Drug Update: New products, indications, and warnings

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Disclosure

- No real or potential conflict of interest to disclose.
- No off-label, experimental or investigational use of drugs or devices will be presented.

References

Found within Presentation

Objectives

- Upon completion of the program, the participant will be able to:
  - Describe characteristics of and recommendations for the use of newly approved medications.
  - Recognize new indications for established products.
  - Identify new warnings about previously approved medications.

To facilitate your learning, specific tables/images can be viewed full page at the end of your handout.

New Medication Class for Treatment of Dyslipidemia

Source:
https://www.nexletol.com/

Bempedoic Acid (Nexletol®)

- What is it?
  - Adenosine triphosphate-citrate lyase (ACL) inhibitor
    - When compared to statin, lowers LDL by action on earlier point in cholesterol synthesis
  - One of a number of LDL-lowering meds called "non-statins"
    - Others include ezetimibe (Zetia®), PCSK-9 inhibitors (alirocumab [Praluent®] evolocumab [Repatha®]).

Bempedoic Acid (Nexletol®) (continued)

- FDA approved indication
  - Adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia ***or*** established atherosclerotic cardiovascular disease who require additional lowering of LDL-C
    - Provides approx. 20% further LDL reduction w statin use

Bempedoic Acid (Nexletol®) True or false?

The effect of bempedoic acid (Nexletol®) use on cardiovascular morbidity and mortality has not been determined.

True

Bempedoic Acid (Nexletol®) (continued)

- Dose
  - 180 mg orally once daily w/without food
- Pharmacokinetics
  - Not a CYP450 substrate
  - Organic anion transporter 3 (OAT3) substrate
    - Responsible for uptake of substrates from blood into renal proximal tubular cells anion transporter
  - Mild OATP1B1, OATP1B3, OAT2 inhibitor

Bempedoic Acid (Nexletol®) Drug Interaction Potential

- Simvastatin
  - Avoid concomitant use of bempedoic acid (Nexletol®) with simvastatin greater than 20 mg.
- Pravastatin
  - Avoid concomitant use of bempedoic acid (Nexletol®) with pravastatin greater than 40 mg.

Where might bempedoic acid fit into dyslipidemia therapy vs. standard dyslipidemia therapy?

Source:
https://www.acc.org/latest-in-cardiology/ten-points-to-remember/2018/11/09/14/28/2018-guideline-on-management-of-blood-cholesterol

Severe Hypercholesterolemia (LDL-C ≥190 mg/dL [≥4.9 mmol/L])

- Start high intensity statin therapy
  - Evidence of improved CVD outcome
  - Anticipate ≥50% LDL reduction w high intensity statin therapy
- If LDL ≥100 mg/dL (≥2.6 mmol/L) w high intensity statin therapy
  - Add ezetimibe (Zetia®)
    - Evidence of improved CVD outcomes
    - Anticipate additional 15–20% LDL lowering

Severe Hypercholesterolemia (LDL-C ≥190 mg/dL [≥4.9 mmol/L]) (continued)

- Example
  - 44-year-old man, non-smoking, normotensive, without DM
    - Presenting LDL-C=240 mg/dL (6.2 mmol/L)
    - Goal LDL <100 mg/dL (2.6 mmol/L)
  - Started on atorvastatin 80 mg daily
    - Resulting LDL-C=110 mg/dL (2.8 mmol/L)
  - Add ezetimibe (Zetia®)
    - Resulting LDL-C=94 mg/dL (2.4 mmol/L)

Severe Hypercholesterolemia (LDL-C ≥190 mg/dL [≥4.9 mmol/L]) (continued)

- LDL-C level on statin plus ezetimibe remains ≥100 mg/dL (≥2.6 mmol/L)
  - ***Plus***
- Multiple factors that increase subsequent risk of ASCVD events
  - Consider adding PCSK9 inhibitor

Severe Hypercholesterolemia (LDL-C ≥190 mg/dL [≥4.9 mmol/L]) (continued)

- Example
  - 44-year-old man, + smoking, HTN, T2DM
    - Presenting LDL-C=240 mg/dL (6.2 mmol/L)
    - Goal LDL-C <70 mg/dL (1.8 mmol/L)
  - Started on atorvastatin 80 mg daily
    - Resulting LDL-C=130 mg/dL (3.4 mmol/L)
  - Add ezetimibe (Zetia®)
    - Resulting LDL-C=110 mg/dL (2.8 mmol/L)
  - Add evolocumab (Repatha®)
    - Resulting LDL-C=50 mg/dL (1.3 mmol/L)

Bempedoic Acid (Nexletol®) Place in Therapy

- Add-on therapy
  - With statin and ezetimibe, still not at LDL goal and injectable therapy not an option
    - Available with ezetimibe as Nexlizet®

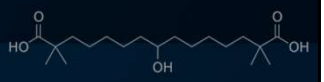

Image source: User:Edgar181, Public domain, via Wikimedia Commons

Severe Hypercholesterolemia (LDL-C ≥190 mg/dL [≥4.9 mmol/L]) (continued)

- Example, with bempedoic acid
  - Rather than PSC9 inhibitors
  - 44-year-old man, + smoking, HTN, T2DM
    - Presenting LDL-C=240 mg/dL (6.2 mmol/L)
    - Goal LDL-C <70 mg/dL (1.8 mmol/L)
  - Started on atorvastatin 80 mg daily
    - Resulting LDL-C=130 mg/dL (3.4 mmol/L)
  - Add ezetimibe (Zetia®)
    - Resulting LDL-C=110 mg/dL (2.8 mmol/L)
  - Add bempedoic acid
    - Resulting LDL-C=88 mg/dL (2.27 mmol/L)

Bempedoic Acid (Nexletol®) Place in Therapy (continued)

- In statin intolerance
  - Instead of statin
    - Anticipate approx. 35% LDL reduction
    - Example=Pretreatment LDL=150 mg/dL (3.9 mmol/L)
    - Post bempedoic acid (Nexletol®) therapy=LDL=~100 mg/dL (2.6 mmol/L)
      - Similar to low intensity statin therapy
        - » Source: https://prescriber.therapeuticresearch.com/Content/Articles/PRL/2020/Apr/Know-How-Nexletol-Stacks-Up-to-Other-Non-Statins

Bempedoic Acid (Nexletol®) Adverse Effects

- Hyperuricemia
  - Assessment of uric acid periodically as clinically indicated
    - No specific time frame provided
    - 3.2-fold greater incidence with administration of bempedoic acid (2.1%) vs. placebo (0.5%)
  - Rate of gout with use
    - 2.5-fold greater incidence of **gout** (1.4% vs. 0.4%, respectively)

Bempedoic Acid (Nexletol®) Adverse Effects (continued)

- Muscle spasm
  - Leading to discontinuing med, 0.5% vs. 0.3% placebo
- Tendon rupture
  - 0.5% in treatment vs. 0% in placebo arm
  - Occurred within weeks to months of med use

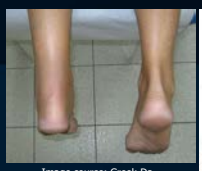

Image source: Grook Da Oger, author; CC BY-SA 3.0 https://commons.wikimedia.org/wiki/File:Rupture_tendon_achil%C3%A9en.jpg

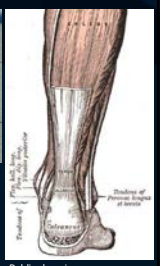

Image source: Public domain, https://commons.wikimedia.org/wiki/File:Achilles-tendon.jpg

Bempedoic Acid (Nexletol®) Adverse Effects True or false?

Tendon rupture with bempedoic acid use is likely more frequently noted in people age >60 years, taking systemic corticosteroid or fluoroquinolone drugs, in patients with renal failure, and in patients with previous tendon disease.

True

Lipid-lowering Medications Costs (goodrx.com)

- Bempedoic acid
  - ~$330/month
- Statins
  - ~$4–10/month
- PCSK-9 inhibitor
  - ~$450/month
- Ezetimibe (Zetia®)
  - ~$60/month

Established medications often get a new FDA indication.

Icosapent Ethyl (Vascepa®)

Icosapent Ethyl (Vascepa®) (continued)

- Established indication
  - As adjunct to diet to reduce TG levels in adult patients with severe (≥500 mg/dL [5.65 mmol/L]) hypertriglyceridemia

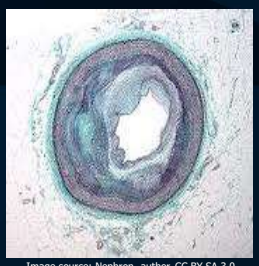

Image source: Nephron, author, CC BY-SA 3.0 https://en.wikipedia.org/wiki/Atherosclerosis#/media/File:RCA_atherosclerosis.jpg

True or false?

In randomized trials, medications that reduce triglyceride levels, such as extended-release niacin and fibrates, have not reduced the rates of cardiovascular events when administered in addition to appropriate medical therapy, including statins.

True

Source: https://www.nejm.org/doi/full/10.1056/nejmoa1812792

REDUCE-IT Trial

- Results
  - Primary composite end point of cardiovascular death, nonfatal myocardial infarction, nonfatal stroke, coronary revascularization, or unstable angina
    - Significantly lower, by 25%, among the patients who received 2 g of icosapent ethyl twice daily than among those who received placebo

Icosapent Ethyl (Vascepa®)

Results:
First FDA approved drug to reduce cardiovascular risk among patients with elevated triglyceride levels as an add-on to maximally tolerated statin therapy.

New Antimicrobial for Community-acquired Bacterial Pneumonia (CABP) and Serious Skin and Soft Tissue Infection (SSSI)

Omadacycline (Nuzyra®)

Omadacycline (Nuzyra®)

- What is it?
  - An aminomethylcycline, a type of tetracycline
- Mechanism of action
  - Action by binding to bacterial 30S ribosomal subunit
    - Bypasses some of resistance seen with other tetracycline forms, such as doxycycline

True or false?

The majority of clinical trials across a variety of infections found no difference in efficacy between bacteriostatic versus bactericidal antimicrobials.

True

Omadacycline (Nuzyra®) FDA Approved Indications

- Treatment of CABP
  - Caused by likely susceptible organisms including *S. pneumoniae*, *S. aureus* (methicillin-susceptible), *H. influenzae*, *H. parainfluenzae*, *K. pneumoniae*, *C. pneumoniae*, *Legionella pneumophila*, *M. pneumoniae*

Image source: CDC, public domain, https://commons.wikimedia.org/wiki/File:Pneumococcus_CDC_PHIL_ID1003.jpg

Clinical Trials

Conclusion:
"Omadacycline was non-inferior to moxifloxacin for the treatment of community-acquired bacterial pneumonia in adults."

Source:
https://www.nejm.org/doi/full/10.1056/NEJMoa1800201

What does that mean for the practicing/prescribing clinician?

"By definition, a non-inferiority trial aims to demonstrate that the test product is not worse than the comparator by more than a small prespecified amount."

Source:
https://pubmed.ncbi.nlm.nih.gov/20413972/

Omadacycline (Nuzyra®) FDA Approved Indications

- Treatment of acute bacterial skin and skin structure infections (ABSSSI)
  - Caused by likely susceptible organisms including Gram-positive bacteria- *Enterococcus faecalis*, *Staphylococcus aureus* (methicillin-susceptible and -resistant) *Staphylococcus lugdunensis, Streptococcus pyogenes*
  - Gram-negative bacteria- *Enterobacter cloacae, Klebsiella pneumoniae*

MRSA's Mechanism of Resistance

- Methicillin=Penicillin form stable in presence of beta-lactamase
  - MRSA implies resistance by mechanism other than beta-lactamase production
  - Same mechanism as DRSP

Image source: CDC, public domain, https://commons.wikimedia.org/wiki/File:Staphylococcus_aureus_VISA_2.jpg

MSSA Methicillin-sensitive *S. aureus*

- Implies *S. aureus* strain where mechanism is beta-lactamase production

Image source: NIH, public domain https://commons.wikimedia.org/wiki/File:Human_neutrophil_ingesting_MRSA.jpg

Clinical Trials

"Omadacycline was non-inferior to linezolid for the treatment of acute bacterial skin and skin structure infections and had a similar safety profile."

Source: https://www.nejm.org/doi/full/10.1056/NEJMoa1800170

Dosage Forms and Strengths

- Tablet
  - 150 mg (equivalent to 196 mg omadacycline tosylate)
- Injectable
  - Powder for reconstitution, 100 mg per vial

Omadacycline (Nuzyra®) – Dosing Treatment Duration 7–14 days

- CABP
  - Loading dose (Day 1)
    - 200 mg IV once ***or*** 100 mg IV × 2 doses
      - No PO loading dose mentioned
  - Maintenance dose
    - 100 mg IV daily ***or*** 300 mg PO daily

Pharm 101 Principle

Do not inject what you can give PO. Then again, you might not have a PO only recommendation.

Injectable vs. Oral Antibiotics: Which works better?

Available at https://emedicine.medscape.com/article/237521-overview

PO vs. Parenteral Antibiotics

- PO pro
  - Lower cost
  - Ease of self-administration
  - Less likely to cause severe allergic reactions
- PO con
  - Adherence
  - Upper GI upset
  - Incorrect patient/provider perception of improved clinical outcomes

PO vs. Parenteral Antibiotics (continued)

- Parenteral pro
  - Able to be given regardless of level of consciousness or degree of GI function
  - Higher rate of patient adherence
- Parenteral con
  - Increased cost
  - Higher risk of severe allergic reaction
  - Need for HCP assistance in receiving medication

True or false?

In a study of patients hospitalized with CAP randomized to receive a short course of IV antibiotics followed by switch to an oral antibiotics had a lower total cost of care and shorter hospital stay than those treated with conventional IV antibiotic therapy.

True

Source: https://www.ncbi.nlm.nih.gov/pubmed/19016815

Omadacycline (Nuzyra®) – Dosing Treatment Duration 7–14 days (continued)

- ABSSSIs
  - Loading
    - IV (Day 1) – 200 mg IV once ***or*** 100 mg IV × 2 doses

      or
  - PO (Days 1, 2) – 450 mg PO daily × 2 days
  - Maintenance dose
    - IV – 100 mg IV daily

      or
    - PO – 300 mg PO daily

Omadacycline (Nuzyra®)

- Dosage modifications
  - Renal or hepatic impairment
    - No dosage adjustment required
      - Any severity of renal or hepatic impairment, including patients with ESRD or those receiving dialysis

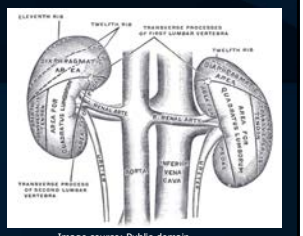

Image source: Public domain, https://commons.wikimedia.org/wiki/File:Gray1123.png

Omadacycline (Nuzyra®) (continued)

- Adverse effects
  - >10%
  - Nausea (21.9%)
  - Vomiting (11.4%)

Image source: CDC, https://www.cdc.gov/niosh/emres/longhourstraining/sleepdeprivation.html

Adverse Effects Class Effect ***or*** Specific to Omadacycline?

- Rare but serious
  - Intracranial hypertension (pseudotumor cerebri)
  - Presents w headache, blurred vision, papilledema

Class Effect

Image source: Jonathan Trobe, M.D., University of Michigan Kellogg Eye Center, author; CC BY 3.0 https://en.wikipedia.org/wiki/Papilledema#/media/File:Papilledema.jpg

Omadacycline (Nuzyra®) (continued)

- Drug interaction overview
  - Avoid coadministration with oral retinoids
    - Possible additive effects on increasing intracranial pressure

Image source: Jonathan Trobe, M.D., University of Michigan Kellogg Eye Center, author; CC BY 3.0 https://en.wikipedia.org/wiki/Papilledema#/media/File:Papilledema.jpg

Adverse Effects Class Effect *or* Specific to Omadacycline?

- Photosensitivity
  - Exaggerated "sunburn reaction," regardless of skin tone
  - Instruct patients to minimize or avoid exposure to natural or artificial sunlight, use sunscreen.

Class Effect

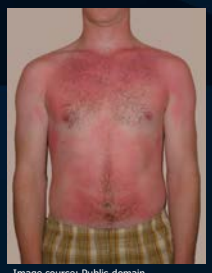

Image source: Public domain https://en.wikipedia.org/wiki/Burn#/media/File:Sunburn.jpg

Omadacycline (Nuzyra®) (continued)

- Directions for use
  - Take on an empty stomach, at least
    - Two hours before eating
    - Four hours after eating

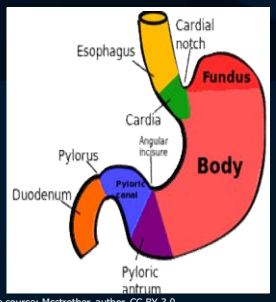

Image source: Mcstrother, author, CC BY 3.0 https://commons.wikimedia.org/wiki/File:Regions_of_stomach.svg

True or false?

While omadacycline and tetracycline are labeled to take on an empty stomach, doxycycline and minocycline do not carry this warning.

True

With All Tetracycline Forms

- Including doxycycline, minocycline omadacycline
  - When taken with metals such as iron, calcium (potential with dairy products), magnesium, aluminum
  - Separate in stomach from metals by ≥2 hours
    - Source: https://www.accessdata.fda.gov/drugsatfda_docs/label/2008/050795s005lbl.pdf

Considering Cost

- Omadacycline (Nuzyra®)
  - Cost=Approx. $220 per tablet
    - Cost=Likely >$1500 for course of therapy
- Doxycycline
  - Cost=Approx. $14 for 14 tabs
    - One-week
      - Source: Drugs.com, GoodRx.com

Teachable Moments

As formulation of products improve, recommendations often change.

American Gastroenterological Association (AGA) on probiotic use

Source:
AGA Clinical Practice Guidelines on the Role of Probiotics in the Management of Gastrointestinal Disorders – Gastroenterology (gastrojournal.org)

Bacterial Probiotics for Antibiotic-associated Diarrhea

- Preventative benefits of bacterial supplements noted first in late 1970s.
  - Older studies completed using considerably less potent products than currently available

Yogurt vs. Supplement

- Usual live culture yogurt
  - 0.1 and 1 billion cells per 6–8 ounces (0.18–0.24 L)
    - Much lower than dose recommended by AGA
    - Yogurt (Activia®) "dose" for GI help, 1–3 containers per day, every day
  - A variety of species
    - *Lactobacillus acidophilus* (most common, often single probiotic), *Bifidus*, and *Lactobacillus casei*

AGA Recommendations

- In adults, children on antibiotic therapy
  - Recommend the use of probiotics over no probiotics for prevention of *C. difficile* infection

Image source: CDC/James Archer, author, CC BY-SA 4.0 https://commons.wikimedia.org/wiki/File:Clostridium_difficile_CDC.jpg

In Antibiotic Therapy – Probiotic Recommendations

- A variety of formulations
  - See recommendations for dosing, duration of therapy
  - 2-strain combination of *L. acidophilus* CL1285 and *Lactobacillus casei* LBC80R
  - 3-strain combination of *L. acidophilus*, *Lactobacillus delbrueckii* subsp *bulgaricus*, and *Bifidobacterium bifidum*
  - 4-strain combination of *L. acidophilus*, *L. delbrueckii* subsp *bulgaricus*, *B. bifidum*, and *Streptococcus salivarius* subsp *thermophilus*

Ileal Pouch-Anal Anastomosis (IPAA)

- AKA
  - Anastomosis of ileum to anus
  - Ileo-anal pouch
  - Restorative proctocolectomy
  - Ileal-anal pull-through
  - J-pouch
  - S-pouch
  - W-pouch

Ileal Pouch–anal Anastomosis (IPAA) (continued)

- Why is this done?
  - When large intestine removed
    - Ulcerative colitis
    - Crohn's disease
      - Select cases
    - Familial adenomatous polyposis
    - Colon cancer
    - Toxic megacolon

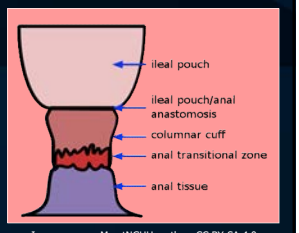

Image source: McortNGHH, author; CC BY-SA 4.0
https://commons.wikimedia.org/wiki/File:Ileal_pouch-anal_anastomosis.svg

Probiotic Use in Pouchitis

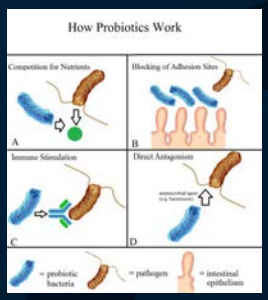

Image source: Rachelshoemaker, author; CC BY-SA 4.0
https://commons.wikimedia.org/wiki/File:Probiotic.png

- In adults and children with pouchitis
  - Recommends the use of probiotics over no probiotics*
    - An 8 probiotic mixture best studied
      - *See guidelines for specific recommended species.

AGA Recommendations

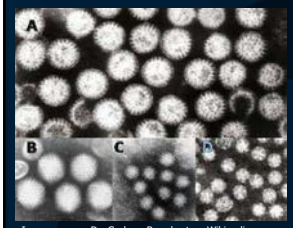

Image source: Dr. Graham Beards at en.Wikipedia, author; CC BY 3.0
https://commons.wikimedia.org/wiki/File:Gastroenteritis_viruses.jpg

- Does not recommend
  - Use of probiotics in children with acute infectious gastroenteritis

AGA Recommendations (continued)

- In preterm (<37 weeks gestational age), low birth weight infants
  - Recommends combination of *Lactobacillus* spp. and *Bifidobacterium* spp. for prevention of necrotizing enterocolitis (NEC) over no and other probiotics*
    - Source: *See guidelines for specific recommended species.

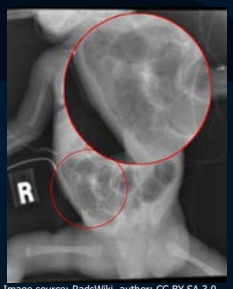

Image source: RadsWiki, author; CC BY-SA 3.0
https://commons.wikimedia.org/wiki/File:Necrotizing_enterocolitis_202.jpg

AGA Recommendations (continued)

- In preterm…(cont.)
  - Recommends combination of…(cont.)
    - NEC – A life-threatening condition of premature infants caused by local infection and inflammation of bowel wall

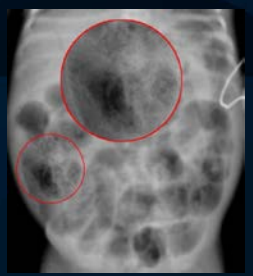

Image source: CC BY-SA 3.0
https://www.wikidoc.org/index.php/File:Necrotizing_enterocolitis_004.jpg

Topical Medication for Treatment of Acne

Novel Mechanism of Action (MOA)

First new MOA for acne therapy in 40 years.

Clascoterone Cream 1% (Winlevi®)

- What is it?
  - Topical androgen receptor inhibitor
- Indication
  - Topical therapy for acne, age ≥12 y
- Mechanism of action
  - Limit dihydrotestosterone binding to the androgen receptors in sebaceous glands.

Image source: Anna Nekrashevich, photographer https://www.pexels.com/photo/fashion-person-woman-girl-6475987/

Clascoterone Cream 1% (Winlevi®) Directions for Use

- Cleanse the affected area gently.
  - To dry skin, apply a thin uniform layer of cream BID.
- Avoid accidental transfer of clascoterone cream 1% (Winlevi®) cream into eyes, mouth or other mucous membranes.
  - If contact with mucous membranes occurs, rinse thoroughly with water.

Clascoterone Cream 1% (Winlevi®) Directions for Use (continued)

- Dose per use
  - Approx. 1 gm
  - Fingertip unit=0.5 g male, 0.4 g female average
- Amount of med per tube
  - 80 G

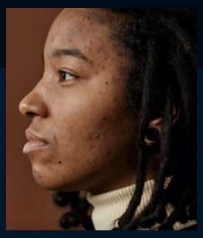

Image source: ShotPot, photographer, https://www.pexels.com/photo/fashion-man-people-woman-6338374/

Clascoterone Cream 1% (Winlevi®) Directions for Use (continued)

- Adverse effects
  - Skin redness, irritation nearly equal in arm of study with active ingredient vs. vehicle (<13%)
- Mean reduction of lesions
  - Active ingredient vs. placebo
    - ~33% vs. 22% noninflammatory lesions
    - ~45% vs. 30% inflammatory lesions

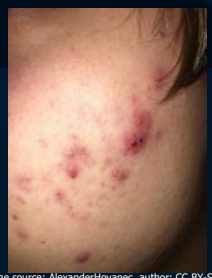

Image source: AlexanderHovanec, author; CC BY-SA 4.0 https://commons.wikimedia.org/wiki/File:Pimples.jpg

Current Antiandrogen Therapies

- Systemic forms
  - Combined hormonal contraception
    - Pill, patch, ring
  - Spironolactone
- Possible clascoterone cream benefit
  - Antiandrogen that can be used regardless of gender assigned at birth

Clascoterone Cream 1% (Winlevi®)

Price: ~$650 for 60 g tube

New Generics

What does that mean for cost of the medication?

New or Soon-to-be Generics

- Proventil HFA®
  - Branded products=~$100 per inhaler
  - Generic albuterol HFA formulation
    - A variety of manufacturers
    - Approx. $50 per inhaler

New or Soon-to-be Generics (continued)

- Epiduo Forte®
  - Adapalene 0.3%/benzoyl peroxide 2.5%
    - Currently, branded= $330/bottle
    - Generic price=TBA
  - For treatment of moderate to severe acne

Image source: Public domain, https://commons.wikimedia.org/wiki/File:Akne-luqend.jpg

New FDA Advisories

Source: https://www.fda.gov/drugs/drug-safety-and-availability/2020-drug-safety-communications

NSAID Use in Later Pregnancy

- What is the advisory?
  - NSAID use ≥20 weeks of pregnancy
- The problem
  - Use can result in kidney dysfunction and resulting low levels of amniotic fluid surrounding the baby and possible complications

NSAID Use in Later Pregnancy (continued)

- Advice
  - Limit prescribing NSAIDs between 20 to 30 weeks of pregnancy and avoid prescribing them after 30 weeks of pregnancy.

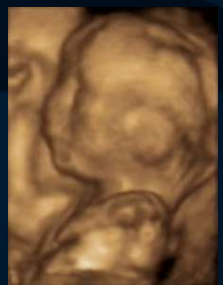

Image source: Staecker, Public domain, via Wikimedia Commons

NSAID Use in Later Pregnancy (continued)

Image source: freestocks@freestocks https://unsplash.com/photos/ux53SGpRAHU

- If NSAID treatment necessary
  - Lowest amount, shortest duration
  - Consider US monitoring of amniotic fluid if NSAID treatment extends beyond 48 hours.
  - Discontinue NSAID, if oligohydramnios found.

Montelukast (Singulair®), Generics Advisory Strengthened

Image source: Dan Meyers, photographer, https://unsplash.com/photos/hluOJZjLVXc

- What is the advisory?
  - U.S. FDA is strengthening existing warnings about serious behavior and mood-related changes including suicidal thoughts, action with montelukast use.

Montelukast (Singulair®), Generics (continued)

- For allergic rhinitis
  - Determined that montelukast should be reserved for those who are not treated effectively with or cannot tolerate other allergy medicines.

Image source: CDC, public domain https://commons.wikimedia.org/wiki/File:Sneeze.JPG#mw-jump-to-license

Montelukast (Singulair®), Generics (continued)

- With asthma
  - Health care professionals consider the benefits and risks of mental health adverse effects before prescribing montelukast.

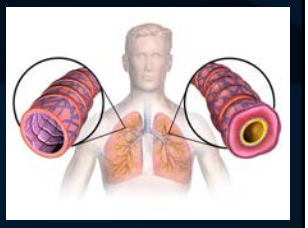

Image source: BruceBlaus, CC BY-SA 4.0, via Wikimedia Commons

Canagliflozin (Invokana®) Warning Removed

- What is the advisory?
  - Based on three clinical trials
    - The **boxed warning** about amputation risk with canagliflozin (Invokana®, Invokamet®, Invokamet® XR) is **removed**.

Image source: Luca Upper, photographer, https://unsplash.com/photos/Z-4kOr93RCI

Great COVID-19 Reference

COVID protocols v2.0.
Brigham and Women's Hospital/Partners In Health/UCSF Institute for Global Health
Available at
https://covidprotocols.org

Conclusion

End of Presentation

Thank you for your time and attention.

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Probiotic Use in Pouchitis

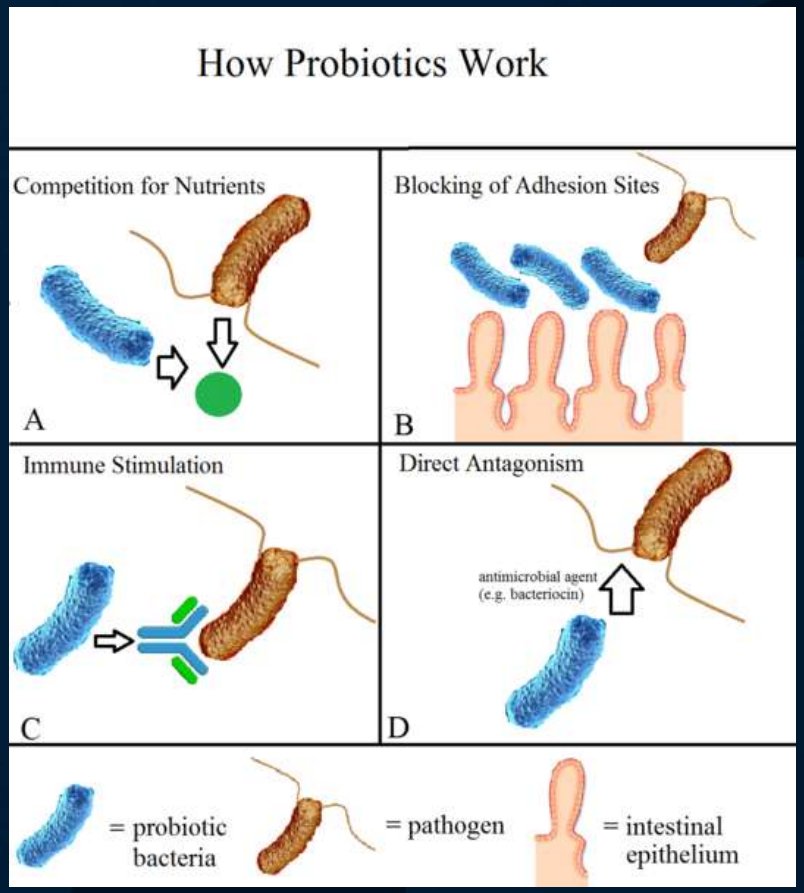

Image source: Rachelshoemaker, author; CC BY-SA 4.0
https://commons.wikimedia.org/wiki/File:Probiotic.png

- In adults and children with pouchitis
  - Recommends the use of probiotics over no probiotics*
    - An 8 probiotic mixture best studied
      - *See guidelines for specific recommended species.