AHCCCS
Arizona Health Care Cost Containment System

# AHCCCS Pharmacy and Therapeutics Committee

17 April 2018

# Introductions & Minutes Approval

- Dr. Sara Salek
  - Meeting Minutes review: January 16, 2018
  - Vote

# Magellan Class Reviews

***Classes for Review: Supplemental Rebate Classes***

- Opioid Dependence Treatment
- Hypoglycemics, Incretin Mimetics/Enhancers
- Hypoglycemics, Insulins & Related Agents
- COPD Agents

# Magellan Class Reviews

***Classes for Review:* Non-Supplemental Rebate Classes**

- Antimigraine Agents, Other
- Antimigraine Agents, Triptans
- Bronchodilators, Inhaled
- Leukotriene Modifiers
- Phosphate Binders
- Sedative Hypnotics
- Topical Steroids – Low, Medium, High & Very High Potency

# Magellan Drug Class Reviews

*Chris Andrews, Pharm.D.*

# Opioid Dependence Treatment

# Opioid Dependence Treatment

***Class Overview: Buprenorphine Products***

- buprenorphine extended-release injection - (Sublocade)
- buprenorphine implant - (Probuphine)
- buprenorphine sublingual - (buprenorphine sublingual tablets)

***Class Overview: Buprenorphine/Naloxone Combination Products***

- buprenorphine/naloxone buccal film - (Bunavail)
- buprenorphine/naloxone sublingual film - (Suboxone)
- buprenorphine/naloxone sublingual tablets - (buprenorphine/naloxone sublingual tablets; Zubsolv)

# Opioid Dependence Treatment

***Class Overview: Naloxone Products***

- naloxone HCl nasal spray - (Narcan)
- naloxone HCl injection - (naloxone syringe, vial)
- naloxone HCl tablets - (naloxone HCl tablets)

***Class Overview: Naltrexone Products***

- naltrexone HCl tablets - (naltrexone HCl tablets)
- naltrexone extended-release microsphere injection - (Vivitrol)

# Opioid Dependence Treatment

- Prescription opioids continue to become increasingly abused
- The 2016 National Survey on Drug Use and Health (NSDUH) reported there was an estimated 28.6 million Americans aged 12 years and older who were current illicit drug users
- There were approximately 11.8 million people aged 12 or older in the United States (U.S.) who misused opioids in the past year
- Approximately 20.1 million people aged 12 or older in 2016 were considered to have a substance use disorder (SUD)
- This includes 15.1 million people with an alcohol use disorder, 7.4 million people with an illicit drug use disorder, and 2.1 million had an opioid use disorder
- Despite the availability of multiple guidelines and resources for the initiation and management of medications for opioid dependency, there is no consensus on the ideal duration of maintenance therapy

# Opioid Dependence Treatment

- Buprenorphine is a partial agonist at the mu-opioid receptor and an antagonist at the kappa-opioid receptor
- Naloxone is an antagonist at the mu-opioid receptor. Buprenorphine/naloxone was co-formulated in order to prevent patients from abusing buprenorphine in combination with other opioids
- Naltrexone is an opioid antagonist with highest affinity for the mu opioid receptor. Naltrexone blocks the effects of opioids by competitive binding at opioid receptors
- There is a risk for opioid withdrawal symptoms during the transition of patients from full opioid agonists to a partial opioid agonist like buprenorphine

# Opioid Dependence Treatment

- In clinical trials, few differences in the adverse event profile were noted among Suboxone sublingual film, Zubsolv sublingual tablets, Bunavail buccal film and buprenorphine sublingual tablets. Comparative data between formulations for induction or maintenance treatment are limited
- There is no maximum duration of maintenance treatment for buprenorphine extended-release injection (Sublocade) or buprenorphine/naloxone sublingual tablet and sublingual and buccal film (Bunavail, Suboxone, Zubsolv, generic)
- For some patients, treatment may continue indefinitely
- Bunavail, Suboxone, Zubsolv and the generic should be prescribed based consideration of visit frequency; provision for multiple refills are not recommended early in treatment or without appropriate follow-up

# Opioid Dependence Treatment

- Medication-assisted treatment (MAT) for opioid addiction using a buprenorphine-containing product or naltrexone formulation should be accompanied by counseling and psychosocial support
- Naloxone hydrochloride nasal spray (Narcan) offers a method for emergency treatment for opioid overdose until medical treatment is obtained; however it is not a substitute for emergency medical care

# Opioid Dependence Treatment

***New Product: Sublocade (buprenorphine microsphere extended-release injection)***

- Indicated for the treatment of moderate to severe opioid use disorder in patients who have initiated treatment with a transmucosal buprenorphine-containing product for a minimum of 7 days
- Should be used as part of a complete treatment program that includes counseling and psychiatric support
- Available as a prefilled syringe containing 300mg/1.5ml or 100mg/0.5ml
- Administered subcutaneously in the abdominal region by a healthcare provider with a recommended initial dose of 300 mg monthly for two doses, followed by a 100 mg monthly maintenance dose
- Safety and efficacy in pediatric patients have not been established

# Opioid Dependence Treatment

***New Product: Sublocade (buprenorphine microsphere extended-release injection)***

- Severe, life-threatening respiratory depression can occur in children who are accidentally exposed to Sublocade.
- Patients with moderate to severe hepatic impairment are not candidates for treatment
- Monitor patients for indications of diversion or progression of opioid dependence/addictive behaviors
- Monitor patients who have discontinued Sublocade therapy for several months for withdrawal and treat appropriately
- Emergent acute pain should be treated with a non-opioid analgesic whenever possible

# Opioid Dependence Treatment

***New Product: Sublocade (buprenorphine microsphere extended-release injection)***

- Two key studies for the use of Sublocade in moderate to severe opioid use disorder include a phase 3 double-blind efficacy and safety study (13-001) and a phase 2 opioid blockade study (13-002)
- Study 13-001 was a 24-week, phase 3, randomized, double-blind, placebo-controlled, multicenter trial in treatment-seeking patients who met Diagnostic and Statistical Manual of Mental Disorders, 5th Edition (DSM-5) criteria for moderate to severe opioid use disorder
- A total of 504 patients were randomized to one of the following groups: 6 once-monthly 300 mg doses of Sublocade (n=201), 2 once-monthly 300 mg doses followed by 4 once-monthly 100 mg doses of Sublocade (n=203), 6 once-monthly doses of placebo (n=100)

# Opioid Dependence Treatment

***New Product: Sublocade (buprenorphine microsphere extended-release injection)***

- All patients received manual-guided psychosocial support at least once a week. Prior to the first dose, patients were initiated on treatment with buprenorphine/naloxone sublingual film with the dose titrated between 8 mg to 24 mg of buprenorphine over a period of 7 to 14 days
- Patients were randomized after cravings and withdrawal symptoms were clinically controlled. After randomization, supplemental dosing with sublingual buprenorphine was not permitted.
- Treatment success was defined as ≥ 80% opioid-free weeks. Efficacy was evaluated based upon weeks 5 through 24 weekly urine drug screens combined with self-reported use of illicit opioid use

# Opioid Dependence Treatment

***New Product: Sublocade (buprenorphine microsphere extended-release injection)***

- Percent of patients who achieved treatment success was statistically significant in both treatment groups receiving Sublocade compared to placebo
- Study 13-002 was an opioid blockade study that evaluated the blockade of subjective opioid effects in 39 patients with opioid use disorder not treatment seeking. Patients were administered Sublocade 300 mg on days 1 and 29. Patients were given placebo or 6 mg or 18 mg of hydromorphone administered intramuscularly on 3 consecutive days in each study week before (baseline hydromorphone challenge) and after receiving Sublocade. All treatment demonstrated blockade for hydromorphone doses following Sublocade injections

# Opioid Dependence Treatment

***Guideline Updates***

- American College of Physicians (ACP) published a Position Paper on prevention and treatment of substance use disorders involving illicit and prescription drugs. Key pharmacologic recommendations include expansion of access to naloxone, expansion of access to medication-assisted treatment for opioid use disorders, establishment of a national prescription drug monitoring program (PDMP), and use of evidence-based guidelines for pain management
- The FDA advises buprenorphine and methadone should not be withheld from patients taking benzodiazepines or other drugs that cause CNS depression. The harm caused by untreated opioid addiction can outweigh these risks

# Opioid Dependence Treatment

***Product Updates:***

- Bunavail is now indicated for induction of buprenorphine treatment for opioid dependence
- There were revisions to Suboxone regarding duration of therapy. There is no maximum recommended duration and treatment should continue as long as it provides benefit
- Modifications were made to Zubsolv labeling regarding induction dosing. It is now specified for use in patients dependent on heroin or other short-acting opioid, but not for patients dependent on methadone or long-acting opioids

# Hypoglycemics, Incretin Mimetics/Enhancers

# Hypoglycemics, Incretin Mimetics/Enhancers

***Class Overview: Amylin Analogues***

- pramlintide - (Symlin)

***Class Overview: Dipeptidyl Peptidase-4 Enzyme Inhibitors (DPP-4)***

- alogliptin - (alogliptin; Nesina)
- alogliptin/metformin - (alogliptin/metformin; Kazano)
- alogliptin/pioglitazone - (alogliptin/pioglitazone; Oseni)
- linagliptin - (Tradjenta)
- linagliptin/empagliflozin - (Glyxambi)
- linagliptin/metformin - (Jentadueto)

# Hypoglycemics, Incretin Mimetics/Enhancers

***Class Overview: Dipeptidyl Peptidase-4 Enzyme Inhibitors (DPP-4)***

- linagliptin/metformin extended-release - (Jentadueto XR)
- saxagliptin - (Onglyza)
- saxagliptin/dapagliflozin - (Qtern)
- saxagliptin/metformin extended-release - (Kombiglyze XR)
- sitagliptin - (Januvia)
- sitagliptin/metformin - (Janumet)
- sitagliptin/metformin extended-release - (Janumet XR)

# Hypoglycemics, Incretin Mimetics/Enhancers

***Class Overview: Glucagon-Like Peptide-1 Receptor Agonists (GLP-1)***

- albiglutide - (Tanzeum)
- dulaglutide - (Trulicity)
- exenatide - (Byetta)
- exenatide extended-release - (Bydureon; Bydureon Bcise)
- liraglutide - (Victoza)
- liraglutide/insulin degludec - (Xultophy)
- lixisenatide - (Adlyxin)
- lixisenatide/insulin glargine - (Soliqua)
- semaglutide - (Ozempic)

# Hypoglycemics, Incretin Mimetics/Enhancers

- Initial treatment for type 2 diabetes (T2DM) consists of diet, exercise, and metformin, followed by other oral anti-diabetic agents and/or insulin
- This approach improves glycemic control, but cannot fully restore beta-cell function
- American Diabetes Association (ADA) 2017 Standards of Medical Care in Diabetes state selection of an anti-diabetic medication should be based on level of glycemic control, adherence to treatment) and relative quickness for lowering blood glucose, adverse effect profile, and nonglycemic effects
- Generally agreed that metformin, if not contraindicated and if tolerated, is the preferred first agent in the treatment of T2DM
- ADA now recommends a target HbA1c of < 7.5% for all age-groups, although individualization is still supported

# Hypoglycemics, Incretin Mimetics/Enhancers

- American Academy of Clinical Endocrinologists (AACE) and the American College of Endocrinology (ACE) updated their algorithm and practice guidelines for the management of T2DM setting a treatment goal of HbA1c ≤ 6.5% for healthy patients with low hypoglycemic risk
- Patients with concurrent illness and at risk of hypoglycemia should have a goal of HbA1c > 6.5%
- AACE/ACE indicates that liraglutide and empagliflozin may offer renal and CV benefit. They also suggest that saxagliptin and alogliptin may be associated with possible CV risk; there may be increased risk of bone fractures with canagliflozin; and increased congestive heart failure (HF) risk with sulfonylureas, glinides, and insulin

# Hypoglycemics, Incretin Mimetics/Enhancers

- In 2017, the American College of Physicians (ACP) updated their recommendations for T2DM with a recommend metformin as first-line therapy and advise that it can be safely used in patients with mild renal impairment and in select patients with moderate impairment
- They recommend to add a SU, TZD, SGLT-2 inhibitor, or DPP-4 inhibitor as second-line therapy
- Amylin Analogues slow gastric emptying, suppresses glucagon secretion, and centrally modulates appetite. They may also be used for type 1 diabetes
- DPP-4 Enzyme Inhibitors increase insulin secretion and reduce glucagon secretion by preventing inactivation of GLP-1
- GLP-1 Receptor Agonists enhance glucose-dependent insulin secretion, suppress elevated glucagon secretion, and slow gastric emptying

# Hypoglycemics, Incretin Mimetics/Enhancers

- No data are available for use of these agents in pediatric populations
- HbA1c improvements for Amylin Analogues average 0.3% to 0.6% with a potential weight reduction of 0.5 kg to 1.5 kg
- HbA1c improvements for DPP-4s average 0.5% to 1%. These agents are weight-neutral and have a low hypoglycemia risk when used as monotherapy or in conjunction
- For GLP-1s, albiglutide averages HbA1c reductions of 0.7% to 0.9%; dulaglutide averages 0.7% to 1.6%; exenatide and liraglutide average reductions in HbA1c of 0.5% to 1.6%; lixisenatide reductions average 0.3% to 0.65%; and semaglutide reductions of 1.4% to 1.5%

# Hypoglycemics, Incretin Mimetics/Enhancers

***New Product: Ozempic (semaglutide)***

- A glucagon-like peptide 1 (GLP-1) receptor agonist indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus (T2DM)
- Not recommended as first-line therapy for patients inadequately controlled on diet and exercise
- Initial dose is 0.25mg SC once weekly for 4 weeks, then increased to 0.5mg once weekly. If additional control is needed, the dose may be further increased to the maximum of 1 mg once weekly, following four week of 0.5mg dosing
- Each pen contains a total of 2 mg in a pen that delivers 0.25 mg or 0.5 mg or in a pen that delivers 1 mg increments

# Hypoglycemics, Incretin Mimetics/Enhancers

***New Product: Ozempic (semaglutide)***

- Contraindicated in patients with a personal or family history of medullary thyroid carcinoma (MTC) or in patients with Multiple Endocrine Neoplasia syndrome type 2
- Carries a boxed warning regarding the risk of thyroid C-cell tumors
- Limited data with use in pregnant women to inform a drug-associated risk for adverse developmental outcomes; it should be used only if the potential benefit justifies the potential risk
- Safety and efficacy of semaglutide have not been established in pediatric patients
- Semaglutide was studied in clinical trials as both monotherapy and as combination therapy

# Hypoglycemics, Incretin Mimetics/Enhancers

***New Product: Ozempic (semaglutide)***

- Ozempic has also been studied in a cardiovascular (CV) outcomes trial
- The safety profile of semaglutide was found to be similar to other GLP-1 agonists
- SUSTAIN 1 (monotherapy) was a multinational, phase 3a, 30-week, double-blind clinical trial comparing the efficacy of semaglutide to placebo in 388 treatment-naive adults with T2DM treated with diet and exercise alone for ≥ 30 days before screening and a baseline hemoglobin A1c (HbA1c) of 7% to 10%. At week 30, HbA1c significantly decreased in both semaglutide treatment groups compared to placebo. A statistically significant decrease was also found in body weight with both strengths of semaglutide but not with placebo

# Hypoglycemics, Incretin Mimetics/Enhancers

***New Product: Ozempic (semaglutide)***

- SUSTAIN 2 (combination therapy; add-on to metformin, thiazolidinedione, or both) was a multinational, phase 3a, 56-week, double-blind, active-control, double-dummy, parallel-group clinical trial compared the efficacy of semaglutide to sitagliptin in 1,231 patients with insufficient glycemic control (HbA1c, 7% to 10.5%) despite stable treatment with metformin, thiazolidinediones, or both. At week 56, HbA1c was reduced by 1.3% in the semaglutide 0.5 mg group, 1.6% in the semaglutide 1 mg group, and 0.5% with sitagliptin for non-inferiority and superiority for both. A statistically significant decrease was also found in body weight with both strengths of semaglutide compared to sitagliptin

# Hypoglycemics, Incretin Mimetics/Enhancers

***New Product: Ozempic (semaglutide)***

- SUSTAIN 3 (combination therapy; add-on to metformin and/or thiazolidinedione and sulfonylureas) was a multinational, randomized, phase 3, 56-week, open-label clinical trial compared the efficacy of semaglutide to exenatide extended-release (ER) in 813 patients with insufficient glycemic control (HbA1c, 7% to 10.5%) despite stable treatment with metformin and/or thiazolidinedione and sulfonylureas. At week 56, HbA1c was reduced by 1.5% in the semaglutide 1 mg group and 0.9% with exenatide ER for noninferiority and superiority. A statistically greater decrease in body weight was also found with semaglutide compared to exenatide ER

# Hypoglycemics, Incretin Mimetics/Enhancers

***New Product: Ozempic (semaglutide)***

- SUSTAIN 4 (combination therapy; add-on to metformin alone or in combination with a sulfonylurea) was a multinational, randomized, open-label, non-inferiority, parallel-group, 30-week, phase 3a, clinical trial compared the efficacy of semaglutide to insulin glargine in 1,089 patients with insufficient glycemic control (HbA1c, 7% to 10%) despite stable treatment with metformin alone or in combination with a sulfonylurea. At week 30, the 0.5 mg and 1 mg semaglutide treatment groups had reductions of 1.21% and 1.64% respectively. The insulin glargine group had a reduction of 0.83%. A weight loss was found in both semaglutide groups compared to weight gain in the insulin glargine group

# Hypoglycemics, Incretin Mimetics/Enhancers

***New Product: Ozempic (semaglutide)***

- SUSTAIN 5 (combination therapy; add-on to basal insulin, with or without metformin) was a multinational, randomized, 30-week, double-blind, phase 3 clinical trial compared the efficacy of semaglutide to placebo in 397 patients with insufficient glycemic control (HbA1c, 7% to 10%) despite stable treatment with basal insulin, with or without metformin. At week 30, the 0.5 mg and 1 mg semaglutide treatment groups had reductions of 1.3% and 1.7%, respectively. The placebo group had a reduction of 0.2%. A weight loss was found in both semaglutide groups compared to weight gain in the insulin glargine group

# Hypoglycemics, Incretin Mimetics/Enhancers

***New Product: Ozempic (semaglutide)***

- SUSTAIN 6 (CV outcomes) was a multinational, phase 3, double-blind, 104-week trial compared CV outcomes in 3,297 patients with type 2 diabetes randomized to either placebo or semaglutide. The primary outcome was a composite of first occurrence of CV death, nonfatal myocardial infarction (MI), or nonfatal stroke. At baseline, 83% of the patients had a history of CV disease, chronic kidney disease, or both, and 17% were at high risk of CV disease. The primary outcome occurred in 6.6% (108/1,648) and 8.9% (146/1,649) of patients assigned semaglutide and placebo, respectively

# Hypoglycemics, Incretin Mimetics/Enhancers

***New Product: Steglujan (ertugliflozin/sitagliptin)***

- A fixed-ratio combination with the DPP-4 inhibitor sitagliptin indicated as an adjunct to diet and exercise to improve glycemic control in adults with T2DM when treatment with both ertugliflozin and sitagliptin is appropriate
- Steglujan has not been studied in patients with a history of pancreatitis
- Steglujan is contraindicated in patients with severe renal impairment, end stage renal disease (ESRD), or on dialysis
- Steglujan or one of its components is associated with an increased risk of urosepsis and pyelonephritis. Monitor patients for signs and symptoms of urinary tract infections and treat if indicated

# Hypoglycemics, Incretin Mimetics/Enhancers

***New Product: Steglujan (ertugliflozin/sitagliptin)***

- Steglujan is not recommended for use in pregnancy during the second and third trimesters
- No information is available regarding the efficacy or safety of Steglujan in patients under 18 years old
- Steglujan is available as 5mg/100mg or 15mg/100mg tablets
- The dose of sitagliptin is not variable (100mg) and the starting dosage for the ertugliflozin component is 5mg by mouth daily, given without regard to food. The dose may be increased to the maximum recommended dose (15mg) if tolerated

# Hypoglycemics, Incretin Mimetics/Enhancers

***New Product: Steglujan (ertugliflozin/sitagliptin)***

- Vertis Factorial - 26-week, double-blind, active-controlled study was performed in 1,233 patients with T2DM who were not adequately controlled (HbA1C, 7.5% to 11%) on metformin monotherapy (≥ 1,500 mg/day) in order to determine the safety and efficacy of ertugliflozin in combination with sitagliptin compared to the individual components
- Participants were randomized to receive ertugliflozin 5 mg, ertugliflozin 15 mg, sitagliptin 100 mg, or coadministration of ertugliflozin/sitagliptin 5/100 mg or ertugliflozin/sitagliptin 15/100 mg once daily
- The primary endpoint, change from baseline HbA1C at week 26, was significantly higher in the combination products

# Hypoglycemics, Incretin Mimetics/Enhancers

***New Product: Steglujan (ertugliflozin/sitagliptin)***

- A -1.5% mean reduction of HbA1C was observed in patients taking ertugliflozin/sitagliptin 5/100 mg and 15/100 mg daily as compared to the individual agents ertugliflozin 5 mg (-1%), ertugliflozin 15 mg (-1.1%), and sitagliptin 100 mg (-1.1%)
- The percent of patients achieving a HbA1C < 7% was 26.4% in patients taking ertugliflozin 5 mg, 31.9% in patients taking ertugliflozin 15 mg, 32.8% in patients taking sitagliptin 100 mg, 52.3% in patients taking ertugliflozin/sitagliptin 5/100 mg, and 49.2% in patients taking ertugliflozin/sitagliptin 15/100 mg

# Hypoglycemics, Incretin Mimetics/Enhancers

***New Product: Steglujan (ertugliflozin/sitagliptin)***

- Vertis Sita –a 26-week, double-blind, placebo-controlled study was performed in 291 patients with T2DM who were not adequately controlled by diet and exercise (HbA1C, 8% to 10.5%) in order to determine the safety and efficacy of ertugliflozin in combination with sitagliptin
- Patients were then randomized to ertugliflozin 5 mg, ertugliflozin 15 mg, or placebo in combination with sitagliptin 100 mg once daily.
- The primary endpoint, change from baseline HbA1C at week 26, was significantly higher in the active combination treatment groups compared to the placebo group

# Hypoglycemics, Incretin Mimetics/Enhancers

***New Product: Steglujan (ertugliflozin/sitagliptin)***

- The mean reduction of HbA1C relative to the placebo group was -1.2% in the ertugliflozin 5 mg + sitagliptin 100 mg group and -1.2% in the ertugliflozin 15 mg + sitagliptin 100 mg group
- Patients in the ertugliflozin 5 mg + sitagliptin 100 mg group were 6.9 times as likely to achieve a HbA1C < 7% than patients in the placebo group and patients in the ertugliflozin 15 mg + sitagliptin 100 mg group were 7.4 times as likely to achieve a HbA1C < 7% than patients in the placebo group
- Patients treated with ertugliflozin and sitagliptin also had greater reductions in body weight compared to placebo

# Hypoglycemics, Incretin Mimetics/Enhancers

***Guideline Updates:***

- The American Diabetes Association (ADA) has released their annual Standards of Medical Care in Diabetes for 2018. Notable updates regarding treatment includes incorporation of medications with known CV benefit (e.g., liraglutide, empagliflozin) after lifestyle management and metformin

# Hypoglycemics, Incretin Mimetics/Enhancers

***Product Updates:***

- Victoza is now approved to reduce the risk of major adverse cardiovascular events (MACE), heart attack, stroke and CV death in adults with Type 2 diabetes and established CV disease. *This is based on the LEADER trial that demonstrated a 13% reduction in the risk of MACE vs. placebo (absolute risk reduction of 1.9%)*
- The FDA approved Bydureon BCise, a continuous-release microsphere suspended in MCT-oil, designed to provide consistent therapeutic levels of exenatide
- Bcise is indicated in adults with T2DM whose blood glucose is not controlled with at least one oral anti-diabetic agent

# Hypoglycemics, Incretin Mimetics/Enhancers

***Product Updates:***

- Bcise is approved as a single-dose auto-injector containing 2 mg exenatide per 0.85ml suspension and is administered SC once-weekly
- Contraindications, warnings, and adverse reactions are similar to those seen with other exenatide-containing products, including boxed warning for risk of thyroid C-cell tumors
- GSK has made a business decision to discontinue manufacturing of Tanzeum. Anticipated depletion of supply is July 2018

# Hypoglycemics, Insulin and Related Agents

# Hypoglycemics, Insulin and Related Agents

***Class Overview: Rapid-Acting Insulins***

- human insulin inhalation powder - (Afrezza)
- insulin aspart - (Fiasp; Novolog)
- insulin glulisine - (Apidra)
- insulin lispro - (Admelog; Humalog; Humalog Junior)

***Class Overview: Regular Insulins***

- human insulin - (Humulin R; Novolin R)

***Class Overview: Intermediate Insulins***

- human insulin NPH - (Humulin N; Novolin N)

# Hypoglycemics, Insulin and Related Agents

***Class Overview: Long-Acting Insulins***

- insulin degludec - (Tresiba)
- insulin detemir - (Levemir)
- insulin glargine U-100 - (Basaglar; Lantus)
- insulin glargine U-300 - (Toujeo)

***Class Overview: Rapid/Intermediate-Acting Combination Insulins***

- insulin aspart 70/30 - (Novolog Mix 70/30)
- insulin lispro 50/50; 75/25 - (Humalog Mix 50/50, 75/25)

***Class Overview: Regular/Intermediate-Acting Combination Insulins***

- human insulin 70/30 - (Humulin 70/30; Novolin 70/30)

# Hypoglycemics, Insulin and Related Agents

- Estimated 30 million Americans have diabetes mellitus (DM) which is responsible for increased morbidity and mortality
- Adequate glycemic control is crucial to minimize chronic microvascular (e.g., blindness, renal dysfunction) and macrovascular (e.g., cardiovascular disease) complications
- Exogenous insulin supplements deficient levels and temporarily restores the body's ability to properly utilize carbohydrates, fats, and proteins
- Multiple insulin products are available and used in the management of both T1DM and T2DM
- The American Diabetes Association (ADA) 2017 Standards of Medical Care in Diabetes advocate that glycemic goals be tailored to individual patient needs

# Hypoglycemics, Insulin and Related Agents

- Insulin therapy is the treatment of choice in pregnancy as it does not appreciably cross the placenta
- AACE/ACE guidelines state insulin is required in all patients with T1DM and advises that insulin therapy be considered for patients with T2DM, when HbA1c > 8%, or oral therapy fails to achieve target glycemic control
- Insulin therapy is contraindicated during episodes of hypoglycemia
- All of the rapid-acting insulins except Fiasp are approved for use in pediatric patients as well as for use in external insulin pumps
- Basaglar (insulin glargine 100 U/ml), and Admelog (insulin lispro 100 U/ml), were approved as 'follow-on' products to Lantus and Humalog respectively

# Hypoglycemics, Insulin and Related Agents

***Product Updates:***

- Humalog Junior KwikPen is approved in adults and children. The 3ml prefilled pen delivers half-unit dosing and will be available as a 5-pack carton
- Fiasp, a rapid-acting human insulin analog, is in adults with diabetic mellitus. It is approved as 100 units/ml in 10ml multiple-dose vials and 3ml FlexTouch pens. Contraindications, warnings and adverse reactions are similar to other rapid-acting insulin analogs. No comparative clinical data available

# Hypoglycemics, Insulin and Related Agents

***Product Updates:***

- Admelog is a rapid-acting human insulin analog indicated in adults and pediatric patients 3 years and older with type 1 diabetes mellitus and adults with type 2 diabetes mellitus. Admelog was approved via the 505(b)(2) pathway and is the first 'follow-on' insulin for Humalog. It is approved as a 100 unit/ml injection in 10ml multidose vial and 3ml prefilled pens
- Toujeo Max Solostar 3ml disposable prefilled pen is approved. Toujeo Solostar 1.5ml prefilled pen was already approved and both pens consist of 300 unit/ml.

# COPD Agents

# COPD Agents

***Class Overview: Antimuscarinics – Short-Acting***

- ipratropium inhalation aerosol - (Atrovent HFA)
- ipratropium inhalation solution - (ipratropium inhalation solution )

***Class Overview: Antimuscarinics – Long-Acting***

- aclidinium bromide - (Tudorza Pressair)
- glycopyrrolate - (Seebri Neohaler)
- tiotropium bromide inhalation spray - (Spiriva Respimat)
- tiotropium inhalation powder - (Spiriva HandiHaler)
- umeclidinium - (Incruse Ellipta)

# COPD Agents

***Class Overview: Beta Agonist/Antimuscarinic Combination – Short-Acting***

- albuterol/ipratropium MDI CFC-Free - (Combivent Respimat)
- albuterol/ipratropium inhalation solution - (albuterol/ipratropium inhalation solution )

***Class Overview: Beta Agonist/Antimuscarinic Combination – Long-Acting***

- formoterol/glycopyrrolate - (Bevespi Aerosphere)
- indacaterol/glycopyrrolate - (Utibron Neohaler)
- tiotropium/olodaterol - (Stiolto Respimat)
- umeclidinium/vilanterol - (Anoro Ellipta)

# COPD Agents

***Class Overview: Phosphodiesterate 4 (PDE-4) Inhibitor***

- roflumilast - (Daliresp)

# COPD Agents

- Chronic obstructive pulmonary disease (COPD) is a disease state characterized by the presence of airflow obstruction due to chronic bronchitis or emphysema
- Airflow obstruction is generally progressive, may be accompanied by airway hyperreactivity, and may be partially reversible
- Progressive persistent obstruction or limitation of airflow is associated with an enhanced chronic inflammatory response in both the airways and the lung to noxious particles or gases
- Exacerbations and comorbidities contribute to the overall severity in individual patients
- COPD continues to be a leading cause of chronic morbidity and mortality worldwide

# COPD Agents

- Both chronic bronchitis and emphysema predispose patients to a common collection of symptoms and impairments in respiratory function
- These include such reductions in forced expiratory volume in one second (FEV1), forced vital capacity (FVC), FEV1/FVC ratio, and forced expiratory flow
- A COPD exacerbation is defined as an acute event characterized by worsening of the patient's respiratory symptoms that varies from the normal daily variations and requires a change in medication
- Prior to 2017, patient groups were categorized into an alphabetic (ABCD) classification system based on exacerbation risk and symptoms in combination with airway limitation
- Patients are now classified separately by *both their GOLD severity and exacerbation/symptom assessment*

# COPD Agents

| 2017 GOLD Guidelines | |
|---|---|
| Assessment of Airflow Limitation | |
| Gold 1 | Mild, FEV1 ≥ 80% predicted |
| Gold 2 | Moderate, FEV1 50% to 79% predicted |
| Gold 3 | Severe, FEV1 30% to 49% predicted |
| Gold 4 | Very severe, FEV1 < 30% predicted |

# COPD Agents

| 2017 GOLD Guidelines | |
|---|---|
| **Assessment of Exacerbation Risk and Symptoms** | |
| Patient Group A | Low Risk, Less Symptoms: 0 to 1 exacerbations per year (not leading to hospitalization); and CAT score < 10 or mMRC grade 0 to 1 |
| Patient Group B | Low Risk, Less Symptoms: 0 to 1 exacerbations per year (not leading to hospitalization); and CAT score ≥ 10 or mMRC grade ≥ 2 |
| Patient Group C | High Risk, Less Symptoms: ≥ 2 exacerbations per year or ≥ 1 exacerbation leading to hospitalization; and CAT score < 10 or mMRC grade 0 to 1 |
| Patient Group D | High Risk, Less Symptoms: ≥ 2 exacerbations per year or ≥ 1 exacerbation leading to hospitalization; and CAT score ≥ 10 or mMRC grade ≥ 2 |

*mMRC - Modified British Medical Research Council questionnaire used only to assesses breathlessness*

# COPD Agents

GOLD Guidelines Group A:

- Short-acting inhaled bronchodilator used on an as-needed basis is recommended as first choice while a long-acting beta$_2$-agonist or anticholinergic and the combination of short-acting inhaled beta$_2$-agonist and short-acting anticholinergic are considered as alternatives

GOLD Guidelines Group B:

- Regular use of a long-acting bronchodilator (beta$_2$-agonist or anticholinergic) is recommended while the combination of a long-acting beta$_2$-agonist and a long-acting anticholinergic is an alternative treatment.

# COPD Agents

GOLD Guideline Group C:

- Fixed combinations of inhaled corticosteroid/long-acting bronchodilators (beta$_2$-agonist or anticholinergic)
- Alternatively, a phosphodiesterase-4 (PDE4) inhibitor plus a long-acting bronchodilator or a long-acting anticholinergic plus a long-acting beta$_2$-agonist

# COPD Agents

- Bronchodilator medications are central to the symptomatic management of COPD
- Act to improve emptying of the lungs, reduce dynamic hyperinflation at rest and during exercise, and improve exercise performance
- Are given either on an as-needed basis for relief of persistent or worsening symptoms or on a regular basis to prevent or reduce symptoms
- Regular treatment with long-acting bronchodilators is more effective and convenient than treatment with short-acting agents
- Combining bronchodilators of different pharmacological classes may improve efficacy and decrease the risk of side effects
- There is insufficient evidence to recommend one long-acting agent over another

# COPD Agents

***New Product: Lonhala Magnair (glycopyrrolate inhalation solution)***

- An long-acting anticholinergic indicated for the long-term, maintenance treatment of airflow obstruction in patients with COPD
- Lonhala Magnair should not be used in the treatment of acute COPD or initiated in acutely deteriorating COPD
- Lonhala Magnair should not be administered concomitantly with other anticholinergic medications
- Available as solution for inhalation in unit-dose 1ml vial containing 25mcg of glycopyrrolate) in a Starter Kit or a Refill Kit
- Maintenance dose for COPD is one vial twice daily using the Magnair nebulizer system

# COPD Agents

***New Product: Lonhala Magnair (glycopyrrolate inhalation solution)***

- Approval of Lonhala Magnair was based on the GOLDEN (Glycopyrrolate for Obstructive Lung Disease via Electronic Nebulizer) trials
- These included two dose-ranging studies (n=378), two 12-week placebo-controlled confirmatory studies (n=1,294) and one 48 week safety study
- GOLDEN-3 and GOLDEN-4 were phase 3, randomized, double-blinded, placebo-controlled, confirmatory trials in patients with moderate to very severe COPD
- Patients were randomized to receive glycopyrrolate 25 mcg, 50 mcg or placebo twice daily. The primary endpoint was the change from baseline in trough forced expiratory volume in 1 second (FEV1) at 12 weeks

# COPD Agents

***New Product: Lonhala Magnair (glycopyrrolate inhalation solution)***

- Patients receiving glycopyrrolate 25 mcg or 50 mcg twice daily resulted in statistically significant changes from baseline in trough FEV1, as compared with placebo
- There was not a sufficient increase in benefit seen to support use of the 50 mcg dose over the 25 mcg dose
- A Phase 3 48 week, randomized (n=1,086), open-label, active-controlled safety trial (GOLDEN-5) evaluated the long-term safety and tolerability of Lonhala Magnair compared to once daily Spiriva HandiHaler
- Primary endpoints were the incidence of adverse events, serious events, and discontinuations due to adverse events. Overall incidence of was similar between the groups.

# COPD Agents

***Guideline Updates***

- The 2017 update to the Global Initiative for Chronic Obstructive Lung Disease (GOLD) guidelines observe that combination bronchodilator use may be more appropriate in patients with less advanced disease, but data does not definitively show LAMA/LABA treatment to be more effective than ICS/LABA

# COPD Agents

***Product Updates:***

- *FDA has approved the SmartTouch for Symbicort inhaler monitoring device for use with Symbicort inhaler; once installed, data regarding date and time of dosing can be transmitted to an app on the patients mobile device; the SmartTouch device also has audio and visual reminders*
- A new 250 mcg strength of Daliresp has been approved. The OPTIMIZE post marketing study evaluated dose up-titration with a starting dose of 250 mcg once daily for four weeks, then a maintenance dose of 500 mcg once daily as a strategy to improve roflumilast tolerability. As a result of the success of the study the 250 mcg dose was approved

# Antimigraine Agents, Other

# Antimigraine Agents, Other

***Class Overview:***

- diclofenac potassium - (Cambia)
- dihydroergotamine mesylate - (dihydroergotamine mesylate injection & nasal; Migranal Nasal)
- ergotamine tartrate - (Ergomar SL)
- ergotamine tartrate/caffeine - (Cafergot; ergotamine tartrate/caffeine; Migergot Rectal)
- isometheptene/caffeine/APAP - (isometheptene/caffeine/APAP)

# Antimigraine Agents, Other

- Migraines account for 10% to 20% of all headaches in adults and affect over 38 million men, women, and children in the United States
- Migraine headaches should be differentiated from regular tension-type headaches. Key criteria for migraine diagnosis includes an episodic headache lasting from 4 to 72 hours with at least two of the following: unilateral pain, throbbing, aggravation of pain upon moving, pain of moderate to severe intensity accompanied by nausea, vomiting, photophobia, or phonophobia
- Treatment of acute migraine attacks includes acetaminophen, non-steroidal anti-inflammatory drugs (NSAIDs), and the ergot alkaloids. NSAIDs, or combinations such as aspirin plus acetaminophen plus caffeine, are recommended as first-line therapy for those patients with mild to moderate migraine pain

# Antimigraine Agents, Other

- Migraine-specific agents (triptans, dihydroergotamine [DHE]) should be used in patients whose migraine attacks do not respond to NSAIDs

# Antimigraine Agents, Triptans

# Antimigraine Agents, Triptans

***Class Overview:***

- almotriptan malate - (almotriptan & (AG); Axert)
- eletriptan HBr - (eletriptan & (AG); Relpax)
- frovatriptan succinate - (frovatriptan; Frova)
- naratriptan HCl - (Amerge; naratriptan)
- rizatriptan benzoate - (Maxalt MLT & Tablets; rizatriptan ODT & tablet)
- sumatriptan - (Imitrex Nasal; sumatriptan nasal)
- sumatriptan sumenthol/camphor - (Migranow Kit)
- sumatriptan succ/naproxen - (sumatriptan/naproxen; Treximet)

# Antimigraine Agents, Triptans

***Class Overview:***

- sumatriptan succinate - (Imitrex Kit, Tablets & Vial; sumatriptan kit, kit (Sun), tablets & vial; Sumavel DosePro; Zembrace Symtouch)
- zolmitriptan - (zolmitriptan ODT, ODT (AG), tablets, tablets (AG); Zomig Nasal, Tablets & ZMT)

# Antimigraine Agents, Triptans

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# Antimigraine Agents, Triptans

- Migraine-specific agents (triptans, dihydroergotamine [DHE]) should be used in patients whose migraine attacks do not respond to NSAIDs
- Due to well-established efficacy, the triptans have become the drugs of choice for treating actual migraine attacks
- The US Headache Consortium, the American Academy of Family Physicians, and the American College of Physicians – American Society of Internal Medicine have recognized that the triptans are effective agents for the acute treatment of migraine
- The guidelines did not demonstrate that any specific triptan was superior to others and triptans appear to be equally safe
- All serotonin agonists in this class are selective 5-$HT_1$ receptor agonists, and when activated are believed to mediate the associated symptoms

# Antimigraine Agents, Triptans

***Product Updates:***

- Relpax (eletriptan) is now available as a generic
- Zecuity (sumatriptan iontophoretic transdermal system) has been discontinued
- Treximet (sumatriptan/naproxen) is now available as a generic
- Sumavel DosePro 6mg/0.5ml injection will be discontinued for reasons that are not related to quality, safety, or efficacy of the product. The 4mg/0.5ml formulation was discontinued in 2016

# Bronchodilators, Beta Agonist

# Bronchodilators, Beta Agonist

***Class Overview: Long-Acting Agents***

- aformoterol tartrate - (Perforomist Solution)
- formoterol fumarate - (Brovana Solution)
- indacaterol maleate - (Arcapta Neohaler)
- olodaterol HCl - (Striverdi Respimat)
- salmeterol xinafoate - (Serevent Diskus)

***Class Overview: Nebulized Agents***

- albuterol sulfate - (AccuNeb; albuterol neb soln 0.63mg & 1.25mg, 2.5mg/0.5ml, 2.5mg/3ml & 100mg/20ml)
- levalbuterol HCl – (levalbuterol neb soln; levalbuterol neb soln conc; Xopenex Neb Soln)

# Bronchodilators, Beta Agonist

***Class Overview: Oral Agents***

- albuterol sulfate - (albuterol ER, syrup & tablet)
- metaproterenol sulfate - (metaproterenol syrup & tablet)
- terbutaline sulfate - (terbutaline)

***Class Overview: Short-Acting Agents***

- albuterol sulfate - (ProAir HFA; ProAir Respiclick; Proventil HFA; Ventolin HFA)
- levalbuterol tartrate - (levalbuterol HFA (AG); Xopenex HFA)

# Bronchodilators, Beta Agonist

- Beta$_2$-agonist bronchodilators are used for the treatment and prevention of bronchospasm associated with asthma, prophylaxis of exercise-induced bronchospasm (EIB), and in the treatment of Chronic Obstructive Lung Disease (COPD)
- Mainstay of asthma therapy is the use of inhaled corticosteroids (ICS) alone or in combination with long-acting beta$_2$-agonists (LABAs) as controller medications
- These agents lead to improvements in symptoms, reducing the need for short-acting beta$_2$-agonists (SABAs) for quick relief by relaxing airway smooth muscle
- Prevalence and incidence of asthma in the U.S. continues to rise, affecting approximately 8.4% of the population

# Bronchodilators, Beta Agonist

- The 2017 GINA guidelines offer a control-based management plan which adjusts treatment through a continuous cycle of assessment and review of the patient's response to therapy as it relates to symptom control, future risk of exacerbations, and side effects
- COPD pharmacotherapy of bronchodilators is intended to decrease symptoms, reduce the frequency and severity of exacerbations, improve health status and exercise tolerance
- Bronchodilator medications are central to management of COPD. They improve emptying of the lungs, reduce dynamic hyperinflation at rest and during exercise, and improve exercise performance
- They are given either as-needed basis for relief of persistent or worsening symptoms or on a regular basis to prevent/reduce symptoms

# Bronchodilators, Beta Agonist

- Regular bronchodilation does not modify the decline of lung function in mild COPD or the prognosis of the disease
- While short-acting beta agonists (SABAs) can be used on an as-needed basis in mild COPD, regular treatment with a long-acting agent is required as the disease progresses
- Delivery system selection as well as the patients' ability to properly use the device are important factors in the clinical success of bronchodilator therapy
- Metered dose inhalers (MDIs) are pressurized spray inhalers, available in suspension and solution
- Spacer chambers may be used with most MDIs to make them easier to use and help deliver a greater amount of medicine to the airway

# Bronchodilators, Beta Agonist

- Dry-powder inhalers (DPIs) are breath-actuated devices that release the medicine in the form of a dry powder upon inhalation
- Nebulizers, may be the only viable alternative delivery system for certain children and those unable to use inhalers due to the inability to synchronize breaths and device actuation
- Some of the newer delivery devices, (like Respimat devices), are not breath-activated, but still require coordination of actuation and inhalation
- Oral dosage forms of albuterol are less utilized than the inhaled forms due to systemic beta-adrenergic stimulation, especially in patients sensitive to these effects, such as those with cardiovascular disease
- Levalbuterol is the R-enantiomer form of albuterol. It has similar efficacy to albuterol and there are no significant differences in adverse effects

# Bronchodilators, Beta Agonist

***Advisory Updates:***

- Based on four large clinical safety trials, the FDA determined that treatment of asthma with long-acting beta agonists (LABA) in combination with inhaled corticosteroids (ICS) does not lead to significantly more serious asthma-related adverse effects than treatment with ICS alone
- The boxed warning regarding asthma-related death has been removed from ICS & LABA labeling (including combination products) and information of these trials has been added. The boxed warning regarding increase risk will remain in labels for single component LABAs

# Bronchodilators, Beta Agonist

| 2017 GINA Guidelines Step Approach | |
|---|---|
| Adults and Pediatrics 6 Years and Older | |
| Step 1 | As-needed reliever medication<br>• Recommended: SABA<br>• Alternative Controller: consider addition of low dose ICS (controller option) |
| Step 2 | One controller AND an as-needed reliever medication<br>• Preferred controller: low-dose ICS + SABA<br>• Alternative controllers: leukotriene modifier or low dose theophylline* (if over 12 years) |
| Step 3 | One or 2 controllers and an as-needed reliever medication<br>• Preferred for adolescents and adults: low-dose ICS AND a LABA as maintenance plus as-needed<br>• SABA OR ICS/formoterol maintenance and reliever therapy†<br>• Preferred for children 6 to 11 years of age: medium dose ICS + as-needed SABA<br>• Alternative controllers: medium- or high-dose ICS, OR low-dose ICS + leukotriene modifier, OR low-dose ICS + sustained-release theophylline*<br>• Sublingual immunotherapy (SLIT) may be considered in adults with allergic rhinitis or house dust mite sensitivity and exacerbations despite ICS use |

# Bronchodilators, Beta Agonist

| 2017 GINA Guidelines Step Approach | |
|---|---|
| Adults and Pediatrics 6 Years and Older | |
| Step 4 | Two or more controllers AND an as-needed reliever medication<br>• Preferred for adolescents and adults: medium/high-dose ICS + LABA plus as-needed SABA OR ICS/ formoterol maintenance and reliever therapy<br>• Preferred for children 6 to 11 years of age: referral to expert for assessment and advice<br>• Alternative controllers:<br>For adults and adolescents: high dose ICS + leukotriene modifier, OR high-dose ICS + sustained release theophylline*, OR adding tiotropium<br>• Sublingual immunotherapy (SLIT) may be considered in adults with allergic rhinitis or house dust mite sensitivity and exacerbations despite ICS use |
| Step 5 | Higher level of care and/or add-on treatment<br>• In addition to Step 4 treatment, refer for add-on treatment:<br>Tiotropium, monoclonal antibody treatment (omalizumab [anti-IgE therapy], mepolizumab or reslizumab [anti-IL-5 therapy]), low dose oral corticosteroids, or sputum guided therapy |

# Bronchodilators, Beta Agonist

| 2017 GOLD Guidelines | |
|---|---|
| Assessment of Airflow Limitation | |
| Gold 1 | Mild, FEV1 ≥ 80% predicted |
| Gold 2 | Moderate, FEV1 50% to 79% predicted |
| Gold 3 | Severe, FEV1 30% to 49% predicted |
| Gold 4 | Very severe, FEV1 < 30% predicted |

# Bronchodilators, Beta Agonist

| 2017 GOLD Guidelines | |
|---|---|
| **Assessment of Exacerbation Risk and Symptoms** | |
| Patient Group A | Low Risk, Less Symptoms: 0 to 1 exacerbations per year (not leading to hospitalization); and CAT score < 10 or mMRC grade 0 to 1 |
| Patient Group B | Low Risk, Less Symptoms: 0 to 1 exacerbations per year (not leading to hospitalization); and CAT score ≥ 10 or mMRC grade ≥ 2 |
| Patient Group C | High Risk, Less Symptoms: ≥ 2 exacerbations per year or ≥ 1 exacerbation leading to hospitalization; and CAT score < 10 or mMRC grade 0 to 1 |
| Patient Group D | High Risk, Less Symptoms: ≥ 2 exacerbations per year or ≥ 1 exacerbation leading to hospitalization; and CAT score ≥ 10 or mMRC grade ≥ 2 |

*mMRC - Modified British Medical Research Council questionnaire used only to assesses breathlessness*

# Leukotriene Modifiers

# Leukotriene Modifiers

***Class Overview:***

- montelukast sodium - (montelukast chewable tablet, granules & tablet; Singulair Chewable Tablet, Granules & Tablet)
- zafirlukast - (Accolate; zafirlukast)
- zileuton- (zileuton ER; Zyflo; Zyflo CR)

# Leukotriene Modifiers

- National Asthma Education and Prevention Program (NAEPP) and 2018 Global Initiative for Asthma (GINA) guidelines recommend inhaled corticosteroids as the cornerstone for the treatment of asthma Leukotriene modifiers are included as potential alternatives or add-on therapy in some patients
- GINA states that leukotriene modifiers are less effective than ICS, but may be appropriate for initial controller treatment for patients unable or unwilling to use ICS, intolerant to ICS, or who also have allergic rhinitis.
- Limited data exist to support the use of leukotriene modifiers in acute asthma
- Leukotriene modifiers are also used as add-on therapy to reduce the dose of the ICS in patients with moderate to severe asthma, and to potentially improve asthma control in patients whose asthma is not controlled with low or high doses of ICS

# Leukotriene Modifiers

- The American Academy of Allergy, Asthma and Immunology (AAAAI) and the American College of Allergy, Asthma, and Immunology (ACAAI) updated their guidelines for the treatment of seasonal allergic rhinitis (SAR) in 2017
- For initial treatment of moderate to severe SAR in patients 15 years and older, the recommendation is for monotherapy with intranasal corticosteroids It was noted that montelukast (Singulair) is the only leukotriene modifier approved for AR and can be considered for patients with co-morbid asthma
- The guidelines acknowledge that many patients require multiple agents for relief from symptoms of AR

# Leukotriene Modifiers

- Currently, high-quality comparative trials of the leukotriene modifiers are lacking
- Selection of a particular agent for the treatment of asthma should be based on the patient's age, current drug regimen (assessing the possibility of drug interactions), and tolerability

# Phosphate Binders

# Phosphate Binders

***Class Overview:***

- calcium acetate - (calcium acetate capsule & tablet; Eliphos; Phoslyra)
- ferric citrate - (Auryxia)
- lanthanum carbonate - (Fosrenol Chewable Tablet; Fosrenol Powder Pack; lanthanum carbonate chewable tablet)
- sevelamer carbonate - (Renvela Powder Pack; Renvela Tablet; sevelamer carbonate powder pack, tablet & tablet (AG))
- sevelamer - (Renagel)
- sucroferric oxyhydroxide - (Velphoro)

# Phosphate Binders

- Chronic kidney disease (CKD) affects approximately 30 million Americans in the United States (U.S.)
- Kidney function deterioration results in decline in the ability to eliminate phosphorus, resulting in hyperphosphatemia, one of the complications of CKD
- Hyperphosphatemia is also a risk factor for cardiovascular disease (CVD)
- The National Kidney Foundation updated their guidelines in 2017 under The Kidney Disease: Improving Global Outcomes (KDIGO) foundation
- Treatment of hyperphosphatemia includes the reduction of dietary phosphorus, phosphate binding therapy, and removal of phosphorus by dialysis

# Phosphate Binders

- Studies have shown control of hyperphosphatemia through dietary phosphorus management, dialysis, and phosphate binders is critical in the prevention and delay of renal osteodystrophy and soft tissue calcifications
- The KDIGO guidelines do not strongly prefer one type of phosphate binder over another for adults
- Selection of an appropriate phosphate binder should be individualized and based on various clinical parameters, not phosphorus lowering alone
- All phosphate binders are efficacious in reducing serum phosphate levels
- One product has not been found to be superior over another and therapy should be individualized to meet the patient's unique medical needs

# Phosphate Binders

***Product Updates:***

- Auryxia (ferric citrate) is now approved as an iron replacement product for the treatment of iron deficiency anemia in adults with Chronic Kidney Disease not on dialysis

# Sedative Hypnotics

# Sedative Hypnotics

***Class Overview: Benzodiazepine Agents***

- estazolam - (estazolam)
- flurazepam HCl - (flurazepam)
- temazepam - (Restoril; temazepam; temazepam 7.5mg & 22.5mg)
- triazolam - (Halcion; triazolam)

# Sedative Hypnotics

***Class Overview: Non-Benzodiazepine Agents***

- doxepin HCl - (Silenor)
- eszopiclone - (eszopiclone)
- ramelteon - (Rozerem)
- suvorexant - (Belsomra)
- tasimelteon - (Hetlioz)
- zaleplon - (zaleplon)
- zolpidem tartrate - (Ambien; Ambien CR; Edluar; Intermezzo; zolpidem; zolpidem SL; zolpidem ER; Zolpimist)

# Sedative Hypnotics

- Insomnia is a symptom complex that comprises difficulties falling asleep, staying asleep, or non-refreshing sleep in combination with daytime dysfunction or distress
- Non-pharmacological measures should be used first to treat insomnia
- The updated2017 American Academy of Sleep Medicine (AASM) guidelines recommend psychological and behavioral strategies, as well as pharmacological interventions
- The guidelines recommend that initial behavioral interventions should include stimulus control therapy or relaxation therapy, or a combination of therapies referred to as cognitive behavioral therapy for insomnia
- Behavioral therapy should always include good sleep hygiene in combination with other therapies

# Sedative Hypnotics

- AASM guideline recommends that pharmacotherapy should be used to treat patients who failed to respond to CBT (Grade: weak recommendation, low-quality evidence)
- AASM recommends zaleplon, triazolam, and ramelteon versus no treatment for sleep onset insomnia (weak recommendations), suvorexant and doxepin over no treatment for sleep maintenance insomnia (weak recommendations), and eszopiclone, zolpidem, temazepam for both sleep onset and sleep maintenance insomnia
- AASM guidelines do not recommend the use of trazodone or tiagabine for sleep onset or sleep maintenance insomnia in adults
- Non-24-hour sleep-wake disorder (N24SWD or non-24) is a chronic circadian rhythm disorder that causes problems with the timing of sleep and sleep patterns. Hetlioz is only for use in N24SWD

# Sedative Hypnotics

- With the exception of zolpidem SL (Intermezzo), all agents should all be administered immediately before going to bed or after the patient has gone to bed and experienced difficulty falling asleep
- Zolpidem SL (Intermezzo) should be utilized for middle of the night awakenings when the patient still has more than 4 hours before planned waking time
- All drugs in this class should be used at the lowest effective dose
- All sedative/hypnotics should be administered with caution to patients exhibiting signs and symptoms of depression
- Patients whose insomnia fails to remit after 7 to 10 days of treatment may need to be evaluated for other medical or psychological issues
- Continuous use should be avoided; patients should be encouraged to use these medications only when necessary

# Sedative Hypnotics

- In 2016, the FDA informed healthcare professionals that concurrent use of opioids and benzodiazepines or other CNS depressants has resulted in serious adverse reactions such as profound sedation, respiratory depression, coma, and death
- Providers should limit prescribing of opioids with benzodiazepines to patients without alternative treatment options
- Selection of a specific sedative hypnotic is based in large part on whether the patient has problems with initiation or maintenance of sleep, co-morbid conditions, side effect tolerance, and availability
- Current treatment guidelines for insomnia do not recommend one agent within this class over another, suggesting treatment be individualized

# Sedative Hypnotics

***Treatment Updates:***

- The FDA has advisied that buprenorphine and methadone should not be withheld from patients taking benzodiazepines or other drugs that cause CNS depression
- While the combined use of these drugs increases the risk of serious side effects, the harm caused by untreated opioid addiction can outweigh these risks

# Steroids, Topical

# Steroids, Topical

***Class Overview: Low Potency Topical Steroid Products***

- alclometasone dipropionate – (alclometasone dipropionate cream & ointment)
- desonide – (Desonate Gel; desonide cream, lotion & ointment; Tridesilon)
- fluocinolone acetonide – (Capex Shampoo; Dema-Smoothe-FS; fluocinolone 0.01% oil)
- hydrocortisone/white petrolatum – (hydrocortisone/min oil/pet ointment)
- hydrocortisone - (Ala-Scalp HP; hydrocortisone cream, gel, lotion & ointment; Texacort)

# Steroids, Topical

***Class Overview: Low Potency Topical Steroid Products***

- hydrocortisone acetate - (MiCort HC)
- Hydrocortisone/skin cleansers - (Aqua Glycolic HC; Dermasorb HC)

# Steroids, Topical

***Class Overview: Medium Potency Topical Steroid Products***

- betamethasone valerate - (betamethasone valerate foam; Luxiq)
- clocortolone pivalate - (clocortolone cream (AG); Cloderm)
- fluocinolone acetonide - (fluocinolone acetonide cream, ointment & solution; Synalar Ointment & Solution)
- fluocinolone acetonide/emollient - (Synalar Cream Kit & Ointment Kit)
- fluocinolone acetonide/skin cleansers - (Synalar TS Kit)
- flurandrenolide - (Cordran Tape; flurandrenolide cream, lotion, lotion (AG) & ointment)
- fluticasone propionate - (Cutivate Cream & Lotion; fluticasone cream, lotion & ointment)

# Steroids, Topical

***Class Overview: Medium Potency Topical Steroid Products***

- hydrocortisone butyrate - (hydrocortisone butyrate cream, cream (AG), lotion, ointment, ointment (AG), solution & solution (AG))
- hydrocortisone butyrate/emollient - (hydrocortisone butyrate/emollient & emollient (AG))
- hydrocortisone probutate - (Pandel)
- hydrocortisone valerate - (hydrocortisone valerate cream & ointment)
- mometasone furoate - (Elocon Cream & Ointment; mometasone furoate cream, ointment & solution )
- prednicarbate - (prednicarbate cream & ointment)

# Steroids, Topical

***Class Overview: High Potency Topical Steroid Products***

- amcinonide - (amcinonide cream & lotion)
- betamethasone dipropionate - (betamethasone dipropionate cream, gel, lotion & ointment; Sernivo Spray)
- betamethasone valerate - (betamethasone valerate cream & ointment)
- betamethasone/propylene glyc - (betamet diprop/prop gly cream, lotion & ointment; Diprolene Ointment)
- desoximetasone - (desoximetasone cream, gel & ointment; Topicort Ointment & Spray)
- diflorasone diacetate - (diflorasone diacetate cream & ointment)
- fluocinonide - (fluocinonide cream, gel, ointment & solution)

# Steroids, Topical

***Class Overview: High Potency Topical Steroid Products***

- fluocinonide/emollient - (fluocinonide emollient)
- halcinonide - (Halog Cream & Ointment)
- triamcinolone acetonide/dimethicone - (Ellzia Pak)
- triamcinolone acetonide/silicones - (DermacinRx Silazone; Silazone-II)
- triamcinolone acetonide - (Kenalog Aerosol; triamcinolone acetonide aerosol, cream, lotion & ointment; Trianex Ointment)
- triamcinolone acetonide/dimethicone/silicones - (DermacinRx Silapak; triamcinolone acetonide/dimethicone)
- triamcinolone/emollient - (Dermasorb TA)

# Steroids, Topical

***Class Overview: Very High Potency Topical Steroid Products***

- clobetasol propionate - (clobetasol lotion; clobetasol propionate cream, gel, ointment, solution, spray & spray (AG); clobetasol shampoo; Clobex Lotion, Shampoo & Spray; Olux; Temovate Cream)
- clobetasol propionate/clobetasol propionate/emollient - (clobetasol propionate foam)
- clobetasol propionate/emollient - (clobetasol propionate/emollient )
- clobetasol propionate/skin cleanser - (Clodan Kit)
- diflorasone diacetate/emollient - (Apexicon E)
- halobetasol propionate - (halobetasol propionate cream & ointment; Ultravate Lotion)
- halobetasol/lactic acid - (Ultravate X Pac Cream & Ointment)

# Steroids, Topical

***Class Overview: Very High Potency Topical Steroid Products***

- fluocinonide/emollient - (fluocinonide emollient)
- halcinonide - (Halog Cream & Ointment)
- triamcinolone acetonide/dimethicone - (Ellzia Pak)
- triamcinolone acetonide/silicones - (DermacinRx Silazone; Silazone-II)
- triamcinolone acetonide - (Kenalog Aerosol; triamcinolone acetonide aerosol, cream, lotion & ointment; Trianex Ointment)
- triamcinolone acetonide/dimethicone/silicones - (DermacinRx Silapak; triamcinolone acetonide/dimethicone)
- triamcinolone/emollient - (Dermasorb TA)

# Steroids, Topical

- Topical corticosteroids are used for a variety of inflammatory skin conditions, including:
- Atopic dermatitis (AD) is a chronic, inflammatory dermatologic condition and is often referred to as "eczema." Commonly occurs in patients affected by asthma and/or allergic rhinitis and is associated with elevated serum IgE levels. AD can occur at any age, but occurs most frequently in children
- Psoriasis is another inflammatory skin condition. Plaque psoriasis is the most common type frequently forming on the elbows, knees, lower back, and scalp. Controlling symptoms typically requires lifelong therapy
- Seborrheic dermatitis is an inflammatory disorder affecting areas of the head and trunk, where sebaceous glands are most prominent

# Steroids, Topical

- Pharmacotherapy choices for these conditions include emollients and topical corticosteroids
- Emollients remain the cornerstone of any AD pharmacotherapeutic regimen
- Topical corticosteroids are the standard of care to which other treatments are compared
- The selection of medication and potency should depend on medication efficacy then severity of disease, location and surface area of affected skin, intended duration of treatment, medication vehicle, patient preference, and the age of the patient.
- In short-term durations of treatment, high potency medications have greater efficacy when compared to less potent medications, but with an increased risk in side effects

# Steroids, Topical

- Increased incidences of adverse dermatologic effects are positively correlated with the medication's frequency and duration of use
- True efficacy and risk of long-term topical corticosteroid use is unknown due to most clinical trials only involving short-term studies
- Recommended in the guidelines of care from the American Academy of Dermatology that continued therapy be supervised and, once a clinical response is demonstrated, a gradual reduction in utilization is appropriate
- There are differing compendia listings for corticosteroid potencies
- Efficacy of the topical corticosteroids is relative to their potency, but individual agents within a potency category are not distinguishable from each other.

# Executive Session

# P&T Public Vote on Recommendations

# Biosimilar Update

*Suzi Berman, RPh*

# BIOSIMILAR UPDATE

- There is no Biosimilar update for this P&T meeting.

- *As a reminder – per AHCCCS Policy 310-V: AHCCCS Contractors shall not transition to a biosimilar drug until AHCCCS has determined that the biosimilar drug is overall more cost-effective to the state than the continued use of the brand name drug.*

# Cough & Cold Preparations in the Pediatric Population

# Cough & Cold Products Discussion

- FDA requires warning safety labeling to cough and cold products for children.
- FDA action limits the use of prescription opioid cough and cold products to adults ages 18 and older and reduces exposure of these products to children.
- Safety information highlighting risks of opioid misuse, addiction, overdose, death and slowed or difficult breathing will be added to the boxed warning on labels of these medications.

# Cough & Cold Products Discussion

- As the result of recent FDA Advisories on the use of cough and cold products containing opioids in the pediatric population, a number of State's have begun placing clinical edits on this population.
- The age restrictions vary by State ranging from 12 to 19 years of age.
- The edits vary to some extent as well ranging from soft edits that may be overridden at the pharmacy to 'hard' prior authorization edits that require the prescribing physician acknowledge awareness of the contraindications and agrees to accept the risks.
- Some states do allow exceptions to the edits/prior authorization requirements in cases such as pediatric cancer, sickle cell disease, or other diagnosis driven considerations.

# New Drug Reviews

## *Non-PDL Classes*

*Chris Andrews, Pharm.D.*

# Three New Products

- Abilify MyCite - aripiprazole tablets with sensor
- Biktarvy - bictegravir/emtricitabine/tenofovir alafenamide
- Juluca - dolutegravir/rilpivirine

# Abilify Mycite (aripiprazole with sensor)

- Abilify Mycite is a drug-device combination product comprised of aripiprazole tablets embedded with an Ingestible Event Marker (IEM) sensor intended to track drug ingestion
- Abilify Mycite carries the same indications as Abilify
- Limitations - not indicated to improve patient compliance; ability of Abilify Mycite to modify aripiprazole dosing has not been established; use of Abilify Mycite to track drug ingestion in real-time or during an emergency is not recommended because detection may be delayed or not occur
- Abilify Mycite is available in the following dosage strengths: 2 mg, 5 mg, 10 mg, 15 mg, 20 mg, and 30 mg

# Abilify Mycite (aripiprazole with sensor)

- The Abilify Mycite System is composed of the following components:
- Aripiprazole tablet embedded with an IEM sensor (ABILIFY MYCITE). The IEM is a 1-mm sized ingestible device embedded in the Abilify Mycite tablet. Upon contact with gastric fluid, magnesium and cuprous chloride within the IEM react to activate and power the device. The IEM then communicates to the MYCITE Patch (wearable sensor) to track aripiprazole ingestion.
- MYCITE® Patch (wearable sensor) that detects the signal from the IEM sensor after ingestion and transmits data to a smartphone; data includes the date and time of ingestion and the unique identification number of the ingestible device. The patch also records physiological metrics (activity level via step count and body position) and transmits to a compatible mobile device

# Abilify Mycite (aripiprazole with sensor)

- MYCITE APP - a smartphone application (app) which is used to display information for the patient, allowing review of medication ingestion as well as enter their behavioral data (patient rated mood and quality of rest). These data can be shared with healthcare providers and caregivers with the patient's consent to a Web-based portal for healthcare professionals and caregivers
- There are two phase 2, multicenter, open-label trials included in the dossier that evaluate the usability of the sensor technology demonstrating overall efficacy of data collection
- The patch will communicate with a paired device within a 9-foot proximity. Patch should remain on whether showering, swimming, or exercising. Patients undergoing an MRI, however, need to remove their patch and replace with a new one as soon as possible

# Abilify Mycite (aripiprazole with sensor)

- There is currently no data available that demonstrates improved adherence, but trials are scheduled to begin after Abilify Mycite is released
- Abilify Mycite is available through prior authorization based on medical necessity
- Recommendation is to not add to the AHCCCS Drug List at this time
- Will review under supplemental antipsychotic class review in July 2018

# Biktarvy (bictegravir/emtricitabine/tenofovir alafenamide)

- Biktarvy is a three drug combination tablet indicated as a complete regimen for the treatment of HIV-1 infections in adults who have no antiretroviral treatment history or to replace the current antiretroviral regimen in those who are virologically suppressed (HIV-1 RNA < 50 copies per ml) on a stable antiretroviral regimen for at least three months with no history of treatment failure and no known substitutions associated with resistance to the individual components.
- This combination therapy contains two nucleoside analog reverse transcriptase inhibitors (NRTIs) and an integrase strand transfer inhibitor (INSTI)
- Biktarvy carries a box warning on the risk of severe acute exacerbations of hepatitis B

# Biktarvy (bictegravir/emtricitabine/tenofovir alafenamide)

- Hepatic function should be closely monitored and anti-hepatitis B therapy administered if needed
- Patients should be monitored for potential onset of immune reconstitution syndrome or lactic acidosis/severe hepatomegaly with steatosis
- Patients may experience new onset or worsening renal impairment. Monitor serum creatinine, estimated creatinine clearance, urine glucose and urine protein when initiating Biktarvy and during therapy
- Monitor serum phosphorus levels in patients with a history of chronic kidney disease

# Biktarvy (bictegravir/emtricitabine/tenofovir alafenamide)

- BIC/FTC/TAF combination is a complete regimen and should not be administered with other HIV medications
- There is no data on the use of Biktarvy in pregnant women with regard to birth defects or miscarriage
- Safety and effectiveness in pediatric patients have not been established
- The recommended dose is one tablet by mouth once daily regardless of food
- Biktarvy was evaluated in two trials with anti-retroviral treatment naive patients and two with treatment experienced patients

# Biktarvy (bictegravir/emtricitabine/tenofovir alafenamide)

- In Trial 1489, 629 ART treatment-naïve HIV patients were randomized 1:1 to receive either BIC/FTC/TAF (n=314) or abacavir/dolutegravir/lamivudine (ABC/DTG/3TC; 600 mg/50 mg/300 mg) (n=315) once daily
- Patients co-infected with HBV were excluded
- Mean baseline plasma HIV-1 RNA was 4.4 log10 copies/ml (range 1.3 to 6.5) and mean baseline CD4+ cell count was 464 cells/mm3 (range 0 to 1,424) and 11% had CD4+ cell counts < 200 cells/mm3
- At baseline, 16% of patients had a viral load > 100,000 copies/ml

# Biktarvy (bictegravir/emtricitabine/tenofovir alafenamide)

- The primary endpoint was viral suppression, defined as HIV-1 RNA < 50 copies/ml at week 48
- Viral suppression was achieved in 92.4% (n=290/314) of patients taking BIC/FTC/TAF and 93% (n=293/315) of patients taking ABC/DTG/3T
- In Trial 1490, 645 ART treatment-naïve HIV patients were also randomized 1:1 to receive either BIC/FTC/TAF or DTG + FTC/TAF (50 mg + 200 mg/25 mg) once daily
- The mean baseline plasma HIV-1 RNA was 4.4 log10 copies/mL (range 2.3 to 6.6) and mean baseline CD4+ cell count was 456 cells/mm3 (range 2 to 1,636) and 12% had CD4+ cell counts < 200 cells/mm3

# Biktarvy (bictegravir/emtricitabine/tenofovir alafenamide)

- At baseline, 19% of subjects had a viral load > 100,000 copies/ml
- At week 48, Trial 1490 demonstrated non-inferiority with 89.4% (n=286/320) of patients taking BIC/FTC/TAF and 92.9% (n=302/325) of patients taking DTG + FTC/TAF achieving the primary endpoint of HIV-1 RNA < 50 copies/ml
- In Trial 1844, a randomized, double-blind study, the efficacy and safety of 563 virologically suppressed HIV patients switched from ABC/DTG/3TC to BIC/FTC/TAF were evaluated
- Patients must have been stable on their baseline regimen for at least 3 months prior to trial entry and had no history of treatment failure

# Biktarvy (bictegravir/emtricitabine/tenofovir alafenamide)

- Patients were randomized 1:1 to either switch to BIC/FTC/TAF at baseline (n=282), or stay on their baseline antiretroviral regimen (n=281)
- The mean baseline CD4+ cell count was 723 cells/mm3 (range 124 to 2,444)
- At week 48, outcomes demonstrated non-inferior efficacy of BIC/FTC/TAF (93.6%) versus ABC/DTG/3TC (95%) virologically suppressed patients
- In Trial 1878, a randomized, open-label study, the efficacy and safety of switching from either ABC/3TC or FTC/TDF (200/300 mg) plus atazanavir (ATV) or darunavir (DRV) (given with either cobicistat or ritonavir) to BIC/FTC/TAF were evaluated in 577 virologically-suppressed HIV patients

# Biktarvy (bictegravir/emtricitabine/tenofovir alafenamide)

- Patients must have been virologically suppressed on their baseline regimen for at least 6 months, must not have been previously treated with any integrase inhibitor (INSTI), and had no history of treatment failure
- Patients were randomized 1:1 to either switch to BIC/FTC/TAF (n=290) or stay on their baseline antiretroviral regimen (n=287).
- At week 48, 92% of BIC/FTC/TAF patients achieved the primary endpoint of virological suppression versus 89% on ATV or DRV regimens

# Biktarvy (bictegravir/emtricitabine/tenofovir alafenamide)

- Recommendation: add to AHCCCS Drug List without prior authorization

# Juluca (dolutegravir/rilpivirine)

- Juluca is a fixed-dose combination of dolutegravir, an integrase strand transfer inhibitor (INSTI), and rilpivirine, a non-nucleoside reverse transcriptase inhibitor (NNRTI)
- Juluca is indicated as a complete regimen for the treatment of HIV-1 infection in adults to replace the current antiretroviral treatment (ART) regimen in those who are virologically suppressed (HIV-1 RNA < 50 copies/ml) on a stable ART regimen for ≥ 6 months with no history of treatment failure and no know substitution associated with resistance to the individual components
- Juluca is not approved in ART-naïve patients or in patients who have not achieved virologic suppression for at least 6 months on their current ART regimen

# Juluca (dolutegravir/rilpivirine)

- Juluca carries a warning for hepatotoxicity; patients with hepatitis B or C are at particular risk
- Depressive disorders have been reported with rilpivirine use, patients should be monitored for signs of increased or developing depression
- Juluca is a single tablet containing dolutegravir 50 mg and rilpivirine 25 mg
- Dosage is one tablet orally once daily with a meal
- Concurrent use of other ART agents is not recommended
- Consider alternatives to macrolide or ketolide antibiotics while taking Juluca

# Juluca (dolutegravir/rilpivirine)

- Data for use during pregnancy is insufficient to assess risk of birth defects or miscarriage; available data show no difference in overall risk
- Safety and efficacy have not been established in pediatric patients
- Increased monitoring for adverse effects is recommended in patients with severe renal impairment
- Safety and efficacy of Juluca was studied in the 148-week, phase 3, open-label, SWORD 1 and SWORD 2 trials
- Adult patients (n=1,024 total) with HIV-1 infection with virologic suppression (HIV-1 RNA < 50 copies/ml) on current 3- or 4-drug ART regimen (INSTI, NNRTI, or protease inhibitor-based) were randomized 1:1 to continue their current stable therapy or switch to Juluca, as individual tablets until week 52 (Early Switch phase

# Juluca (dolutegravir/rilpivirine)

- After week 52, all patients received Juluca until week 148 (Late Switch phase)
- Pooled data demonstrated that the primary endpoint of virologic suppression was achieved by 95% of patients in each group at 48 weeks
- Incidence of serious adverse event were similar between groups; however, more patients withdrew from the study due to adverse events in the Juluca group (21 patients) compared to the current therapy group (3 patients)
- The secondary endpoint of mean bone mineral density (BMD) increased from baseline to week-48 in patients who switched from a tenofovir disoproxil fumarate (TDF)-containing regimen to Juluca

# Juluca (dolutegravir/rilpivirine)

- Recommendation to not add Juluca to the AHCCCS Drug List at this time; the two drugs in this product are available without prior authorization on the AHCCCS Drug List

# P&T Public Vote

## *New Drugs in Non-PDL Classes*

# P&T Meeting Dates

- **Next Meeting Dates:**
  - Tuesday, July 17, 2018
- **Future 2018 Meeting Dates:**
  - Tuesday, October 22, 2018

# Agenda Items For The Next Meeting Tuesday July 17, 2018

Please send agenda items to:

- Robin Davis – Robin.Davis@azahcccs.gov
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# Thank You.