media/amgen/repositorysites/pi-amgen-com/evenity/evenity_pi_hcp_english.ashx accessed 02-01-2020

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Dermatology

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Minocycline topical (Amzeeq)

- First topical minocycline product for the treatment of moderate – severe acne in individuals 9 years of age and older
  - Available as a foam – 4%
  - Do not use < 9 years of age (bone growth and tooth discoloration)
- Apply to the skin 1 hour prior to bed
  - Do not shower or wash off after application

https://druginserts.com/lib/rx/meds/amzeeq-1/ accessed 01-30-2020

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Minocycline topical (Amzeeq)

- Avoid in pregnancy or lactation
  - TCNs can cross the placenta when taken orally
- Warnings/side effects
  - Hepatotoxicity has been reported with oral TCN
  - Photosensitivity
  - Tissue hyperpigmentation
  - Headache (3%) vs. 2% of subjects treated with placebo (most common side effect)
- Cost:
  - $592.00 for 1 month

https://druginserts.com/lib/rx/meds/amzeeq-1/ accessed 01-30-2020

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Gastroenterology

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Tenapanor (Ibsrela)

- Indications:
  - Irritable bowel syndrome with constipation (IBS-C) in adults
- Class:
  - Sodium/Hydrogen Exchanger 3 (NHE3) Inhibitor
  - Works by inhibiting NHE3 on the surface of the enterocytes, thus reducing sodium absorption from small intestine and colon
  - More water enters the colon, increasing colonic transmit time. Also decreases visceral sensitivity (pain)
- Dosage:
  - 50 mg PO BID immediately before breakfast and dinner

https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/211801s000lbl.pdf accessed 02-01-2020

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Tenapanor

- Warnings/Precautions:
  - Avoid use in 6 – 12 years of age
  - Safety has not been established in pediatric patients
- Contraindications:
  - Do not use in children < 6 years of age (increase in death in juvenile mice)
    - Severe dehydration

https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/211801s000lbl.pdf accessed 02-01-2020

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Tenapanor

- Side effects:
  - Diarrhea (15-16%) vs Placebo – 4%
  - Abdominal distension (2-3%) vs. Placebo – 1%
  - Flatulence (3%) vs. Placebo – 1%
  - Severe diarrhea (2.5%)
  - Dizziness (2%) vs. Placebo – 1%
- Efficacy:
  - Responder: 37% vs. 24%
  - Responder trial 2: 27% vs. 19%

https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/211801s000lbl.pdf accessed 02-01-2020

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Tenapanor

- Advantages:
  - Another option to compete in an already crowded market
- Competitors:
  - Guanylate Cyclase –C Agonist (Linaclotide, Plecanatide)
  - Polyethylene Glycol
  - Lubiprostone
  - Tegaserod
- Cost:
  - TBD

https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/211801s000lbl.pdf accessed 02-01-2020

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Women's Health

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Bremelanotide acetate (Vyleesi)

- Indication:
  - Indicated for the treatment of premenopausal women with acquired, generalized hypoactive sexual desire disorder (HSDD) as characterized by low sexual desire that causes marked distress or interpersonal difficulty
- Class:
  - Melanocortin receptor agonist
  - The mechanism by which VYLEESI improves HSDD in women is unknown.

https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=9146ae05-918b-483e-b86d-933485ce36eb accessed 02-01-2020

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Bremelanotide acetate

- Dosage:
  - 1.75 mg subcutaneously via the autoinjector to the abdomen or thigh, as needed, at least 45 minutes before anticipated sexual activity
  - One dose every 24 hours (maximum)
  - No more than 8 doses per month

https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=9146ae05-918b-483e-b86d-933485ce36eb accessed 02-01-2020

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Bremelanotide acetate

- Warnings and Precautions:
  - Transient increase in blood pressure and decrease in heart rate: Occurs after each dose and usually resolves within 12 hours.
  - Focal hyperpigmentation (breasts, face) – 1% or less
    - The MC1R is expressed on melanocytes; binding at this receptor leads to melanin expression and increased pigmentation.
  - Nausea (40%); up to 13% required anti-emetic therapy with 8% discontinuing
  - Avoid pregnancy (7 pregnancies occurred, 1 spontaneous loss)
  - Use with caution in severe liver or kidney disease

https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=9146ae05-918b-483e-b86d-933485ce36eb accessed 02-01-2020

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Bremelanotide acetate

- Contraindications:
  - Premenopausal women
  - Men
  - Uncontrolled hypertension or cardiovascular disease
- Efficacy:
  - 2 DB, Placebo-controlled trials
  - FSFI (female sexual dysfunction index) Desire Domain Score improved in both clinical trials from placebo

https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=9146ae05-918b-483e-b86d-933485ce36eb accessed 02-01-2020

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Bremelanotide acetate

- Side effects:
  - Nausea (40% vs. 1.3%)
  - Flushing (20.3% vs. 0.3%)
  - Injection site reactions: (13.2% vs. 8.4%)
- Drug-drug interactions:
  - May slow gastric emptying
  - Avoid NALTREXONE (will decrease naltrexone levels)

https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=9146ae05-918b-483e-b86d-933485ce36eb accessed 02-01-2020

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Bremelanotide acetate

- Advantages:
  - No other product like this on the market
  - No competitor
- Cost:
  - Eligible Commercially Insured patients and Cash-Paying patients may pay $0 copay on 1st prescription, then pay no more that $99 for each 4-single dose refills

https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=9146ae05-918b-483e-b86d-933485ce36eb accessed 02-01-2020

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Neurologic

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Solriamfetol (Sunosi)

- Indication:
  - To improve wakefulness in adults with excessive daytime sleepiness associated with narcolepsy or obstructive sleep apnea
- Class:
  - Dopamine and norepinephrine reuptake inhibitor (DNRI)
  - Schedule IV

https://pp.jazzpharma.com/pi/sunosi.en.USPI.pdf accessed 02-01-2020

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Solriamfetol

- Dosage:
  - Take immediately upon awakening; with or without food.
  - Starting dose for patients with narcolepsy: 75 mg once daily.
  - Starting dose for patients with OSA: 37.5 mg once daily.
  - Dose may be increased at intervals of at least 3 days.
  - Maximum dose is 150 mg once daily.

https://pp.jazzpharma.com/pi/sunosi.en.USPI.pdf accessed 02-01-2020

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Solriamfetol

- Warnings and Precautions
  - Renal impairment
    - Moderate impairment: Starting dose is 37.5 mg once daily. May increase to 75 mg once daily after at least 7 days.
    - Severe impairment: Starting dose and maximum dose is 37.5 mg once daily.
    - End stage renal disease (ESRD): Not recommended.
  - Increased BP and heart rate
  - Psychiatric symptoms
  - Avoid in pregnancy and lactation

https://pp.jazzpharma.com/pi/sunosi.en.USPI.pdf accessed 02-01-2020

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Solriamfetol

- Contraindications:
  - MAO inhibitor use within past 14 days
- Efficacy:
  - 930 patients evaluated in clinical trials
  - 18 - 75 years of age
  - 12-week, DB, placebo-controlled trials
  - Improved mean-wakefulness beginning at 1 hour and lasting through 9 hours post dose
    - Statistical significance over placebo
    - Maintained x 12 weeks
    - 52 week safety study/efficacy also conducted; benefits continued

https://pp.jazzpharma.com/pi/sunosi.en.USPI.pdf accessed 02-01-2020

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Solriamfetol

- Drug-drug interactions: none
- Side effects:
  - Decreased appetite (9% vs. 1%)
  - Insomnia (5% vs. 4%)
  - Anxiety: (6% vs. 1%)
  - Headache (16% vs. 7%)
  - Nausea (7% vs. 4%)
- Advantages: another option in the market

https://pp.jazzpharma.com/pi/sunosi.en.USPI.pdf accessed 02-01-2020

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Solriamfetol

- Competition:
  - Modafinil (Provigil)
  - Armodafinil (Nuvigil)
  - Pitolisant (Wakix)
- Cost:
  - Cash patients: $699.00 per month
  - Savings cards: $9.00 per month available

https://pp.jazzpharma.com/pi/sunosi.en.USPI.pdf accessed 02-01-2020

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Lemborexant (Dayvigo)

- Indication: Insomnia characterized by difficulties with sleep onset or sleep maintenance
- Class:
  - Orexin receptor antagonist
  - Competition: Suvorexant (Belsomra) – Schedule IV
- Dosage:
  - 5 mg and 10 mg
- Expected available in 1st Q- 2020
- CYP3A4 substrate (avoid with mod-strong inhibitors)
- Awaiting FDA ruling on schedule

https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2019/212028Orig1s000ltr.pdf accessed 02-01-2020

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Esketamine (Spravato)

- Indication:
  - Indicated, in conjunction with an oral antidepressant, for the treatment of treatment-resistant depression
- Class:
  - Non-competitive N-methyl D-aspartate (NMDA) receptor antagonist
  - Believed to target the NMDA receptors in the brain, increasing glutamate – which then activate AMPA receptors to increase mood, thoughts and cognition

http://www.janssenlabels.com/package-insert/product-monograph/prescribing-information/SPRAVATO-pi.pdf accessed 02-01-2020

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Esketamine

- Dosage:
  - Generally given 8 treatments and then tapered
    - 56 mg day 1; then 56-84 mg intranasally 2x per week x 4 weeks; then 56 -84 mg every 1 -2 weeks
  - Administered by an MD; 28 mg per device with each device delivering 2 sprays
- Side effects:
  - Increased blood pressure, nausea, vomiting, perceptual disturbances, disassociation
- Schedule IV medication

http://www.janssenlabels.com/package-insert/product-monograph/prescribing-information/SPRAVATO-pi.pdf accessed 02-01-2020

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Esketamine

- Contraindications:
  - Aneurysmal vascular disease (including thoracic and abdominal aorta, intracranial and peripheral arterial vessels) or arteriovenous malformation
  - Intracerebral hemorrhage

http://www.janssenlabels.com/package-insert/product-monograph/prescribing-information/SPRAVATO-pi.pdf accessed 02-01-2020

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(Ubrogepant) Ubrelvy

- Indication:
  - Indicated for the acute treatment of migraine with or without aura in adults
  - It is not indicated for the prevention of migraine
- Class:
  - Calcitonin gene-related peptide receptor antagonist
  - Competes for CGRP receptors sites and blocks binding
- Dosage:
  - 50 mg – 100 mg at the onset of the headache
  - May repeat x 1 in 2 hours; maximum of 200 mg in a 24-hour period
  - With or without food

https://media.allergan.com/products/Ubrelvy_pi.pdf accessed 01-25-2020

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Ubrogepant

- Drug – Drug Interactions:
  - Avoid with strong CYP 3A4 inhibitors (increase ubrogepant exposure by up to 10 fold)
    - Ketoconazole, itraconazole
    - Clarithromycin, erythromycin
    - Ritonavir, indinavir, nelfinavir
  - Strong CYP 3A4 inducers (decrease ubrogepant exposure and possible efficacy by 80%)
    - Rifampin
    - Hypericum
    - Phenytoin
    - Barbiturates

https://media.allergan.com/products/Ubrelvy_pi.pdf accessed 01-25-2020

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Ubrogepant

- Drug – Drug Interactions:
  - Moderate – weak CYP 3A4 inhibitors
    - Moderate: Dose reduction to 50 mg with no repeat dosing
      - Diltiazem, verapamil
      - Cyclosporine, fluvoxamine
      - Fluconazole
      - Ciprofloxacin
      - Grapefruit juice
    - Weak: 50 mg initial and 50 mg repeat dosing

https://media.allergan.com/products/Ubrelvy_pi.pdf accessed 01-25-2020

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Ubrogepant

- Precautions/Warnings
  - Has not been studied in severe/end stage renal or hepatic disease
  - Do not use in pregnancy or lactation
    - In rats, no teratogenic effects however, there were pregnancy loss in the rats at high doses
  - Not studied in children at this time
  - Studies included patients 18 – 75 years but limited number of individuals over 65 years

https://media.allergan.com/products/Ubrelvy_pi.pdf accessed 01-25-2020

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Ubrogepant

- Efficacy:
  - Pain free at 2 hours:
    - 19.2% (50mg), 21.2% (100mg), and 11.8% (placebo)
  - Pain relief at 2 hours
    - S1: 60.7% (50mg), 61.4 (100mg) and 49.1% (placebo)
    - S2: 62.7% (100mg) and 48.2% (placebo)
  - Relief of most bothersome symptom at 2 hours
    - S1: 38.6% (50mg), 37.7% (100mg), 27.8% (placebo)

https://media.allergan.com/products/Ubrelvy_pi.pdf accessed 01-25-2020

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Ubrogepant

- Side effects:
  - Nausea: 2%(P), 2%-50 mg, 4%-100 mg
  - Somnolence: 1%(P), 2%-50 mg, 3%-100 mg
  - Dry mouth: 1%(P), 1%-50 mg, 2% - 100 mg
- Advantages:
  - Well-tolerated
  - May be used in individuals with CV risk factors
  - New class/option
  - 10 pill package

https://media.allergan.com/products/Ubrelvy_pi.pdf accessed 01-25-2020

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Ubrogepant

- Competition:
  - None in the class
  - Triptans – largest competitor
- Cost:
  - Cash: 85.00 per pill

https://media.allergan.com/products/Ubrelvy_pi.pdf accessed 01-25-2020

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Quick Updates and Additional Approvals

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Tegaserod (Zelnorm)

- Available again
- Selective serotonin-4 receptor agonist
- Indication: IBS-C in women < 65 years
- Dosage: 6 mg 1 pill two times daily; administered 30 minutes prior to a meal
  - If no improvement in 6 weeks, d/c
- Renal adjustment: CC < 30 mL/min: avoid

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Additional Indications

- Canaglifozin (Invokana): Approved to reduce risk of end-stage renal disease, CV death and risk of hospitalization from CHF
- Dapagliflozin (Farxiga): Approved to reduce the risk of hospitalization from CHF in adults with Type 2 diabetes and cardiovascular disease or multiple cardiovascular risk factors

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Mepolizumab (Nucala)

- FDA approval for add-on therapy for patients 6 – 11 years of age with severe eosinophilic asthma

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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

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Additional Approval

- Liraglutide (Victoza): approved for Type 2 diabetes in children: ≥ 10 years of age
- Dupilumab (Dupixent): chronic rhinosinusitis in adults with nasal polyposis
  - IL-4 receptor antagonist
  - Already approved for patients with asthma

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Additional Approvals and Updates

- Empagliflozin, linagliptin, and metformin (Trijardy)
  - SGLT2, DPP-4, Biguinide
- Ethinyl estradiol and etonogestrel (EluRyng)
  - First generic of NuvaRing
  - Approved December 11, 2019
- Peanut Allergen Powder (Palforzia)
  - Oral immunotherapy
  - Approved January 31, 2020

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Immunizations

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PCV13

- PCV13: no longer recommended for routine use at age 65 years.
  - It is now an optional vaccination at age 65 years
  - In the 5 years since the 2014 PCV13 implementation, there is little evidence that the vaccination has had an impact on PCV13 serotype related diseases
  - Now a “shared decision making” recommendation
  - If the patient has immunocompromising conditions, the recommendation stands

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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
  - Approved by FDA and recommended by CDC

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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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What's Coming in 2020?

- Bupivacaine/meloxicam: post-operative pain management
- Dasotraline: dopamine/norepinephrine reuptake inhibitor for binge eating disorder

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

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