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Counseling Patients on Common Summer Maladies

Summer is here and judging by the traffic leading to our shore areas here in New Jersey, people are taking full advantage of the season and are ready to enjoy the sunshine in the same way it was in the good old days of BC (before COVID-19). Summer camps are in full swing, and beaches, pools, and water parks are filling up. Pharmacies may also begin to fill up with patients seeking OTC remedies for various summer maladies. Keep these pearls in mind when counseling patients at the counter:

Sunscreen

Results of a survey conducted by the American Academy of Dermatology showed that even though Americans agree that sun protection is important, many misunderstand how to protect themselves. For example, 65% of respondents admitted to forgetting to reapply sunscreen, and 67% believe—incorrectly—that SPF 30 sunscreen offers twice the protection as SPF 15. In reality, the SPF number indicates how much UVB light a sunscreen can filter out: 93% for SPF 15 compared with 97% for SPF 30.

Swimmer’s Ear

Those who frequent the pool or beach may find themselves experiencing a case of otitis externa, commonly known as swimmer’s ear. This bacterial infection is caused by water that sat for too long in the outer ear canal, allowing bacteria to grow. Although anyone can experience swimmer’s ear, it is most often seen in children. Treatment for this condition can include antibiotic or corticosteroid ear drops, and OTC analgesics, and symptoms typically resolve in 7 to 10 days.

Bug Bites and Stings

Bugs are a common hazard faced by those who spend time outside. The list of bugs that bite or sting is long, but mosquito bites and bee stings are 2 of the most common culprits of summertime discomfort. Mosquito bites can cause redness, swelling, and itching; bee venom leads to itchy or stinging sensations. Itch can be relieved using hydrocortisone cream or calamine lotion. An antihistamine like cetirizine (Zyrtec) or diphenhydramine (Benadryl) will also help.

Stay safe, stay cool, and enjoy the summer! =)

Thank you for reading.

Mike Hennessy Jr
President and CEO
of MJH Life Sciences®

REFERENCES:
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**Important Safety Information for FLEQSUVY™ (baclofen oral suspension)**

**INDICATIONS AND USAGE:**
- FLEQSUVY is indicated for the treatment of spasticity resulting from multiple sclerosis, particularly for the relief of flexor spasms and concomitant pain, clonus, and muscular rigidity.
- FLEQSUVY may also be of some value in patients with spinal cord injuries and other spinal cord diseases.

**Limitations of Use:** FLEQSUVY is not indicated in the treatment of skeletal muscle spasm resulting from rheumatic disorders.

FLEQSUVY is a concentrated formulation. Verify the strength and the dose of the product prior to prescribing, dispensing, and administering.

**Important Safety Information**

**CONTRAINDICATIONS:**
FLEQSUVY is contraindicated in patients with hypersensitivity to baclofen.

**WARNINGS AND PRECAUTIONS:**
- **Adverse Reactions from Abrupt Withdrawal of FLEQSUVY:** Abrupt discontinuation of baclofen, regardless of the cause, has resulted in adverse reactions that include hallucinations, seizures, high fever, altered mental status, exaggerated rebound spasticity, and muscle rigidity. In rare cases, handicap has progressed to rhabdomyolysis, multiple organ-system failure, and death. Therefore, reduce the dosage slowly when FLEQSUVY is discontinued, unless the clinical situation justifies a rapid withdrawal.

**Neonatal Withdrawal Symptoms:** Withdrawal symptoms in neonates whose mothers were treated with oral baclofen throughout pregnancy have been reported starting hours to days after delivery. The symptoms of withdrawal in these infants have included increased muscle tone, tremor, jitteriness, and seizure. If the potential benefit justifies the potential risk to the fetus and FLEQSUVY is continued during pregnancy, gradually reduce the dosage and discontinue FLEQSUVY before delivery. If slow withdrawal is not feasible, advise the parents or caregivers of the exposed neonate of the potential for neonatal withdrawal.

**Drowsiness and Sedation:** Drowsiness and sedation have been reported in up to 63% of patients taking baclofen, the active ingredient in FLEQSUVY. Patients should avoid operation of automobiles or other dangerous machinery and activities made hazardous by decreased alertness when starting FLEQSUVY or increasing the dose until they know how the drug affects them. Advise patients that the central nervous system depressant effects of FLEQSUVY may be additive to those of alcohol and other CNS depressants.

**Poor Tolerability in Stroke Patients:** FLEQSUVY should be used with caution in patients who have had a stroke. Baclofen has not significantly benefited patients with stroke. These patients have also shown poor tolerability to the drug.

**Exacerbation of Psychotic Disorders, Schizophrenia, or Confusional States:** FLEQSUVY should be used with caution in patients suffering from psychotic disorders, schizophrenia, or confusional states. If treated with FLEQSUVY, these patients should be kept under careful surveillance because exacerbations of these conditions have been observed with oral baclofen administration.

**Exacerbation of Autonomic Dysreflexia:** FLEQSUVY should be used with caution in patients with a history of autonomic dysreflexia. The presence of nociceptive stimuli or abrupt withdrawal of FLEQSUVY may cause an autonomic dysreflexic episode.

**Exacerbation of Epilepsy:** FLEQSUVY should be used with caution in patients with epilepsy. Deterioration in seizure control has been reported in patients taking baclofen.

**Posture and Balance Effects:** FLEQSUVY should be used with caution in patients where spasticity is utilized to sustain upright posture and balance in locomotion or whenever spasticity is utilized to obtain increased function.

**Ovarian Cysts:** A dose-related increase in incidence of ovarian cysts was observed in female rats treated chronically with oral baclofen. Ovarian cysts have been found by palpation in about 4% of the multiple sclerosis patients who were treated with oral baclofen for up to one year. In most cases, these cysts disappeared spontaneously while patients continued to receive the drug. Ovarian cysts are estimated to occur spontaneously in approximately 1% to 5% of the normal female population.

**ADVERSE REACTIONS:**

- The most common (up to 15% or more) adverse reactions in patients were drowsiness, dizziness, and weakness.

**DRUG INTERACTIONS:**

- CNS Depressants and Alcohol: FLEQSUVY can cause CNS depression, including drowsiness and sedation, which may be additive when used concomitantly with other CNS depressants or alcohol.

**USE IN SPECIAL POPULATIONS:**

- Pregnancy: Based on animal data, may cause fetal harm. Because baclofen is excreted unchanged through the kidneys, it may be necessary to reduce the dosage in patients with impaired renal function.

The Important Safety Information does not include all the information needed to use FLEQSUVY safely and effectively. For additional safety information, please see accompanying full Prescribing Information for FLEQSUVY.

To report SUSPECTED ADVERSE REACTIONS, contact Azurity Pharmaceuticals, Inc. at 1-800-461-7449, or FDA at 1-800-FDA-1088 or www.fda.gov/MedWatch.

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PP-FLE-US-0007
Wellbeing Checkup™: Extreme Stressors
Donna Hallas, PhD, CPNP, PPCNP-BC, PMHS, FAANP, FAAN, discusses extreme stressors and how addressing them with patients can help providers manage their own stress.

Deep Dive™ into Diversity and Equity in Health Care
Brandi Kaye Freeman, MD, MS, assistant professor of pediatrics and associate vice chair for diversity, equity, and inclusion for the department of pediatrics at the Children’s Hospital of Colorado, shares her insights into using evidence-based practices to eradicate health inequities that affect vulnerable populations.

Second Opinion™: CGRP for Migraine
Neurologists Lauren Natbony, MD, and Deena Kuruvilla, MD, discuss real-world experiences with the CGRP class of medications for migraine.

Wellbeing Checkup™: Managing Chronic Stress
Jennifer Bourgeois, PharmD, a clinical pharmacist and founder of Well & Free, LLC, shares her tips for managing chronic stress, prioritizing rest, and practicing self-care as a pharmacist.

Many parents, caregivers, and clinicians have been waiting for a vaccine for younger children, and this action will help protect those down to 6 months of age.

Notable Quotables
—ROBERT M. CALIFF, MD, FDA Commissioner, on the FDA and CDC authorization of the Pfizer-BioNTech and Moderna COVID-19 vaccines for children aged 6 months to 5 years.

READ MORE: https://bit.ly/3HH6olw
Important Safety Information

EPRONTIA™ (topiramate) oral solution, 25 mg/mL

Indications:
- Initial monotherapy for the treatment of partial-onset or primary generalized tonic-clonic seizures in patients 2 years of age and older.
- Adjunctive therapy for the treatment of partial-onset seizures, primary generalized tonic-clonic seizures, or seizures associated with Lennox-Gastaut syndrome in patients 2 years of age and older.
- Preventive treatment of migraine in patients 12 years of age and older.

Inform patients that a calibrated measuring device is recommended to measure and deliver the prescribed dose accurately. A household teaspoon or tablespoon is not an adequate measuring device.

Additional Important Safety Information

Warnings and Precautions:
- Acute Myopia and Secondary Angle Closure Glaucoma: A syndrome consisting of acute myopia with secondary angle closure glaucoma has been reported in patients receiving EPRONTIA (topiramate). Symptoms typically occur within 1 month of initiation of EPRONTIA therapy. Symptoms include acute onset of decreased visual acuity and/or ocular pain. Ophthalmologic findings include myopia, anterior chamber shallowing, ocular hyperemia (redness), and increased intraocular pressure. Primary treatment to reverse symptoms is discontinuation of EPRONTIA.
- Cognitive/Neuropsychiatric Adverse Reactions: The most frequent adverse reactions can be classified into 3 categories: 1) cognitive-related dysfunction (confusion, difficulty with concentration, difficulty with memory, speech or language problems); 2) psychiatric/behavior disorders; 3) somnolence or fatigue.
- Visual Field Defects: Visual field defects have been reported in clinical trials and post-marketing experience in patients receiving topiramate. In clinical trials, most of these events were found to be reversible after topiramate discontinuation. If visual problems occur, consideration should be given to discontinuing the drug.
- Metabolic Acidosis: Metabolic acidosis was commonly observed in adults and pediatric patients in clinical trials and is caused by renal bicarbonate loss due to carbonic anhydrase inhibition by topiramate. Conditions or therapies that predispose patients to acidosis (such as renal disease, severe respiratory disorders, status epilepticus, diabetics, ketogenic diet, or specific drugs) may be additive to the bicarbonate lowering effects of topiramate.

Cognitive/Neuropsychiatric Adverse Reactions: EPRONTIA can cause cognitive/neuropsychiatric adverse reactions. The most frequent adverse reactions can be classified into 3 categories: 1) cognitive-related dysfunction (confusion, difficulty with concentration, difficulty with memory, speech or language problems); 2) psychiatric/behavior disorders; 3) somnolence or fatigue.

Fetal Toxicity: EPRONTIA can cause fetal harm when administered to pregnant women. The benefits and risks should be considered when administering this drug in women of childbearing potential.

Withdrawal of Antiepileptic Drugs: EPRONTIA should be gradually withdrawn to minimize the potential for seizures or increased seizure frequency. If rapid withdrawal is required, appropriate monitoring is recommended.

Serious Skin Reactions: Serious skin reactions (Stevens-Johnson Syndrome [SJS] and Toxic Epidermal Nekrolysis [TEN]) have been reported. EPRONTIA should be discontinued at the first sign of a rash unless the rash is clearly unrelated to the drug. If signs or symptoms suggest SJS/TEN, use of this drug should not be resumed and alternative therapy should be considered. Inform patients about the signs of serious skin reactions.

Hyperammonemia and Encephalopathy (Without and With Concomitant Valproic Acid Use): Topiramate treatment can cause hyperammonemia with or without encephalopathy, the risk of which appears to be dose-related, and which has been reported more frequently with concomitant use of valproic acid. In patients who develop unexplained lethargy, vomiting or changes in mental status associated with topiramate, hyperammonemic encephalopathy should be considered and an ammonia level should be measured.

Kidney Stones: EPRONTIA can cause an increased risk of kidney stones. The concomitant use of topiramate with any other drug producing metabolic acidosis, or potentially in patients on a ketogenic diet, may increase the risk of kidney stone formation. Instruct patients to stay well hydrated while taking EPRONTIA.

Hypermotility with Concomitant Valproic Acid Use: Hypermotility has been reported in association with topiramate use with concomitant valproic acid both in conjunction with hyperammonemia and in the absence of hyperammonemia. Consider discontinuation of topiramate or valproate in patients who develop hypermotility. Blood ammonia levels should be assessed during clinical management.

Adverse Reactions:
- The most common side effects for EPRONTIA include:
  - Tingling of the arms and legs
  - Not feeling hungry
  - Nausea
  - A change in the way foods taste
  - Diarrhea
  - Weight loss
  - Nervousness
  - Upper respiratory tract infections
  - Speech problems
  - Tiredness
  - Dizziness
  - Sleepiness/drowsiness
  - Slow reactions
  - Difficulty with memory
  - Pain in the abdomen
  - Fever
  - Abnormal vision
  - Decreased feeling or sensitivity, especially in the skin

These are not all the possible side effects of EPRONTIA.

Use in Specific Populations:

Women of Reproductive Potential:
- Women of reproductive potential who are not planning a pregnancy should use effective contraception because of the risks of oral clefts and small for gestational age (SGA).

Renal Impairment:
- The clearance of EPRONTIA is reduced in patients with moderate (creatinine clearance 30 to 69 mL/min/1.73 m²) and severe (creatinine clearance <30 mL/min/1.73 m²) renal impairment. A dosage adjustment is recommended in patients with moderate or severe renal impairment.

Patients Undergoing Hemodialysis:
- EPRONTIA is cleared by hemodialysis at a rate that is 4 to 6 times greater than in a normal individual. A dosage adjustment may be required.

The Important Safety Information does not include all the information needed to use EPRONTIA safely and effectively. Visit EPRONTIA.com for full prescribing information.

To report SUSPECTED ADVERSE REACTIONS, contact Azurity Pharmaceuticals, Inc. at 1-855-379-0383, or FDA at 1-800-FDA-1088 or www.fda.gov/MedWatch.

HCP-EPR-1.6

When my daughter received a type 1 diabetes (T1D) diagnosis about 18 months ago, I could not even express how devastated I felt. I have been a pharmacist for about 20 years and even with my background, it was overwhelming. Managing diabetes is a constant job. Whether the patient has T1D or T2D, the condition can be very stressful. As I joined various online support groups, I noticed a lot of discussions about diabetes burnout.

The CDC acknowledges that diabetes burnout is real, noting that “over time, the emotional burden of managing diabetes can cause burnout.” Drug Topics interviewed several experts about how pharmacists can help patients or caregivers who are experiencing diabetes burnout.

Amanda Lane, MS, RD, LDN, CDCES, is the founder of Healthful Lane Nutrition, LLC. “Diabetes distress or burnout can look different for everyone,” she said. “Some patients may be angry about their medications or checking blood glucose; others may brush it off with vague terms like ‘it’s all good,’ avoiding appointments, and not refilling medications on time.”

Stephanie Redmond, PharmD, CDCES, BC-ADM, cofounder and vice president of the Diabetes Doctor is a clinical pharmacist and diabetes educator. When ascertaining whether a patient has diabetes burnout, she looks for the following signs:

• The patient is not refilling prescriptions on time, indicating they are not taking medication.
• The patient does not bring in their meter, which is a sign they are not checking blood glucose as directed.
• The patient has not followed up in a long time or does not want to talk about their diabetes.

According to Lane, patients who need more medications or higher doses feel like they are doing something wrong. In these cases, “helping the patient or a caregiver learn how to fill a pillbox can be a super helpful way to combat diabetes distress,” she explained. “Seeing all the pill bottles multiple times per day can be overwhelming, but having a box that has the right medications portioned out can be less overwhelming.”

For certain patients, Lane recommends continuous glucose monitoring (CGM). However, she noted that first there should be a conversation about comfort level with new technology. “Some patients are more stressed by managing the increased technology that CGM requires, whereas others find the decreased finger sticks and increased glucose readings to be incredibly helpful,” she added.

“Pharmacists are more involved than ever in CGM dispensing and education,” Redmond added. “Wearing a CGM can have a huge real-time impact and teach lessons that checking blood glucose never can. [Patients can] see the benefits immediately of taking a medication, going on a walk, or eating nuts vs chips for a snack.”

Lane noted that Medicare covers CGM in patients meeting specific criteria. Those with T1D or T2D with multiple daily injections or other qualifying criteria can typically get CGM through their insurance. However, the insurance may dictate the brand of CGM that is covered.

Redmond suggested that pharmacists use motivational interviewing techniques, such as asking open-ended questions and giving the patient time to respond. “I love restating what they told me, to give them a chance to react in a positive way—[for example], ‘You feel like nothing you do helps your blood sugars.’ This gives the patient a chance to respond: ‘Well, when I walk on Saturday, I...’”
noticed Sundays are my best day,” she explained.

Redmond also encouraged pharmacists to focus on the patient’s good blood glucose days, rather than the bad, and to brainstorm together on what makes the difference. “This helps encourage self-reflection,” she said.

Pharmacists can also give patients hope and encouragement. “They are not alone,” Redmond said. “It is helpful to find a support community—even online—of other individuals living with diabetes who have ideas or diet/exercise/lifestyle tips that have worked for them.” Pharmacists can remind patients to seek support—but not medical advice—from their peers.

Pharmacists should also help patients with a plan of action when they check blood glucose. “If you are checking blood [glucose] but not doing anything with that information, it really seems pointless to check,” Redmond noted. Pharmacists can ensure that the patient has a plan for how to treat highs and lows, as well as a glucagon prescription—and, crucially, knows how to use it and can train loved ones or caregivers to administer it during a hypoglycemic emergency.

Redmond tells her patients, “Focus on how to make your next decision a good one. Even if you ate chocolate cookies all day and feel like the day is wasted, you don’t have to commit to going to the gym for the next week or eating zero carbs. Just make your next decision, whether it’s dinner or a snack at bedtime, a healthier one. Or maybe it’s taking a 10-minute walk after dinner. One decision at a time seems easier than trying to undo a whole year’s worth of bad lifestyle habits. Small changes have a big impact in the end.”

Redmond also reminds pharmacists to counsel patients on their medications. “Often, patients take different medications for their diabetes and don’t understand why they would take more than one. But if they understand that they work in different ways or have different benefits, they are more likely to take them.”

"Often, patients take different medications for their diabetes and don’t understand why they would take more than one. But if they understand that they work in different ways or have different benefits, they are more likely to take them.”

Stephanie Redmond, PharmD, CDCES, BC-ADM

REFERENCE

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The COVID-19 pandemic has upended the world of respiratory diseases. Every cough and snuffle raises red flags in a clinical area that already was a drain on health care resources. Roughly 12% of adults in the United States have chronic sinusitis, and about 2.7 million physician and 234,000 emergency department visits are attributed to this diagnosis each year.

Drawing the line between acute sinusitis and other respiratory bugs can be difficult, though. As with many other conditions driven by viral infection, there is little clinicians can really offer patients for sinusitis other than supportive care and calls for patience.

As COVID-19 transmissions are lessening, patients and providers are equally concerned about respiratory symptoms, but experts say the pandemic isn’t really changing the game plan for sinusitis.

“I think the biggest thing I try to explain to patients is the disease process,” said Jane Carnazzo, MD, of Children’s Hospital and Medical Center in Omaha, Nebraska.

Observing mucus changes can help patients determine where they are in a bout with sinusitis, she explained; green mucus is common for about a week after infection and doesn’t signal a severe infection.

“When it comes to sinusitis, your acute sinusitis is going to be someone who is sick for 10 to 14 days. You have to give a cold a good week to get better,” she added.

A high fever or copious amounts of mucus right away is a different story, she said, but this level of infection isn’t common.

COVID-19 isn’t the only worry when it comes to respiratory symptoms, Carnazzo added. Antibiotic resistance is a real problem and one she said she tries to educate her patients about. Prescribing antibiotics may give patients a peace of mind regarding their symptoms, but Carnazzo said 75% of her patients don’t return for a prescription after a bit of education about what to expect and what is normal in terms of symptoms and progression of sinusitis.

Besides education, she says offering patients an alternative for symptom management can help. People like to turn to OTC remedies that dry out mucus at the first sign of illness—but, she explained, this is the opposite of how sinusitis should be managed.

“You want the nose to drain. When it comes to preventing a sinus infection, it’s the best you can do,” she said.

Saline rinses have become a popular choice among her patient population, Carnazzo added, but lavage can sometimes make symptoms worse. Instead, things like promoting crying, exposure to cold weather, and anything else that can help make the nose run well.

The exception, she explained, is children who have issues that could increase mucus retention, immune deficiencies, and conditions including Down syndrome that may predispose a child to smaller sinus cavities. Even with these patients, though, Carnazzo explained that providers should use caution about jumping to antimicrobial treatments.

Time is an important tool in the provider’s arsenal, and many patients will improve in about a week with little intervention. It’s also to be expected that some children will appear to have chronic sinus problems, but constant antibiotic therapy isn’t an option, she noted.

“Kids in day care have runny noses all the time but you can’t just keep them on antibiotics,” she said. “It’s just a matter of trying to sort it out. Give it some time and try to get them to clear their nasal passages. Don’t try to dry it up too much.”

Pushing OTC medications isn’t much help, she added, and imaging studies like x-ray and computed tomography scans are not generally recommended for diagnosis.

The best thing health care providers can do is to get a good history and description of how symptoms developed, what they feel like, and when they are worse.

“History, symptoms, and presentation are key,” Carnazzo said, to
management. “Chronic sinus issues may need imaging, but lab work and imaging are really not necessary. Just because the sinuses are plugged doesn’t mean they are infected.”

Purulent drainage is the key symptom in diagnosing an infection that needs more intervention, she said. Providers also need to remember a less common differential diagnosis: foreign objects.

Foul or smelly drainage—especially on just 1 side of the nose—is a red flag that something may be stuck in the nasal cavity, Carnazzo said.

Overall, the best practice for sinusitis is to stress patience and exercising restraint when it comes to antibiotics and medications that dry mucus. Mucus is an annoying symptom, but drainage is what sinusitis needs.

“We’re always looking for a quick and easy fix, even if there isn’t one,” Carnazzo added.

For symptom relief, Carnazzo tends to point parents to menthol products, hydration, and humidifiers rather than OTC medications. If antibiotics are needed, Carnazzo says amoxicillin is the first choice, while zithromax is not recommended because of resistance. The lowest-spectrum antibiotic is always best to use first, she added.

“Just telling them it will take time and offering comfort is key,” she said.

This article originally appeared in the June issue of our sister publication Contemporary Pediatrics®.

For references, go to ContemporaryPediatrics.com/trends-in-sinusitis

Rachael Zimlich, BSN, RN is a freelance medical writer in Cleveland, Ohio. She has nothing to disclose.
ON THE HORIZON

SPECIALTY DRUG PIPELINE

UPDATES FOR 2022

The specialty drug pipeline includes first- and next-in-class drugs across the oncology and immunology spaces.

By Lauren Biscaldi
he specialty drug pipeline has expanded accordingly with an expected continued growth of 8% per year through 2025. At the 2022 American Society of Health-System Pharmacists (ASHP) Summer Meetings & Exhibition, held in June in Phoenix, Arizona, 2 sessions broke down the latest updates and highlighted some of the most notable drugs in the pipeline. Keep reading for a selection of pipeline updates in oncology and immunology and visit drugtopics.com for full coverage of each of these sessions.

**Next-in-Class Treatments**

**Lead Oncology Drug Pipeline**

According to Sandra Cuellar, PharmD, we’re living in the golden age of oncology.

“If you look at the past decade of FDA oncology approvals, we have made remarkable progress with immune checkpoint inhibitors, with sophisticated biologic agents such as antibody-drug conjugates, bispecific monoclonal antibodies, [and] targeted therapies,” Cuellar, a clinical associate professor and clinical oncology pharmacist at UI Health/University of Illinois at Chicago College of Pharmacy, said during her presentation. “In the past decade or so...the number of drug approvals in oncology is over 330.”

The majority of these approvals (59%) are for label expansion. The poster child, she added, is pembrolizumab (Keytruda), which has 33 indications over 13 individual disease states. Twenty-five percent of approvals were the first approval of a next-in-class drug, and 16% were for drugs with a new mechanism of action, with 7 such drugs approved in 2020.
Melanoma
According to Cuellar, melanoma was one of the first cancers that saw the efficacy of immune checkpoint inhibitors (ICIs). “In this particular cancer, we had very poor outcomes,” she said. “The approval of [ICIs] really did improve outcomes.” To build on that success, researchers turned to LAG3, an immune checkpoint protein that is upregulated in melanoma.

Nivolumab Plus Relatlimab-rmbw Combination Therapy
Preclinical data support the idea of using nivolumab and relatlimab-rmbw (Opdualag), 2 dual ICIs that have demonstrated synergistic activity. Results of the RELATIVITY-047 trial (NCT03470922), which evaluated the efficacy of nivolumab and relatlimab-rmbw combination therapy in a global, randomized, double-blind phase 3 trial, demonstrated that in a population of 694 patients with untreated unresectable or metastatic melanoma, the median progression-free survival rate was 10.12 months vs 4.63 months with nivolumab therapy alone.

Nivolumab and relatlimab-rmbw (Opdualag) is a first-in-class therapy approved by the FDA on March 18, 2022, for the frontline treatment of adult and pediatric patients 12 years or older with unresectable or metastatic melanoma. It is formulated as an injection of 240 mg nivolumab and 80 mg relatlimab per 20 mL (12 mg and 4 mg per mL) and administered in adults and pediatric patients weighing at least 40 kg as 480 mg nivolumab and 160 mg relatlimab intravenously over a 30-minute period every 4 weeks.

Non-Small Cell Lung Cancer (NSCLC)
“As an oncology pharmacist...this has been probably the most remarkable progress I have witnessed,” said Cuellar. “Why is that? We started out 20-plus years ago treating [NSCLC] as 1 disease,” typically with paclitaxel and carboplatin (CarboTaxol). However, Cuellar explained, patients were frequently experiencing negative outcomes, leading to a shift in thinking around the disease and an understanding that different histologies of NSCLC require different therapies, including squamous cell and adenocarcinoma. Today, patients with NSCLC undergo tissue or liquid biopsy and next-generation tumor sequencing to determine which oncogenic mutation is driving their disease.

Poziotinib
Over time, researchers have continued to identify mutations responsible for driving NSCLC, including in HER2. Between 2% and 3% of patients with NSCLC have a HER2 mutation, most commonly an exon 20 insertion, representing an unmet need in therapy. Enter poziotinib, a potent, irreversible inhibitor of cancers with EGFR and HER2 exon 20 mutations. The phase 2 ZENITH20 clinical trial (NCT03318939) included 7 cohorts with either EGFR or HER2 exon 20 mutations. Cuellar focused on patients in cohort 2, which included those with HER2 exon 20 insertion mutations who were previously treated and received an oral, once-daily dose of poziotinib 16 mg. In total, 27.8% of patients met the primary end point of overall response rate; duration of response was 5.1 months, and median progression-free survival was 5.5 months.

Poziotinib is a next-in-class investigational therapy with a likely indication for metastatic NSCLC with HER2 exon 20 insertion mutations with an anticipated Prescription Drug User Fee Act (PDUFA) date of November 24, 2022. Tentative dosing is oral, 16 mg once daily until progression or unacceptable toxicity.

Patritumab Deruxtecan
“Up to 30% of [patients with NSCLC] have an EGFR-activating mutation,” said Cuellar. “Of these EGFR mutations, about 83% express HER2 protein,” which is associated with increased metastases, decreased survival, and increased resistance. Cuellar noted that although there are several approved treatments for patients with EGFR mutations, there are limited treatments available for those who progress or have resistance to first-line EGFR tyrosine kinase inhibitor agents.

Patritumab deruxtecan, an investigational, first-in-class HER3-directed antibody-drug conjugate, may one day be an option for this group of patients. In a multicenter, open-label, multicohort phase 1 trial (NCT03250491), researchers identified a dose of 5.6 mg/kg administered intravenously every 3 weeks as the correct dose for a dose expansion trial. Efficacy of this dose was evaluated in 57 patients, while safety and tolerability of all doses, ranging from 3.2 mg/kg to 6.4 mg/kg, were evaluated in 81 patients.

Within the cohort, median time to response was 2.6 months, median duration of response was 6.9 months, and median progression-free survival was 8.2 months. “[These are] very early preliminary data, but [this is] very promising, especially in a patient population that’s heavily pretreated,” said Cuellar. Adverse events were common; 11% led to treatment discontinuation, 21% led to dose reduction, and 37% led to dose interruption. Patritumab deruxtecan was granted an FDA breakthrough therapy designation on December 23, 2021. Tentative dosing is 5.6 mg/kg intravenously every 3 weeks until progression or unacceptable toxicity.

Adagrasib
The KRAS G12C mutation occurs in approximately 13% of cases of NSCLC. Adagrasib is an investigational drug that irreversibly and selectively binds to KRAS G12C in its inactive state, blocking both cell growth and proliferation.

The nonrandomized, open-label, phase 1/2 KRYSTAL-1 study (NCT03785249) evaluated adagrasib in patients with KRASG12C–mutated solid tumors or unresectable or metastatic disease who had progressed on standard treatment. “The phase I study demonstrated that the dose that was going to be further investigated was 600 mg twice a day,” Cuellar explained. “In the phase 2 component, they looked at monotherapy in [NSCLC],
colon cancer, and other solid tumors.”

In an NSCLC cohort of 79 patients, adagrasib demonstrated an overall response rate of 58% with a 9.5-month median duration of treatment, 12.6-month median duration of response, and 8.3-month progression-free survival; 36% of participants experienced grade 3/4 adverse events.

As a next-in-class drug, adagrasib received an FDA Breakthrough Therapy designation on June 25, 2021, and has an anticipated PDUFA date of December 14, 2022. The drug is administered orally with a tentative dosing of 600 mg twice daily until progression or unacceptable toxicity.

Breast Cancer

According to Cuellar, the most common type of breast cancer—both in her practice and in the United States—is hormone receptor–positive breast cancer. “Endocrine therapy is the backbone in the treatment of hormone-positive breast cancer,” she said. “And unfortunately, although we do have good efficacy outcomes with endocrine therapy, we do see up to 42% of patients do not become resistant to endocrine therapies.”

Mutations the ESR1 gene that inhibit its localization to the plasma membrane are one of the “primary culprits” of endocrine therapy resistance. “We do have selective estrogen receptor degraders, or SERDs, that are indicated in the metastatic setting and have demonstrated some efficacy in patients with mESR1 metastatic breast cancer,” Cuellar explained, including fulvestrant (Faslodex), administered to patients via intramuscular injection.

Elacestrant

Data from the EMERALD trial (NCT03778931), initially presented at the 2021 San Antonio Breast Cancer Symposium, highlighted elacestrant, an investigational, nonsteroidal, orally bioavailable SERD. The global, open-label, randomized, phase 3 trial included patients (men and postmenopausal women) with estrogen receptor–positive, HER2-negative advanced or metastatic breast cancer who had progressed after 1 or 2 lines of endocrine therapy treatment, one of which included a CDK4/6 inhibitor. Patients received elacestrant or standard of care, either fulvestrant or an aromatase inhibitor.

“This is a very resistant patient population,” Cuellar said. “Unless patients have visceral crisis or symptomatic visceral disease, the standard of care in treating these patients is exhausting these endocrine options.”

Other oral SERDs in development include giredestrant and amcenestrant, both in phase 2 and phase 3 trials; rintodestrant, currently in phase 1 research; and camizestrant, currently being evaluated in 2 phase 3 trials and 1 phase 2 trial. Elacestrant is a next-in-class investigational therapy that has received an FDA fast track designation. Tentative dosing is 400 mg orally daily until progression or unacceptable toxicity.

Immunoology Pipeline Includes New Approvals and Expanded Indications

Immunoology drugs represent a significant portion of the pipeline and are forecast as a key area of growth for specialty pharmacy. Caitlyn Anne Young, PharmD, a PGY-2 investigational drugs and research pharmacy resident at Michigan Medicine in Ann Arbor, shared the latest updates in immunology therapies with a specific focus on dermatology, gastrointestinal, and respiratory conditions.

Dermatology

Dermatology updates were focused on atopic dermatitis, plaque psoriasis, and psoriatic arthritis.

Abrocitinib

Abrocitinib (CibinQo) was FDA approved in January 2022 for the treatment of moderate to severe atopic dermatitis (AD), with a recommendation for use in cases refractory to treatment after biologic therapies and other disease-modifying anti-rheumatic drugs have been trialed—making abrocitinib a second-line therapy for the disease.

Data from the JADE clinical trials (NCT03349060, NCT03575871, and NCT03720470), which compared abrocitinib vs placebo and dupilumab (Dupixent), contributed to the approval. Most notably, Young said, abrocitinib demonstrated rapid control over itch response, a secondary end point that is particularly important for patients’ quality of life. Some dose-dependent adverse events were observed, including thrombocytopenia with increased dose levels, she added.

Prior authorization requirements vary, but typically, patients must have tried and failed at least 1 high-potency topical corticosteroid and at least 1 systemic therapy before abrocitinib approval will be granted. Abrocitinib is available as a once-daily 100-mg oral tablet with a maximum daily dose of 200 mg.

Deucravacitinib

Deucravacitinib is a novel, first-in-class selective oral tyrosine kinase 2 inhibitor for moderate to severe plaque psoriasis with an anticipated FDA approval date of September 2022. The drug inhibits signaling of IL-23,
IL-12, and type 1 interferons without inhibiting Janus kinase (JAK) 1, 2, or 3.

In the POETYK-FSO1 and POETYK-FSO2 clinical trials (NCT03624127 and NCT03611751, respectively), investigators compared deucravacitinib with placebo and apremilast (Otezla) 30 mg twice daily, which is the current standard-of-care dosing for moderate to severe plaque psoriasis. "In terms of its primary and secondary end points, deucravacitinib performed really, really well," said Young. "There are really promising outcomes here with no really alarming safety signals." Deucravacitinib is formulated as an oral, once-daily 6-mg tablet.

**Bimekizumab**

Bimekizumab (Bimzelx) is another drug aimed at treating moderate to severe plaque psoriasis with "a little bit of a different mechanism of action compared with the other IL-17 monoclonal antibodies," said Young. "IL-17 is thought to be proinflammatory and heavily involved in inflammation... compared with [tumor necrosis factor alpha (TNF-α)]. However, IL-17F is also expressed specifically in psoriatic skin lesions."

Three clinical trials—BE VIVID (NCT03370133), BE SURE (NCT03412747), and BE RADIANT (NCT03536884)—compared bimekizumab with ustekinumab, adalimumab, and secukinumab, respectively; in all trials, bimekizumab demonstrated superiority in primary clinical end points. However, Young added, "one thing to note is that [bimekizumab shows] much higher rates of oral candidiasis...so patients will need to be counseled on the potential development of thrush."

In May 2022, the FDA issued a complete response letter indicating that the approval process will be halted until certain preapproval indication criteria are addressed. "Although it was anticipated for possible approval later this year, we may be looking more so to 2023," Young added. Bimekizumab is formulated as a subcutaneous injection and dosed at 320 mg every 4 weeks with maintenance dosing every 4 to 8 weeks.

**Gastrointestinal Label Expansions**

"We’re seeing a lot of label expansions happening for currently marketed drugs," said Young. Two drugs on that list are being investigated for potential label expansions to treat both ulcerative colitis (UC) and Crohn disease: risankizumab (Skyrizi), an IL-23 IgG1 monoclonal antibody indicated for moderate to severe plaque psoriasis and psoriatic arthritis (PsA), with a projected 2022 third quarter approval; and guselkumab (Tremfya), another IL-23 IgG1 monoclonal antibody approved for plaque psoriasis and PsA projected to be approved in 2023.

Upadacitinib (Rinvoq)—a JAK-STAT inhibitor currently also approved for AD, rheumatoid arthritis (RA), and PsA—received FDA approval of the label expansion in March 2022.

Other drugs seeking label expansion for gastrointestinal conditions include golimumab (Simponi), an anti–TNF-α monoclonal antibody for RA, PsA, ankylosing spondylitis, and UC in adults. Approval is being sought for the treatment of UC in children and adolescents aged 2 to 17 years and is projected for 2023. Vedolizumab (Entyvio) is an α4β7 integrin inhibitor already approved for UC and Crohn disease; the proposed indication is a subcutaneous formulation for UC therapy slated for 2023.

Ozanimod (Zeposia), a S1P receptor modulator for UC and multiple sclerosis, is currently under investigation as a therapy for Crohn disease. This drug rounded out the list, with a projected approval date of 2024.

**The Respiratory Pipeline**

"Respiratory therapies” have been a little bit slower in terms of pipeline development, with only 1 really notable medication that [was] approved late last year," said Young.

That drug was tezepelumab (Tezspire), an add-on maintenance treatment for asthma in patients 12 years and older, which Young described as “a broad indication compared with other biologic medications in this class.” Rather than using other therapies off label, first-in-class tezepelumab offers patients an on-label monoclonal antibody option with a novel mechanism of action: It is a thymic stromal lymphopoietin (TSLP) blocker; IgG2a monoclonal antibody that binds to human TSLP and blocks interaction with the TSLP receptor.

The pivotal NAVIGATOR and PATHWAY trials (NCT03474279 and NCT02054130) demonstrated strong efficacy and safety, with minimal adverse events noted.

Tezepelumab was approved by the FDA in December 2021 and is dosed as a 210-mg subcutaneous injection every 4 weeks; compared with other monoclonal antibodies on the market, it must be administered in a clinic by a health care provider.

For references, visit drugtopics.com.
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Health care providers play an important role in adolescent sex education, including in discussions on contraceptive use. Adolescents may start engaging in sexual activity while undergoing the numerous physical and emotional changes that occur during their transformative period. By the age of 20 years, approximately 80% of young women have had sexual intercourse; however, adolescents (aged 15 to 19 years) have limited understanding of the various contraceptive methods available to them, and the lowest rates of contraceptive use. Counseling individuals about the various methods of contraception and increasing access to care can help address unplanned pregnancies and sexually transmitted diseases.

Contraception
Various methods of contraception are available for adolescents (Table 1). Medical providers should counsel them on the efficacy, safety, and adverse effects of contraception, informing them about the most effective options. Contraceptive options from most effective to least effective are as follows: intrauterine devices/progestin implants, progestin injections, and combined oral contraception (pills, patch, vaginal ring). Regarding efficacy, discussing aspects of “typical” use and “perfect” use is also recommended. Perfect use is when a contraceptive is used correctly all the time, whereas typical use takes human error into account; this includes missing pills or forgetting to change a patch, as well as using a condom. Common adverse effects are listed in Table 2.

Intrauterine Contraception
Intrauterine devices (IUDs) are small, T shaped, and flexible. Currently, 3 are approved in the United States: levonorgestrel (Mirena) 52 mg, levonorgestrel (Skyla) 13.5 mg, and a copper-containing device (Paragard). Levonorgestrel 52 mg is approved for use for 3 years, levonorgestrel 13.5 mg for 5 years, and the copper IUD for 10 years. These devices are highly effective with a failure rate of less than 1%. Multiple data articles support the safety of these devices in adolescent patients.

**Best Practices on Discussing Birth Control for Adolescents**

There are numerous methods of contraception available for adolescents.

By Danielle M. Alm, PharmD, BCPS, BCPPS; Reina Puri; and Christine Payne

**TABLE 1. EFFECTIVENESS OF CONTRACEPTIVE OPTIONS**

<table>
<thead>
<tr>
<th>LEAST EFFECTIVE</th>
<th>EFFECTIVE</th>
<th>INTERMEDIATELY EFFECTIVE</th>
<th>MOST EFFECTIVE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Withdrawal</td>
<td>Male condoms</td>
<td>Injectables</td>
<td>Implants*</td>
</tr>
<tr>
<td>Spermicides</td>
<td>Diaphragm</td>
<td>LAM</td>
<td>IUD*</td>
</tr>
<tr>
<td>Female condoms</td>
<td>Pills</td>
<td>Female sterilization</td>
<td></td>
</tr>
<tr>
<td>Fertility awareness methods</td>
<td>Patch</td>
<td>Vasectomy</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Vaginal ring</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Long-acting, reversible contraceptives
Terms Key: IUD, intrauterine device; LAM, lactational amenorrhea method
Adolescents may start engaging in sexual activity while undergoing the numerous physical and emotional changes that occur during their transformative period. and by the age of 20 years, approximately 80% of young women have had sexual intercourse

Adolescents need to be taken for at least 21 consecutive days for efficacy against unplanned pregnancy. The timing of contraception use varies and should be taken into consideration when choosing between the pill form, injectable form, patch, or vaginal ring. Adolescents can start these products immediately or can wait until their next menstrual cycle. Preferring a Sunday start or starting on the first day of the next menstrual cycle is common. This will ensure the adolescent is not pregnant before starting contraceptives. Current data, however, do not support evidence of any adverse effects of contraceptive hormone exposure on fetal development.

**Progestin Implants**
A progestin implant is a thin, flexible, single rod containing etonogestrel, which is placed under the skin of the upper arm. Etonogestrel 68 mg (Nexplanon) has 3 years of effectiveness. Implants are highly effective with a failure rate of less than 1%. These exert their action by thickening cervical mucous, thinning the endometrial lining, and inhibiting ovulation. Implants do not seem to have a high impact on bone mineral density, as higher levels of estradiol are seen in females using implants vs a progestin injection. Implants are an option for adolescents who prefer not to take scheduled medication daily or who prefer longer-term protection.

**Progestin Injection**
Depot medroxyprogesterone acetate (DMPA; Depo-Provera) is an injection administered every 3 months with a 96% efficacy rate in pregnancy prevention. DMPA causes anovulation and thickening of the cervical mucous by inhibiting pituitary gonadotropins. Advantages of this product include infrequent dosing, discrete- ness, improvement in dysmenorrhea, and protection against iron-deficiency anemia and endometrial cancer. Disadvantages include having to access a health care provider for injections, menstrual cycle irregularities, delayed fertility return, weight gain, headache, and hair loss. Weight gain is a concern for adolescents who gain more than 5% of body weight after 6 months of use. A black box warning exists for the drug’s potential to cause bone mineral density loss in the first 2 years of use; however, the American College of Obstetricians and Gynecologists states no restriction on the length of time that DMPA can be used. During this time, adolescents should be counseled on adequate daily intake of calcium and vitamin D (1300 mg calcium; 600 IU vitamin D), weight-bearing exercises, and smoking cessation.

**Combined Hormonal Contraception**
Three different methods exist that contain both an estrogen and progestin: pill, patch, and vaginal ring. The 4- to 7-day hormonal-free interval can be used monthly or extended to once every several months. Data have shown safety with the extended approach. Hormonal contraception

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### TABLE 2. CONTRACEPTIVE CLINICAL PEARLS<sup>2,3,7</sup>

<table>
<thead>
<tr>
<th>CONTRACEPTIVE METHODS</th>
<th>INTRAUTERINE DEVICES*</th>
<th>PROGESTIN INJECTION*</th>
<th>PROGESTIN IMPLANTS</th>
<th>ORAL PILLS*</th>
<th>PATCH*</th>
<th>VAGINAL RING*</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Levonorgestrel product ADRs</strong>&lt;sup&gt;**&lt;/sup&gt;</td>
<td>Abnormal/unscheduled bleeding major reason for discontinuation</td>
<td><strong>ADRs</strong></td>
<td><strong>BBW</strong></td>
<td><strong>ADRs</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Menstrual bleeding</td>
<td>Breast tenderness</td>
<td>Increased VTE risk due to higher estrogen levels (1.6 times higher)</td>
<td>Vaginal discharge</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dysmenorrhea</td>
<td>Irregular bleeding</td>
<td></td>
<td>Vaginal discomfort</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acne</td>
<td>Headache</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Breast tenderness</td>
<td>Weight gain</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Headaches</td>
<td>Nausea</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Mood changes</td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td><strong>Copper product ADRs</strong></td>
<td><strong>ADRs</strong></td>
<td><strong>Do not prescribe</strong></td>
<td><strong>ADRs</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Increase menstrual blood loss</td>
<td>Headache</td>
<td>Severe, uncontrolled hypertension</td>
<td>Hyperpigmentation</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dysmenorrhea</td>
<td>Weight gain</td>
<td>Ongoing hepatic dysfunction</td>
<td>Contact dermatitis</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Acne</td>
<td>Complicated valvular heart disease</td>
<td>Skin irritation</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* 7-day backup contraceptive needed
**Levonorgestrel only
Terms Key: ADRs, adverse drug reactions; BBW, black box warning

**Contraceptive Patch**

Contraceptive patches (Xulane, Zafemy) contain 150 µg norelgestromin and 35 µg ethinyl estradiol. The patch is worn weekly for 3 weeks and removed for 1 week to induce a withdrawal bleed. The abdomen, upper torso, upper arm, and buttocks are safe places on which to place the patch.<sup>1,3,7</sup>

**Contraceptive Vaginal Ring**

The vaginal ring (NuvaRing) is a round, flexible device that is inserted into the vagina weekly for 3 weeks that contains 15 µg ethinyl estradiol and 120 µg etonogestrel. During the doctor visit, patients should be shown a pelvic model to help explain where the vaginal ring will be; they should be reassured the ring will not fall out and that it can remain in during sexual intercourse.<sup>1,3,7</sup>

For references, visit drugtopics.com.

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Optimizing Outcomes for Pediatric Infusion Therapy

An expert offers considerations and developmentally appropriate interventions to promote high-quality, patient-centered pediatric infusion care. By Keith Loria

Pediatric patients in need of infusion therapy face the same access barriers as their adult counterparts. But they also deal with the added challenges of finding sites of care and infusion providers that are accustomed to caring for children.

Robert Dracker, MD, MHA, MBA, CPI, medical director of Summerwood Pediatrics & Infuscare Medical Services in Liverpool, New York, spoke on these issues at the 2022 National Infusion Center Association (NICA) Annual Conference, held June 17 and 18, 2022, in New Orleans, Louisiana.

Dracker discussed considerations and developmentally appropriate interventions to promote high-quality, patient-centered pediatric infusion care. Dracker started with a question: "What is infusion medicine?" There is no standard definition, he said, so he crafted his own, drawing on his decades of experience in the field.

Dracker defined this growing sector as, "the health care specialty involved with the clinical science and practice of administering parenteral fluids, medications, biologic, and cellular therapies to adults and children."

Dracker also touched on the unique needs of children who will be receiving intravenous (IV) or parenteral medications. Compared with an emergency department visit or for a hospitalized child, outpatient infusion therapy is semi-ejective and scheduled, allowing time to prepare the child for the therapy.

"This is a very difficult thing to do for a child in general," he said. "A [provider] should explain the need for the therapy and obtain an informed consent in some cases, particularly with regards to some of the newer biologic therapies for diagnoses like eczema and psoriasis."

He compared general therapy considerations with important concerns specific to dealing with pediatric patients, reminding health care professionals that children are not just tiny adults. Things to know and factor into the care include the age of the child and any developmental issues, how ill the child is (acute vs chronic), who is with the child at the visit, any preexisting conditions that could complicate the therapeutic intervention, and the child's understanding of the treatment and informed consent.

Dracker spoke about the importance of establishing a relationship between a provider and the infusion site team; there must be open communication between both to address issues such as special needs of a particular patient, who will be monitoring the response and follow up labs, and how to partner medically with regards to new emerging therapies.

Dracker also noted that treating a child may raise the anxiety of the medical team, so a collaborative approach is helpful, especially at the start of the therapy. He stressed that an open, interactive relationship between the provider's practice and the therapy site is critical for care.

"There should obviously be communication between both regarding currently available and emerging therapies, the needs for prior authorization, follow-up lab work required, and the fact that the infusion center staff will commonly see the patient during treatment more often than the dermatologist, which means that the response to treatment, or lack thereof, should also be conveyed back to the referring office," he said.

Providers can take steps to prepare children for treatment in this environment by familiarizing the child with the environment, explaining each step of the process, and surrounding them with love, affection, and even "bribes" such as cartoons, books, and snacks.

In general, parents are fairly motivated to ensure that their child receives their therapy on a scheduled basis. It is important to provide a reminder to parents for an upcoming appointment with regards to date and time. Dracker also urged infusion providers to make an attempt to accommodate a child's needs, especially related to school and activities.

Dracker also touched on vascular access issues in pediatric patients, the importance of being honest with children, and steps the FDA is taking to ensure access to safe and effective medical products for children.

At the conclusion of his talk, Dracker shared his hope that attendees could walk away with the understanding that children have special needs when it comes to infusion therapy treatments and that in many ways, these providers are treating a whole family—an experience that can be positive or negative depending upon the efforts made and the accommodations provided.

REFERENCE

According to Erin O’Connor Prange, MSN, CRNP, of Children’s Hospital of Philadelphia in Pennsylvania, drugs for attention-deficit/hyperactivity disorder (ADHD) have been on the market for more than 45 years, beginning with methylphenidate (Ritalin), which was approved in 1955. [Editor’s note: Although not included in the Diagnostic and Statistical Manual of Mental Disorders until 1968, methylphenidate was originally prescribed for fatigue and depression.] According to a 2016 study, roughly 6 million children in the United States have ADHD, said Prange. Boys receive a diagnosis twice as frequently as girls, but overall, 77% of these children were receiving treatment, with roughly 32% of them having both behavioral and medication treatment.

What is a snapshot look at a child with ADHD? Prange, who was speaking at the 43rd National Conference on Pediatric Health Care in Dallas, Texas, in March 2022, explained that the main component of this developmental learning disorder is poor executive functioning in tasks. These include planning, time management, attention, organization, and self-control. Additionally, during the months that children were learning remotely due to the COVID-19 pandemic, impaired communication, eye strain, distractions, and anxiety were also reported, largely as a result of the struggle with virtual and hybrid learning.

Nonmedication treatment for ADHD includes cognitive behavioral therapy, extra time on test taking, creating lists (eg, what to put in the school backpack), and bouncy bands and wiggle seats for desks. The newest (those that have become available over the past 5 years) and most commonly prescribed drugs for the disorder include the nonstimulant viloxazine (Qelbree); for stimulants, there are now several methylphenidates (Cotempia, Adhansia, Aptsensio, Jornay) and amphetamines (Dyanavel, Adzenys, and Mydayis).

Before starting a patient on stimulants, the American Academy of Pediatrics recommends a thorough cardiovascular assessment, including patient and family health histories; evaluation of all medications being used; and a physical exam focused on cardiovascular disease risk factors. Prange also reviewed the adverse effects for stimulant medications, which include, but are not limited to, decreased appetite, trouble sleeping, headache, weight loss, and mood swings. She also encouraged audience members to seek out a copy of the ADHD medication guide, available at addwarehouse.com, which provides books, assessment products, and training programs for ADHD and related conditions.

Stay tuned for the August issue of Drug Topics®, featuring an in-depth look at the latest in managing pediatric and adult ADHD.

REFERENCES
1. Prange EO. ADHD treatment explosion: new meds are here! Presented at: 43rd National Conference on Pediatric Health Care; March 23, 2022; Dallas, TX.
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Independent and small chain pharmacy owners are often far too busy to focus on creating success through OTC retail sales—understandably so. They face the trifecta of dispensing lifesaving medications, honoring their Hippocratic Oath, and focusing on getting remuneration from insurance companies. Finally, they must deal with the overall management responsibilities inherent in owning a retail business with employees, and all that comes with it.

How and why should they pay attention to that vast wasteland of their front end? Let’s start with some essential truths: Americans—and plenty of individuals worldwide—are true red, white, and blue consumers. I contend that as soon as your customers hand off their prescriptions, they often scratch their bottom and look for something to eat, drink, or read. If they’re older or ailing, they usually look for somewhere to get off their feet.

I focus on these obvious human behaviors because recognizing them is the foundation of successful retailing. Where your patients sit or congregate are the prime locations to merchandise products that are purchased impulsively. All pharmacies are provided with, and utilize, their drug wholesalers’ OTC products planogram. There are departments of analgesics, cough and cold remedies, foot care, and so on. If someone needs these products, they will seek them out or ask for help finding them. Most of these departments are critical and are required to take care of patients’ needs. But a pitfall of these departments is that they’re based on national averages; there are bound to be nonselling items taking up space and creating non-income-producing inventory. Additionally, many of these items can be found anywhere, often at a discounted price—particularly in the major chains. Even so, these products are a necessary evil. But these issues can be mitigated by culling out the “dogs” and through creativity elsewhere in the store.

To create change in any business, it is helpful to take an alternative outside view. If any retailer looks down at their product mix and departments, they might come to some rather easy, obvious conclusions. For example, if a store had 20 feet of greeting cards displayed on old, discolored metal shelving, a business owner might quickly guess that, with people texting and emailing assorted greetings, there may have been
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a drop-off in these sales. They might imagine a terrific variety of cards in only 10 feet of space, presented on an upgraded display. With an inventory-reducing sale, they would (1) lower their inventory to an appropriate level and (2) make available space for a fresh, new department with sales-producing merchandise. This isn’t an attack on the greeting card industry, but an example to make a point.

"As soon as pharmacy customers hand over their prescription, they look for something to eat, drink, or read while waiting for their medication to be filled."

Another general no-no in retailing is holding on to dead merchandise. I once stood in an average-size pharmacy with a small front counter. Although there was limited room available, they found the space to display a small, cut-open cardboard box containing assorted discolored greeting cards for 10 cents each! If asked, I would have recommended that they burn them—or at least toss them in the trash—and instead use that limited, precious, highly viewed space to display a tester of either a specialty hand lotion or pain relief cream, something not available at a chain store. The resulting sales are an obvious, immediate win, and the potential of creating future refill sales from those limited-availability products is often more important. Decisions like those can turn the store into a go-to destination for sought-after specialty brands and products. Making a store unique, interesting, and visually appealing can be rather easily accomplished, and presenting new, impulsively purchased items that have counter or floor displays—provided by manufacturers!—can create quick, long-term results.

Recognizing categories of items that show movement offers an opportunity to add companion products to build success. Snacks, candy, gifts, toys, cell phone accessories, and crossover health food industry alternative remedies are some great options.

At the end of the day, additions, subtractions, and moving around products and departments will make a substantial impact on a pharmacy’s bottom line. Recruiting an employee to aid in the project can be very helpful, and great improvements can often be accomplished quickly and with relative ease. Remember, you’re paying rent for that front-end real estate; it should help pay the light bill and the rent as well!

We must be prepared for successes and failures in our selection of new product mixes. It’s always wise to walk before we run amok. Close out mistakes and expand or evolve successes. Many improvements take mindful, but minimal, effort. Success breeds success, so the process can be mildly addictive. Take these suggestions as prescribed, and remember to have fun along the way and bank the fruits of your labor. —

Dan Langerman is the owner of Langermania.
Three years ago, my wife, Denise, planned another vacation of a lifetime. In 2001 and 2013, we had traveled, with our parish priest and our kids, to Italy on a pilgrimage to various religious sites. We had a marvelous time. This trip, though, would be different: We were going to Germany, where all of my grandparents are from. My dream to see the Passion Play in Oberammergau would become a reality in May 2020. The Passion Play was performed there first in 1634 and every 10 years thereafter as a thanksgiving offering for the village being spared from the plague. The Passion Play deviated from every 10-year schedule only twice: in 1940, during World War II, and again in 2020 for the COVID-19 plague. The Germans seemed to know that COVID-19 would last longer than 1 year and rescheduled the performance for 2022. We were excited to get tickets to the second performance on May 15.

Whenever I travel to a different locale, I like to stop by the pharmacy for a quick visit. In Germany, it is easy to find a pharmacy. Each store is designated by a big, red A for apotheke. Pharmacies, by German law, are owned and operated by a pharmacist who has graduated from an accredited school of pharmacy. It is a strange experience when you walk in. The employees, technicians, and pharmacists are sharply dressed in white lab coats with name tags. Throughout the country, pharmacies had the same vibe: calm, quiet, and professional—unlike the chaos in some American pharmacies. Each pharmacist we talked to happened to be a woman and spoke English with proficiency.

Prescription products were available only in unit-of-use blister packs. I asked one pharmacist if they ever split the boxes and received a firm no in response. These boxes were dispensed as a single unit, QR-coded with the lot and expiration date entered on the patient's profile. There are absolutely no stock bottles and no prescription vials.

German pharmacists do not frequently receive electronic prescriptions. Instead, patients carry a pink and white prescription blank from their physician. There are no directions or drug names on the blank; there is a serial number that, when entered, populates the drug name, quantity, and directions for use. This information is contained in a central database and it is virtually impossible for a pharmacist to enter data incorrectly. There is no chance the pharmacist will enter amitriptyline 100 mg for an order written for amitriptyline 10 mg.

All pharmacies in Germany utilize the same formulary. Patients pay 10% of the cost of the prescription: between €5 and €10, maximum. Can you imagine a prescription in your pharmacy having a maximum co-pay of $10? Best of all, there are no prior authorizations in the pharmacy; everything is approved.

Of all the wonderful experiences Denise and I had interacting with our fellow pharmacists, our encounter in Oberammergau stands out. It was Sunday afternoon and I went to the apotheke to buy a box of ibuprofen 400 mg. When she rang up the sale, she warned me that there would be a €2.5 inconvenience fee because it was a Sunday purchase. I told her I would be honored to pay a surcharge; I've always been annoyed with Sunday shoppers. Of the prescriptions we fill on a Sunday, seldom are there more than a few true emergencies.

The German population is covered by a national insurance, which seems satisfactory to most of the citizens there. They have had national health insurance since 1883 thanks to Otto Von Bismarck's social legislation. Today, the German government spends $685 for health care for the average citizen. Compare that with the United States, which spends over $1000. When it comes to providing drugs to our patients, we could learn a lot from the Germans about safety, cost containment, and satisfaction of its pharmacists.
HEALTH SYSTEMS

Conferences Review
ASHP Summer Meetings and Exhibition

By Lauren Biscaldi and Miranda Hester

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osters presented at this year’s American Society of Health-System Pharmacists (ASHP) 2022 Summer Meetings and Exhibition—held June 11 to 15, 2022, in Phoenix, Arizona—provided a wealth of knowledge for health-system pharmacists. From medication adherence to biosimilar switching, read on for a selection of Drug Topics® onsite coverage. To read the rest of our meeting content, scan the QR code or visit drugtopics.com.

Integrated Health-System Pharmacy Models Are Associated With Medication Adherence, Fewer Adverse Effects

Patients who filled prescriptions in an integrated health-system specialty pharmacy model were likely to report low rates of missed medication doses and adverse effects (AEs), according to one poster.1

To determine whether patient-reported outcomes are associated with patient-perceived medication effectiveness in a health-system specialty pharmacy setting, researchers—led by Elizabeth D. Bryan, PharmD, of Vanderbilt Specialty Pharmacy/Vanderbilt University Medical Center in Nashville, Tennessee, and colleagues—conducted a single-center, retrospective analysis of patients prescribed specialty medications from rheumatology, multiple sclerosis, neurology, dermatology, or asthma and allergy clinics. Outcomes were assessed after the patient completed 2 medication refill questionnaires during a 3-month period (January to March 2020).

Primary study outcomes were the frequency of patient-reported outcomes related to perceived medication effectiveness, missed doses, and medication AEs. The researchers utilized electronic health records to collect demographic and prescribed medication data, while patient-reported outcomes and pharmacist intervention data were gathered from a specialty pharmacy patient management database.

The cohort included 1398 patients across 6 specialty pharmacy clinics (66% women; 86.5% White; mean age, 56 years). Just over 50% of patients were from the rheumatology clinic, while asthma and allergy patients represented only 3.3% of patients.

A total of 4125 medication refill questionnaires were completed, with a total of 172 missed doses reported, most commonly because of instructions to hold medication for illness or medical procedures.

Patients reported AEs just 41 times (1%); most reported effectiveness as either good or excellent (72% and 25%, respectively). Among those who did not report AEs, odds of reporting higher effectiveness were 7.49 times higher than for those who did (95% CI, 3.31-16.95). Similarly, patients who did not report a missed dose were 2.13 times more likely to report higher effectiveness (95% CI, 1.42-3.19).

“Patients filling specialty medication within an integrated health-system pharmacy model reported low rates of missed doses and AEs,” the researchers concluded. “Additionally, patients who did not report missed doses or AEs were significantly more likely to have higher perceived effectiveness of treatment.”

Identifying Patient Barriers to Monoclonal Antibody Therapy for COVID-19

For much of the pandemic, monoclonal antibody therapy has been an important tool to prevent severe COVID-19 in patients with mild to moderate disease who were at high risk of severe illness or hospitalization. Research1 presented at this year’s meeting by Jennifer L. Rafferty, PharmD, of St. John Fisher College Wegmans School of Pharmacy/
“Patients filling specialty medication within an integrated health-system pharmacy model reported low rates of missed doses and [AEs and] patients who did not report missed doses or [AEs] were significantly more likely to have higher perceived effectiveness of treatment.”

Elizabeth D. Bryan, PharmD, and colleagues

Rochester Regional Health in Rochester, New York, sought to catalog the barriers to monoclonal antibody therapy to discover areas for further educational need.

A single-center, retrospective chart review examined the real-world utilization of monoclonal antibody therapy. A patient was included if they had a positive COVID-19 test within 10 days of symptom onset, met the criteria set by the FDA emergency use authorization for monoclonal antibody therapy, and had been referred to a clinical pharmacist. Those who had been given oxygen therapy or had been hospitalized for COVID-19 before referral were excluded.

Patients were split into a nonmonoclonal group, which included all eligible patients who had not received treatment within the 10-day window, and the monoclonal group that included patients who had documentation of administration within 10 days of symptom onset. The primary outcomes included the ratio of patients who did not receive therapy and the reasons for not receiving it.

There were 231 potential candidates for monoclonal antibody therapy referred to clinical pharmacists, 197 of whom met the inclusion criteria. Just 33 patients were given treatment. Among the 164 who qualified but did not receive monoclonal antibody treatment, 55 declined therapy because of mild illness or improving symptoms. Twenty-two patients did not receive the therapy because the patient’s primary care provider did not order monoclonal antibody treatment. In this subset, 11 were not given treatment by the provider because of mild symptoms; the reason for denial was unknown for 7 patients, and 1 patient died within 30 days of complications of COVID-19.

The investigators concluded that despite authorization for treating mild to moderate illness in patients with a high risk of more severe outcomes, many did not use monoclonal antibodies because of the mild nature of their illness.

“As COVID-19 treatments are rapidly changing, this study has identified a need for education targeting patients at high risk for severe illness,” the author concluded.

Comprehensive Medication Management Could Be Key to Reducing Cost, Improving Chronic Disease Markers

Clinical markers of chronic disease may be improved by ambulatory care pharmacists engaging in comprehensive medication management. Anna Pham, PharmD, of Intermountain Healthcare in Salt Lake City, Utah, presented a poster at the meeting examining the impact and value of such services.

Investigators matched study participants 1:2 into an experimental cohort composed of patients taking medication for chronic diseases who worked with an ambulatory care pharmacist and a control cohort of patients who did not. Intervention patients were eligible for inclusion if they had at least 2 comprehensive medication management appointments at least 3 months apart with an ambulatory care pharmacist from January 2020 to December 2020; control patients were eligible if they had 2 primary care visits at least 3 months apart.

The primary outcome was the utilization of the emergency department and hospital from January 2020 to December 2020. Secondary outcomes included the cost savings analysis of emergency department and hospital use data as well as a comparison of patient disease markers before and after the interventions.

The cohort included 300 patients: 100 in the intervention group and 200 in the control group. A look at health system utilization found an average of 7.1 emergency department visits per 1000 patients in the intervention cohort vs 11.4 in the control (P = .018). Furthermore, the control group had an average of 5.0 inpatients per 1000 patients vs 3.1 in the intervention group (P < .01).

Using estimated admission costs, the differences in admission represented a reduction of $46,574 for the emergency department and $306,912 for inpatient visits with the aid of
pharmacist intervention. No statistical differences were seen between the 2 groups for blood pressure and lipid panels, but the intervention group did see an average reduction in hemoglobin A1c from 8.97% before comprehensive medication management to 7.95% ($P < .01$) after a year, whereas the control group saw an average increase from 8.85% to 9.37% ($P < .43$) in the same time span.

"(Comprehensive medication management) provided by ambulatory care pharmacists were shown to reduce (emergency department) and inpatient visits...which may lead to monetary savings to the health system," the author concluded.

**Does Pharmacist Involvement Affect the Rate of Infliximab Biosimilar Switching?** Although the first infliximab biosimilar product came to market in 2016, uptake of this medication has been slow, attributable to hesitancy among providers to utilize biosimilar agents in chronic disease management.

Investigators shared results of their research into whether the inclusion of an inflammatory clinical pharmacist on patient care teams could promote uptake of infliximab biosimilars. Through a retrospective cohort study, researchers used electronic medical record data to identify adults with chronic disease managed on infliximab originator or biosimilar product, who received infusions at facilities associated with a large academic medical center. Medications included in the study were originator infliximab (Remicade), infliximab-dyyb (Inflectra), infliximab-afbda (Renflexis), and infliximab-axxq (Avsola).

Researchers used prescriber’s National Provider Identifier (NPI) number to assign the prescriber to a group with—or without—pharmacist involvement. The primary outcome for the study was whether patients who were managed on originator infliximab were switched to a biosimilar during the study period: fifty-nine percent received only originator infliximab; of the remaining 41% of patients, 32% received only a biosimilar infliximab, and 9% were switched from the originator to a biosimilar product.

Within the group of patients not managed by a pharmacist-involved provider, 35% received only an infliximab biosimilar, while 26% received only a biosimilar and 9% switched to a biosimilar during the study.

Among those managed by providers with pharmacist involvement, 47% received a biosimilar product, 37% received only biosimilars, and 10% were switched to a biosimilar during the study period.

"Regardless of provider-pharmacist involvement, patients were most likely to stay on 1 formulation of infliximab, whether the originator or biosimilar product," the researchers wrote. "Our findings suggest that pharmacist involvement and collaboration within specialty clinic spaces promotes infliximab biosimilar use."

"As more high-cost specialty drugs lose patent exclusivity, pharmacist integration into these clinic spaces will be an important cost-savings tool in growing provider comfort with and utilization of biosimilar agents," they concluded.

**REFERENCES**

1. Bryan ED. Assessing patient-reported outcomes within an integrated health system specialty pharmacy. Presented at: American Society of Health-System Pharmacists 2022 Summer Meetings and Exhibition; June 11-15, 2022; Phoenix, AZ. Poster 40-M.


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Novel, Dual-Targeted Treatment for T2D Is FDA Approved

Tirzepatide is a once-weekly subcutaneous injection to treat type 2 diabetes in conjunction with diet and exercise. by Kathryn Wheeler PharmD, BCPS

In May 2022, the FDA approved tirzepatide (Mounjaro) for the treatment of type 2 diabetes (T2D) in conjunction with diet and exercise. Tirzepatide has a dual mechanism of action as an agonist to glucose-dependent insulinotropic polypeptide (GIP) receptors and to glucagon-like peptide-1 (GLP-1) receptors. As such, tirzepatide acts to modulate insulin and glucagon release, which can improve blood glucose control.

The approved starting dosage of tirzepatide is 2.5 mg once weekly as a subcutaneous injection to the abdomen, thigh, or upper arm. Injection sites should be rotated weekly. As needed for glycemic control, the dosage may be increased by 2.5 mg every 4 weeks, with a maximum dose of 15 mg injected subcutaneously weekly. Tirzepatide may be administered without regard to meals. Tirzepatide is supplied as a package of 4 prefilled, single-dose pens. The medication can be stored in the refrigerator but is stable at room temperature for up to 21 days.

For references, visit drugtopics.com