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NYS-ACCP Insider

Long Island University
Arnold & Marie Schwartz College of Pharmacy and Health Sciences

Special Points of Interest:

Synopsis of LIU: ACCP Newsletter

The 2022-2023 academic year was exciting and eventful for members of the Long Island University (LIU) Pharmacy's American College of Clinical Pharmacy (ACCP) student chapter. With a combination of virtual and mostly in-person meetings, the LIU-ACCP executive board worked hard to provide students with a fulfilling year of informative Professional Development Program (PDP) events, fundraisers, guideline and journal clubs, and outreach opportunities. Thanks to our chapter advisors, Dr. Fischetti and Dr. Khaimova who helped us develop informative and exciting experiences for the students.

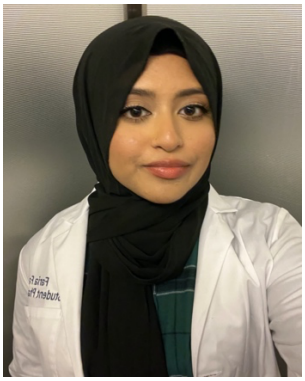
During the Fall semester, our first event was the annual JDRF One Walk to help raise money and be in support of Type 1 Diabetes research. This event was held both in person and online. We also held a workshop meeting with Dr. Timothy Nguyen, who is a Professor of Pharmacy Practice here at LIU Pharmacy. The event instructed students on how to read a research article and provided students with useful skills and insight into primary literature evaluation. These skills will help serve students through the rest of their pharmacy education and for future careers. As many students are interested in residency training, we collaborated with the Rho Chi Honor Society for a PDP about residency at the Brooklyn VA with the Residency Program Director (RPD), Dr. Charles Sharkey. This was a great opportunity for students to learn more about residency and provided the ability to network with an RPD. We also collaborated with ASHP for the Hackensack University Medical Center Residency showcase with PGY1 RPD, Dr. Ruchi Jain, as well as hosting a PDP event on pharmacy research, with Dr. Oriel Averion who is a Research Pharmacist at Columbia University Irving Medical Center. This was an amazing opportunity for students to learn about research that pharmacy students can become involved with.

During the Spring semester, we held a PDP with Dr. Jaclyn Cusumano on research and fellowship opportunities as a PharmD. We learned about a brand-new Infectious Diseases

Research Fellowship program through LIU Pharmacy that Dr. Cusumano has founded and that students will be able to apply to in the future. In addition, we had guest speaker, Dr. Abigail White who spoke about residency opportunities and held Pharmacy Student Leadership Development PDP with Dr. Eli Mosseri, a former PGY2 Resident in Corporate Pharmacy Administration and Leadership. Finally, we held a fundraiser for the Kimberly Coffee Foundation, to help raise awareness for the Meningitis B vaccine and work to improve legislation.

In addition to our PDPs and guest speakers, we also hosted multiple guideline and journal clubs. During the Fall, guideline club topics included the Treatment of Latent Tuberculosis Infection. We also had a guideline club on Antithrombotic Treatment in Patients with COVID-19. We had one journal club event on the SGLT2 Inhibitors combined with Insulin for Treatment of Type II Diabetes. During the Spring, we held guideline clubs on the Management of Fever and Neutropenia in Pediatric Patients with Cancer and Hematopoietic Cell Transplantation Recipients and The Management of Atopic Dermatitis in Adults with Topical Therapies. In addition, journal clubs during the Spring semester including The Use of Intramuscular Chlorpromazine versus Intramuscular Olanzapine for the Management of Acute Agitation and Aggression in Youth and CPIC Guideline for Pharmacogenetics-Guided Warfarin Dosing.

In the 2023-2024 academic year, the LIU-ACCP student chapter will have a combination of in-person and virtual events. We are always prepared to continuously provide ACCP members with an enriching clinical pharmacy experience. Together, with Dr. Fischetti our chapter looks forward to a fulfilling year.



Faria Farid, President-Elect, Pharm.D. Candidate, LIU-AMSCOP, Class of 2026
Reviewed by Briann Fischetti, PharmD, MBA, BCACP, AAHIVP

New Drug Review: Xacduro (sulbactam/durlobactam)

The Food and Drug Administration (FDA) has approved Xacduro (sulbactam for injection; durlobactam for injection) for the treatment of hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia, caused by susceptible isolates of *Acinetobacter baumannii-calcoaceticus* complex in patients 18 years of age and older[1]. It is the first co-packaged pathogen-targeted therapy which contains sulbactam, a beta-lactam antibacterial and beta-lactamase inhibitor, as well as durlobactam, a beta-lactamase inhibitor.

The FDA approval was based on an array of scientific evidence, including results from the Phase 3 ATTACK trial evaluating the safety and efficacy of sulbactam/durlobactam versus colistin in patients with infections caused by *Acinetobacter*.[3] *Acinetobacter* poses a significant danger to hospitalized patients, who are generally very ill and particularly susceptible to infections. Although *Acinetobacter* infections are treated with antibiotics, many *Acinetobacter* infections are resistant to antibiotics, such as carbapenems, making them more difficult to treat. Trial data showed treatment with sulbactam/durlobactam was non-inferior to collistin when measuring death from any cause 28 days after treatment for a confirmed infection of drug-resistant Acinetobacter baumannii[4]. Sulbactam/durlobactam was well tolerated and exhibited a favorable safety profile. Additionally, a statistically significant difference in clinical cure rates was observed; 61.9% with sulbactam/durlobactam vs 40.3% with colistin[4].

For hospital acquired pneumonia and ventilatory associated pneumonia, the recommended dosage of sulbactam/durlobactam is 1 gram of sulbactam and 1 gram of durlobactam every 6 hours administered by intravenous (IV) infusion over 3 hours in adults with a creatinine clearance (CrCl) of 45 to 129 mL/min. The recommended duration of treatment with sulbactam/durlobactam is 7 to 14 days, but therapy should be guided by the patient's clinical status. Adjustments to the dosing regimen for sulbactam/durlobactam are recommended for patients with a CrCl less than 45 mL/min and CrCl greater than or equal to 130 mL/min. Patients undergoing intermittent hemodialysis (HD) should start therapy immediately after the completion of HD. Dosing adjustments are listed in **Table 1.** Furthermore**,** sulbactam/durlobactam was shown to significantly lower the incidence of nephrotoxicity compared to collistin[3]. Fewer serious adverse events were also observed, and there was lower treatment discontinuation due to adverse reactions with one patient experiencing anaphylactic shock. The most common adverse reactions (incidence > 10%) with sulbactam/durlobactam are liver test abnormalities, diarrhea, anemia, and hypokalemia. Before initiating therapy with sulbactam/durlobactam, careful inquiry should be made concerning previous hypersensitivity reactions to carbapenems, penicillins, cephalosporins, other beta lactams, and allergens[1].

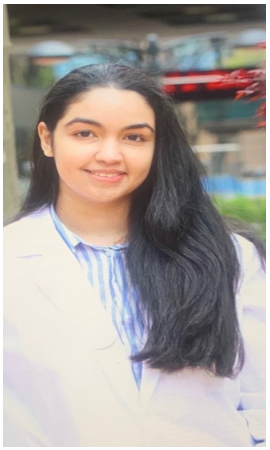
Table 1: Dosage of Xacduro (sulbactam/durlobactam) in Patients (18 years and older) based on Renal Function[1]

Dosage	Estimated CrCl (mL/min)	Frequency
sulbactam 1 g and durlobactam 1 g	≥130	Every 4 hours
	45-129	Every 6 hours
	30-44	Every 8 hours
	15-29	Every 12 hours
	< 15	Every 12 hours for the first 3 doses (0, 12, and 24 hours), followed by every 24 hours after the third dose* For patients currently receiving Xacduro whose CrCl declines to less than 15: Every 24 hours

***For patients on HD, the dose should be administered after the dialysis has ended**

References:

1. Xacduro. Package insert. Innoviva; 2023. Accessed October 22, 2023. https://innovivaspecialtytherapeutics.com/wp-content/uploads/2023/05/Xacduro_Full_Prescribing_Information.pdf.
2. Centers for Disease Control and Prevention. Acinetobacter. Healthcare-Associated Infections (HAIs). Updated November 13, 2019. Accessed October 22, 2023. https://www.cdc.gov/hai/organisms/acinetobacter.html
3. Innoviva Specialty Therapeutics announces FDA approval for Xacduro® (sulbactam for injection; durlobactam for injection), co-packaged for intravenous use. News release. May 23, 2023. https://www.businesswire.com/news/home/20230523005961/en/Innoviva-Specialty-Therapeutics-Announces-FDA-Approval-for-XACDURO%C2%AE-sulbactam-for-injection-durlobactam-for-injection-Co-packaged-for-Intravenous-Use.
4. Kaye KS, Shorr AF, Wunderink RG, et al. Efficacy and Safety of sulbactam-durlobactam versus colistin for the treatment of patients with serious infections caused about Acinetobacter baumannii-calcoaceticus complex: a multicentre, randomised, active-controlled, phase 3, non-inferiority clinical trial (ATTACK). *Lancet Infect Dis.* 2023;23(9):1072-1084. Doi:10.1016/S1473-3099(23)00184-6



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Reviewed by Briann Fischetti, PharmD, MBA, BCACP, AAHIVP

Chronic Kidney Disease: A Brief Overview

Chronic kidney disease (CKD) is a disease characterized by progressive damage of the kidneys and loss of kidney function persisting for more than 3 months.[1] It involves a gradual loss of kidney function over time where the kidneys cannot filter blood as well as they should. Advanced CKD can cause dangerous levels of fluids, electrolytes, and wastes to build up in your body if left untreated and is a leading cause of death worldwide. The most common causes of CKD in adults are high blood sugar levels and high blood pressure.[2] Other risk factors can include obesity, heart disease, a family history of CKD, and older age.[2] Common symptoms of CKD include fatigue, poor appetite, muscle cramping, trouble sleeping, shortness of breath, nausea and vomiting, and

urinating either too much or too little.[3] Treatment for CKD focuses on slowing the progression of kidney damage.

CKD can be diagnosed by using various methods including blood and urine tests. This includes one or more of the following: the glomerular filtration rate (GFR), if the GFR is less than 60mL/min/$1.73m^2$for >3 months, albuminuria (urine albumin ≥ 30mg per 24 hours or urine albumin to creatinine ration (ACR) ≥ 30mg/g for > 3 months; abnormalities in urine sediment, imagining suggestive of kidney damage; renal tubular disorders; or history of kidney transplantation.[1] The most precise measurement of ACR comes from a first-morning urine sample, due to high biological variability in urine albumin excretion over the course of the day.

Once a diagnosis of CKD has been made, the following step is to determine staging, which is based on GFR, albuminuria, and causes of CKD. Staging of GFR is classified as below:

Table 1: Prognosis of CKD by GFR and albuminuria category [4]

				Persistent albuminuria categories, description, and range		
				A1	A2	A3
				Normal to mildly increased	Moderately increased	Severely increased
				<30 mg/g	30-300 mg/g	>300 mg/g
GFR categories, description, and range (mL/min/1.73 m²)	G1	Normal or high	≥90			
	G2	Mildly decreased	60-89			
	G3a	Mildly to moderately decreased	45-59			
	G3b	Moderately to severely decreased	30-44			
	G4	Severely decreased	15-29			
	G5	Kidney failure	<15			

Note: Green: low risk (if no other markers of kidney disease, no CKD) Yellow: moderately increased; Orange: high risk; Red: very high risk

Effective management of patients with diabetes and CKD can include implementing lifestyle modifications such as a healthy diet, weight loss, exercise, and smoking cessation. According to the Kidney Disease Improving Global Outcomes (KDIGO) guidelines, Patients with diabetes and CKD should be treated with a comprehensive strategy to reduce risks of kidney disease progression and cardiovascular disease.[4] Effective glycemic control can also help delay the progression of CKD. Diabetic drugs that are largely cleared by the kidneys should be avoided in patients with CKD. This includes sulfonylureas such as glyburide. First-line treatment for glycemic control in patients with Type 2 diabetes (T2D) and CKD is sodium glucose cotransporter-2 inhibitors (SGLT2i) and an additional drug therapy as needed for glycemic control.[4] SGLT2i help prevent the progression of CKD by reducing sodium and glucose reabsorption in the proximal tubule, which increases sodium delivery to the distal nephron leading to constriction of the afferent arteriole resulting in a reduced GFR and intraglomerular pressure independent of its effect on glycemic control. SGLT2i should be used when eGFR is ≥ 20 mL/min/1.73 m^2.[4] Most patients with T2D, CKD, and an eGFR ≥30 mL/min/1.73 m^2 would benefit from treatment with both metformin and an SGLT2i.[4] Glucagon-like peptide-1 agonist (GLP-1) is also a preferred treatment choice for patients who have both T2D and CKD and cannot tolerate SGLT2i.

CKD takes a long time to develop and often does not have any signs and symptoms in the early stages until at least 80 percent of kidney function is lost.[5] A patient may not know they have CKD unless they get tested for it. Prevention of CKD in T2D can be achieved through a healthy lifestyle, exercise, glycemic control, and blood pressure control. The hemoglobin A1C is a blood test that shows the average blood glucose level over the past 3 months. As lifestyle modifications, it is recommended to limit sodium intake to less than 2 grams/day.[4] Also smoking cessation and losing weight are advised. According to the KDIGO guidelines, a goal hemoglobin of A1c is <7% for most patients. Many people with diabetes also develop high blood pressure, which can also damage the kidneys. An angiotensin-converting enzyme inhibitor (ACEI) or an angiotensin II receptor blocker (ARB) is recommended in adults with hypertension and CKD, especially in those with high ACR. According to the KDIGO guidelines, the recommended goal of systolic and diastolic blood pressure of less than 130mm Hg and less than 90mm Hg respectively.[4]

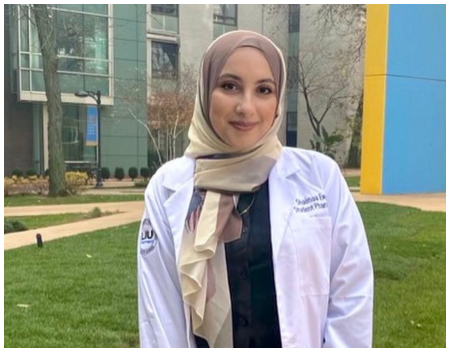
Follow-up and monitoring are recommended after initiating therapy. After beginning treatment and lifestyle modifications to treat CKD repeated urine and blood tests must be done to determine if urine albumin levels have improved. It's stage-based monitoring, so more advanced stages of CKD such as Stages 4 and 5 would need to be checked every 3 to 6 months compared to stage 2 CKD which is checked annually.

In conclusion, CKD is characterized by the progressive damage of the kidneys where individuals with hypertension and diabetes are considered most at risk. Effective management of hypertension and diabetes can help slow down further progression of CKD in patients as well as implementing lifestyle modifications such as a healthy diet, weight loss, exercise, and smoking cessation. Some pharmacological treatments are preferred compared to others due to their kidney benefits. SGLT-2 inhibitors and GLP-1 agonists are preferred in diabetic patients with CKD unless contraindicated compared to medications such as sulfonylureas. They have good glycemic control and kidney protective properties. Follow-up with repeated urine and blood tests is advised to keep patients' CKD under control.

References:

1. Chen TK, Knicely DH, Grams ME. Chronic Kidney Disease Diagnosis and Management: A Review. *JAMA*.2019;322(13):1294–1304. doi:10.1001/jama.2019.14745
2. CKD risk factors. Centers for Disease Control and Prevention. June 1, 2023. https://www.cdc.gov/kidneydisease/publications-resources/annual-report/ckd-risk-prevention.html#:~:text=Diabetes%20and%20high%20blood%20pressure,can%20help%20keep%20kidneys%20healthy. Accessed October 18, 2023
3. What is chronic kidney disease? - NIDDK. National Institute of Diabetes and Digestive and Kidney Diseases. https://www.niddk.nih.gov/health-information/kidney-disease/chronic-kidney-disease-ckd/what-is-chronic-kidney-disease. Accessed November 16, 2023.
4. KDIGO 2022 clinical practice guideline for diabetes management in CKD. https://kdigo.org/wp-content/uploads/2022/03/KDIGO-2022-Diabetes-Management-GL_Public-Review-draft_1Mar2022.pdf. Accessed October 18, 2023.

5. Diabetes and chronic kidney disease. Centers for Disease Control and Prevention. December 30, 2022. https://www.cdc.gov/diabetes/managing/diabetes-kidney-disease.html. Accessed November 16, 2023.



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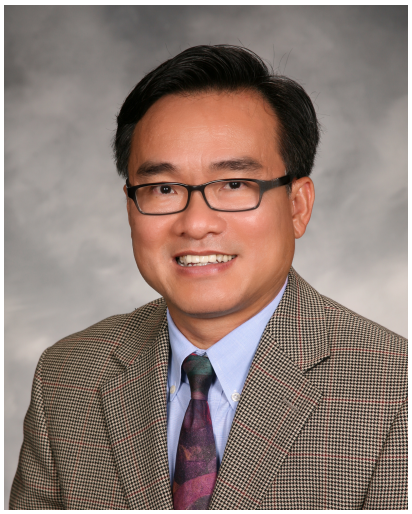
Reviewed by Timothy Nguyen, PharmD, MBA, BCPS, CCP, FASCP

Clinical Spotlight: Dr. Timothy Nguyen Pharm.D., MBA, BCPS, CCP, FASCP



Dr. Timothy Nguyen is a Professor of Pharmacy Practice at the College of Pharmacy at Long Island University in Brooklyn, NY. Dr. Nguyen earned his Bachelor of Science from Rutgers, The State University of New Jersey in 1996. He went on to earn his Doctor of Pharmacy (Pharm.D.) from Philadelphia College of Pharmacy in 2001 and Master of Business Administration from Long Island University in 2021. He obtained his Board Certification of Pharmacotherapy (BCPS) in 2011 and joined the faculty of LIU Pharmacy in 2009. He teaches pharmacotherapy with a focus on kidney disease, electrolytes, and the urinary system alongside maintaining a practice site at Mount Sinai hospital (Mount Sinai Kidney Center) where he takes APPE students on rotation in

General Medicine. Dr. Nguyen also serves as a preceptor for PGY1 and PGY2 residents at his institution. Dr. Nguyen is heavily involved in research in both the pharmacy and kidney programs. His recent publications include, “Tirzepatide (Mounjaro): A Dual Glucose-dependent Insulinotropic Polypeptide and Glucagon-Like Peptide-1 Agonist for the Management of Type 2 Diabetes Mellitus" published online in 2022 and “Nonsteroidal Anti-inflammatory Drugs Use in Older Adults and Kidney Disease" published online in September 2022. His practice expertise resides in pharmacy education, acute care, kidney disease, nephrology, dialysis and clinical pharmacology.

1. **What made you so interested in pharmacotherapy?**
   I was always curious about the sciences. If I need to take a medication, I want to know what it is, how it works, which medication is better for me, and which one has more side effects. I think pharmacy is the best profession out there for students interested in the healthcare field because you know so much about medications, diseases, the human body, and you understand how important it is to take certain medications, how it helps, and the side effects.

2. **What made you so interested in research?**
   As a student in college, I had a lot of curiosity. I was always interested when I read people’s research about new drugs coming out, and I was always amazed at how these scientists and pharmacists developed these things and how they were able to communicate these things with patients. I developed a lot of interest in it, but I wasn’t sure if I was really able to do it. Just like any student–you’re not sure what you’re going to be doing when you finish school. I worked throughout pharmacy school, returned to receive my Pharm.D., and got my clinical training. I was always interested in scholarly activity, in the dissemination of information in terms of publishing information, and in working with students to establish research initiatives. Coming to LIU is where this really started for me. I wish there were more opportunities for me to get involved in research as a student, but at the time, when I went to school, there weren't a lot of opportunities like there are now.

3. **What factors contributed to your current specialty?**
   Like a student in college, I wasn’t sure what I wanted to do or where I was going to work when I finished school. Fortunately, when I was doing my rotation, I had good exposure to kidney-related activities. Then, I went back to school to get my Pharm.D.. When I graduated it used to be a Bachelor of Science and then we had the opportunity to get our Pharm.D. degree. During my time getting my Pharm.D., I also learned a lot about kidney disease and developed an interest in it. Very fortunately after my Pharm.D., I got a clinical position to work in the hospital and developed more experience in kidney areas. It then so happened that there was a renal specialist position available, and I gave it a try and got it. I worked for a specialty clinical pharmacy in nephrology at a dialysis center for about seven to eight years. I had a lot of support from the director of pharmacy there who helped me train and develop in this area.

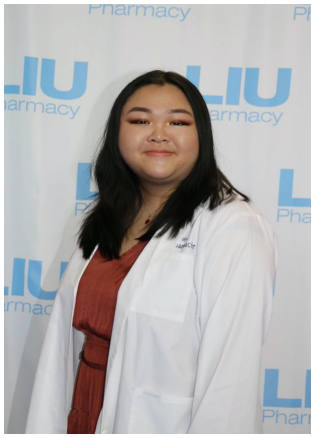
4. **What does a typical week of yours look like?**
   A typical week can be very busy and depends if I'm teaching classes. It is especially busy in the beginning of the semester when I teach MOST. I have to be at school for most of the day, but also on site for my students. For example, on the days I teach, I leave my house by 6:30AM to get to the office before 9AM classes and to alleviate all the traffic and commuting problems. When I finish teaching around 12PM, I have to rush back to my site where I spend time with my APPE students and finish around 5 or 6 PM. On other days, if I don't need to go to campus. On days I need to go on rounds with my students, I need to be at the hospital before 8AM and I can leave around 4 or 5 PM.

5. **What would you say was the most difficult part of the path to becoming who you are today as a pharmacist?**
   There are always things in the way, but I am very adjustable. I do a lot of mindfulness thinking, as you may see in my classes. One example is that transitioning from a clinical position to an academic position was a big adjustment for me. I took a lot of mindfulness, I took a lot of time for myself, and I also know that adjusting to anything new isn't easy. I took my time in the beginning, adjusted, and got used to whatever came. I hope that I will be able to maintain and continue educating future pharmacists in the kidney areas. We have many new, promising agents available for treating kidney disease, like SGLT2 inhibitors and finerenone. I hope to keep up with that information in terms of translating that information into the classroom and helping educate future pharmacists in the area of kidney and electrolytes.

6. **What kind of advice would you give a student interested in pursuing residency?**
   Pharmacy students have a lot of opportunities right now such as club activities and PDPs where people come and talk to you about different opportunities. I encourage students to work as a pharmacy technician or an intern in the community, hospital, or really any setting related to pharmacy. Residency is very good, but it's a process. I encourage students to develop a portfolio for residency. To build up your portfolio, I recommend participating in extracurricular activities, asking faculty for research opportunities, volunteering at various venues, and doing leadership in different club activities. Residency program directors look for many things in a candidate: academics, extracurricular activities, interviewing capabilities, and engagement during school. However, even if students feel they may not meet the requirements, I think they should still apply. Some people may be very good at their residency program even if they don't have any experience, but experience is always helpful.

7. **Can you discuss why you chose to obtain a Master of Business Administration (MBA) and if you have any recommendations on why it would be a good fit for some pharmacy students?**
   One of the best opportunities in the pharmacy profession is that you can go on to do other things. You could become a lawyer, go to medical school, you can practice in things not even related to clinical pharmacy. If you want to do administration or work in the industry, you could obtain your MBA. Here at LIU, they have dual-degree programs and if students

have the opportunity to do that. However, let's say you didn't do a dual degree program. If you work for industry, they may pave the way for you to go back to get your MBA. If you work for a hospital or community and want to go back to get your higher education, I recommend it as well. For me, I love school, so higher education is important. I think everybody who has the opportunity should consider it. It is a strength to have additional training.



Jazmine Li, Pharm.D. Candidate, Secretary, LIU-AMSCOP, Class of 2026
Reviewed by Briann Fischetti, PharmD, MBA, BCACP, AAHIVP

Nirsevimab: RSV Monoclonal Antibody for the Prevention of RSV in Infants and Children

Respiratory syncytial virus (RSV) is a viral infection that causes inflammation of the respiratory tract. While most cases are mild, with symptoms similar to the common cold, more severe cases may lead to pneumonia and bronchiolitis.[1] As RSV is considered the leading cause of hospitalizations in individuals under the age of one, advancements in the way of early prevention are instrumental in reducing the prevalence of this disease in infants. RSV can be especially dangerous and life threatening for infants in which common symptoms include irritability, decreased activity, apnea, and decreased appetite along with a runny nose and a cough that may progress to wheezing or lead to difficulty breathing.[2]

Created through the partnership of AstraZeneca and Sanofi, the FDA has recently approved the use of Beyfortus (nirsevimab) in July of 2023 for infants, especially those with a compromised immune system. According to the prescribing information, nirsevimab is indicated for the prevention of RSV in neonates and infants who were born during or are entering their first RSV season. In this population, neonates or infants weighing < 5kg are recommended to be given 50 mg by intermuscular (IM) injection while those where are ≥ 5kg are recommended to receive 100 mg by IM injection.[3] This medication is also indicated for use in children up to 24 months of age who are vulnerable to severe RSV through their second RSV season. For this specific population, it is recommended that patients receive a single 200 mg dose that is to be administered as two IM injections (2 x 100 mg) at different areas of the outer thigh.[3]

Nirsevimab contains monoclonal antibodies which provide the infant with passive immunity against RSV. The CDC considers infants under 8 months who were born during, or are

entering, their first RSV season (November-March) as strong candidates for this medication as well as children between the ages of 8-19 months who have a higher risk for RSV and are entering their second RSV season.[4] Infants are considered at an increased risk if they were born prematurely with chronic lung disease, are immunocompromised, or have cystic fibrosis. Infants under the age of 8 months do not need to receive nirsevimab if their mother received an RSV vaccine at least 14 days prior to birth.[5] Side effects of nirsevimab include pain, redness and swelling in the injection area however, no allergic reactions were reported during clinical trials.

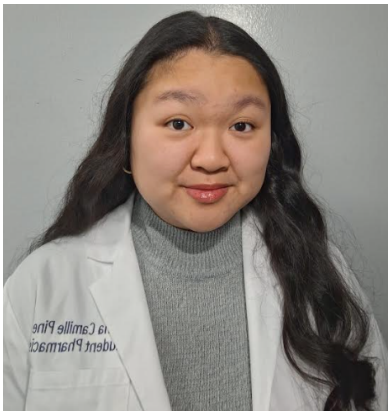
A study by Hammitt et al found that nirsevimab had a greater potency compared to palivizumab and had an extended half-life in vivo.[6] This allows infants to receive nirsevimab once a year, at the beginning or prior to the RSV season while children who received palivizumab needed the vaccine once a month during the season. Clinical trials have demonstrated the efficacy of nirsevimab with the primary endpoint measured being the incidence and risk of medically attended RSV lower respiratory tract infections (MA RSV-LRTIs) caused by RSV with bronchiolitis and pneumonia.[7] Sanofi's Phase 3 MELODY trial was conducted on infants born at least 35 weeks gestation showed 74.5% efficacy in reducing the risk of MA RSV LRTI when comparing to infants given nirsevimab (1.2%) and those given a placebo (5.0%).[7] Similarly, Phase 2b clinical trials were conducted on infants born between 29 and 35 weeks gestation, showed 70.1% efficacy in reducing the risk of MA RSV LRTI when comparing infants given nirsevimab (2.6%) and those given a placebo (9.5%).[7]

Given that nirsevimab has been recently approved and in high demand, there is currently a shortage in the distribution of this medication. Currently, Sanofi is accepting no new orders for the 100 mg dose, as the overall demand has exceeded the supply allotted for this season. In addition, Sanofi has postponed new orders for the 50 mg dose and is focusing on the distribution of existing orders. On November 16, 2023, Sanofi plans to reopen their ordering system for the 50 mg dose of the medication, allowing customers with an allocation to place a new order. It is not expected that providers without an allocation will be able to order this season, as mentioned by a spokesperson. Sanofi ensures that the remaining stock is supplied equitably through the Vaccines for Children Program, in collaboration with the CDC. Sanofi released a statement and is working with the CDC and AstraZeneca to ensure adequate distribution of available doses. They are also working together to determine a way to increase and accelerate the supply of nirsevimab in order to help health care providers protect infants against RSV.[8]

References:

1. Collaco J. Respiratory syncytial virus (RSV). Johns Hopkins Medicine. December 22, 2022. Accessed November 12, 2023. https://www.hopkinsmedicine.org/health/conditions-and-diseases/respiratory-syncytial-virus-rsv.
2. RSV in infants and Young Children. Centers for Disease Control and Prevention. August 4, 2023. Accessed November 12, 2023. https://www.cdc.gov/rsv/high-risk/infants-young-children.html.
3. Beyfortus. Prescribing information. Sanofi-aventis U.S. LLC; 2023. Accessed November 12, 2023. https://products.sanofi.us/beyfortus/beyfortus.pdf
4. RSV Vaccination: What Parents Should Know | CDC. www.cdc.gov. Published September 20, 2023. https://www.cdc.gov/vaccines/vpd/rsv/public/child.html. Accessed October 18, 2023

5. RSV (Respiratory Syncytial Virus) Vaccination | CDC. www.cdc.gov. Published August 30, 2023. https://www.cdc.gov/vaccines/vpd/rsv/index.html. Accessed October 18, 2023
6. Hammitt LL, Dagan R, Yuan Y, et al. Nirsevimab for Prevention of RSV in Healthy Late-Preterm and Term Infants. *New England Journal of Medicine*. 2022;386(9):837-846. doi:https://doi.org/10.1056/nejmoa2110275. Accessed October 18, 2023
7. Beyfortus (nirsevimab-alip) Efficacy & Safety Results. www.beyfortus.com. https://www.beyfortus.com/hcp/efficacy-and-safety. Accessed October 18, 2023
8. Jenco M. Sanofi pausing new orders for nirsevimab; CMS sets payment rates. Publications.aap.org. Accessed November 12, 2023. https://publications.aap.org/aapnews/news/27258/Sanofi-pausing-new-orders-for-nirsevimab-CMS-sets?searchresult=1.
9. Berland E. Sanofi Beyfortus (nirsevimab-alip) Injection Update. Press room - press releases. November 6, 2023. Accessed November 12, 2023. https://www.news.sanofi.us/2023-11-06-Sanofi-Beyfortus-TM-nirsevimab-alip-Injection-Update.



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