October 2021

Inside this issue:

Thank you to Darius Fisher, Grady Graham, and Samantha Triplett for their contributions to this newsletter.

Pharmacy in the News:

FDA Authorizes Booster Dose of Pfizer-BioNTech COVID-19 Vaccine for Certain Populations

As of September 22, 2021, the FDA has approved emergency use authorization of the Pfizer-BioNTech COVID-19 vaccine for specific patient populations.

Those eligible include:

- Individuals 65 years of age and older,
- Individuals 18 through 64 years of age at high risk of severe COVID-19,
- Individuals 18 through 64 years of age whose frequent institutional or occupational exposure to SARS-CoV-2 puts them at high risk of serious complications.

Reference

Oral CGRP Receptor Antagonist "Atogepant" Approved by FDA for Preventative Treatment of Migraines

Atogepant (Qulipta) presents a convenient and promising preventative treatment for those suffering with migraines.

- At the lowest available dose of 10 mg, atogepant (Qulipta) has been shown to reduce migraine days by an average of 3.7 days per month in a phase 3 trial.
- Atogepant also showed a favorable adverse effect profile when compared to placebo.

Reference

Projected Physician Shortages Add to the Argument for Provider Status for Pharmacists

Studies indicate that the United States may be facing a shortage of 139,160 physicians by the year 2030.

- Geographic distributions indicate worsening "primary care provider deserts" in the future.
- Pharmacists may be able to bridge the gap in care with medical services such as medication management, immunizations, point-of-care testing, and chronic disease management.
- Granting provider status to pharmacists may incentivize expansion into medically underserved areas.

Reference

Newly Approved Drugs

Recently Approved Drugs:

aducanumab-avwa (Aduhelm), Biogen; 06/07/2021
Indication: Treatment of Alzheimer's disease initiated in a patient with mild cognitive impairment or mild dementia.

MOA: Monoclonal antibody directed against aggregated forms of amyloid beta.

Dosing: Starting dose of 1 mg/kg titrated over 7 IV infusions up to 10 mg/kg. IV infusions are administered over approximately 1 hour every 4 weeks and at least 21 days apart.

odevixibat (Bylvay), Albireo Pharma; 07/20/2021
Indication: Treatment of pruritus in patients 3 months and older with progressive familial intrahepatic cholestasis (PFIC).

MOA: Reversible inhibitor of ileal bile acid transporter (IBAT). Decreases reabsorption of bile acids from terminal ileum.

Dosing: 40 mcg/kg by mouth once daily in the morning with a meal. Dosage may be increased in 40 mcg/kg increments up to 120 mcg/kg if no improvement.

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finerenone (Kerendia), Bayer; 07/09/2021
Indication: Patients with CKD associated with type 2 diabetes to reduce the risk of kidney and heart complications.

MOA: Non-steroidal, selective antagonist of the mineralocorticoid receptor.

Dosing: If eGFR greater than or equal to 60, then 20 mg by mouth once daily. If eGFR greater than or equal to 25 and less than 60, then 10 mg by mouth once daily.

anifrolumab-fnia (Saphnelo), AstraZeneca; 07/30/2021
Indication: Treatment of moderate to severe systemic lupus erythematosus (SLE) in adults receiving standard therapy.

MOA: Monoclonal antibody that selectively binds to subunit 1 of type I IFN receptor (IFNAR1) to inhibit signaling, thereby blocking biologic activation of type I IFNs.

Dosing: 300 mg via IV infusion over a 30-minute period, every 4 weeks.

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belumosudil (Rezurock), Kadmon Holdings; 07/16/2021
Indication: Treatment of chronic graft-versus-host disease (GVHD) in patients 12 years and older after failure of at least 2 prior systemic therapies.

MOA: Inhibitor of rho-associated, coiled-coil containing protein kinase-2 (ROCK-2). Down-regulates proinflammatory responses from regulation of STAT3/STAT5 phosphorylation and shifting Th18/Treg balance. Also inhibits pro-fibrotic signaling.

Dosing: 200 mg by mouth once daily until progression of chronic GVHD requires new systemic therapy.

atogepant (Qulipta), AbbVie; 09/28/2021
Indication: Preventive treatment of episodic migraine in adults.

MOA: Calcitonin gene-related peptide (CGRP) receptor antagonist.

Dosing: 10 mg, 30 mg, or 60 mg by mouth once daily.

Recently Approved Generics

- linagliptin (Trajenta) 08/31/2021
- linagliptin and metformin (Jentadueto) 08/30/2021
- tofacitinib ER (Xeljanz XR) 08/19/2021
- varenicline (Chantix) 08/11/2021
- paliperidone palmitate ER (Invega Sustenna injectable suspension) 07/06/2021

Anticipated Generics for 2021-2022

- dabigatran (Pradaxa) December 2021
- everolimus (Afinitor Disperz) October 2021
- magnesium sulfate anhydrous, potassium sulfate, sodium sulfate (Suprep) January 2022
- dexlansoprazole (Dexilant) January 2022

Must have Apps!

Medscape

Clinical Information, Clinical Tools, and Medical News.

Clinical Information	Clinical Tools
• Drug monographs • Diseases and Conditions • Procedures	• Calculators • Drug Interaction Checker • Pill Identifier • Formulary Finder • Pricing

Medscape Formulary Finder

Open Medscape and click the "More" tab.

Select "Formulary" to search for the drug to see the formulary coverage.
- If the drug has a generic it will have you select either the brand or generic drug.

Select "Add or Remove Plans"
- If using formulary finder for the first time the app will make you pick a plan.

Search for the plan to see formulary coverage for that drug.

Click on the plan to view additional information regarding to formulary coverage.

Select the drug class to view coverage information for similar drugs.

Formulary Information

- Tier
- Restrictions

Writing Tips

Anthropomorphisms

- Do you know what **anthropomorphisms** are?
- Are you using **anthropomorphisms** when you write?

Proofreading Tips

- Do you want to improve your draft and final writing?

Need more? Check these out!

Drug Information Question of the Month

Question: What information is available on the efficacy of the mRNA vaccines against the delta variant, and is there any data comparing the rate of developing severe illness between vaccinated vs. unvaccinated patients with the delta variant?

With the delta variant recently becoming the most prevalent SARS-CoV-2 infection (1)(5), I anticipate that additional data and studies will become available in the next coming weeks to months.

The Mayo Clinic has been assessing vaccine efficacy monthly since January 2021, and recently published their data collected from January to July 2021. The relevant data to the question is in **Table 1**. This article is a pre-print, meaning that it has not yet been peer-reviewed, therefore the data has not been evaluated. This study primarily assessed the efficacy of the two currently utilized mRNA vaccines in the United States, Moderna and Pfizer, for prevention of SARS-CoV-2 infection, COVID-19 associated hospitalizations, and ICU admissions. According to this study, a reduction was seen between April to July 2021 in the effectiveness of the mRNA vaccines in the prevention of SARS-CoV-2 infection with the delta variant (2). While a reduction was seen in the efficacy of SARS-CoV-2 infection prevention in July 2021, the rates for prevention of COVID-19 associated hospitalizations remained high despite delta variant prevalence (2). The Mayo Clinic also included data from January to July 2021 comparing the mRNA vaccinated population to those that are unvaccinated which I have included in **Table 2**. This data was stratified based on time after receiving vaccination showing that it is more likely to be infected with SAR-CoV-2 in the week after receiving the first dose of the vaccine than in the 2 weeks following the second dose of the vaccine (2). Receiving both doses of the mRNA vaccine, whether Moderna or Pfizer, reduces the risk of contracting COVID-19 (2). In addition, the Mayo Clinic analyzed the effectiveness of the mRNA vaccines compared to unvaccinated individuals and stratified based on the month; this data is included in **Table 3** (2). Based on this data we see that as time progresses to July 2021, the incidence rate ratio of COVID-19 infections in vaccinated individuals has increased from February, indicating higher incidences of vaccine breakthrough infections (2).

Table 1. Mayo Clinic mRNA Vaccine Efficacy

	Moderna (mRNA-1273) N=25,869	Pfizer (BNT162b2) N=25,869
Effectiveness in preventing SARS-CoV-2 infection. (January to July 2021)	86% (95% CI, 81% to 90.6%)	76% (95% CI, 69% to 81%)
Effectiveness in preventing COVID-19 associated hospitalization. (January to July 2021)	91.6% (95% CI, 81% to 97%)	85% (95% CI, 73% to 93%)
Effectiveness in preventing ICU admission. (January to July 2021)	93.3% (95% CI, 57% to 99.8%)	87% (95% CI, 46% to 98.6%)
Effectiveness in preventing SARS-CoV-2 infection (January to April 20, 2021) Pre-Delta Variant	93.3% (95% CI, 85.7% to 97.4%)	86.1% (95% CI, 82.4% to 89.1%)
Effectiveness in prevention of SARS-CoV-2 infection (July 2021 – Delta Variant)	76% (95% CI, 58% to 87%)	42% (95% CI, 13% to 62%)

Table 1. mRNA Vaccine Efficacy relative to time. Data sourced from Mayo Clinic, Rochester, Minnesota. This article has not been peer reviewed, therefore, the data included has not been evaluated.

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Table 2. Vaccine effectiveness against SARS-CoV-2 infection and other COVID-19 associated outcomes in Minnesota.

		Moderna (mRNA-1273) / Unvaccinated	Pfizer (BNT162b2) / Unvaccinated	Moderna (mRNA-1273) / Pfizer (BNT162b2)
Days 1-7 following first vaccination dose	Positive SARS-CoV-2 PCR Test	1.1 (0.76 to 1.5)	0.84 (0.58 to 1.2)	1.3 (0.89 to 1.8)
	COVID-19 Associated Hospitalization	0.75 (0.21 to 2.5)	0.25 (0.026 to 1.3)	3 (0.54 to 30)
	COVID-19 Associated ICU Admission	0 (0 to 5.3)	0 (0 to 5.3)	N/A
On or after 14 days following the second vaccination dose	Positive SARS-CoV-2 PCR Test	0.14 (0.094 to 0.19)	0.24 (0.19 to 0.31)	0.56 (0.36 to 0.83)
	COVID-19 Associated Hospitalization	0.084 (0.03 to 0.19)	0.15 (0.07 to 0.27)	0.57 (0.17 to 1.7)
	COVID-19 Associated ICU Admission	0.067 (0.0016 to 0.43)	0.13 (0.014 to 0.54)	0.53 (0.0089 to 10)

Table 2. Incident Rate Ratios (IRR) comparing vaccinated to unvaccinated and their associated 95% CI. Data sourced from Mayo Clinic, Rochester, Minnesota from January to July 2021. This article has not been peer reviewed, therefore, the data included has not been evaluated.

Table 3. Longitudinal analysis of vaccine effectiveness against breakthrough infections in Minnesota, split by month.

Month	Moderna (mRNA-1273) / Unvaccinated	Pfizer (BNT162b2) / Unvaccinated	Moderna (mRNA-1273) / Pfizer (BNT162b2)
February	0 (0 to 44)	0 (0 to 39)	N/A
March	0.091 (0.018 to 0.29)	0.11 (0.028 to 0.31)	0.83 (0.12 to 4.9)
April	0.085 (0.033 to 0.18)	0.12 (0.059 to 0.23)	0.69 (0.23 to 2)
May	0.069 (0.022 to 0.17)	0.17 (0.087 to 0.31)	0.4 (0.11 to 1.2)
June	0.38 (0.15 to 0.88)	0.18 (0.046 to 0.53)	2.1 (0.56 to 9.4)
July	0.24 (0.13 to 0.42)	0.58 (0.38 to 0.87)	0.41 (0.21 to 0.76)

Table 3. Incident Rate Ratios (IRR) comparing vaccinated to unvaccinated and their associated 95% CI stratified by month. Data sourced from Mayo Clinic, Rochester, Minnesota from February to July 2021. This article has not been peer reviewed, therefore, the data included has not been evaluated.

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The CDC produces a Morbidity and Mortality Weekly Report (MMWR) with data specific to hospitalized patients. A section of the report is dedicated to fully vaccinated, hospitalized patients (1). This data is presented in **Table 4**. Based on the data of individuals hospitalized and are vaccinated, I calculated the data that would represent the hospitalized individuals that are unvaccinated; this is not reported in the MMWR. Of the patients currently hospitalized with COVID-19, 11.8% are vaccine breakthrough infections and the remaining cases are in unvaccinated individuals (1). In another MMWR from the CDC with data specific to nursing home residents in the pre-delta period (March 1 to May 9, 2021) the effectiveness against infection for mRNA vaccines was 74.7% (95% CI, 70.0% to 78.8%) (3). In the delta period (June 21 to August 1, 2021) the overall effectiveness against infection was reduced to 53.1% (95% CI, 49.1% to 56.7%) (3). The reduction from May to August 2021 from 74.7% to 53.1%, respectively, indicates diminished efficacy of the mRNA vaccines against the delta variant. Another CDC MMWR with data specific to frontline workers also describes a reduction in the effectiveness of mRNA vaccines in preventing COVID-19 infection in the delta period (4). In the pre-delta period, the mRNA vaccine efficacy was 91% (95% CI, 81% to 96%) (4). Once the delta variant became prominent in the United States, the mRNA vaccine efficacy was reduced to 66% (95% CI, 26% to 84%) (4).

The CDC has some patient friendly resources available that discuss the evidence surfacing regarding the vaccine efficacy against the delta variant (6), I've included the link to the CDC's site at the end of the references.

Table 4. CDC Hospitalized Patients

	Overall (N=3,089) Total Hospitalized patients	Cases (N=1,194) Hospitalized patients with COVID-19	Controls (N=1,895) Hospitalized patients without COVID-19
Fully Vaccinated	1,129 (36.6%)	141 (11.8%)	988 (52.1%)
Pfizer-BioNTech	666 (59.0%)	95 (67.4%)	571 (57.8%)
Moderna	463 (41.0%)	46 (32.6%)	417 (42.2%)
Unvaccinated*	1,960 (63.4%)	1,053 (88.2%)	907 (47.9%)

Table 4. Data collected from March 11 to July 14, 2021, in adults ≥18 years of age that were admitted to 21 hospitals in 18 states.
*This data has been calculated to represent the unvaccinated hospitalized patients. This data is calculated and inferred from the data provided by the CDC.

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