Coronavirus edition, Issue 13

The Script

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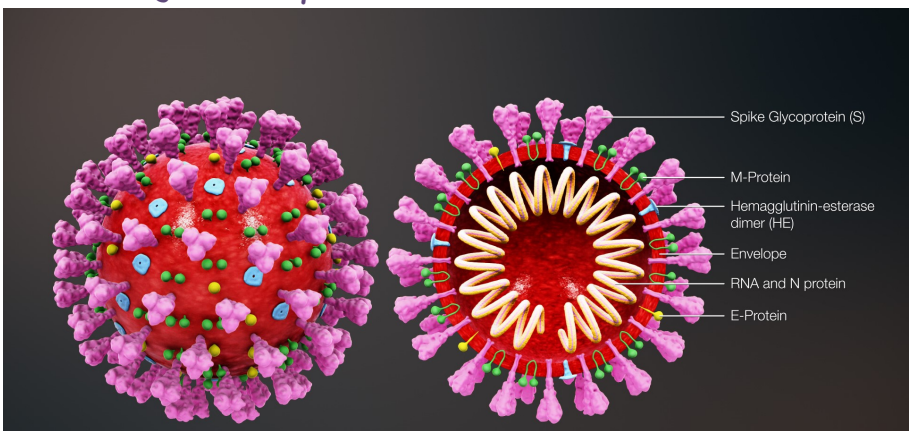
Coronavirus Disease 2019 (COVID-19)

By Christopher Brown, Pharm.D., BCPS



https://www.scientificanimations.com, 2020, 3D medical animation still shot showing the structure of coronavirus, https://www.scientificanimations.com/wiki-images/, accessed 29 Dec 2020, <https://commons.wikimedia.org/wiki/File:3D_medical_animation_coronavirus_structure.jpg>.

In December 2019, several new cases of unexplained pneumonia were reported in Wuhan, China. The source was later discovered to be a new coronavirus. This new coronavirus was named severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) and the disease caused by SARS-CoV-2 was named coronavirus disease 2019 (COVID-19). COVID-19 quickly became a global pandemic and life, as most of the world knew it, was changed.

Coronaviruses (CoV) are a group of viruses that are enveloped with single-stranded RNA inside (see image above). They can cause a variety of diseases involving different bodily systems like respiratory, enteric, hepatic, and neurological, in humans and other animals. Based on the similarities of its genetic sequence, SARS-CoV-2 likely originated in bats. In the past most coronaviruses capable of infecting humans have caused mild respiratory illness. However, besides SARS-CoV-2, in recent history there have been two new coronaviruses that caused severe disease: severe acute respiratory syndrome CoV (SARS-CoV) and Middle East respiratory syndrome CoV (MERS-CoV). SARS-CoV infected more than 8,000 people with a mortality rate of around 10%. MERS-CoV infected over 857 people with a mortality rate of around 35%. As of January 20, 2021 SARS-CoV2 has infected more than 97,859,000 people worldwide and over 2,093,000 people have died. In the United States of America there have been over 25,100,000 cases with over 418,000 deaths. This means that more than 1 out of every 1,000 Americans has died of COVID-19 to date.

The spike (S) protein located on the envelope (see image above) is critical for SARS-CoV-2 as it mediates receptor binding to the angiotensin-converting enzyme 2 (ACE2) receptor, fuses with the host membrane, and helps its transmissibility. The S protein binds the ACE2 receptor around 10 to 20 times better than the S protein of SARS-CoV, which is likely why it spreads so effectively in humans. (continued on page 2).

In This Issue:

Please share your thoughts, comments, and/or suggestions with us.

Do you have an idea for a story? Is there information we can provide you?

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NORMAN REGIONAL Health System

Coronavirus Disease 2019 (COVID-19)- Continued from page 1

By Christopher Brown, Pharm.D., BCPS

The average time from exposure to SARS-CoV-2 and the appearance of symptoms is about 5 days and ranges from 2 to 14 days. The main symptoms of COVID-19 are fever, fatigue, dry cough, myalgia, and dyspnea (see table below for a more complete list). Symptoms can range in severity from asymptomatic to severe respiratory failure. It is estimated that around 40% of infections are asymptomatic and that these individuals can transmit the virus to others for potentially longer than 14 days. This is referred to as silent spread and is likely one of the main reasons why SARS-CoV-2 continues to plague many countries.

COVID-19 Symptoms
Onset: Typically 2-14 Days after Exposure to the Virus
Fever or Chills
Cough
Shortness of Breath or Difficulty Breathing
Fatigue
Muscle or Body Aches
Headache
New Loss of Taste or Smell
Sore Throat
Congestion or Runny Nose
Nausea or Vomiting
Diarrhea

In accordance with CDC guidelines, Norman Regional Health System (NRHS) developed the COVID-19 Pandemic Policy (OP9100-020) which outlines what to do in case of an exposure. For details please see the policy referenced above.

There are two main phases of COVID-19 thought to drive its progression. Early in the course of infection, it is largely driven by viral replication. While later in the course of infection, it is largely driven by the body's exaggerated immune/inflammatory response to the virus. This is why it is hypothesized that antiviral therapies would have the best efficacy early in the course of disease, while immunosuppressive and anti-inflammatory therapies would have the best efficacy in the latter phase of COVID-19.

Over the course of the pandemic, treatment of COVID-19 has evolved considerably. It seems like the entire world is studying COVID-19, and as those studies shed light on current treatments, new recommendations are made. In brief, in the beginning azithromycin and hydroxychloroquine were used to treat COVID-19; however, after looking at the available evidence, NIH guidelines recommend against use of hydroxychloroquine with or without azithromycin in hospitalized patients due to lack of evidence showing benefit. The other medications that have been hypothesized to be helpful or harmful, but ultimately recommended against use, are outside the scope of this article.

Currently, remdesivir is the only FDA approved drug for the treatment of COVID-19. Its use is recommended in hospitalized patients requiring supplemental oxygen, but not requiring invasive mechanical ventilation or extracorporeal membrane oxygenation. NRHS criteria for remdesivir use is in SARS-CoV-2 positive patients on oxygen within 7 to 10 days of symptom onset. It is not routinely recommended for patients who require mechanical ventilation due to the lack of data showing benefit in this population. Dexamethasone was found to improve survival in hospitalized patients who required supplemental oxygen, with the greatest benefit being in patients on mechanical ventilation. Thus, dexamethasone use is strongly recommended in this population. Dexamethasone is not recommended in hospitalized patients who do not require supplemental oxygen.

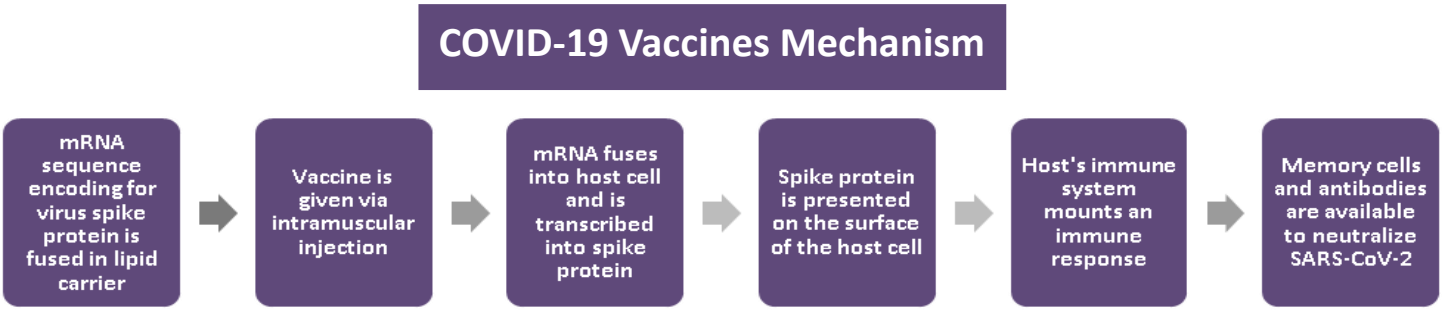
Convalescent plasma has an emergency use authorization from the FDA for treatment of COVID-19 and NRHS criteria for use is in SARS-CoV-2 positive patients within 7 days of symptom onset, age 18 years or older, and IgG negative. Convalescent plasma is not recommended for use in patients with more than 7 days of symptoms as it has not been proven to be effective in the hyperinflammatory phase of COVID-19.

Today, new therapies have received emergency use authorizations from the FDA. These include monoclonal antibodies for outpatient treatment as well as the newly developed mRNA vaccines. The remainder of this newsletter is dedicated to providing the most recent information on these new therapies as well as a COVID-19 specific drug shortages update.

COVID-19 Vaccines

By Michaela Metts, Pharm.D.

As of December 2020, the COVID-19 vaccines made by Pfizer-BioNTech and Moderna were the first commercially available vaccines to utilize mRNA technology. Potential mRNA vaccines against rabies, influenza, Zika, and others have been studied in small, early-phase trials; however, these were never brought to market, because results revealed lower-than-expected neutralizing antibodies in serum. Despite these issues, these vaccines proved safe as the most common adverse effects were injection site reactions. Over the years, mRNA vaccine technology has significantly improved, increasing their ability to produce immunogenicity and therefore increase their efficacy. With the onset of the global COVID-19 pandemic, mRNA vaccines have been given a second chance, and those developed have yielded promising results.



mRNA vaccines work by delivering genetic instructions for host cells to make an antigen. In the case of COVID-19, the target antigen is the immunogenic portion of the SARS-CoV-2 spike (S) protein. The antigen created by host cells is then presented on the outside of the cell, which mimics a natural infection and elicits both a cellular and humoral immune response. This mechanism is similar to that of live attenuated vaccines, such as those for varicella and measles, mumps, and rubella. However, there are several genetic advantages. mRNA does not integrate into host DNA, thereby eliminating any risk of insertional mutations. Since mRNA is unstable, it requires lipid nanoparticles to act as a protective vehicle to deliver it to host cells. This lipid membrane, in turn, protects the mRNA from neutralization via preexisting antibodies, which can limit the effectiveness of viral vector, live-attenuated, and protein-based vaccines. Furthermore, because the mRNA encodes for only a portion of the virus (spike protein), these vaccines cannot cause COVID-19. mRNA vaccines also have the benefit of scalable production. Unlike live attenuated or protein-based vaccines, mRNA vaccines do not have to be grown in eggs or other cells; therefore, they are not easily subject to contamination and can be produced quickly and on a larger scale via enzymatic reactions.

There are some potential disadvantages to mRNA vaccines, such as lack of long-term studies, commercial availability, and concern for waning or short-term immunity. However, both the Pfizer-BioNTech and Moderna mRNA vaccines have been shown to be effective and safe in on-going phase 3 clinical trials (see table on next page for a side-by-side comparison). As of mid-November 2020, the Pfizer-BioNTech data showed that it was 95% effective at preventing COVID-19 infection at least 7 days after completing the two-dose series (21 days apart). There were only 8 cases of COVID-19 in the vaccine group compared to 162 cases in the placebo group. This efficacy was similar across age groups, genders, racial and ethnic groups, and participants with comorbidities (obesity, type 2 diabetes mellitus, chronic kidney disease, asthma, etc.). As of late November 2020, the Moderna data demonstrated 94.1% efficacy at least 14 days after completing the two-dose series (28 days apart) with 11 COVID-19 cases in the vaccine group versus 185 cases in the placebo groups. As with the Pfizer vaccine, efficacy was similar across gender, racial and ethnic groups, and participants with comorbidities; however, efficacy dropped to 86.4% for those 65 years of age and older. (continued on page 4).

COVID-19 Vaccines—Continued from Page 3

By Michaela Metts, Pharm.D.

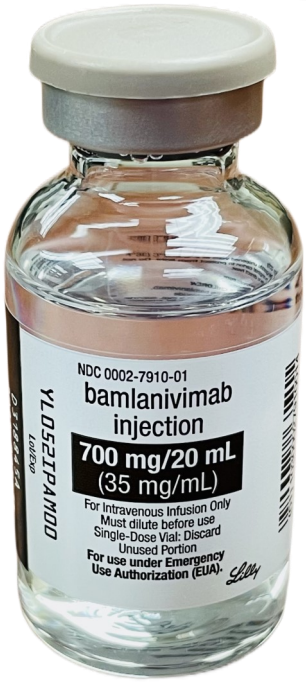
Adverse effects were similar between the two products. Pfizer-BioNTech reported the most common solicited adverse reactions as injection site reactions (84.1%), fatigue (62.9%), headache (55.1%), muscle pain (38.3%), chills (31.9%), joint pain (23.6%), and fever (14.2%). These were more frequent after Dose 2 than after Dose 1 and were generally less frequent in participants older than 55 years of age as compared to younger participants. Moderna reported the most common solicited adverse reactions as injection site pain (91.6%), fatigue (68.5%), headache (63.0%), muscle pain (59.6%), joint pain (44.8%), and chills (43.4%). These were more frequent after dose 2 than after dose 1 and were generally less frequent in participants older than 65 years of age as compared to younger participants.

Comparison of COVID-19 Vaccines

	Pfizer-BioNTech Vaccine	Moderna Vaccine
Mechanism	**SARS-CoV-2 spike glycoprotein (S) antigen encoded by RNA and formulated in lipid nanoparticles (LNPs).**	**SARS-CoV-2 spike glycoprotein (S) antigen encoded by RNA and formulated in lipid nanoparticles (LNPs).**
Age Groups	**16 years and older**	**18 years and older**
Administration	**Intramuscular**	**Intramuscular**
Schedule	**2 doses, 21 days apart**	**2 doses, 28 days apart**
Storage	**Stored frozen at -70°C (-94°F)** **Use within 5 days at refrigerated temperatures (not reconstituted)** **Use within 6 hours at room temperature (after reconstitution)**	**Stored frozen at -20°C (-4°F)** **Use within 7 – 14 days at refrigerated temperatures** **Use within 6 hours at room temperature**
How Supplied	**Multidose vial (5 doses/vial)** **0.9% NS diluent packaged separately and stored at room temperature**	**Multidose vial (10 doses/vial)**

The Pfizer-BioNTech and Moderna COVID-19 vaccines are ushering a new phase of vaccine technology. They also represent the best hope for slowing or ending the pandemic as both products were granted approval for use under the Food and Drug Administration Emergency Use Authorization in December 2020. However, the pandemic will not end overnight as vaccination on a global scale will be needed to effectively attenuate the spread of COVID-19. Some experts have predicted that achieving herd immunity will require up to 80 to 90% of a given population to be immune either through prior infection or vaccination.

Vaccination efforts are well underway at Norman Regional Health System. Currently, phase one has already been completed using the Pfizer-BioNTech vaccine and phase two is ongoing. Many of our staff and providers have received the vaccination and more shipments of vaccine are expected to continue to be sent to hospitals across the United States as availability allows. As we and our communities increase the percentage of people immunized, our numbers of positive cases should begin to decline. There seems to be an end to the pandemic in sight, a light at the end of the proverbial tunnel, a welcomed end to this unbelievable experience.



Bamlanivimab

By Cong Vu, Pharm.D.

COVID-19 has dominated the news headlines for much of 2020. This disease created an unprecedented challenge to healthcare systems across the world and its impact is extensive, with far reaching consequences. Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) poses a public health threat for which therapeutic agents are urgently needed. In response, several treatment options have been explored and bamlanivimab, a monoclonal antibody, was developed by Eli Lilly. This article summarizes the essential details of bamlanivimab and its use.

Bamlanivimab is a recombinant, neutralizing human IgG1 monoclonal antibody directed against the spike protein of SARS-CoV2. Researchers at AbCellera discovered the anti-spike neutralizing antibody from the blood of one of the fist COVID-19 patients. Bamlanivimab binds to the receptor domain of the SARS-CoV-2 spike protein thus blocking the virus from attaching to the ACE2 receptors on human cells.

On November 9, 2020, the FDA issued an Emergency Use Authorization (EUA) for bamlanivimab for the treatment of non-hospitalized patients with mild-to-moderate COVID-19 who are at high risk for progressing to severe disease and/or hospitalization. Bamlanivimab is authorized for patients with a positive viral test for SARS-CoV-2 and should be administered as soon as possible within 10 days of symptom onset. For high risk criteria definitions, see table below.

The data supporting the EUA for bamlanivimab are based on the BLAZE-1 trial, which was a phase two randomized, placebo-controlled, single-dose trial in non-hospitalized patients with mild-to-moderate COVID-19 symptoms. A total of 462 participants were randomized to receive a single, 1-hour intravenous infusion of bamlanivimab 700 mg, 2800 mg, 7000 mg, or placebo within three days of a positive COVID-19 viral test.

The primary endpoint of the trial was change in viral load from baseline to Day 11(± 4 days), which was measured by a nasopharyngeal swab. **The secondary endpoint** was COVID-19-related hospitalizations or emergency room visits within 28 days of treatment.

By day 11, only patients who received the 2800 mg dose of bamlanivimab had a statistically significant decrease in viral load compared to placebo. The decline in viral load was not significantly different between those who received the 700 mg or 7,000 mg dose of bamlanivimab versus placebo. At day 29, the percentage of patients who were hospitalized with COVID-19 was **1.6%** (5 of 309 patients) in the bamlanivimab group and **6.3%** (9 of 143 patients) in the placebo group. In a post-hoc analysis of participants at high risk for progression to severe COVID-19 (aged **≥** 65 years or BMI **≥** 35), the percentage who were hospitalized was **4%** in the bamlanivimab group and **15%** in the placebo group. The trial also demonstrated a possible reduction in symptom severity as early as day 2, with the most pronounced effects observed in the high-risk cohorts (age ≥ 65 or BMI ≥ 35). (continued on page 6).

High Risk Criteria for Progression to Severe COVID-19	
At least ONE of the following:	• Age ≥ 65 years • BMI ≥ 35 • Diabetes Mellitus • Chronic Kidney Disease • Immunosuppressive Disease • Currently receiving immunosuppressive treatment
Age ≥ 55 years AND at least ONE of the following:	• Cardiovascular Disease • Hypertension • Chronic Obstructive Pulmonary Disease • Other Chronic Respiratory Disease
Age 12 to 17 AND at least ONE of the following:	• BMI > 85th percentile age and gender based on the CDC growth charts • Sickle Cell Disease • Congenital or Acquired Heart Disease • Neurodevelopmental Disorder (e.g. Cerebral Palsy) • A Medical Related Technological Dependence (e.g. Tracheostomy, Gastrostomy, or Positive Pressure Ventilation [not related to COVID-19]) • Asthma or Reactive Airway • Other Chronic Respiratory Disease that Requires Daily Medication for Control

Bamlanivimab—Continued from Page 5

By Cong Vu, Pharm.D.

Treatment with bamlanivimab was generally well-tolerated with the safety profile similar to that of placebo. However, it should be emphasized that treatment with bamlanivimab is only reserved for non-hospitalized patients. The NIH-sponsored ACTIVE-3 clinical trial evaluated bamlanivimab versus placebo in hospitalized patients with COVID-19 was halted due to lack of clinical benefit in hospitalized patients. Currently, bamlanivimab is one of the products used in our Outpatient COVID-19 Infusion Center.

Casirivimab and Imdevimab

By Charles Whitman, Pharm.D.

Despite the efforts of the many pharmaceutical companies, COVID-19 continues to be widespread throughout the United States and has overwhelmed many healthcare systems. After patients become infected with COVID-19, many exhibit few or no symptoms despite having high viral loads, and many can be treated on an outpatient basis. In smaller, more severe cases, the COVID-19 infection can progress to hypoxemia, leading to hospitalization and the need for supplemental oxygen. As stated in an earlier article, SARS-CoV-2 gains entry into cells by binding its spike protein to the receptors of human angiotensin-converting enzyme 2. Due to this entry mechanism, the receptor binding domain of the SARS-CoV-2 spike protein receptor has become an important target site for developing immunotherapies to prevent viral entry into human cells.

Regeneron Pharmaceuticals has developed REGN-COV2, an "antibody cocktail" consisting of two noncompeting SARS-CoV-2 neutralizing antibodies (Casirivimab and Imdevimab) that target this viral entry mechanism. Regeneron chose to pursue an "antibody cocktail" because of previous experience with emergence of treatment-resistant mutant viruses. Preclinical studies confirmed that REGN-COV2 protects against emergence of mutant viruses seen with either single antibody. In studies with nonhuman primates, REGN-COV2 has shown profound antiviral activity by reducing viral load when administered as prophylaxis and improving viral clearance when administered as treatment.

Currently, there are ongoing Phase 1 and 2, randomized, double-blind, placebo-controlled trials conducted at 96 centers in the United States to evaluate the safety and efficacy of REGN-COV2 for the outpatient treatment of mild to moderate COVID-19. In an interim analysis, a total of 799 patients were randomized in a 1:1:1 ratio to receive an infusion of 2400 mg of REGN-COV2, 8000 mg of REGN-COV2, or placebo. The **primary endpoint** was time-weighted average daily change in viral load from baseline to day 7. The **secondary endpoint** was a composite of medically attended visits related to COVID-19, including hospitalization or emergency department, urgent care, physician office, or telemedicine visits within 28 days of treatment.

For the **primary endpoint**, the average daily change in viral load from baseline to day 7 was a 0.68 $\log_{10}$ copies/mL statistically significant, greater reduction with REGN-COV2 vs. placebo (combined dose groups; $p < 0.0001$). Figure 1 on the next page gives a graphical representation of the mean change in viral load over time with the trial agents and placebo.

On the **secondary endpoint**, **2.8%** of patients in the combined dose group had a medically attended visit related to COVID-19 vs. **6.5%** in the placebo group ($p = 0.024$). Treatment with REGN-COV2 was shown to reduce COVID-19 related visits by 57% through day 29. In patients with one or more risk factor (including age > 50 years old; BMI > 35; cardiovascular, metabolic, lung, liver, or kidney disease; immunocompromised status), treatment with REGN-COV2 was shown to reduce COVID-19 related medical visits by **72%** ($p = 0.0065$). (continued on page 7).

Casirivimab and Imdevimab—Continued from Page 6

By Charles Whitman, Pharm.D.

Based on the findings from this interim analysis, an Emergency Use Authorization (EUA) was issued for REGN-COV2 on November 21, 2020, shortly after the EUA for bamlanivimab was issued. The EUA approved the use of REGN-COV2 in patients at a high risk for progression to severe disease requiring hospitalization (for high risk criteria, please refer to the table in the bamlanivimab article on page 5).

Both bamlanivimab and REGN-COV2 are being used in our Outpatient COVID-19 Infusion Center at the Hospitality House, just South of the Porter campus. As the pandemic continues, it is exciting that we now have two potential treatment options for the outpatient management of mild to moderate COVID-19 in those at a high risk for progression to severe disease. Hopefully, the use of these agents will prevent severe disease so that we can reduce COVID-19 related hospitalizations and finally have some control over the pandemic. As of 12/31/2020, 271 patients have been treated with both bamlanivimab and REGN-COV2 at the Hospitality House. Of those, only 6 patients eventually required hospitalization and 11 required an ED visit.

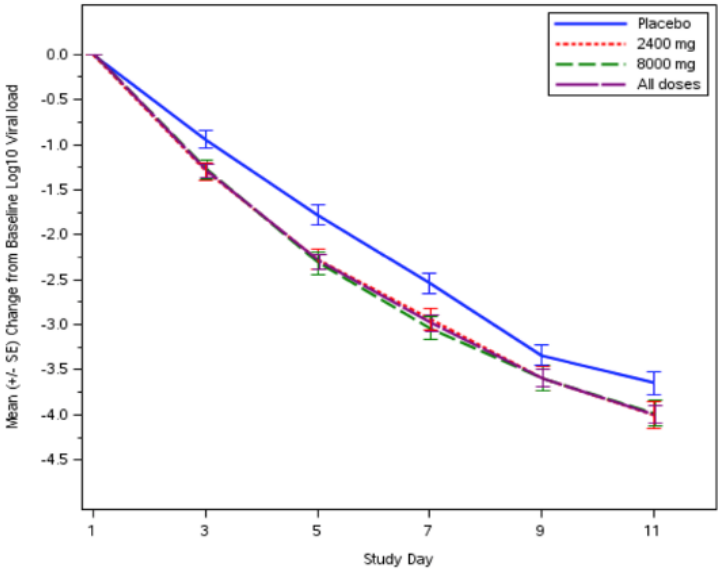


Figure 1. Mean Change from Baseline in SARS-CoV-2 Viral Load Over Time. Reprinted from the FDA. Fact sheet for health care providers: emergency use authorization (EUA) of casirivimab and imdevimab. Copyright 2020, with permission from Regeneron Pharmaceuticals, Inc.

Critical Medication Shortages Related to COVID-19

By Donna Wilk, CPhT

MEDICATION	ACTION PLAN
Albuterol Sulfate Multi-Dose Inhalers (Ventolin, ProAir, Proventil)	No supply issues at this time. NRHS has adequate stock on hand of multiple size inhalers.
Cisatracurium Injection (Nimbex)	Product remains on limited allocation. NRHS has adequate stock on hand and are ordering product daily.
Dexamethasone Injection (Decadron)	No supply issues at this time. NRHS has adequate stock on hand.
Dexamethasone Tablets (Decadron)	Out of 6 mg tablets at this time. NRHS has adequate stock on hand of 2mg and 4mg tablets.
Dexmedetomidine Injection (Precedex)	Product remains on allocation. NRHS has adequate stock on hand.
Enoxaparin Injection (Lovenox)	Product remains on allocation. NRHS has adequate stock on hand.
Etomidate Injection (Amidate)	No supply issues at this time. NRHS has adequate stock on hand.
Fentanyl PCAs	Fentanyl injection availability has tightened. We are working on increasing stock. Empty PCA cartridge availability has improved slightly and we have adequate stock on hand.
Heparin 25,000 unit Drips	Product availability is limited. NRHS has increased PAR levels and has adequate stock on hand.
Propofol Injection (Diprivan)	Due to current situation in U.S., product is difficult to obtain. NRHS has been able to maintain supply on a week to week basis. In light of this, we are reviewing all available options should the situation worsen. Patients requiring doses at high rates will be considered

**This table is not inclusive. If you wish to see all reported nationwide shortages please refer to https://www.ashp.org/Drug-Shortages/Current-Shortages.

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The Script A Publication of the Department of Pharmacy

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