

Pharmacy Phacts: Updates in Medications

Cheryl Maslouski, PharmD, RPh, BCACP Clinical Pharmacist, Primary Care Network Nationwide Children's Hospital

MedNet21
Center for Continuing Medical Education



Objectives

- Discuss two new medicines for the treatment of Attention-Deficit/Hyperactivity Disorder (ADHD)
- Integrate new asthma treatment guidelines into patient care
- List two new treatments for infectious diseases
- Provide three examples of medication cost-savings
- Discuss two safety concerns of medications from the presentation

Case — ADHD

- ML is an 8yo male with diagnoses of ADHD, autism, and insomnia who you are seeing in clinic for follow-up of conditions.
- His medications include methylphenidate XR suspension (QuillivantTM) 20mg qam and clonidine 0.1mg TID.
- He is not able to swallow solid dosages and has taste and sensation aversions when crushing tablets or opening capsules.
- His ADHD is well-controlled and vital signs are stable.

Case — ADHD

Caregivers are happy with his therapy, but they would like to decrease the number of times per day they give him clonidine. What are their options?

- a. Change to guanfacine ER 1mg tablet at bedtime.
- b. There are no options and will have to continue therapy.
- c. Initiate clonidine XR suspension (Onyda[™] XR) 0.1mg po qHS and d/c 0.1mg tablets
- d. Change clonidine to melatonin liquid 1mg at bedtime.

Case — ADHD

Caregivers are happy with his therapy, but they would like to decrease the number of times per day they give him clonidine. What are their options?

- a. Change to guanfacine ER 1mg tablet at bedtime.
- b. There are no options and will have to continue therapy.
- c. Initiate clonidine XR suspension (Onyda™ XR) 0.1mg po qHS and d/c 0.1mg tablets.
- d. Change clonidine to melatonin liquid 1mg at bedtime.

Clonidine XR suspension 0.1mg/mL

- Alpha₂-adrenergic agonist FDA approved for the treatment of ADHD in pediatric patients ≥6 years of age
- Once daily at bedtime
- Monotherapy or adjunct to stimulants
- Side effects and safety concerns are the same as clonidine tablets
- Store at room temperature for 30-60 days
- Adapter and dosing syringe
- Citrusy, orange flavor

Clonidine XR suspension 0.1mg/mL

| Initial Dose | Titrate | Maximum Dose | Discontinue Therapy |
|--------------|---------------|-----------------|------------------------|
| 0.1mg at | 0.1mg every 7 | 0.4mg once | Decrease by 0.1mg |
| bedtime | days | daily | every 3-7 days |

- NOT interchangeable on a mg-mg basis with tablet formulations.
- Suspension or crush tablets?
- Insurance coverage



Photo credit: Jillian Gould, PharmD, RPH

Case — ADHD

- CL is a 10yo female with a diagnosis of ADHD who is being seen in your clinic for follow-up of ADHD.
- Her ADHD is sub-optimally treated with stimulant therapy,
 limited by patient's failure to grow. Her vital signs are stable.
- She has tried alpha-agonists in addition to her stimulant but was not able to tolerate somnolent side effects.

Case — ADHD

CL's caregivers would like to know what other medicines are available. Which do you suggest?

- a. Add a stimulant from a different class.
- b. Add viloxazine ER
- c. Add bupropion.
- d. Add cyproheptadine.

Case — ADHD

CL's caregivers would like to know what other medicines are available. Which do you suggest?

- a. Add a stimulant from a different class.
- b. Add viloxazine ER
- c. Add bupropion.
- d. Add cyproheptadine.

Norepinephrine Reuptake Inhibitors (NRI's)

| | Atomoxetine (Strattera®) | Viloxazine ER (Qelbree®) |
|-----------------|-----------------------------|-------------------------------|
| Dosage Form | Capsule | Capsule |
| Administration | Swallow whole | Swallow whole or open |
| Dosing | mg/kg, titrate after 3 days | 100mg – 600mg, titrate weekly |
| Frequency | 1-2x daily | Daily |
| Onset of action | 2 weeks | 1 week |
| Generic | Yes | No |
| Safety | Suicidal ideation, liver | Suicidal ideation |
| Metabolism | CYP2D6 | CYP1A2 |

Atomoxetine or Viloxazine ER

 50 patients with combined-type ADHD at a psychiatric center in an open-label, voluntary crossover study of atomoxetine and viloxazine ER

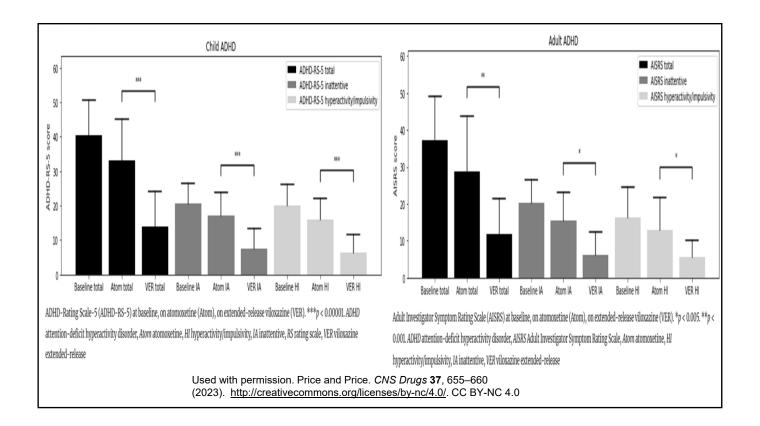
| Study Subjects | Pediatric | Adult | |
|-------------------------------|-------------------|--------------------|--|
| Number | 35 | 15 | |
| Age (average, range) | 11.9 (6-17) years | 29.3 (20-51) years | |
| Sex | 94.3% male | 73.3% male | |
| Race | 94.3% white | 93.3% white | |
| Concomitant stimulant therapy | 42.9% | 73.3% | |

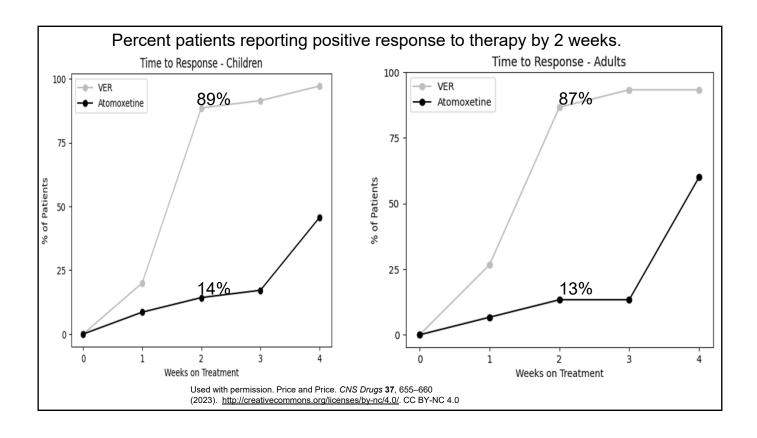
Atomoxetine or Viloxazine ER

 Pediatric ADHD Rating Scale and Adult Investigator Symptom Rating Scale

Atomoxetine 5-day Viloxazine washout ER

- Maximum treatment of 4 weeks each
- Atomoxetine average daily dose: 60mg (25-100mg)
- Viloxazine ER average daily dose: 300mg (100-600mg)





Atomoxetine or Viloxazine ER

- No one discontinued due to lack of response
- · Discontinued for side effects
 - o 36% discontinued atomoxetine
 - 4% discontinued viloxazine ER
- 96% participants preferred viloxazine ER over atomoxetine
- 85% were able to taper psychostimulants

Atomoxetine or Viloxazine ER

- Limitations
 - Very small population
 - Unblinded, open-label, retrospective chart review
 - No placebo group
 - Potential placebo effect, period effect, carryover effect
- Strengths
 - Pediatric and adult participants
 - Validated rating scales
 - Real-world clinic setting
- Barrier = insurance preferences

Two Truths and a Lie—ADHD

- a. High doses of amphetamines may be linked to risk of psychosis over methylphenidate in adolescents and young adults.
- Patients that take stimulants or norepinephrine reuptake inhibitors for treatment of ADHD should be monitored for cardiovascular side effects.
- c. Stimulant adverse effects can be expected at the same incidence in all patients no matter their age.

Two Truths and a Lie—ADHD

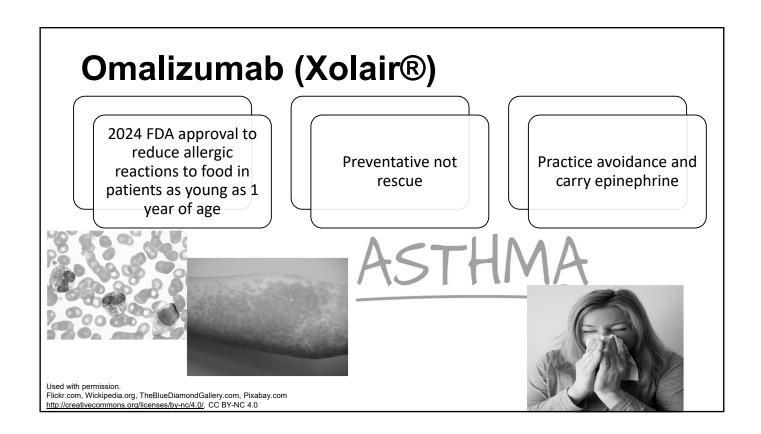
- a. High doses of amphetamines may be linked to risk of psychosis over methylphenidate in adolescents and young adults.
- Patients that take stimulants or serotonin reuptake inhibitors for treatment of ADHD should be monitored for cardiovascular side effects.
- c. Stimulant adverse effects can be expected at the same incidence in all patients no matter their age.

Two Truths and a Lie—Allergies

- a. A new warning for cetirizine and levocetirizine is the possibility of developing kidney stones.
- b. Omalizumab is approved to reduce allergic reactions to food in patients 1 year of age and older.
- c. neffy® is the name of a new epinephrine nasal spray approved by the FDA.

Two Truths and a Lie—Allergies

- a. A new warning for cetirizine and levocetirizine is the possibility of developing kidney stones.
- b. Omalizumab is approved to reduce allergic reactions to food in patients 1 year of age and older.
- c. neffy® is the name of a new epinephrine nasal spray approved by the FDA.



Epinephrine nasal spray (neffy®)



 Approved for patients down to 4 years of age.

o15-29kg: 1mg/0.1mL
o≥30kg: 2mg/0.1mg

- Similar to other sprayers
- Clinical trials for approval:
 - oFour adult studies
 - o1 pediatric study
- Compared to intramuscular epinephrine

Used with permission. Firstaidforlife.org.uk http://creativecommons.org/licenses/by-nc/4.0/. CC BY-NC 4.0

Epinephrine nasal spray (neffy®)



- Side effects
 - Nasal discomfort, tingling, dryness
 - o Epistaxis
 - oSneezing, rhinitis or congestion
 - Anxiety or dizziness
- 1 sprayer in 1 naris
 - Repeat in 5 minutes in the same nostril if needed.
- Prescribe at least 2 devices + refills
- About \$200 per carton of 2
- Instant savings down to \$25 for 4

Used with permission. Firstaidforlife.org.uk http://creativecommons.org/licenses/by-nc/4.0/. CC BY-NC 4.0

Case—Asthma

TL is a 23yo female in clinic for a follow-up of her persistent asthma.

She expresses to you her frustration with having to have 2 inhalers for the treatment of her asthma. Her medications include medium-dose inhaled corticosteroid (ICS) daily BID and albuterol as needed (prn).

TL needs at least 2 puffs of albuterol for her asthma symptoms, and albuterol works sometimes. She is adherent to her ICS.

A friend mentioned to TL that her doctor gave her one inhaler to use daily and as needed, and TL tells you she is interested in something similar.



Case — Asthma

Which of the following points should you *not* include in your counseling about SMART (single maintenance and reliever therapy) to TL?

- a. ICS-formoterol inhaler patents have been extended since the FDA approved them for use as SMART.
- b. ICS-formoterol SMART regimen significantly reduces the risk of severe exacerbations compared to traditional daily controller + prn albuterol regimens.
- c. The preferred product for SMART is budesonide + formoterol.
- d. ICS-formoterol inhaler can also be used before physical activity.

Case — Asthma

Which of the following points should you *not* include in your counseling about SMART (single maintenance and reliever therapy) to TL?

- a. ICS-formoterol inhaler patents have been extended since the FDA approved them for use as SMART.
- b. ICS-formoterol SMART regimen significantly reduces the risk of severe exacerbations compared to traditional daily controller + prn albuterol regimens.
- c. The preferred product for SMART is budesonide + formoterol.
- d. ICS-formoterol inhaler can also be used before physical activity.

SMART/MART Pearls

PRN doses of ICS-formoterol are just 1 puff

Can be used in any patient 4 years of age an older

Patients with a history or risk of adverse events to systemic steroids Doses of ICS depend on the patient's age (4-11yo and ≥12yo)

Max daily doses: 4-11yo = 8 puffs 12yo+ = 12 puffs Do not HAVE to rinse after prn doses

Prescriptions should be written for 2 inhalers per dispense Works as quickly as albuterol and as well as having 2 inhalers

Two Truths and a Lie—Asthma

- Uninsured patients can get low-cost inhalers for treatment of asthma and chronic obstructive pulmonary disease (COPD).
- b. Providers are excelling in the adoption and implementation of Global Initiative for Asthma (GINA) asthma guidelines.
- Montelukast has recently been found to attach to receptors in the brain that impact psychiatric functioning.

Two Truths and a Lie—Asthma

- Uninsured patients can get low-cost inhalers for treatment of asthma and chronic obstructive pulmonary disease (COPD).
- b. Providers are excelling in the adoption and implementation of Global Initiative for Asthma (GINA) asthma guidelines.
- Montelukast has recently been found to attach to receptors in the brain that impact psychiatric functioning.

Case—COPD

DM is a 66yo male who you are seeing for a COPD exacerbation follow-up; he is back to baseline. He is a 20-pack year former smoker. His medication regimen includes umeclidinium-vilanterol 6.25mcg-25mcg/actuation dry powder inhaler, 1 inhalation once daily; and albuterol 90mcg/actuation metered dose inhaler, 2 puffs with a spacer q4h prn cough, wheeze, shortness of breath.

The clinic pharmacist reports that the patient is adherent to treatment and has good device techniques.

He is not a candidate for LABA/LAMA/ICS triple therapy because he does not have an elevated eosinophil count.

Case—COPD

DM would like to know if there is anything else that can be done to prevent exacerbations. Which of the following do you discuss with him as an option?

- a. There are no additional medicines that can be added.
- b. Initiate dupilumab sub-q injections.
- c. If he has another exacerbation, you will send him to the hospital for treatment with benralizumab.
- d. Initiate azithromycin 500mg three times weekly.

Case—COPD

DM would like to know if there is anything else that can be done to prevent exacerbations. Which of the following do you discuss with him as an option?

- a. There are no additional medicines that can be added.
- b. Initiate dupilumab sub-q injections.
- c. If he has another exacerbation, you will send him to the hospital for treatment with benralizumab injection.
- d. Initiate azithromycin 500mg three times weekly.

Case—COPD

Seeing how sick DM gets with his COPD, his wife would like help with her smoking cessation efforts. Which of the following suggestions can you give her?

- a. Nicotine replacement as monotherapy
- b. Change to cigars
- c. DM should hide his wife's cigarettes and lighter
- d. ZYN® nicotine pouches

Case—COPD

Seeing how sick DM gets with his COPD, his wife would like help with her smoking cessation efforts. Which of the following suggestions can you give her?

- a. Nicotine replacement as monotherapy
- b. Change to cigars
- c. DM should hide his wife's cigarettes and lighter
- d. ZYN® nicotine pouches



Used with permission. En.wikpedia.org http://creativecommons.org/licenses/by-nc/4.0/. CC BY-NC 4.0

Respiratory Syncytial Virus (RSV) Immunoglobulin

| | Nirsevimab (Beyfortus®) | Clesrovimab (Eflonsia™) | |
|--------------------|---|-------------------------|--|
| Dosage Form | Prefilled syringe for injection | | |
| Administration | Intramuscular | | |
| Dosing | <5kg = 50mg ≥5kg = 100mg 2nd RSV season = 200mg (2 x 100mg) | 105mg | |
| Target population | <8 months of age 8-19 months of age at increased risk | <8 months of age | |
| Frequency | Once unless vulnerable for a 2nd season | Once | |
| Age Limitation | Up to 24 months of age | Up to 12 months of age | |
| Length of immunity | At least 5 months | | |
| Price | \$556 for all doses | | |

Two Truths and a Lie—Infectious Disease

- Treating a female's sexual male partner for bacterial vaginosis has no effect on the female patient's risk of recurrence.
- b. Solupenem etzadroxil and probenecid (Orlynvah™) is a new antibiotic to treat female urinary tract infections.
- c. Gepotidacin (Blujepa™) is a new antibiotic successful in treating female urinary tract infections and gonorrhea.



Used with permission. www.pexels.com http://creativecommons.org/licenses/by-nc/4.0/. CC BY-NC 4.0

Two Truths and a Lie—Infectious Disease

- a. Treating a female's sexual male partner for bacterial vaginosis has no effect on the female patient's risk of recurrence.
- b. Solupenem etzadroxil and probenecid (Orlynvah™) is a new antibiotic to treat female urinary tract infections.
- c. Gepotidacin (Blujepa™) is a new antibiotic successful in treating female urinary tract infections and gonorrhea.



Used with permission. www.pexels.com http://creativecommons.org/licenses/by-nc/4.0/. CC BY-NC 4.0

Insulin Affordability

| Brand | Package Size | Daily Dose | Day's Supply | Price |
|---|-----------------|---------------|-----------------|-------|
| Lantus [®] SoloStar [®] 100 units/mL | Any quantity! | Any dose! | 30 days | \$35 |
| Toujeo® SoloStar® 300 units/mL | Any quantity! | Any dose! | 30 days | \$35 |







Used with permission. commons.wikimedia.org http://creativecommons.org/licenses/by-nc/4_0/_CC BY-NC 4_0

Insulin Affordability

| Walmart's ReliOn [®] Brand | Package Size | Daily Dose | Day's Supply | Price |
|---|----------------------------|---------------|-----------------|-------|
| -NPH 100 units/mL -Regular 100 units/mL -70/30 100 units/mL | 10mL vial | 80 units | 12 days | ~\$25 |
| -NPH 100 units/mL -Regular 100 units/mL -70/30 100 units/mL | 5 - 3mL pens per carton | 80 units | 18 days | ~\$43 |

DOAC "Affordability"

- Rivaroxaban 2.5mg tablet
 - Indicated for the reduction of major cardiac events in adults with coronary artery disease and peripheral artery disease
 - o 10mg, 15mg, 20mg, and starter packs are brand name
 - o#60 for 30 days \$150-\$200
- Eliquis® Direct-to-Consumer Sales
 - o Eliquis 360 Support Program
 - o Under- and uninsured patients
 - o~43% discount
 - Medicare averages \$230

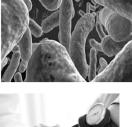


Used with permission. Sciencepolicyjournal.org http://creativecommons.org/licenses/by-nc/4.0/. CC BY-NC 4.0

Medication Safety

- Disposal
 - DEA Take Back Days
 - Mail-back envelopes
 - Collection receptacles
- Probiotics in premature babies
- Tirzepatide and oral contraceptives
- Testosterone replacement and the heart







Used with permission. Commons.wikimedia.org. Flickr.com. http://creativecommons.org/licenses/by-nc/4.0/. CC BY-NC 4.0

Summary

- Clonidine XR (Onyda[™] XR) suspension and viloxazine ER (Qelbree[®]) are two newer ADHD medicines.
- New medicines and new ways to treat allergic reactions and asthma exist.
- Nirsevimab (Beyfortus[®]) and clesrovimab (Eflonsia[™]) are passive antibodies to prevent severe RSV infection in infants.
- Solupenem etzadroxil (Orlynvah™) and Gepotidacin (Blujepa™) are new antibiotics to treat female UTI

Summary

- Manufacturers have programs to make medications like insulin and inhalers more affordable, but not all generic medications are affordable.
- Safety concerns about medications revolve around issues such as disposal, side effects, and drug-drug interactions.