

PEDIANEWS

The Official Newsletter of RxPups - Student Society of Pediatric Advocates

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OUR MISSION

The Student Society of Pediatric Advocates is a student organization affiliated with the University of Georgia College of Pharmacy. We are a student group associated with the Pediatric Pharmacy Advocacy Group. The Mission of the SSPA is to bring awareness to the proper use of medication therapy in pediatric populations through various service and education-based initiatives. Service activities center around lending our medication-based knowledge to pediatric patients and their parents in our community. Educational activities are directed toward student members in an effort to safely and effectively extend pharmacy practice to pediatric populations by building relationships with mentors and professionals in the health care community, as well as supplementing didactic coursework with lectures by specialists and our peers. Overall, SSPA advocates for the safety and happiness of young patients while learning and having fun along the way. The purpose of our newsletter is to educate pharmacy students about pediatric pharmacy and advocate for pediatric patients within the University of Georgia College of Pharmacy.



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Allergen Immunotherapy for Atopic Dermatitis

Written by Hope Elrod and Ashton Dickinson, PharmD Candidates 2024

Atopic dermatitis, most commonly known as eczema, is a chronic disease-causing irritation of the skin and occurs at any age. It is characterized by pruritus, rash, and dry, cracked skin. Common sites of inflammation are areas prone to rubbing and drying, such as the elbows or knees. [1] Atopic dermatitis is a multifactorial disease involving genetic mutations, changes to immune response, and exposure to specific allergens. Genes help control proteins, such as filaggrin, that help the skin act as a barrier. [1] When there is a mutation, barriers change and allow moisture to escape exposing the skin to the environment. Keratinocytes in the skin release signals causing nerve endings to be active, in turn amplifying the immune reaction. This reaction is then diagnosed through skin and blood tests. [1]

Atopic dermatitis can affect any age; however, it is most commonly seen in the pediatric population. According to the National Eczema Association, 9.8 million children in the US have atopic dermatitis and one-third have moderate to severe presentations of the disease. [2] A child is at greater risk of developing this chronic condition if they have a family history or other known allergies. Ways to help prevent atopic dermatitis reactions are by avoiding environmental triggers such as fragrances, soaps, tobacco smoke, and air pollutants. [3] While there is no cure for this disease, there are a variety of medications available to relieve symptoms. If atopic dermatitis is left untreated, it can cause bacterial infections, allergic dermatitis, loss of sleep from itching, and respiratory disease. [5]

Current therapy for atopic dermatitis consists

of moisturizing the skin, reducing itch, treating inflammation, and preventing skin infections. [4] Emollients are used to moisturize the skin, repair, and maintain the skin barrier. These products may contain ceramides, filaggrin degradation products, avenanthramides, glycyrrhetic acid, shea nut derivatives, and palmitamide monoethanolamine. [4] Emollients such as creams and lotions are often available over the counter. While emollients are the cornerstone for treatment, first-generation antihistamines, like hydroxyzine, can be used at night to treat active disease and promote sleep. [4]

To treat inflammation, topical corticosteroids prescribed to be applied twice a day until symptoms are resolved. Infants and young children are treated with lower potency, while older children are treated with higher potency products. [3] Common low potency topical corticosteroids include hydrocortisone 1% to 2.5%, mild triamcinolone 0.25% or 0.1%, and fluocinolone 0.025%. Higher potency topical corticosteroids are high potency mometasone 0.1% and fluocinonide 0.05%. [4] NSAIDs can be used second line, depending on a child's age and comorbidities. [3] Skin infections are a common occurrence with atopic dermatitis and can be treated through topical antibiotics, specifically targeting staph and strep bacteria species. While these medications are most commonly seen in treating atopic dermatitis, immunotherapy has made its way into practice and has been shown to reduce disease severity and prevent future allergic responses. [3]

In a study conducted in a specialist allergy center in South Korea between June 2015 and

February 2018, 60 patients between the ages of 5 through 17 with a clinical diagnosis of atopic dermatitis due to dust mites were enrolled into a randomized control trial evaluating the effectiveness of sublingual immunotherapy. [5] Half of the study population received the sublingual therapy for 12 months while the other received a placebo for the same duration and the effects were monitored at regular 3 month intervals. [5] The evaluations consisted of four measures: scoring of atopic dermatitis measurement (SCORAD) to determine treatment effectiveness (scores between 0 to 103), the 6 point investigator global assessment tool (IGA) to assess the severity of disease (0 = no inflammation up to 6 = severe disease) a visual analog scale to determine the symptoms being experienced (0 = none up to 10 = severe), and a skin prick test to determine serum levels of specific immunoglobulin E (IgE) and immunoglobulin G4 (IgG4) to house dust mites obtained. [5] No statistical difference was observed between either of the groups or those who withdrew from the study. All patients sensitized to mites such as *Dermatophagoides farina* and *Dermatophagoides pteronyssinus* were confirmed through a SCORAD score of 9 to 103 and a positive skin prick test for enrollment into this study. [5]

The sublingual immunotherapy (SLIT) used in this study is Staloral (stallergenes Greer) consisted of equal parts of *Dermatophagoides farina* and *Dermatophagoides pteronyssinus* mite species. Patients receiving treatment experienced a significant improvement (p value < 0.001) in symptoms quantified by a decrease in the mean SCORAD measurements from 30.2 at baseline to 20.7 at 3 months. [5] These effects were documented to continue through the test period as the SCORAD was 21.5 at 12 months. Those in the control group, however, only saw a significant difference at the end of 12 months (p value = 0.026). [5] Levels of *Dermatophagoides farina* - specific IgG4 also indicated a significant desired immune response of those receiving the SLIT treatment from 0.6 at baseline to 1.0 at 12 months (p value = 0.012) unlike the control group that proved to be nonsignificant. Two or more sensitizations, or adverse responses to stimuli, are also significantly lower in those patients within the 12-month period who received treatment (p value = 0.021). [5] This can be seen summarized in table 1. The authors concluded that treatment with SLIT in this patient population for atopic dermatitis improves disease severity as well as aid in preventing sensitization to other allergens. [5]

Figure 1. Patient Randomization

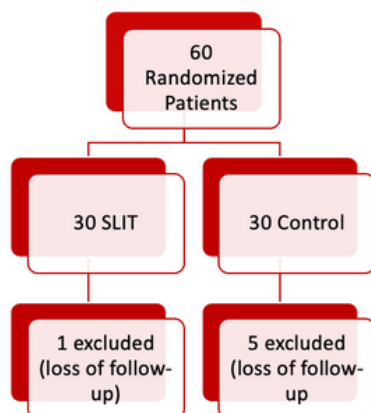


Table 1. SCORAD, IGA, and *Dermatophagoides farina* - Specific IgG4, at Baseline and Follow-Up Visits

	Visit	SLIT (n = 29)	Control (n = 25)	P-Value
SCORAD Total	Baseline	30.2	30.4	0.96
	Month 3	20.7	26.6	0.021
	Month 6	22	27.1	0.175
	Month 9	21.8	25.7	0.192
	Month 12	21.5	24.3	0.386
IGA	Baseline	2.5	2.5	0.859
	Month 3	2.0	2.4	0.048
	Month 6	1.8	2.4	0.006
	Month 9	1.9	2.4	0.024
	Month 12	2.1	2.4	0.140
<i>Dermatophagoides farina</i>-Specific IgG4	Baseline	0.6	0.5	0.338
	Month 12	1.0	0.6	0.013

Although this study proved that SLIT could be beneficial in the pediatric population, it had a small sample size and was limited to a specialist allergy center in South Korea. The results may not be generalizable to the US population and future studies would have to be completed with a larger sample size and a more diverse population. However, this study was effective at showing the potential of SLIT on the pediatric population. SLIT can be self-administered, does not require injection, and carries a lower risk of severe adverse reactions. Overall, with more research and future studies, this therapy has the potential to improve quality of life- especially in the pediatric population.

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Community Acquired Pneumonia in the Pediatric Population

Written by Laura E. Ramirez, PharmD Candidate 2023

Antimicrobial resistance is a top 10 threat to global health according to the World Health Organization. Historically, there is debate comparing longterm antibiotic treatments to short term antibiotic treatments concerning more resistant pathogens and illness exacerbations. Community acquired pneumonia (CAP) is one of the most common and serious illnesses in the pediatric population. [1] Recently, there has been increased discussion around the number of days for an antibiotic regimen prescribed for adults who have CAP. [2] A recent article discussing the “PTC trial” addressed the 5 to 7 day antibiotic course for the treatment of CAP in adults; however, unlike the adult population, there is still very little current research on CAP in the pediatric population. *The Pharmacy Times* published an article addressing this lack of research. Since 2011, many trials have been performed that focus on the possibility of reducing the guideline driven recommendation for children with CAP from a 10 day antibiotic regimen to 5 to 7 days. [3]

The SCOUT-CAP Randomized Clinical Trial questions if a 5 day regimen of antibiotics is superior to a 10 day regimen for the treatment of non-severe pneumonia in young children demonstrating early clinical response. [4] The trial was a randomized double-blind placebo-controlled clinical trial in outpatient clinic, urgent care, or emergency settings in 8 US Cities. A total of 380 healthy children between the ages of 6 months to 6 years of age with non-severe CAP demonstrating early clinical improvement were included in the study. The trial took place over 3 years starting in 2016 and ending 2019. The primary end point was the end of treatment response adjusted for duration of

antibiotic risk (RADAR), a composite end point that ranks each child’s clinical response, resolution of symptoms, and antibiotic-associated adverse effects in an ordinal desirability of outcome ranking (DOOR). In a subset of children, throat swabs were collected between study days 19 and 25 to quantify antibiotic resistance genes in oropharyngeal flora. [3]

Table 1. Comparison of Standard Course versus Short Course Antibiotic Therapy

	Standard Course (191 patients)			Short Course (189 patients)		
Inadequate Clinical Response	3 patients			6 patients		
Persistent Symptoms	29 patients			25 patients		
Antibiotic-Associated Adverse Effects	169 events			182 events		
Severity of Antibiotic Adverse Effects	Mild	Moderate	Severe	Mild	Moderate	Severe
	65	19	2	66	19	1

From the above SCOUT-CAP study we can conclude that more research is necessary in the pediatric population in regards to CAP treatment duration. The above study proved that a shorter duration is beneficial. As research on this topic is needed to support and confirm the results of this study. With a shorter antibiotic regimen, we could increase adherence to the regimen and decrease antibiotic resistance.

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A Clinical Pharmacist Spotlight: Pediatric Oncology, Not as Inaccessible as You Might Think

Written by Rebecca DeSantis, PharmD Candidate 2025

A pediatric oncology clinical pharmacist may be considered by some as a highly specialized area of pharmacy practice. However, it might be surprising to learn its practical skill set applies to a multitude of clinical areas. Certainly not for the faint of heart, it is a position which offers opportunities to apply pharmacy knowledge and skills. From how to design treatment regimens for children to pharmacist prescribing in New York state, I was able to glean words of wisdom and perspective after speaking with Dr. Jennifer Thackray, PharmD, BCPS, BCPPS of Memorial Sloan Kettering Cancer Center of New York.

Dr. Thackray's rise to her current position began in college at the University of Oklahoma pursuing a biochemistry degree when she discovered a passion for pharmacy. She then attended University of Oklahoma for pharmacy school, then University of North Carolina for her PGY-1 and PGY-2 residencies in pediatrics. During her residencies, she found herself focusing more on oncology. After completing her PGY-2, she joined the Memorial Sloan Kettering Cancer Center. Dr. Thackray knew she did not want to just stabilize patients and discharge them. She was drawn to direct patient care, because it allowed for prospective intervention and emerging situations, while still allowing her to continue to follow the patient afterward treatment. With prescribing rights in New York allowing for significant autonomy, she spends half of her day with patients and the other half answering drug information questions for her providers.

When asked how she kept up with the ever-changing world of oncology and especially in

pediatrics, she stated it could be difficult to counsel patients on the unknowns. Often her patients are receiving single patient drugs, or phase 1 or 2 trial drugs. It is critical to rely on the foundations established in pharmacy school and training. Often, a new drug builds on a foundation of others and counseling points can be assembled from them. Additionally, it is crucial for her to continue to invest in her professional development. For those interested in following in Dr. Thackray's footsteps, she recommends finding an environment where attending conferences and literature review are valued and encouraged.

Dr. Thackray offered some suggestions for students. The further you specialize, the less you use the general knowledge. Learn as much as you can, knowing you will hone these skills further during residency. Pathophysiology and pharmacotherapy foundations are the best building blocks to focus on. The one skill set she did not originally think would be as valuable as it is: interdisciplinary communication. This includes using softer skills such as active listening, communication which invites discussion, and considering the concerns of others. She finds residents and students are often hesitant or shy about speaking up. The point of these experiences is to bring your valuable perspective and drug knowledge to the team.

Lifelong learners will find a position in clinical pediatric oncology rewarding, as it is high intensity and includes a long-term patient following. Leaning on foundational knowledge and finding common threads leads to success. Pediatric oncology is a

dynamic practice which can easily translate to success in a plethora of opportunities pharmacy has to offer. Dr. Thackray has potently demonstrated how practicing at the top of a pharmacist license has priceless benefits to pharmacist, organization, and ultimately the patient.

Lanadelumab-flyo: The First FDA-Approved Prophylaxis Treatment for Hereditary Angioedema in Pediatric Patients

Written by Allison Lopez, PharmD Candidate 2025

Hereditary Angioedema (HAE) is an inherited genetic disease resulting in severe and unpredictable episodes of painful swelling and accumulation of fluid in the tissues of the hands, airways, genitals, face, feet, and intestinal tract. HAE affects 1 in 50,000 people around the world. [1] Presenting in children as young as 3 years of age, HAE causes a fluid buildup blocking normal blood and lymphatic flow which leads to other serious life-threatening symptoms such as airway obstruction, and eventually asphyxiation. [2] A dysfunction in the C1 esterase inhibitors (C1-INH), also known as complement proteins, has been determined to be the cause of HAE. These complement proteins aid in normal fluid flow through the capillaries as well as in and out of cells. [1] There are two types of HAE, with type I being far more common than type II and accounting for 85% of cases. [2] Type I HAE results from depleted numbers of complement proteins, and type II HAE results from the presence of abnormal complement proteins. [2] The symptoms of HAE usually start in early childhood and worsen after puberty with the frequency of episodes varying from patient to patient. [2]

Lanadelumab (Takhzyro) is a human IgG1 monoclonal antibody injection made from Chinese hamster ovary cells that binds and inhibits plasma kallikrein, a serum protease that plays an important role in several inflammatory responses affected by HAE. Lanadelumab is currently available to more than 60 countries around the world. Adverse effects of lanadelumab include injection site muscle pain (29%), injection site erythema (14%), injection site swelling (5%), injection site reactions (5%), dizziness (<5%), and upper respiratory infections (<5%). [3]

On February 3, 2023, the Food and Drug Administration (FDA) approved the supplemental Biologics License Application (sBLA) for the first prophylaxis treatment of hereditary angioedema in pediatric patients ages 2 to less than 12 years of age based on the results of the SPRING Study. Prior to this approval, patients ages 6 to less than 12 years with HAE required a treatment of other therapies that needed to be dosed every 3 to 4 days, while children ages 2 to less than 6 years had no approved prophylaxis treatment. The recommended prophylactic dose of lanadelumab is 150 mg/1 mL solution for injection in a single-dose prefilled syringe. Patients ages 2 to less than 6 years should be dosed every 4 weeks and patients ages 6 to less than 12 years should be dosed every 2 weeks. [3]

The SPRING Study was a Phase III open-label, non-controlled clinical trial including 21 patients ages 2 to less than 12 years with HAE. The study aimed to test the safety, efficacy, and pharmacokinetic and pharmacodynamic parameters of lanadelumab in this specific patient population, to determine if children develop antibodies to the medication, and to see if prophylactic treatment of HAE reduced the number and severity of HAE episodes in children. Primary outcome measures included the number of patients with adverse events, the number of patients with clinically significant laboratory abnormalities, plasma concentrations of lanadelumab, steady state concentrations, clearance, and volume of distribution. Secondary outcome measures included the number of attacks during the treatment period, the number of patients without an attack, and the plasma kallikrein

activity of the patients. Inclusion criteria included a documented diagnosis of type I or type II HAE, ages 2 to 11, a baseline attack rate of 1 attack per 3 months, and strict adherence to the treatment protocol. Exclusion criteria included a diagnosis of another concomitant angioedema, pregnancy or breastfeeding, dosing of another investigational drug within 4 weeks of beginning the trial, and having an active infection or illness. [4] The study treated the 21 patients for 52 weeks and found that the frequency of HAE episodes were reduced by a mean of 94.8% reducing the average of 1.84 episodes per month to 0.08 episodes per month. 16 of the patients never experienced an episode creating a final average of 99.5% days without an episode. [3] No serious or life-threatening adverse events occurred during the study and no patients withdrew from the program due to adverse events. Only seven patients reported any adverse events at all related to treatment, and they all were pertaining to the injection site. [5]

Table 1. Outcomes of the SPRING Study

Frequency of HAE Attacks	94.8% Reduction
Attack-Free Patients	76.2%
Attack-Free Days	99.5%
Treatment-Related Adverse Events	33.3%

Overall, this approval of long-term prophylactic treatment for HAE is a step in the right direction for catching this rare genetic disease early and treating its symptoms before they progress early into puberty. This painful, debilitating disorder can affect patients physically and emotionally, and prevention of these symptoms as young as 2 years of age will be life-changing for these patients.

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Combating Childhood Obesity

Written by Leslie Phillips, PharmD Candidate 2024

Historically, childhood obesity has been recognized as a serious health issue in the United States. Over the past 30 years, the prevalence has increased from 15% to over 30%, making it the most common chronic disease in children. This rapid increase in obesity affects over 14 million children and adolescents and the associated comorbidities have also increased. These comorbidities are primarily cardiovascular diseases including diabetes, hyperlipidemia, hypertension, and heart failure. As pharmacists, we must recognize and address this risk factor to make appropriate interventions and improve patient outcomes. [1]

Obesity in children is defined as a body mass index (BMI) greater than or equal to the 95th percentile for children and teens of the same age and sex. Although BMI does not consider the difference of muscularity, it is still the standard measurement used when classifying weight categories. The American Academy of Pediatrics (AAP) recently released updated guidelines for the evaluation and treatment of children and adolescents with obesity. The academy recommends behavior and lifestyle treatment such as motivational interviewing, nutritional support, and increased physical activity for younger children, however, for children 12 and older, weight loss medications are appropriate add-ons to therapy. With the recent Food and Drug Administration (FDA) approval of two additional medications in 2022, there are now four treatment options for children 12 years and older with obesity— orlistat, liraglutide, phentermine and topiramate, and semaglutide. [2]

Orlistat (Xenical®) was approved in 2003 for the management of obesity in pediatric

patients 12 years and older. Orlistat acts as a reversible inhibitor of gastric and pancreatic lipase which leads to an inhibition of dietary fats. [3]

Liraglutide (Saxenda®) gained FDA approval for chronic weight management among pediatric patients 12 years and older in 2020. It is used adjunctively to strict lifestyle interventions. Liraglutide is a glucagon-like peptide-1 (GLP-1) receptor agonist which acts on parts of the brain regulating appetite and caloric intake decreasing inappropriate glucagon secretion. This results in slowed gastric emptying and decreased food intake. [4]

Phentermine and topiramate (Qsymia®) was approved by the FDA in 2022 for the treatment of obesity for adolescents aged 12 to 17. The mechanism of action for weight loss is not completely understood. However, phentermine seems to work on the central nervous system (CNS) to reduce appetite as topiramate suppresses appetite and enhances satiety through the blockage of neuronal voltage-dependent sodium channels and the enhancement of gamma-aminobutyric acid (GABA-A) activity. [5]

Semaglutide (Wegovy®) is the first once-weekly weight-loss medication for adolescents and was approved in 2022. It is used as adjunct therapy coupled with a calorie-reduced diet and physical activity in pediatric patients aged 12 to 17 years. Semaglutide is a GLP-1 receptor agonist and acts on parts of the brain regulating appetite and caloric intake. By increasing dependent insulin secretion, it slows gastric emptying and decreases inappropriate glucagon secretion.

[6]

Table 1. Comparison of Treatments for Pediatric Obesity [3, 4, 5, 6]

	Orlistat	Liraglutide	Phentermine and Topiramate	Semaglutide
FDA Approval	December 2003	December 2020	June 2022	December 2022
Pharmacologic category	Lipase inhibitor	GLP-1 receptor agonist	Anorexiant	GLP-1 receptor agonist
Administration	Oral capsule	Subcutaneous injection	Oral capsule	Subcutaneous injection
Dosing	120 mg	0.6 mg titrated to a maintenance dose of 3 mg	3.75 mg/23 mg titrated to a maximum dose of 7.5 mg/23 mg phentermine to topiramate ratio	0.25 mg titrated to a maintenance dose of 2.4 mg
Frequency	Three times daily with each main meal containing fat	Once daily	Once daily	Once weekly
Contraindications	Pregnancy, chronic malabsorption syndrome, cholestasis	Family or personal history of medullary thyroid cancer (MTC), multiple endocrine neoplasia syndrome (MEN2), pregnancy	Hyperthyroidism, glaucoma, concurrent use of monoamine oxidase inhibitors (MAOIs), pregnancy	Family or personal history of MTC, MEN2
Common Adverse Effects	Vitamin deficiency, abdominal pain, bowel urgency	Constipation, nausea, diarrhea, headache	Increased heart rate, constipation, headache	Abdominal pain, constipation, headache
Clinical Pearls			REMS program required	

The alarming rise of childhood obesity within the United States should be a wake-up call to healthcare professionals. As obesity rates continue to rise in our children and adolescents, so will the risk of developing comorbidities that will reduce length and quality of life. New guidelines from the AAP now recommend the use of medications along with lifestyle modifications for the treatment and management of childhood obesity. With newly approved medicines, pharmacists can play an important role in helping combat childhood obesity.

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