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Pharmacy in the Era of Telehealth

Over the past year, we’ve seen a rapid integration and swift adoption of telehealth services penetrating the health care space. Although telehealth existed before the coronavirus disease 2019 pandemic, its popularity surged into response to social distancing efforts and widespread lockdowns a year ago. Legislators temporarily lifted many barriers to its adoption, allowing expanded use among providers and patients. This raises the question: How will telehealth evolve beyond the pandemic?

It’s safe to assume that telehealth won’t completely replace in-person health care. Patients won’t stop visiting their local pharmacies. But pharmacists can learn how to better integrate technology and telepharmacy models to enhance the already quality care they provide. In this issue’s cover story, we dive into the innovative ways pharmacists are doing just that—from remote sterile compounding to secure medication storage and virtual care consults. Visit page 8 to learn more.

As these changes bring the industry new insight, Drug Topics® aims to continue to serve its readers with practical insights and relevant information. We recognize that the independent pharmacy channel is an integral part of the nation’s health care system, accounting for 35% of pharmacy locations. To serve this group of pharmacy professionals, last month we launched Total Pharmacy®, a new resource designed to provide accessible information and actionable business solutions for professionals in the independent pharmacy space. The unique patient experience offered by these stores will improve access and outcomes in today’s value-based health care model, and we look forward to supporting the needs of this niche group. You’ll find dedicated resources in each Drug Topics® issue, such as this month’s piece on measuring profitability performance on page 18, and online at totalpharmacy.com.

In this issue, you’ll also find coverage from the American Pharmacists Association 2021 Annual Meeting & Exposition, which was held virtually from March 12 to 15. Learn more about updates in diabetes care and newly approved therapeutics on page 14 and turn to page 16 for highlights from the conference’s annual immunization update session.

Thank you for reading.

Mike Hennessy Sr,
Chairman and Founder of MJH Life Sciences™
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Drug Topics® is published monthly and Drug Topics Digital Edition is issued every week by MultiMedia Healthcare LLC, 2 Clarke Drive, Suite 100 Cranbury, NJ 08512. One-year subscription rates: $61 in the United States & Possessions; $109 in Canada and Mexico; all other countries, $109. Single copies (prepaid only) $10 in the United States; $10 in Canada and Mexico; all other countries, $15. Include $6 per copy for U.S. postage and handling. Periodicals postage paid at Trenton, NJ 08635 and additional mailing offices. POSTMASTER: Please send address changes to Drug Topics®, PO Box 457, Cranbury, NJ 08512-0457. Canadian GST number: R12413131RT001. Publications Mail Agreement Number 400 11038. Return undeliverable Canadian addresses: NEX Global Solutions PO Box 255424 London, ON N6C 6B2, CANADA. Printed in the U.S.A. © 2021 MultiMedia Medical LLC. All rights reserved. No part of this publication may be reproduced or transmitted in any form or by any means, electronic or mechanical, including photography, recording, or information storage and retrieval without permission in writing from the publisher. Authorization to photocopy items for internal educational or personal use, or the internal educational or personal use of specific clients, is granted by MJH Life Sciences for libraries and other users registered with the Copyright Clearance Center, Inc., 222 Rosewood Drive, Danvers, MA 01923, 978-760-8400 or visit http://www.copyright.com online. For uses beyond those listed above, please direct your written request to Permission Dept. email: etemple-morris@mmhgroup.com. Unsolicited manuscripts, photographs, art, and other material will not be returned. Publisher assumes no responsibility for unsolicited manuscripts, photographs, art, and other material. MJH Life Sciences provides certain customer contact data (such as customers’ names, addresses, phone numbers, and email addresses) to third parties who wish to promote relevant products, services, and other opportunities that may be of interest to you. If you do not want MJH Life Sciences to make your contact information available to these parties for marketing purposes, simply email mmhinfo@mmhgroup.com and a customer service representative will assist you in removing your name from MJH Life Sciences’ lists. Drug Topics® disclaims any claims or other information appearing in any of the advertisements contained in the publication, and cannot take responsibility for any losses or other damages incurred by readers in reliance on such content. Drug Topics welcomes unsolicited articles, manuscripts, photographs and other materials; but cannot be held responsible for their safekeeping or return. Library Access: Libraries offer online access to current and back issues of Drug Topics® through the EBSCO host databases. To subscribe, email mmhinfo@mmhgroup.com.
EDITORIAL MISSION: Drug Topics® is the top-ranked pharmacy resource for community and health-system professionals. Since 1857, readers have turned to Drug Topics® for coverage of issues and trends important to the practice of pharmacy, and for a forum in which they can share viewpoints and practical ideas for better pharmacy management and patient care.
On March 8, 2021, the CDC issued the first set of guidelines for individuals who have received either 2 doses of the Pfizer/BioNTech or Moderna coronavirus disease 2019 (COVID-19) vaccines or 1 dose of the Johnson & Johnson/Janssen vaccine. For purposes of the guidance, an individual is considered fully vaccinated against COVID-19 at 2 weeks after receiving the second dose of the 2-dose vaccines and at 2 weeks after receiving the single-dose vaccine. The recommendations are also only for settings that do not involve health care.

The guidance also recommends that fully vaccinated individuals continue to do the following:
- Wear a well-fitted face covering in public.
- Continue mask wearing, social distancing, and other infection control measures when visiting with unvaccinated individuals at increased risk of severe disease or if visiting with unvaccinated individuals from multiple households.
- Undergo testing if COVID-19 symptoms occur.
- Follow CDC and health department travel requirements.
- Continue avoiding medium- and large-sized in-person gatherings.

Fully vaccinated individuals can do the following:
- Visit with other fully vaccinated individuals in an indoor space without mask wearing or social distancing.
- Visit with unvaccinated individuals from a single household without mask wearing or social distancing if the unvaccinated individuals are at low risk for severe COVID-19 disease.
- Abstain from quarantine and testing after a known exposure if the exposure was to asymptomatic individuals.

Visit contemporarypediatrics.com to read the full article.

US Adults Prefer to Receive COVID-19 Vaccine From Pharmacy Over Mass Vaccination Event

Most Americans prefer to receive their coronavirus disease 2019 (COVID-19) vaccines from a trusted health care provider, such as their pharmacist or physician, rather than being immunized at a mass event, according to the results of a recent survey.

The new survey, which was released by the National Community Pharmacists Association (NCPA) and conducted by Public Policy Polling from February 26 to 27, asked 1390 adults a variety of questions about COVID-19 vaccinations. Twenty-four percent of respondents indicated that the pharmacy would be their first choice for where to receive the COVID-19 vaccine. Thirty-six percent listed a doctor’s office as their first choice and 23% said they would prefer to be immunized at a clinic, health center, or medical office.

Only 4% reported a preference to be immunized at a mass vaccination event, such as events where thousands of recipients wait in parking lots or sports stadiums to be vaccinated by public health officials. However, of those who have received their vaccine, 17% said they received it at a mass vaccination event, whereas 9% received it at a pharmacy or other store, according to the results.
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Drugs Topics® interviewed Lee Rosebush, PharmD, JD, MBA, partner at BakerHostetler law firm, on the regulatory and compliance challenges facing pharmacists in administering COVID-19 vaccines.

In the 3-part interview, Rosebush highlighted the major regulatory considerations, including interchangeability issues, data reporting requirements, and eventual FDA approvals of the vaccines. In offering guidance, Rosebush urged pharmacists to review their state plan for individuals eligible for receiving the vaccine and to follow proper procedures in documenting. Diligent record keeping is especially important because of the differences between the vaccines. For example, the Pfizer vaccine doses are given 21 days apart, whereas Moderna's are given 28 days apart.

Rosebush also discussed cost considerations regarding COVID-19 vaccines. "My 1 big pet peeve with a lot of the discussions around the PR of free vaccines is they ignore some of the other costs besides just the shot itself," Rosebush said. He noted that the peripheral issues of other costs, such as the supplies required to administer the vaccine as well as personnel time, can affect the pharmacy’s bottom line. "As pharmacists, if we’re going to walk away from the bench and dispensing prescriptions to be able to do this, we need to ensure the survival of our pharmacies while we’re administering these [moving forward]."

To watch the full interview, visit www.drugtopics.com/expert-interviews.

CMS Increases Medicare Reimbursement for COVID-19 Vaccines

By Jennifer Barrett

The Centers for Medicare & Medicaid Services (CMS) increased the Medicare payment amount for administering the coronavirus disease 2019 (COVID-19) vaccine. Effective for COVID-19 vaccines administered on or after March 15, 2021, the national average payment rate for physicians, hospitals, pharmacies, and many other immunizers will be $40 to administer each dose of the vaccine. This nearly doubles the Medicare reimbursement rate for the administration of the vaccine per dose.

The National Community Pharmacists Association (NCPA) issued a statement in support of the higher reimbursement rate.

“There are more than 21,000 small business community and long-term care pharmacies in the country,” NCPA CEO B. Douglas Hoey, MBA, RPh, said in a statement. "Many are administering the vaccine now, but some would lose money at the current reimbursement rate."

Study: Regular Exercise Can Benefit Individuals With Migraine

By Christine Blank

Individuals who exercise regularly may reduce their rate of migraine triggers; more than two-thirds of individuals with migraine do not get enough exercise, according to the results of a new preliminary study.

The findings, which will be presented at the American Academy of Neurology’s 2021 Virtual Annual Meeting being held April 17 to 22, showed that those who endure a minimum of 2.5 hours of moderate to vigorous exercise per week had a reduced rate of migraine triggers such as stress, depression, and sleep problems.

The study involved more than 4,600 participants. Of the participants in the group who did not exercise, 5% had low headache frequency and 48% had high headache frequency. Of those in the high-exercise group, 10% had low headache frequency and 28% had high headache frequency, according to the data. Additionally, 47% of participants in the group that did not exercise reported depression compared with 25% of those in the group that exercised the most. Thirty-nine percent of participants in the no-exercise group reported anxiety compared with 28% in the high-exercise group.
Patients with migraines had a much worse experience with symptoms during the coronavirus disease 2019 (COVID-19) pandemic, according to recent research.¹

In a study published in the Journal of Headache and Pain, investigators reported an increase in migraine frequency and severity among patients compared with the prepandemic period. The investigators administered an online, self-reported survey that included demographic, migraine-related, COVID-19–specific, and overall psychosocial variables between July 15 and July 30, 2020.

During the pandemic, approximately 60% of patients indicated an increase in migraine frequency, 16% indicated a decrease in frequency, and 10.3% indicated a transition to chronic migraine.

Additionally, most of these patients (61.5%) did not communicate with their neurologists during this time. Nearly half (46.9%) reported adherence to treatment and 58.7% said they overused analgesics. This may make it more important for pharmacists to provide counseling about treatment options for patients with migraine.

Moreover, approximately 80% of patients reported symptoms of anxiety and/or depression during the pandemic and 78% had sleep disturbances. Long-term strategies should be validated and implemented to deliver quality care for patients with migraine, with emphasis on psychosocial well-being, the investigators concluded. ■

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SCALING UP

TELEPHARMACY FOR THE FUTURE

By Fred Gebhart
Telepharmacy has gone from a pilot project to accepted practice in 25 states, according to Jessica Adams, PharmD, director of regulatory affairs for Telepharm, an early telepharmacy provider acquired by Cardinal Health in 2016. Many states who do not have telepharmacy rules in place today, are in some stage of approving telepharmacy as pharmacists and patients continue to push the need for access to pharmacy care. As pharmacists, providers, patients, payers, and regulators recognize the benefits that telehealth can bring to pharmacy, technology-based services will continue to expand.

At its simplest, telepharmacy allows a pharmacist to supervise a remote dispensing site via Health Insurance Portability and Accountability Act-compliant, 2-way audio-visual technology. The pharmacist remotely supervises the telepharmacy technicians, verifies prescriptions, and counsels patients from their host pharmacy location. Newer iterations are combining remote oversight with other familiar technologies to expand the reach of pharmacy care.
COVER STORY / SCALING UP TELEPHARMACY FOR THE FUTURE

Remote Sterile Compounding
One of the newest expansions is using remote verification for sterile intravenous (IV) compounding at the University of North Carolina (UNC). Pharmacists saw the potential to balance workload across multiple pharmacies that were using BD Pyxis IV Prep to prepare sterile IV solutions, explained Lindsey B. Amerine, PharmD, MS, BCPS, director of pharmacy and associate professor of clinical education at the UNC Eshelman School of Pharmacy in Chapel Hill, North Carolina. She proposed a double-arm, prospective study of remote versus onsite verification at 4 UNC pharmacies.

The Pyxis system uses gravimetric-based technology to weigh and verify compounded products, Amerine explained. The system images the compounding process, which is typically managed by a technician and reviewed by a local pharmacist. Because the onsite pharmacist was using images generated by the system, there was no obvious difference between reviewing images in the next room or 25 miles away.

Results of the 90-day trial demonstrated no difference in accuracy or safety for remote versus local oversight, and resulted in an annualized cost savings of nearly $24,800, according to Amerine. “When we did the study, the state had no rules around this kind of telepharmacy,” Amerine said, “so we designed the trial with remote plus onsite review of all compounded sterile products.” When the coronavirus disease 2019 (COVID-19) pandemic started, “we received a waiver from the board of pharmacy to be able to do this remote sterile product check as long as the health emergency lasts,” she said.

“Our next initiative is to be able to use telepharmacy routinely in the long term to do more workload sharing across sites. There is also the advantage of having a pharmacist able to check product from anywhere in the hospital. Not being tied to the pharmacy frees you up to spend more time with patients,” she added.

Secure Medication Storage
Roger Rose, RPh, director of pharmacy services for Wickenburg Community Hospital, opened the first telepharmacy in Arizona in 2019. Wickenburg has long had a satellite clinic in the town of Congress, which is about 16 miles away. With a population of 3500, Congress is too small to support an onsite pharmacist, Rose said. The drive to Wickenburg to fill prescriptions is not always practical for patients.

“We were doing deliveries to the Congress clinic twice a day, but that didn’t always work, either,” Rose said. “Patients still had to go home after their clinic visit, then come back later, or maybe the next day. Too many prescriptions never got picked up.”

When Arizona approved telepharmacy in 2018, Rose had a solution and 2 more problems. One was security. Most telepharmacy operations he visited had a single technician handling the entire operation.

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A Pharmacist in Every Room
Adam Chesler, PharmD, MBA, senior vice president for pharmacy integration at VillageMD, a network of primary care clinics, envisions a day when every patient in nearly 2000 primary care clinics can have a pharmacist consult. Some consults will likely come through an in-person Walgreens pharmacist. Walgreens is investing $1 billion to support up to 700 new...
Village Medical primary care clinics at its locations by 2025. Other consults will likely come via telepharmacy.

“Having a pharmacist directly involved in care improves patient outcomes,” said Chesler. “By integrating a pharmacist into primary care, we have shown significant, sustained increases in medication adherence to treat cholesterol, diabetes, and hypertension. We can utilize telepharmacy and telehealth technology by taking an iPad or tablet into any exam room and having a conversation between the pharmacist, physician, and patient anywhere, anytime.”

The telepharmacy technology already exists, and VillageMD already has a focus on pharmacy integration. Patients with multiple chronic disease states or those who use multiple pharmacies have an elevated risk of therapy failure. These patients already receive in-person or telephonic pharmacy consultations, as do discharged and homebound patients. Telepharmacy can further expand this reach. Pharmacists in these settings have full access to patient electronic medical records, a common communication platform with clinicians, and collaborative practice agreements with delegated prescribing authority.

“We are taking full financial risk for many Medicare patients,” Chesler explained. “The physicians here understand that the best way, the only way, to successfully improve outcomes and reduce costs is by having pharmacists directly integrated into the care team. Having a pharmacist on the care team is integral to our success, and telepharmacy can help make that integration happen.”

**Smoothing Regulatory Bumps**

As telepharmacy evolves, regulators are playing catch-up. On a federal level, the COVID-19 pandemic called for loosened telehealth restrictions overall during the public health emergency. The Centers for Medicare & Medicaid Services (CMS) expanded the number of covered services that can be provided via telehealth. Many of these changes are noted as temporary during the COVID-19 emergency period. However, as telehealth benefits prove valuable, it is the hope that these changes will carry over post pandemic, enabling telepharmacy expansion.

Many states already had telepharmacy laws in place prior to the pandemic. California’s legislature authorized telepharmacy in 2018. It took 2 years to work out the regulatory details and open the state’s first telepharmacy Arizona’s first telepharmacy was 6 years in the making.

“When we first asked, the state pharmacy board told us they had no regulations and nothing in the practice act that would let them authorize telepharmacy for the hospital’s remote clinic,” said Rose. “Five years later, they had changes to the practice act, called us back for a hearing in July, and we were licensed the next April.”

Outreach to the state board, showing up at board meetings, and providing public comments make the difference, said Adams. “Each state is unique and has its own challenges, but access is an issue everywhere. Telepharmacy has been proved to work for 20 years and is now permitted in 25 states. If pharmacists attend board of pharmacy meetings and explain how telepharmacy can reduce gaps in pharmacy care that their patients are experiencing, it can make a positive difference in getting telepharmacy moving,” she explained.

Changing pharmacy regulation and legislation is a team sport, Adams continued. Arizona was slow to adopt telepharmacy in part because chain pharmacists feared remote oversight could lead to job losses. The Arizona Pharmacy Association demanded language in the practice act to safeguard pharmacist employment.

Rural health associations can be solid partners, particularly for pharmacists seeking to bring telepharmacy to underserved rural areas. Federally qualified health centers, health systems, and physician practices that recognize the advantages of bringing pharmacy to the care team can help build support.

“The basic message is telepharmacy safely provides greater access to pharmacist care,” Adams said. “Why are we not using a proven technology to help ensure that our patients are getting the best pharmacy care possible? The more stakeholders you bring to support your message, the more likely you are to get a positive response.”

For references, visit drugtopics.com.
COVID-19 Therapy Pipeline Update

Here’s an overview of what’s in the late-stage pipeline.

By Kendall Haney, PharmD Candidate; and Jonathan Ogurchak, PharmD, CSP

The treatment landscape for patients with coronavirus disease 2019 (COVID-19) infections is constantly evolving, particularly as new information related to the disease is identified. The following is a current glance at several agents under investigation to keep you up-to-date with the latest advancements.

**Bamlanivimab**

Bamlanivimab is a recombinant human immunoglobulin G1K monoclonal antibody (mAb) originally developed by the National Institute of Allergy and Infectious Diseases (NIAID), AbCellera, and Eli Lilly and Company from blood samples of the first patients to recover from COVID-19 in the United States. The mAb targets COVID-19 spike proteins to prevent the virus from binding to angiotensin-converting enzyme 2 (ACE2) on the surface of host cells, effectively preventing entry for replication. A phase 1 clinical trial began in May 2020 and ended in August 2020, enrolling patients hospitalized with COVID-19 who were not mechanically ventilated to assimilate an adverse effect (AE) profile and monitor changes in viral load with the addition of bamlanivimab. The drug is undergoing phase 2 and phase 3 trials.

**BLAZE-1 (NCT04427501)**

Phase 2, or BLAZE-1, started in June 2020 and is a randomized, double-blind, placebo-controlled clinical trial targeting early treatment with bamlanivimab in over 3000 patients with mild to moderate symptomatic COVID-19. The study’s goal is to evaluate safety and efficacy with monotherapy and in combination with additional antibody treatment for 12 weeks. Three doses are being tested in the monotherapy treatment arms: 700 mg, 2800 mg, and 7000 mg. Primary outcome data were reported in September 2020 showing significant reduction in viral load and hospitalization with AEs including infusion-related reactions and anaphylaxis.

**BLAZE-2 (NCT04497987)**

Phase 3, or BLAZE-2, is a randomized, double-blind, placebo-controlled clinical trial and, like BLAZE-1, is in progress. The study focused on enrolled staff and patients in nursing home settings to evaluate the use of bamlanivimab for the prevention of COVID-19 in this high-risk patient population.

Based on the BLAZE-1 results, the FDA granted emergency use authorization (EUA) on November 9, 2020, for treatment with 1 administration of bamlanivimab 700 mg intravenous (IV) infused over 1 hour in patients 12 years and older with mild to moderate COVID-19 at high risk for hospitalization within 10 days of symptom onset. On February 9, 2021, bamlanivimab received another EUA in combination with etesevimab to treat patients 12 years and older with mild to moderate COVID-19 at high risk for hospitalization; dosing is specified as 700 mg of bamlanivimab and 1400 mg of etesevimab infused over 16 to 21 minutes within 10 days of symptom onset. This additional EUA was established based on outcomes reported through the BLAZE-1 trial on January 26, 2021, demonstrating that use of bamlanivimab with etesevimab decreased hospitalizations and deaths by 70%.

**Ivermectin**

Ivermectin is an agent being considered for possible use in early COVID-19 treatment and is undergoing phase 3 clinical trials. Ivermectin is...
approved by the FDA as a broad-spectrum anthelmintic agent indicated for use in humans and animals. The primary mechanism of action targets the glutamate-gated chloride channels in nematodes, but has additional action that targets α/β-mediated nuclear transport in many RNA viruses such as West Nile and influenza.7,9 There has been evidence to show that the α/β-mediated nuclear transport is considered an essential component for viral replication/transmission in the severe acute respiratory syndrome coronavirus (SARS-CoV) strain.6,9 Australian investigators conducted a study that tested the effects of ivermectin on cell cultures infected with COVID-19 and determined that viral production was completely blocked for 48 hours after initial exposure to the drug; however, the study used doses up to 100 times the standard oral maximum plasma concentration.12 The National Institutes of Health released a statement on January 14, 2021, saying that ivermectin has insufficient data for current use for treatment of COVID-19 after multiple studies have shown conflicting results. As of October 1, 2020, Temple University in Philadelphia, Pennsylvania, is conducting a phase 3, randomized, parallel-arm, triple-masking clinical trial (NCT04530474) studying the use of single-dose ivermectin at 0.15 to 2.0 mg/kg per dose (maximum 12.0 mg) against placebo in patients 18 years or older with estimated completion on June 30, 2021.9

**Bucillamine**

Bucillamine is an antirheumatic medication commonly used in South Korea and Japan that is being researched for use in mild to moderate COVID-19 infections.10 The University of California San Francisco discerned that thiol-based medications may provide treatment for COVID-19 infection.11 Regarding the mechanism of action of SARS-CoV, it is understood that virus entry into the cell is dependent on conformational changes that occur between the disulfide and thiol structures on the surface of the virus that take place when exposed to the ACE2 receptor.11,12 Revive Therapeutics began a phase 3 multicenter, double-blind, randomized clinical trial (NCT04504734) for prophylactic use of bucillamine in patients with COVID-19 with mild to moderate symptoms on November 27, 2020.13-16 The study enrolled 1000 participants and assigned them to 3 separate arms: bucillamine 100 mg 3 times a day, bucillamine 200 mg 3 times a day, or placebo 3 times a day for 14 days to determine whether the drug decreases occurrence of hospitalization or death.11,13 The phase 3 clinical trial is estimated to have been completed on February 1, 2020.13 Previously, bucillamine was approved to be used in the expanded access protocol (EAP) by the Institutional Review Board in hospitalized patients with COVID-19 without FDA approval. Revive Therapeutics released a statement on December 23, 2020, detailing aims to expand the EAP to include use of the drug in mild to moderate patient populations because of its easily accessible oral formulation.11,15

**BRII-196 and BRII-198**

BRII-196 and BRII-198 are 2 human mAbs used in combination to target and bind to the COVID-19 virus to prevent the spread of infection.14 BRII Biosciences Limited has reached phase 2/3 double-blind, randomized clinical trials with combination treatment of BRII-196 and BRII-198 mAb infusions in patients with mild to moderate COVID-19 symptoms.15,17 The trial (NCT04518410) is a part of the ACTIV-2 protocol that partners with the NIAID to coordinate and accelerate outpatient medication research for COVID-19 treatment.16,18 A total of 2000 patients 12 years or older with mild to moderate COVID-19 symptoms at high risk for hospitalization were enrolled in the ACTIV-2 trial and randomly divided into 2 treatment arms, one receiving the combination mAb infusion and the other receiving the placebo and then monitored for 12 weeks.16,17 The primary outcome is to determine the effect on symptom duration, AEs, and patient hospitalization and/or mortality within 28 days after treatment.16,17

**Regdanvimab**

Celltrion, based in South Korea, has proceeded with researching regdanvimab (CT-P59, Regkirona), a mAb selected for its ability to target COVID-19 and prevent the binding to the host cell, reducing viral load.19,20 Results from the randomized, double-blinded phase 2/3 clinical trials with combination treatment of trial medications, including regdanvimab, in hospitalized patients with severe cases of COVID-19 with no other treatment options; Celltrion is pursuing authorization for emergency use approval.21

For references, visit drugtopics.com.

Kendall Haney is a PharmD candidate at Duquesne University School of Pharmacy in Pittsburgh, Pennsylvania, anticipated to graduate in spring 2021.

Jonathan Ogurchak, PharmD, CSP, is the CEO and cofounder of STACK, a pharmacy information management platform, and serves as preceptor for a virtual Advanced Pharmacy Practice Experiential Rotation for specialty pharmacy, during which this article was composed.
Diabetes Treatment Guidelines, Practices Advance Despite COVID-19 Focus in Health Care

A session held during the American Pharmacists Association 2021 Annual Meeting and Exposition provided an update on diabetes practice changes and new treatments. By Fred Gebhart

Coronavirus disease 2019 (COVID-19) has flooded media headlines and health care practices for the past year, but diabetes has not taken a pandemic holiday. Professional groups continue to publish and update practice guidelines and the FDA continues to work on new diabetes drug applications. During a virtual session titled “New and Approved: Your Annual Diabetes Update” at the American Pharmacists Association Annual Meeting and Exposition, which was held March 12 to 15, Jennifer D. Smith, PharmD, BCACP, BC-ADM, CDCES, a clinical pharmacy specialist for the US Department of Veterans Affairs, provided an update on treatment advances in type 2 diabetes (T2D).

Continuous Glucose Monitoring
The FDA has approved continuous glucose monitoring (CGM) for ambulatory care, but pandemic pressures are spurring the use of CGM in all practice settings, especially inpatient. “You are going to see more CGM in the hospital setting,” said Smith during her presentation.

The FDA has not approved CGM for inpatient use, Smith noted. But a growing number of institutions are using CGM to reduce patient contact and consumption of personal protective equipment during the pandemic. As health system practices and procedures increasingly promote CGM, pharmacists should remember that CGM is not appropriate for intensive care or other critically ill patients, Smith said. All CGM use should be supervised to ensure that appropriate adjustments to insulin doses can be made in a timely manner. The American Diabetes Association (ADA) guideline goal for CGM is to maintain patients within their target glucose range at least 70% of the time, she noted.

New Glycated Hemoglobin Targets
It is also important to individualize glucose targets, according to Smith. The ADA’s global glycated hemoglobin (A1c) target is less than 7%. New 2021 guidelines target from less than 7% to less than 7.5% for healthy adults 55 years or older. Patients with complex cases might do better with an A1c target of less than 8%. However, in very complex cases, targeting A1c goals may not be helpful.

“Instead, let’s keep our patients comfortable and avoid glycemic extremes,” Smith said. “The goal is to avoid all hypoglycemia and any symptomatic hyperglycemia.”

Chronic Kidney Disease

A1c is the appropriate measure of glycemic control, but A1c accuracy and precision declines with advanced CKD, in dialysis, or when using erythropoietin-stimulating agents. Individualize A1c targets from less 6.5% to less 8.0% based on comorbidities. A glucose management indicator derived from CGM may be useful for glycemic assessment, especially in patients for whom A1c is not accurate because of declining kidney function, dialysis, or other treatment factors.

Metformin plus a sodium-glucose cotransporter 2 inhibitor (SGLT2i) can be used as a first-line treatment for T2D in CKD. Avoid SGLT2i treatment if the patient has an estimated glomerular filtration rate (eGFR) below 30 mL/min/1.73 m² and stop SGLT2i in dialysis. The preferred agents for patients with a low eGFR are a dipeptidyl peptidase 4 inhibitor, insulin, and a thiazolidinedione. The preferred add-on agent for all patients is a long acting glucagon-like peptide-1 (GLP-1) receptor agonist.
The ADA takes a different approach. For patients with CKD and no albuminuria, the ADA recommends a GLP-1 receptor agonist or SGLT2i with proven cardiovascular disease benefit. For patients with CKD and albuminuria, use a SGLT2i with a documented reduction in CKD progression. For patients who cannot use a SGLT2i, a GLP-1 receptor agonist is acceptable.

**Dyslipidemia**

The American Association of Endocrinology (AACE) and the American College of Endocrinology (ACE) published a new algorithm for the comprehensive management of dyslipidemia and prevention of cardiovascular disease. Lifestyle changes remain the primary management tool, but treatment recommendations have been updated since AACE/ACE last addressed dyslipidemia in 2017.

The low-density lipoprotein cholesterol (LDL-C) goal for high-risk patients with diabetes and no other risk factors is 100 mg/dL. The triglycerides (TG) goal is less than 150 mg/dL. Recommended treatment is a moderate- to high-intensity statin as needed. Major risk factors include advancing age, elevated non–high-density lipoprotein cholesterol (HDL-C), elevated LDL-C, reduced high-density lipoprotein cholesterol (HDL-C), diabetes, hypertension, CKD, cigarette use, or family history of atherosclerotic cardiovascular disease (ASCVD).

For very high-risk patients who have diabetes with 1 or more risk factors, the LDL-C goal is less than 70 mg/dL and the TG goal is less than 150 mg/dL. Add ezetimibe, a PCSK9 inhibitor, colesevelam, or bempedoic acid, depending on LDL needs.

For extreme-risk patients with established clinical ASCVD and diabetes, the LDL-C goal is less than 55 mg/dL and the TG goal is less than 150 mg/dL. Add a PCSK9 inhibitor, ezetimibe, colesevelam, or bempedoic acid, depending on LDL needs. For patients with diabetes, 2 or more risk factors and TG 135 to 499 mg/dL, add icosapent ethyl.

**Heart Failure**

Patients with heart failure with reduced ejection fraction (HFrEF), left ventricle ejection fraction less than 45%, the ADA recommends an SGLT2i with proven heart failure benefits. Prescribers have multiple choices, according to Smith.

Two agents, dapagliflozin and empagliflozin, have primary heart failure data. Three agents—empagliflozin, canagliflozin, and dapagliflozin—have shown reduction in heart failure and reduction of CKD progression in cardiovascular outcome trials.

**Overbasalization**

The 2021 ADA guidelines introduced a new concept: overbasalization, which is characterized as an excessive basal dose of insulin. Too much basal insulin can overcorrect fasting glucose levels, which then rebound to excessive levels, Smith explained. Typical examples of overbasalization are an elevated bedtime-morning glucose differential, greater than 50 mg/dL; an elevated postprandial differential, hypoglycemia, and high glucose variability.

Guidelines noted overbasalization is a potential concern anytime the basal dose exceeds 0.5 U/kg/d, Smith said. Any indication of overbasalization should prompt reevaluation of insulin dosing to reduce glucose variability.

**Glucocorticoid Therapy**

High-dose glucocorticoids can increase the need for insulin. Patients with diabetes who start high-dose prednisone for an asthma flare, for example, need a corresponding increase in insulin. Neutral protamine Hagedorn insulin protocol is the standard approach for once-daily or twice-daily steroids, Smith said.

Insulin formulation and dose should match the steroid. A long-acting steroid needs a long-acting insulin, and increasing doses of steroids need increasing doses of basal, prandial, and correctional insulin. The ADA recommends an increase of 0.1 IU/kg of insulin for each 10 mg/d of prednisone to a maximum of 0.4 IU/kg for 40 mg or more of prednisone.

**New Agents Coming**

At least 4 new agents are in the pipeline, Smith reported.

- **Tirzepatide**, a once-weekly “twincretin” combination of a GLP-1 receptor agonist and a glucose-dependent insulinotropic polypeptide, showed solid phase 3 data in T2D. A cardiovascular outcomes trial is ongoing.

- **Finerenone**, a nonsteroidal selective mineralocorticoid receptor antagonist, reduced the risk of composite cardiovascular outcomes in patients with CKD and T2D in the FIDELIO-DKD trial (NCT02540993). The agent’s application has been submitted to the FDA, she said, and a decision is expected sometime this summer.

- **Dasiglucagon**, a prefilled rescue pen for severe hypoglycemia, is under review by the FDA.

- **Insulin icodect**, a once-weekly basal insulin, showed efficacy and safety profiles similar to once-daily insulin glargine U100 in T2D.

For references, visit drugtopics.com.
**Updates in Pharmacy-Based Immunization Practices**

A session at the American Pharmacists Association 2021 Annual Meeting and Exposition addressed recent immunization practice changes. By Jennifer Barrett, Senior Editor

During a virtual session at the American Pharmacists Association (APhA) 2021 Annual Meeting and Exposition, which was held March 12 to 15, experts provided updates in pharmacy-based immunizations. Stephan L. Foster, PharmD, APhA’s liaison to the CDC’s Advisory Committee on Immunization Practices (ACIP), and Jeffrey Goad, PharmD, professor and chair of the Department of Pharmacy Practice at Chapman University School of Pharmacy in Irvine, California, discussed the evolving practice of pharmacy-based immunization from coronavirus disease 2019 (COVID-19) vaccines and common routine immunizations to upcoming vaccines in the pipeline.1

**Schedule Changes**

Foster and Goad presented the recent updates to immunization schedules for children, adolescents, and adults. The 2021 childhood immunization schedule included the following changes2:

- **Influenza:** Revised to reflect the recommendations for the 2020-2021 season. The Special situations section was updated with language for individuals who have egg allergy with symptoms other than hives. In addition, the circumstances under which the live attenuated influenza vaccine (LAIV4) should not be used were updated to include children younger than 2 years and more detailed information on the use of LAIV4 after the receipt of influenza antiviral medications.

- **Meningococcal groups A, C, W, and Y (Men ACWY):** MenACWY-FTT (MenQuadfi) has been added as an option. In addition, the Special situations section has been updated with information on the recommendations for use of MenACWY-CRM (Menveo) in infants who received dose 1 at age 3 to 6 months.

Additionally, edits were made in the Notes section to improve readability and clarification of the schedule for diphtheria, tetanus, pertussis, haemophilus influenzae, hepatitis A, hepatitis B, human papillomavirus (HPV), pneumococcal 13-valent conjugate, and pertussis (Tdap) vaccines.2

In the adult immunization schedule, changes also included edits to tables and notes for hepatitis A, hepatitis B, HPV, influenza, Men ACWY, meningococcal B, pneumococcal, Tdap, and zoster vaccines. The hepatitis B vaccination recommendations were revised to recommend shared clinical decision-making (SCDM) for individuals with diabetes 60 years and older. Additionally, SCDM was also included for the HPV vaccine for individuals aged 27 to 45 years.3

For both adult and childhood vaccination schedules, ACIP added notes to recommend the use of COVID-19 vaccines within the scope of the emergency use authorization or biologics license application for the particular vaccine.3

**COVID-19**

Developments around COVID-19 vaccines are constantly changing, making it imperative for pharmacists to stay up-to-date. Currently authorized vaccines in the United States include Pfizer-BioNTech’s BNT162b2, Moderna’s mRNA-1273, and Johnson & Johnson’s Ad26.COV2.S. AstraZeneca’s viral vector vaccine AZD1222 may be another vaccine on the horizon in the coming weeks. Novavax’s NVX-CoV2373, a protein subunit vaccine, is also in phase 3 trials.1

Pharmacists must be cognizant of the differences in vaccine doses and storage among all vaccines (see Table).1

Currently, the CDC has no preference as to which of the COVID-19 vaccines is used, but none of the vaccines should be interchanged for the series. However, if different vaccines are accidentally used for the first and second doses, no extra doses...
are required. Additionally, COVID-19 vaccines were not studied simultaneously with the administration of other vaccines. Therefore, the CDC recommends avoiding administering other vaccines within 14 days of a COVID-19 vaccine, unless the benefits are deemed to outweigh the potential risks.\(^1\)

**Influenza**

The presenters provided an overview of available influenza vaccines and updated virus selection for the 2021-2022 vaccines. The World Health Organization’s recommendations for the composition of quadrivalent flu virus vaccines for the 2021-2022 season include the following:\(^1\)

**Egg-based vaccines**
- an A/Victoria/2570/2019 (H1N1) pdm09-like virus,
- an A/Cambodia/e0826360/2020 (H3N2)-like virus,
- a B/Washington/02/2019 (B/Victoria lineage)-like virus, and
- a B/Phuket/3073/2013 (B/Yamagata lineage)-like virus.

**Cell- or recombinant-based vaccines**
- an A/Wisconsin/588/2019 (H1N1)pdm09-like virus,
- an A/Cambodia/e0826360/2020 (H3N2)-like virus,
- a B/Washington/02/2019 (B/Victoria lineage)-like virus, and
- a B/Phuket/3073/2013 (B/Yamagata lineage)-like virus.

On March 5, 2021, the FDA approved Flucelvax (Seqirus) for an expanded indication for use in individuals 2 years and older.\(^4\) Flucelvax is the only cell-based influenza vaccine that has been licensed by the FDA for use in the United States. Cell-based flu vaccine production does not use flu viruses grown in eggs, and therefore it allows the vaccine to avoid egg adaptation.\(^3,5\) The vaccine was initially approved in May 2016 for individuals 4 years and older.\(^1\)

**Other Vaccine Updates**

**Pneumococcal**

Higher-valent pneumococcal conjugate vaccines are anticipated for license in June 2021 and July 2021 for Pfizer’s 20-valent pneumococcal conjugate (PCV20) and PCV15 (Merck), respectively. Additionally, licensure for children is anticipated for Q2 to Q3 2022 for PCV15 or mid-2023 for PCV20. Both PCV15 and PCV20 are well-tolerated and have a safety profile similar to PCV13 (Pfizer). Both vaccines are immunogenic, with PCV15 eliciting an immunological response superior for serotype 3 at 30 days post vaccination. A pneumococcal workgroup was formed by ACIP to review considerations for use of both higher-valent vaccines in the general population of US adults and in adults with certain underlying conditions.\(^3\)

**Herpes Zoster**

The CDC recommends that healthy adults 50 years and older receive 2 doses of the recombinant zoster vaccine (RZV, Shingles; GlaxoSmithKline), separated by 2 to 6 months, to prevent shingles and complications from the disease.\(^6\)

At the October 2020 ACIP meeting, officials presented that RZV postlicensure safety monitoring in the Vaccine Adverse Event Reporting System (VAERS) is generally consistent with the safety profile observed in prelicensure clinical trials, including for the risk of Guillain-Barré syndrome (GBS). Additionally, Vaccine Safety Datalink (VSD) data from postlicensure safety monitoring showed that the previous preliminary safety signal for Bell palsy did not persist. There was also no sustained evidence of increased risk of GBS among RZV recipients. An overall increased risk of GBS was identified in a review of GBS cases following herpes zoster infections from 2010 to 2018.\(^1\) A working group is reviewing evidence regarding the use of RZV in immunocompromised adults.\(^6\)

For references, visit drugtopics.com.

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**TABLE. COVID-19 VACCINE COMPARISONS FOR DOSE AND STORAGE\(^1\)**

<table>
<thead>
<tr>
<th>Name</th>
<th>PFIZER/BIONTECH</th>
<th>MODERNA</th>
<th>JOHNSON &amp; JOHNSON</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vaccine type</td>
<td>mRNA</td>
<td>mRNA</td>
<td>Adenovirus vector</td>
</tr>
<tr>
<td>FDA emergency use</td>
<td>December 11, 2020</td>
<td>December 18, 2020</td>
<td>February 27, 2021</td>
</tr>
<tr>
<td>authorization</td>
<td>Regimen</td>
<td>Doses per vial</td>
<td>Storage requirements</td>
</tr>
<tr>
<td>Two 0.3-mL doses 21 days apart</td>
<td>Two 0.5-mL doses 28 days apart</td>
<td>5 doses per vial (6 doses acceptable); reconstituted</td>
<td>Standard freezer up to 2 weeks</td>
</tr>
<tr>
<td>2 doses</td>
<td>10 doses per vial (11 doses possible); no reconstitution</td>
<td>5 doses per vial; no reconstitution</td>
<td>Standard freezer</td>
</tr>
<tr>
<td>One 0.5-mL dose</td>
<td>One 0.5-mL dose</td>
<td>Standard refrigerator</td>
<td>Standard refrigeration</td>
</tr>
</tbody>
</table>

**COVID-19, coronavirus disease 2019**
Assess and Manage Your Pharmacy’s Profitability

Examine the most essential financial key performance indicators for pharmacy businesses. by Keith Loria

To be successful, independent pharmacists must identify the most essential financial key performance indicators (KPIs) for their businesses. For pharmacy owners, having a simple awareness of their pharmacy’s specific KPIs is crucial, according to Christopher Cella, RPh, national vice president for RxOwnership at McKesson, a no-fee resource for independent pharmacies seeking financial and ownership transaction guidance. “Some owners need help identifying what measures are important and what needs to be monitored from a financial standpoint,” he said. “Once that is established, how do their results match up against other pharmacy owners in similar market areas, demographics, and services? After you know what your financial results are, you need to understand how to interpret these results as well as understand what levers can be or need to be adjusted to change your results.”

Matthew Johnson, PharmD, chief pharmacy officer for FDS, a Fort Worth, Texas-based pharmacy solutions company, said pharmacists must identify critical actions that drive volume and profitability—and then determine which ones are most advantageous. “In an environment with high unit costs and low margins, profit takes precedence over revenue,” he said. “Utilize shorter feedback loops. Use KPIs that can be measured on daily and weekly cadences. A quarterly view is helpful, but it is far too long to wait before correcting the course.”

All pharmacists should ask themselves certain questions. For instance, do you manage your expenses? Or do you consider your store to be operating efficiently if at the end of the month there is money left over in your account after paying expenses?

Pay Attention to Controllable Costs

When it comes to helping pharmacists discover KPIs to help inform them on areas of profitability, Cella said independent pharmacy owners must identify their controllable costs. These are expenses one can alter that will directly affect financial results. “The 3 that come to mind, and the easiest to control, are inventory, payroll, and utilities,” he said. “Any change—positive or negative—in either inventory, payroll, or utilities will directly affect your bottom line. Typically, your payroll and inventory are also your largest numbers on the expense line of your profit-and-loss statement. Even if things are looking bleak financially, any pharmacist can control these 3 expenses by being diligent.

When it comes to inventory, Cella suggested using a replenishment system and a medication synchronization process. “Inventory should not be ordered immediately after a medication is dispensed,” he said. “It should be ordered just in time for the next prescription fill.” It is important to consider factors such as expiration dates and turnover rates for different products to avoid overstocking and potential profit loss from unused medications.

As for payroll, pharmacists should determine whether they are getting the most out of their employees and have the correct number of individuals on payroll assigned to legitimate tasks. Consider whether you are paying your employees according to market averages. “For utilities, are you monitoring your thermostat and keeping it in the right range?” Cella asked. “Do you have your lights and air conditioning on timers? Being aware of your controllable expenses and making meaningful changes can help the bottom line.”
“Managing the financial performance of a pharmacy is distinctly challenging. It is one of the few businesses where identical inventory can sell at wildly different prices depending on the payer.”  

Matthew Johnson, PharmD

Identify Areas to Improve Profits
Scott McDougall, MPharm, director and registered manager of The Independent Online Pharmacy, said sourcing the right medicines at the appropriate times in the correct quantities can affect profitability of independent pharmacies. “Some products are evergreen and will always be in demand, such as migraine medicine, while other products are seasonal, such as acne in colder months,” he said. “Your supplier should be able to provide enough stock to cater to these peaks and troughs in demand from consumers, and you should have an accurate planning schedule of how you stock seasonally relevant medicines and in what quantities.”

Another good way to improve profitability is to focus on medicines with the highest profit margins and build KPIs around those opportunities, according to Johnson. “High-level financial reports are often a great starting point,” he said. “Reporting allows pharmacists to dig deeper into brand versus generic sales, reimbursements by plan, and high-cost prescriptions.”

Once these areas of opportunity are pinpointed, Johnson explained, diagnostic tools can reveal the root causes of profitability changes. Often these opportunities can be categorized at the claim, patient, drug, or payer level. “For example, sometimes decreased profitability is not due to a [National Drug Code (NDC)] but rather a change in payer composition of patients prescribed those NDCs,” he said. “Uncovering these blind spots can inform the best KPIs to rally your team around.”

Late refills are prioritized by profitability. Johnson noted that in some cases pharmacies can recover significant profit up to hundreds of thousands of dollars in annual yield just on the KPIs related to late refills. Some KPIs used around this area of focus are the number of calls per week, total call time per week, and total recovered profit per week.

Johnson also suggested leveraging staff incentive programs to drive results. “Pharmacists drive the most significant results by using incentive programs that tie staff actions and outcomes to a reward,” he said. “It’s helpful to have a tech platform that automatically tracks staff contributions.”

Additionally, he recommended supercharging the prioritization of worklists. “Pharmacists can leverage technology recommendation tools to place a higher priority on adherence tasks when those patients are also tied to performance measures that have a higher impact on [direct and indirect remuneration] fees,” he said.

Optimize Financial Reporting
Independent pharmacists should also pay attention to their financial work-sheets, such as the monthly profit-and-loss statement, the balance sheet, and year-end statements. “As the owner, they should be receiving or producing a monthly profit-and-loss statement at the very least,” Cella said. “This will allow them to review revenue, gross profit, expenses, and net profit immediately after they occurred in the previous month. Pharmacy owners can see previous months’ results as well as month-over-month trends.”

This monthly report allows owners to make changes quicker and adjust as needed. Yearly reports do not show a picture of each month and it is very difficult to make changes at the end of the year if you do not know when an issue occurred.

Technology solutions that automate calculations are highly beneficial, making it easier to identify and track the most meaningful KPIs. Removing this manual process gives the pharmacy staff more time to focus on execution. Pharmacists can tap into resources such as RxOwnership, National Community Pharmacists Association Digest, or an accountant to help guide them in placing their businesses in better situations.

Final Thoughts
It is critical for pharmacists to make data-driven decisions as close to real time as possible. “Managing the financial performance of a pharmacy is distinctly challenging,” Johnson said. “It is one of the few businesses where identical inventory can sell at wildly different prices depending on the payer. Furthermore, cash flow projections become painstakingly complex from the retroactive DIR fees and stretched payment cycles.”

The coronavirus disease 2019 pandemic showcased to the public how quickly pharmacies can reinvent and reinvist themselves in their communities. A new era of pharmacy is dawning, in which profit from pharmacy services will eventually eclipse profit from prescriptions. As pharmacies prepare to take these leaps, it is more important than ever to maximize profit and efficiency.
Independent Pharmacy’s Best-Kept Secret in COVID-19 Vaccination

Stories about independent pharmacies not offering coronavirus disease 2019 (COVID-19) vaccines have flooded the local media in places like Philadelphia, Pennsylvania, and Colorado, but a different story is being told on the East and West coasts.

“Independent pharmacies and pharmacy owners can get the vaccine faster because it’s easier for them to communicate with county and city officials,” said Miguel Oseguera, CPhT, owner of Familia Farmacia in Modesto, California.

“Independent pharmacies and pharmacy owners can get the vaccine faster because it’s easier for them to communicate with county and city officials.”

Miguel Oseguera, CPhT

Ejtemai has a plan that will allow him to immunize patients quickly and efficiently. His current strategy is to vaccinate 25 to 50 patients at the same time. His pharmacy has 2 rooms that can be used for the mass immunizations, where patients will be able to maintain a safe social distance. Each room will hold scheduled immunizations at least an hour apart.

Patients receiving the vaccine will have completed and submitted their registration online before heading to the pharmacy. A staff member will check identification and paperwork to confirm that the patient qualifies. Once the patient is cleared, a pharmacist will administer the COVID-19 vaccine. Ejtemai plans to have 2 to 3 immunizers in the room giving vaccinations in series after confirming registration.

“By the time the immunizers get close to finishing giving out the shots in the first room, the 20-minute observation period would have already passed for most patients,” said Ejtemai. “Instead of moving people from room to room, you can move the vaccinator to the next room.”

Both Ejtemai and Oseguera serve communities of color, and they believe that independent pharmacies play a role in helping minority populations get the vaccine. Ejtemai attributes this to the fact that pharmacists working in independent stores can gain patient trust more easily than chain pharmacies can.

“When you go to a chain pharmacy, you see one pharmacist today another tomorrow, and you don’t make the connection,” he said. “Not only do my patients see me all the time, but they know my wife and my kids, too.”

He said that establishing a rapport with patients of color can be helpful in encouraging those who may be skeptical to be vaccinated. This especially holds true in Black and Hispanic communities that have historically been distrustful of the medical community because of the longstanding history of discrimination, biases, and mistreatment in the health care community.

Oseguera echoed Ejtemai’s sentiments that minority communities tend to respond more favorably to vaccines in the independent setting. He noted that members of his Mexican community who are reluctant to get the COVID-19 vaccine are more likely to be vaccinated when the person administering the shot looks like them.

Like big box pharmacies, some independent pharmacies are struggling to get some doses of any of the COVID-19 vaccines, which remain in limited supply. Regardless, Ejtemai and Oseguera offer the following tips to help independent pharmacies immunize their patients.

1. Consider participating in programs that increase access to vaccines. Independent pharmacies can access vaccines through 2 channels: the Federal Retail Pharmacy Program and pharmacy networks such as LeaderNet, Medicine Shoppe, and CPESN USA that service independent pharmacies.

2. Take the initiative to meet with local government officials about your vaccine needs. Unlike pharmacy chains, independents have less bureaucracy, so making these decisions can lead to faster results.

3. Take advantage of the intimacy and increased opportunity for patient interaction that independent pharmacy settings offer. A strong pharmacist-patient relationship can help solve medication-related problems because the patient will be more likely to communicate with the pharmacist.
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Reducing Pharmaceutical Waste in the Store

Pharmacists can take steps to ensure safe disposal of unused or expired medications. By Aine Cryts

Warfarin, a lifesaving medication, is commonly used to treat blood clots and reduce their occurrence, thus preventing heart attack, stroke, or other serious conditions such as deep vein thrombosis in the legs or a pulmonary embolism in the arteries of the lungs.

Warfarin is a derivative of a naturally occurring substance originally discovered in 1940 as a compound in moldy hay. In 1948, the substance was marketed as rat poison. Because of its high degree of acute oral toxicity, warfarin is in the FDA’s Toxicity Category I, the most serious such designation.

Elizabeth Isaac, PharmD, a medication safety pharmacist at UMass Memorial Medical Center in Worcester, Massachusetts, said safe disposal of warfarin requires pharmacists to contract with a biomedical waste vendor. Patients taking warfarin are advised to go on birth control as warfarin can interfere with fetal development. It is also important for women who are pregnant or breastfeeding, and men who want to become fathers to take precautions when handling this substance, Isaac added.

“You need to make it as easy as possible [for employees] to do the right thing.”

Elizabeth Isaac, PharmD

“[For one thing] we know that pharmaceutical waste, if not disposed of correctly, can end up in our drinking water…The [Environmental Protection Agency (EPA)] has come out with guidance about not allowing pharmaceutical waste into our water supply,” she said.

In addition, results of a 2015 study showed that pharmaceuticals in treated wastewater released into streams and other bodies may affect fish. The pharmaceuticals included in the study were hydrocodone, methadone, oxycodone, tramadol, methocarbamol, fluoxetine, paroxetine, venlafaxine, and temazepam.

Isaac said pharmacists should work with waste management vendors and their colleagues in hospital-based environmental health and safety departments for guidance on appropriate disposal of drugs.

She also has some practical advice: Creating open and clearly labeled containers to capture pharmaceutical waste is a must. “You need to make it as easy as possible [for employees] to do the right thing,” she added.

Keep Track of Medication Expiration Dates

Results of a 1963 study showed that a form of tetracycline, an antibiotic that can be used to treat acne and skin infections, caused renal tubular acidosis when outdated. However, some investigators disputed this finding. Other medications lose their potency over time. Examples include oral nitroglycerin, insulin, anticonvulsants, warfarin, digoxin, thyroid preparations, federal and state agencies engaged in regulating pharmaceutical drugs.

Specifically, he recommends that pharmacists learn how the various drug lists published by the Resource Conservation and Recovery Act, the United States Pharmacopeial Convention (USP) 800, and the National Institute for Occupational Safety and Health (NIOSH) may affect their pharmacies.

“It’s super important to understand the various lists of drugs because the EPA list is different from the USP 800 list. Additionally, NIOSH, [a] subsidiary of the CDC, has undergone extensive changes to their list and [has] published a new draft list in 2020 that is up for approval now,” Smith said.

The implications of these changes are numerous, including additions and removals of various active product ingredients and their classifications, said Smith. NIOSH recently communicated that modifications to its list should be approved in 2021, he added.

Prioritize Pharmacy Waste Management

Pharmacists are busy, but focusing on pharmacy waste must be a priority.

Federal and State Agencies

Chris Smith, RPh, director of product strategy for provider solutions at Inmar Intelligence, a Winston-Salem, North Carolina–based technology and data analytics services provider, observes that there are numerous
and oral contraceptives.\(^6\)

According to the FDA,\(^7\) certain expired medications can succumb to bacterial growth, whereas antibiotics that have lost their potency may be unsuccessful in treating infections, which can result in more serious illness and antibiotic resistance.

Most medications expire when they get to approximately 90% effectiveness, said Timothy Burkart, PharmD, an assistant professor of clinical practice in pharmacy at the University of Findlay in Ohio. After that, the chemicals start to break down and the medications become less stable.

Managing medication expiration dates is often done manually, explained Burkart. That means an intern pharmacist or a pharmacy technician will each be responsible for their own section of the pharmacy where they are tracking expiration dates. Once a month, they’ll look at the medications’ expiration dates and pull to the front medications that will expire after a year. An easy way to manage expiring medications is to flag them by marking the label with a bright dot, he said. Medications that are due to expire within a year should be pulled off the shelves and disposed of appropriately, advised Burkart.

Stephen Eckel, PharmD, MHA, associate dean for global engagement and associate professor at UNC Eshelman School of Pharmacy in Chapel Hill, North Carolina, said that although pharmacy interns and technicians can do this work, it is ultimately the pharmacist’s responsibility.

There are costs associated with having these medications incinerated, which is something pharmacy leaders should know, added Eckel. Expired medications are less likely to be an issue at retail pharmacies, where less inventory is kept on hand. By contrast, it is much more time-consuming and an ongoing process at hospital pharmacies where inventory is higher, he explained.

Isaac said hospital pharmacists should sustain relationships with team members in the environmental health and safety department who work closely with waste management vendors. It is just as important to work collaboratively with nurse managers throughout the hospital about proper medication disposal, she added.

**Participate in Drug Take-Back Days**

Expired or unused medications can have a negative impact on the environment and their communities. For example, unused opioid medications that are not disposed of appropriately can be diverted and exacerbate the nation’s opioid crisis, said Burkart. Burkart has helped organize drug take-back days, where members of the public can safely and easily turn in prescription drugs.

Overdose death accounts reached more than 86,000 individuals for the 12-month period that ended in July 2020, STAT reported in March.\(^8\) Pharmacists can participate in National Prescription Drug Take Back Day, which occurs on April 24 this year. They can also plan events with local law enforcement, said Burkart.

Partnering with local law enforcement is a must because opioids are regulated by the US Drug Enforcement Administration, among other federal and local agencies, he explained. “There are special rules about how you get rid of these drugs. They have to be taken out of circulation from the general population.”

Typically, opioid medications are destroyed through incineration at locations—sometimes old steel mills—at high temperatures. Filters are used to manage the release of smoke, which prevents the smoke from leaking into the environment, Burkart explained.

**4 Medications You Might Not Know Are Hazardous**\(^9\)

**Chemotherapy drugs**

They’re classified as an antineoplastic drug, along with cytotoxic and oncology drugs. Working with these substances during pregnancy could impact a woman’s chance of miscarriage or having a child with a birth defect.

**Lindane**

This substance is formulated in low concentrations in shampoo to treat head lice and is only applied for brief periods of time. It’s highly toxic to humans, which means it has to be kept out of drinking water.

**Inhalers**

Although the drugs inside inhalers aren’t considered hazardous, they are stored in compressed gas; this means they could be combustible.

**Nicotine**

This depends on the state where you practice. Nicotine was reevaluated by the Environmental Protection Agency in January 2020 for removal as hazardous, but not all states have adopted this change.

**Engage in Ongoing Planning and Education**

Smith advises pharmacists to conduct a thorough assessment of the pharmacy through the lens of regulatory compliance, employee and patient safety, and public safety. Also helpful is building a plan for handling exposures, spills, or other potentially harmful incidents; the plan should inform policies that deter abuse and diversion, he added.

Pharmacists must provide training for staff and patients, said Smith. Staff members need to know what to do if an incident occurs. Equally important, patients need to know about safe medication disposal techniques; advertising Drug Take-Back Days helps, as does providing a drug take-back kiosk at the pharmacy, he said.\(^9\)

For references, visit drugtopics.com.
New Drug Approval Update: What Pharmacists Should Know

Get the latest information on new treatments approved and marketed in the past year. By Gabrielle Ientile, Assistant Editor

In a virtual presentation during the American Pharmacists Association 2021 Annual Meeting and Exposition, which was held March 12 to 15, Daniel Hussar, PhD, MS, dean emeritus and Remington Professor Emeritus of Pharmacy, Philadelphia College of Pharmacy, University of the Sciences in Pennsylvania, discussed newly available drugs for indications related to cardiovascular disease, insomnia, migraine, and coronavirus disease 2019 (COVID-19), among others. Hussar used a New Drug Comparison Rating (NDCR) system to evaluate the safety, efficacy, and administration value of the list of new drugs.

According to Hussar, he intentionally centered his presentation on the drugs for which pharmacists are most likely to receive prescriptions, medication orders, or questions from patients.

Bempedoic Acid for Hypercholesterolemia

The first drug that Hussar presented was bempedoic acid (Nexletol; Espe-rion) for the treatment of hypercholesterolemia. The significance of the new drug indication is clear, according to Hussar. “Heart disease is the leading cause of death in the United States,” he said. “[Heart disease causes] an estimated 650,000 deaths each year. That’s higher than cancer-related deaths over the last year, it’s higher than the COVID-19-related deaths...and higher than the number of deaths occurring each year as a result of smoking-related complications.”

Bempedoic acid is an adenosine triphosphate-citrate lyase inhibitor that is administered orally as an adjunct to diet and maximally tolerated statin therapy for the treatment of heterozygous familial hypercholesterolemia or established cardiovascular disease in patients who require additional lowering of low-density lipoprotein cholesterol (LDL-C). The first step in treating hypercholesterolemia is dietary modification. If this strategy fails, the most preferred treatment is a statin, according to Hussar. “So, as we look at the indication, bempedoic acid is indicated as an adjunct, [which] means we’re adding it to diet and maximally tolerated statin therapy,” Hussar said.

Hussar cited clinical trials reporting that adjunct treatment with bempedoic acid led to the additional lowering of LDL-C by approximately 18%. “When we can add that to the benefit of the statin, that’s all the better,” Hussar said.

**Advantages of bempedoic acid:**
- its unique mechanism of action;
- its ability to extend the LDL-C–lowering effect of the statins;
- the low risk for it to cause skeletal muscle adverse events (AEs), such as myopathy; and
- its low propensity for reacting with other drugs.

**Disadvantages of bempedoic acid:**
- It’s not a first-line treatment for lowering LDL concentrations.
- The effect of cardiovascular morbidity and mortality remains unknown.
- The drug may cause hyperuricemia and gout, and tendon rupture.
- It has not been evaluated in pediatric patients.

Based on the NDCR rating system, Hussar rated bempedoic acid at a 4, pointing to significant advantages, including that it is a good option for patients who do not tolerate statins well.

Lemborexant for Insomnia

Lemborexant (Dayvigo; Eisai) is an orexin receptor antagonist indicated to be administered orally for the treatment of insomnia in adults. “Lemborexant may have a familiar ring for you because this is the second drug that is classified as an orexin receptor antagonist, joining suvorexant, which was initially approved and marketed about 7 years ago, under the brand name Belsomra,” Hussar said.

There are various patterns of insomnia, Hussar explained. Patterns associated with sleep onset describe patients who have difficulty falling asleep, whereas sleep maintenance issues occur when patients have a hard time staying asleep. In the case of lemborexant, data showed that the new agent has both fast onset and long duration of action.

In a clinical trial, lemborexant was more effective than zolpidem extended release 6.25 mg. “I like comparisons like that, when companies are willing to do that,” Hussar said. “But keep in mind that a 6.25-mg dose of zolpidem extended release is a low dose, and a lot of individuals are on the 12.5-mg potency.”

However, lemborexant has not been compared with suvorexant. “I identify that as a disadvantage, when studies against the comparable agents could have been conducted but were not,” Hussar said. For this reason, lemborexant received a rating of 3, as the drug
does not have any important advantages or disadvantages when compared with its predecessor, suvorexant, according to Hussar.

**Lumateperone for Schizophrenia**

Lumateperone tosylate (Caplyta; Intra-Cellular Therapies) is indicated to be administered orally for the treatment of schizophrenia in adults. The drug is similar to other orally administered atypical antipsychotic agents, including risperidone. “Most of the antipsychotic drugs have actions; typically, it’s a combined effect on certain serotonin receptor subtypes and certain dopamine receptors,” Hussar said.

Compared with risperidone, lumateperone may be less likely to cause extrapyramidal symptoms, weight gain, and hyperprolactinemia. As for its downsides, lumateperone may be less effective. Additionally, clinical response is less predictable with lumateperone, and the drug is offered in only 1 potency. “Think of some of the other antipsychotic drugs available in multiple potencies, actually a rather wide range of potencies,” Hussar explained.

“But… it is true that some individuals who either don’t experience the efficacy but do experience AEs with one of these agents…may respond much better to the use of another agent. So, some would say that any new antipsychotic drug is welcomed as an option,” Hussar continued. Regardless, Hussar gave lumateperone a rating of 2, citing its unpredictability in response.

**Ozanimod for Multiple Sclerosis**

Indicated for the treatment of multiple sclerosis (MS), ozanimod (Zeposia; Celgene) is a sphingosine 1-phosphate (S1P) receptor modulator administered orally. There are a few different subtypes of S1P receptors. “Whereas the first of these agents, fingolimod, exhibits activity at 4 of the 5 known receptor subtypes of S1P, the newest agent has a more selective action in acting at S1P receptor subtypes 1 and 5,” Hussar said. In effect, ozanimod is less likely to cause cardiovascular AEs than other MS treatments.

Not only that, but treatment with ozanimod also doesn't require cytochrome P450 2C9 genotype testing, unlike some of the other drugs indicated for MS. Ozanimod is administered for relapsing forms of MS, which represents approximately 85% of patients, Hussar said.

One disadvantage of ozanimod is its potential to interact with a wider range of other drugs. Additionally, as an immunomodulator drug, ozanimod must be monitored for the possible increased risk of infection, according to Hussar. “I’ve given this drug a rating of 4—more advantages than disadvantages,” Hussar said.

**Lasmiditan Hemisuccinate for Migraine**

“The condition for which more new drugs were approved and marketed during 2020 than any other is migraine headache,” Hussar presented. An estimated 37 million Americans suffer from migraines in a range of severities and they are often debilitating, he said. Lasmiditan (Reyvow; Eli Lilly and Company) is a serotonin 1F receptor agonist approved for the treatment of adult patients with acute migraine with or without aura.

**Advantages of lasmiditan:**

- It has a more selective action and has not been associated with vasoconstrictive effects.
- It is safer for use in a broader range of patients compared with similar drugs.
- It is less likely to lead to chest, throat, neck, or jaw pain or pressure, or lower seizure threshold.

However, lasmiditan has some drawbacks. It has not been directly compared with triptans in clinical studies. Other limitations are its higher likelihood to interact with heart rate-lowering drugs and to cause a central nervous system depressant action.

Lasmiditan received a rating of 4. “The message here is, yes, some individuals can benefit, but there are many others that don’t respond with the benefit that we would hope here when using these agents,” Hussar said.

**Remdesivir for SARS-CoV-2**

Lastly, Hussar spent time discussing remdesivir (Veklury; Gilead) for the treatment of COVID-19. Remdesivir is the first drug to be approved by the FDA for COVID-19 infection, according to Hussar. The drug is a severe acute respiratory syndrome coronavirus 2 nucleotide analogue RNA polymerase inhibitor, indicated for intravenous administration in adults and pediatric patients 12 years and older and weighing at least 40 kg who are hospitalized for COVID-19.

The largest clinical study for remdesivir set a primary end point of time to recovery. Hussar explained. “With the use of this drug, the median time to recovery was 10 days in comparison with a 15-day time to recovery when placebo was added to usual supportive care,” Hussar said.

Still, remdesivir has not yet demonstrated its ability to reduce the mortality rate in patients with COVID-19. Given the unprecedented situation, Hussar gave remdesivir a rating of 4. “It’s an important step forward. And my expectation is that we will see that the most effective [treatment] involves a combination of agents,” Hussar said.

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Pharmacists are uniquely positioned to develop and implement chemotherapy stewardship programs that allow them to lead multidisciplinary teams for establishing treatment paradigms that promote evidence-based, cost-effective therapies, according to Jason Bergsbaken, PharmD, BCOP, pharmacy coordinator for regional oncology services at UW Health in Madison, Wisconsin. Like antimicrobial stewardship programs, chemotherapy stewardships can help improve management of a constantly changing treatment landscape.

Chemotherapy stewardship programs provide the tools needed to improve patient outcomes. Currently, the American Society of Clinical Oncology (ASCO) has no guidance on developing or implementing chemotherapy stewardship programs. According to Kristen Ward, PharmD, an oncology pharmacist based in Sacramento, California, any oncology pharmacist can help establish a formal stewardship program by working collaboratively. “The aim of these programs is to train oncology pharmacists to provide high quality, cost-effective, specialty care to patients with cancer and hematologic disorders [in a way] that promotes independent critical thinking, creativity, and a culture of mutual respect with other health care providers,” she said.

Bergsbaken, a member of the National Comprehensive Cancer Network (NCCN) Pharmacy Directors Committee, said pharmacists can facilitate informed patient decision-making by incorporating anticipated treatment outcomes and costs. “At the individual patient level, pharmacists may help patients navigate complex treatment authorization networks to minimize out-of-pocket burden to patients,” Bergsbaken said. He explained that although recent expansions in treatment options are exciting, incremental improvements in patient outcomes are often overshadowed by substantially increased costs resulting in diminishing returns for society. “It is increasingly important to improve transparency of anticipated treatment outcomes with the overarching goal of maximizing therapeutic benefit while minimizing toxicity through the appropriate, targeted, and efficient use of available resources and therapies,” said Bergsbaken.

One of the primary purposes of chemotherapy stewardship programs is to ensure that facility resources are used appropriately based on gold standard guidelines such as NCCN’s or ASCO’s. Pharmacists typically encounter situations where an option for patient care does not align with these guidelines and is denied by a third-party payer. Matthew Paliughi, PharmD, a staff oncology pharmacist who has worked in inpatient and outpatient settings in Fresno and Clovis, California, said in such situations careful case analysis between pharmacist, physician, and insurance authorization team experts can result in a decision that is not detrimental to the patient in terms of efficacy and untowardly high co-payment. The interventions require reviewing phase 2 and 3 study data and reporting to prescribers.

“A current opportunity is the incorporation of biosimilar agents into routine prescribing, where pharmacists can be the initiators of conversation with physicians and facility pharmacy and therapeutics committees to help provide staggering cost savings to the organization with zero clinical detriment,” Paliughi explained. “Oncology is a rapidly evolving field that sees a newly approved agent entering the market on a nearly monthly basis. Because of this, pharmacy can become an asset when working together with the rest of the team to ensure excellent patient care and organizational success,” he said.
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IN MY VIEW / DISPENSED AS WRITTEN

By Peter A. Kreckel, RPh

I n October 2020, I started a new position as director of clinical services at Nickman’s Drug Store in Fayette County, Pennsylvania. Fayette County shares the border with West Virginia, our new home. Our goal was to live closer to our daughter and son-in-law, and especially our adorable 4-year-old grandson. We are also 1 hour closer to Pittsburgh, where our son’s family, including our 2 granddaughters, lives. However, in April 2021, I am making another career change.

One sacrifice I have to make is resigning from my teaching position at St Francis University, which is now 2.5 hours away. I will miss my Thursday mornings with the students and our interactions. Most of all, I will miss the spirit of St Francis University. Their tagline is “Become That Someone,” which is attributed to Jack Twyman, who cared for their most renowned graduate, Maurice Stokes, class of 1955.

In the final game of the 1957-1958 regular season, Stokes fell and suffered a subsequent brain injury. Three days later, on a flight to a playoff game in Detroit, Stokes suffered a series of seizures on the plane, leaving him paralyzed and unable to speak. Stokes and Twyman played for the National Basketball Association’s (NBA) Cincinnati Royals. The league provided no health insurance or pension plan.

Twyman began raising money for Stokes’ care by enlisting the help of the NBA’s stars. The first charity basketball game organized by Twyman was in 1958 and attracted 65 of the 90 players in the league. In 1964, the NBA players threatened to boycott the All-Star game in Boston, Massachusetts, forcing the owners to finally consider health and pension benefits. This act of defiance led to the riches the game enjoys today.

However, none of this was to benefit Stokes. For the next 12 years, Twyman took care of him, acting as his guardian. Stokes died in 1970 at the age of 36. When asked about providing care to Stokes, Twyman was quoted as saying, “Maurice was on his own, something had to be done, and somebody had to do it. I was the only one that was there, so I became that someone.”

On Thursday mornings I drive past the Stokes Athletic Center on my way to Sullivan Hall to teach pharmacology to a class of 55 physician assistant science students. I often think of the Twyman-Stokes relationship, and how helpless Stokes felt, because he could never repay Twyman for all his efforts. I am sure that after every hospital visit (12 years’ worth), Twyman got his payment in knowing he helped someone who truly needed him. I hope for the morning that I teach that my overwhelmed students see me as that someone who not only teaches this most difficult subject, but also cares deeply about them and their knowledge base needed to practice their profession.

What I will truly miss most after my 16-year teaching career at St Francis is the ability to affect future physician assistants. I taught them year-round from the beginning of June until the beginning of May for at least 3 hours on Thursday mornings. During that time slot, I strived to become that someone that they needed.

In the lifesaving profession of pharmacy we are given opportunities to become that someone daily. Whether we volunteer at a coronavirus disease 2019 vaccination clinic, teach a patient with a new diagnosis of diabetes how to use a blood glucose meter, or teach an Advanced Pharmacy Practices Experience student how to give compassionate care, we become that someone. More than ever with the disjointed health care so prevalent in our nation, our patients need us.

The next time you are doing medication synchronization to promote adherence, counseling a new mother on dosing of an antibiotic for otitis media, or giving a shingles or flu shot, for that space in time you have an opportunity to become that someone. As for me, the satisfaction of knowing I made a difference in their health care is what keeps me so energized with this amazing profession, even in this disjointed health care system.”

More than ever with the disjointed health care so prevalent in our nation, our patients need us.
On January 22, 2021, the FDA approved voclosporin (Lupkynis; Aurinia Pharmaceuticals) for the treatment of adult patients with active lupus nephritis (LN) in combination with a background immunosuppressive therapy regimen. Voclosporin is an oral calcineurin inhibitor immunosuppressant. Its activity results in inhibition of lymphocyte proliferation, production of T-cell cytokines, and expression of T-cell activation surface antigens. This is the first FDA-approved oral therapy for LN, a condition that can cause irreversible kidney damage and increase risk of kidney failure, cardiac events, and death.

The results of a 52-week randomized, double-blind, placebo-controlled trial (NCT03021499) show the efficacy of voclosporin in participants with a diagnosis of systemic lupus erythematosus and class III or IV LN (alone or in combination with class V LN) or class V LN. A total of 357 participants were randomized to receive either voclosporin 23.7 mg twice daily (n = 179) or placebo (n = 178). All participants received background immunosuppressant therapy targeted to a dose of 1 g twice daily and corticosteroid therapy adjusted to achieve a dose of 2.5 mg/d by week 16 of the study. The primary efficacy end point is the proportion of patients achieving complete renal response at week 52. At week 52, a higher proportion of participants achieved complete renal response in the voclosporin arm than the placebo arm (40.8% vs 22.5%; OR, 2.7; 95% CI, 1.6-4.3; P < .001). Administration of voclosporin compared with placebo is associated with a reduction in the time to urine protein-to-creatinine ratio of less than or equal to 0.5 mg/mg (median time of 169 days vs 372 days; HR, 2.0; 95% CI, 1.5-2.7). A greater proportion of participants who received voclosporin for 1 year in addition to background therapy achieved a reduction in kidney inflammation in comparison with those who received background therapy alone.

Prior to initiating voclosporin, obtain a baseline estimated glomerular filtration rate (eGFR) and blood pressure. Monitor renal function and blood pressure regularly throughout treatment. The most common adverse effects (AEs) include decreased eGFR (26%), hypertension (19%), diarrhea (19%), headache (15%), anemia (12%), and cough (11%). Other potential AEs include lymphoma, serious infections, nephrotoxicity, neurotoxicity, hyperkalemia, corrected QT interval prolongation, and pure red cell aplasia.

Voclosporin is a cytochrome P450 (CYP) 3A4 substrate. Avoid coadministration with moderate and strong CYP3A4 inducers. Voclosporin is a P-glycoprotein inhibitor; other medications may require a dose reduction when used in combination with voclosporin. Dose adjustments are recommended in severe renal impairment and mild to moderate hepatic impairment. Voclosporin should be avoided in pregnant patients. Patients on voclosporin should avoid live vaccines.

Voclosporin is administered as a 7.9-mg capsule. It must be swallowed whole on an empty stomach. Recommended starting dose is 23.7 mg orally every 12 hours. Voclosporin is approved in combination with mycophenolate and corticosteroids. Concomitant administration of voclosporin and cyclophosphamide should be avoided; further study is required to establish safety and efficacy of the combination.
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