PHARMACY UPDATE

November 13, 2020

COVID-19 RELATED UPDATES

Disclaimer: We are getting frequent COVID-19 related questions about drug concerns and potential interactions. This information is up to date as of November 11, 2020. We will do our best to keep you up to date with this ever-evolving situation.

Note: There are no Food and Drug Administration (FDA) approved therapies for treatment or prevention of COVID-19 in the outpatient setting or for prevention in the inpatient setting. Only Remdesivir is FDA approved for treatment in the inpatient setting. If possible, it is best to have patients enrolled in a clinical trial when treating COVID outside of these parameters.

INFLUENZA AND COVID-19 TREATMENT GUIDELINES

The National Institutes of Health's COVID-19 Treatment Guidelines were recently updated to include recommendations regarding the concurrence of flu season and the ongoing COVID-19 pandemic. Due to the similarities in symptom presentation, flu vaccine prophylaxis and diagnostic testing are essential for the cocirculating viruses.

Influenza vaccine:

- Despite lack of data, it is recommended that persons with COVID-19 get an inactivated dose of the influenza vaccine. However, the CDC suggests deferring the influenza vaccine if the person is in quarantine and there are concerns that post-vaccination symptoms might cause diagnostic confusion. In addition, if the person has suspected or confirmed COVID-19 and is symptomatic, healthcare personnel should consider deferring the influenza vaccine until the patient has fully recovered from acute illness.
    - Refer to the CDC Interim Guidance for more information regarding influenza vaccines during the COVID-19 pandemic: https://www.cdc.gov/vaccines/pandemic-guidance/index.html

Diagnosis of COVID-19 and Influenza:

- It is recommended that hospitalized patients with acute respiratory illness get tested for both viruses. Influenza testing is only recommended in outpatients with acute respiratory illness if the results will change clinical management of the patient. Testing for other pathogens should be considered depending on clinical circumstances.

Antiviral treatment:

- The treatment of influenza is the same in all patients regardless of SARS-CoV-2 coinfection. Initiation of oral or enterically-administered oseltamivir treatment is recommended in hospitalized patients as soon as possible, without waiting on influenza testing results. Antiviral treatment for influenza can be stopped once influenza has been ruled out.

Reference: https://www.covid19treatmentguidelines.nih.gov/special-populations/influenza/

POTENTIAL DRUG SHORTAGES (OUTPATIENT/COVID RELATED ONLY)

The Health Plan of Southwestern Health Resources, Care N' Care has been monitoring potential drug shortages related to COVID-19 in outpatient settings. Care N' Care is able to gather data from up-to-the-minute pharmacy claims as well as information coming into the call centers from its members and pharmacies. The shortages are confirmed through the American Society of Health-System Pharmacists (ASHP) website. Please note, these are for outpatient drugs obtained in a retail setting only. The status for currently reported shortages are listed below:

Hydroxychloroquine tablets- There is currently availability from many different manufacturers now, but not all. Care N' Care Members, that take this drug for Non-COVID illnesses are able to fill prescriptions for this drug.

Albuterol Sulfate Metered Dose Inhalers- There are many generic products available from Par and Teva manufacturers, as well as name brand: ProAir, Ventolin HFA and Proventil HFA.

Flovent Inhalers, famotidine tablets and hydrocortisone tablets -There is now some availability and Care N' Care members have been filling prescriptions for these products.

For additional information and updates on drug shortages please visit the American Society of Health-System Pharmacists website or the FDA website.

GENERAL PHARMACY UPDATE

Disclaimer: This is the most update information at the time of publication. The General Pharmacy Update Newsletter section is providing these tips on lower cost alternatives to higher cost non-preferred prescription drugs. The key objective is to provide physicians with information. Ultimately, decisions about patient care, including prescriptions, are based on a physician's individual medical judgment.

TRULICITY® 3 MG & 4.5 MG DOSES APPROVED FOR TYPE 2 DIABETES.

The Food and Drug Administration (FDA) approved 2 additional dosage strengths of Trulicity®[2] (dulaglutide) 3 mg and 4.5 mg in September 2020, for the treatment of type 2 diabetes. This is in addition to the currently available 0.75 mg and 1.5 mg dulaglutide doses.

The approval was based on data from the randomized, double-blind, parallel-arm phase 3 AWARD 11[1] trial that evaluated the efficacy and safety of once weekly dulaglutide 3mg and 4.5mg compared with once weekly dulaglutide 1.5mg in 1842 adult patients with type 2 diabetes who were inadequately controlled on metformin. Patients were randomized to 1:1:1 dulaglutide 1.5 mg (n=612), 3 mg (n=616), or 4.5 mg (n=614) once weekly. The primary end point was a change in HbA1c from baseline to week 36. Other secondary end points included change in body weight and the proportion of patients achieving HbA1c <7% at week 36.

Study results[1] showed that treatment with dulaglutide 3 mg and 4.5 mg led to statistically significant reductions in HbA1c and weight compared with dulaglutide 1.5 mg.

- **4.5 mg** (A1C: -1.9 percent, weight: -10.4 pounds)
- **3.0 mg** (A1C: -1.7 percent; weight: -8.8 pounds)
- **1.5 mg** (A1C: -1.5 percent; weight: -6.8 pounds)

While the percentage of patients who achieved a goal A1c of 7% increased by 6.8% and 13.1% with the 3 mg and 4.5 mg doses compared to the 1.5 mg dose, the absolute change in A1c and weight were relatively small. The clinical significance of the benefits of these doses and their utility will need to be weighed by providers on an individual patient basis.

With regards to the safety profile for the higher doses, dulaglutide (3 mg and 4.5 mg) was found to be consistent with the 1.5 mg dose. The most common adverse reactions reported were nausea, vomiting, diarrhea and dyspepsia.

1. Frias J, Ruiz LN, Li YG, et al. Efficacy and safety of higher dulaglutide doses (3.0 mg and 4.5 mg) when added to metformin in patients with type 2 diabetes: a phase 3, randomized, double-blind, parallel arm study (AWARD-11. Diabetes 2020 Jun; 69(Supplement1) https ://doi.org/10.2337/db20-357-OR
2. Trulicity [package insert]. Indianapolis, IN: Eli Lilly and Company; 2020.

TEXAS GOVERNOR EXTENDS WAIVER FOR TREATMENT OF CHRONIC PAIN

Effective November 3, 2020, Governor Abbot has extended the Texas Medical Board's request to temporarily suspend Title 22, Chapter 174.5 (e) (2)(A) of the Texas Administrative Code. The suspension taken in response to the COVID-19 crisis, which allows telephone refills for established chronic pain patients who have been seen within the last 90 days in person or by virtual visit, has been extended until January 2, 2021, "or for the duration of the time period that the Governor's disaster declaration of March 13, 2020 in response to the COVID-19 pandemic is in effect, whichever is shorter, pursuant to Section 2001.034 of the Texas Government Code." This temporary suspension of Title 22 is intended to help chronic pain patients maintain continuity of care and avoid adverse consequences from abruptly running out of their pain medication.

For further guidance, please review the TMB's telemedicine FAQs on its COVID-19 website, as well as the Drug Enforcement Administration's COVID-19 website for federal requirements.

1. TMB Approves New Emergency Rule Related to Issuance of Prescriptions. Press release. Texas Medical Board, November 3, 2020.

For questions or concerns regarding information within this newsletter, Contact: Pharmacy@Southwesternhealth.org