$9 FOR A 90-DAY SUPPLY*

For adults on maximally tolerated statins with TG ≥150 mg/dL and established CVD or diabetes and ≥2 CVD risk factors

Add VASCEPA® (icosapent ethyl) to a statin for an additional 25% CV risk reduction

INDICATIONS AND LIMITATIONS OF USE

• VASCEPA® (icosapent ethyl) is indicated as an adjunct to maximally tolerated statin therapy to reduce the risk of myocardial infarction, stroke, coronary revascularization and unstable angina requiring hospitalization in adult patients with elevated triglyceride (TG) levels (≥150 mg/dL) and established cardiovascular disease or diabetes mellitus and 2 or more additional risk factors for cardiovascular disease.
• VASCEPA is indicated as an adjunct to diet to reduce TG levels in adult patients with severe (≥500 mg/dL) hypertriglyceridemia. The effect of VASCEPA on the risk for pancreatitis in patients with severe hypertriglyceridemia has not been determined.

IMPORTANT SAFETY INFORMATION

• VASCEPA is contraindicated in patients with known hypersensitivity (e.g., anaphylactic reaction) to VASCEPA or any of its components.
• VASCEPA was associated with an increased risk (3% vs 2%) of atrial fibrillation or atrial flutter requiring hospitalization in a double-blind, placebo-controlled trial. The incidence of atrial fibrillation was greater in patients with a previous history of atrial fibrillation or atrial flutter.
• It is not known whether patients with allergies to fish and/or shellfish are at an increased risk of an allergic reaction to VASCEPA. Patients with such allergies should discontinue VASCEPA if any reactions occur.

The wholesale price of VASCEPA is $344.22 for 120 1g capsules and $402.73 for 240 0.5g capsules. Commercially insured patients can save with the VASCEPA Savings Card. VASCEPA Savings Card may not be used to obtain prescription drugs paid in part by some Federal or State Programs, or where prohibited by law; see vascepahcp.com for more information. Generic icosapent ethyl capsules available from Hikma Pharmaceuticals do not have an approved indication for cardiovascular risk reduction. Amarin retains exclusivity for cardiovascular risk reduction and the Hikma generic should not be dispensed for this indication.

With the rise of COVID-19 cases nationwide, the Office for Civil Rights (OCR) has temporarily lifted penalties associated with private telehealth communications between health care providers and their patients. For additional information, please visit the temporarily updated guidelines at hhs.gov/hipaa.
GROUNDBREAKING RESULTS
On top of a statin, VASCEPA is proven to reduce the risk of a life-threatening CV event1 by an additional 25%2

IRREPRESSIBLE OF TG LEVELS
VASCEPA showed robust CV risk reduction irrespective of achieved TG levels2

AVAILABLE COST SAVINGS
With the VASCEPA Savings Card, commercially insured patients can pay as little as $9 for a 90-day supply. Subject to eligibility. Restrictions apply*

Scan to see plans that only cover VASCEPA.

Indicate "Dispense as written (DAW)" or "Brand medically necessary" to help ensure your patients are getting the benefits of VASCEPA

IMPORTANT SAFETY INFORMATION (cont’d)
• VASCEPA was associated with an increased risk (12% vs 10%) of bleeding in a double-blind, placebo-controlled trial. The incidence of bleeding was greater in patients receiving concomitant antithrombotic medications, such as aspirin, clopidogrel or warfarin.
• Common adverse reactions in the cardiovascular outcomes trial (incidence ≥3% and ≥1% more frequent than placebo): musculoskeletal pain (4% vs 3%), peripheral edema (7% vs 5%), constipation (5% vs 4%), gout (4% vs 3%) and atrial fibrillation (5% vs 4%)
• Common adverse reactions in the hypertriglyceridemia trials (incidence ≥1% more frequent than placebo): arthralgia (2% vs 1%) and oropharyngeal pain (1% vs 0.3%)
• Adverse Events, Product Complaints, or Special Situations may be reported by contacting AmarinConnect at 1-855-VASCEPA, emailing AmarinConnect@Amarincorp.com, or calling the FDA at 1-800-FDA-1088
• Patients receiving VASCEPA and concomitant anticoagulants and/or anti-platelet agents should be monitored for bleeding

Please see adjacent Brief Summary of full Prescribing Information for VASCEPA or go to www.vascepahcp.com.

*Offer Restrictions: May not be used to obtain prescription drugs paid in part by Federal or State Programs including Medicare, Medicaid, Medicare Advantage, Medicare Part D, Tricare, VA. Most eligible, insured patients will pay as little as $9 of their copay for either each month or a 90 day fill, with a maximum savings of up to $150 per month or $450 on a 90 day fill. Not for use by residents of VT, nor medical professionals licensed in VT. This offer is not valid for those patients under 18 years of age or patients whose plans do not permit use of a copay card. Void where prohibited by law, taxed, or restricted. Eligible patients include those who participate in commercial insurance, through a healthcare exchange, or pay cash. Offer good through December 31, 2021.

1Cardiovascular events including myocardial infarction, stroke, coronary revascularization, and unstable angina requiring hospitalization.

5 WARNINGS AND PRECAUTIONS

4 CONTRAINDICATIONS

2.1 Prior to Initiation of VASCEPA

4 USE IN SPECIFIC POPULATIONS

1 INDICATIONS AND USAGE

2 DOSAGE AND ADMINISTRATION

3 DOSAGE FORMS AND STRENGTHS

2.2 Dosage and Administration

6 ADVERSE REACTIONS

7.1 Increased Bleeding Risk with Anticoagulants and Antiplatelet agents

8.1 Pregnancy

3.1 Atrial Fibrillation/Flutter

3.4 Rhabdomyolysis

4.1 Atrial Fibrillation or Atrial Flutter

4.2 Potential for Allergic Reactions in Patients with Fish Allergy

4.3 Bleeding

5.1 Atrial Fibrillation/Flutter

5.2 Potential for Allergic Reactions in Patients with Fish Allergy

5.3 Bleeding

5.4 Hypertriglyceridemia

5.5 Other Lipid Alterations

8.2 Lactation

8.3 Children

8.4 Pediatric Use

8.5 Geriatric Use

8.6 Neonatal Impairment

A VASCEPA® (icosapent ethyl) capsule contains omega-3 fatty acids, in the form of eicosapentaenoic acid (EPA), obtained from the oil of fish. It is not known whether patients with allergies to fish or shellfish are at an increased risk of an allergic reaction to VASCEPA. Inform patients with known hypersensitivity to fish or shellfish about the potential for allergic reactions to VASCEPA and advise them to discontinue VASCEPA and seek medical attention if any reactions occur.

5.3 Bleeding

VASCEPA capsules are supplied as:

• 0.5 gram amber-colored, oval, soft-gelatin capsules imprinted with VASCEPA
• 1 gram amber-colored, oblong, soft-gelatin capsules imprinted with VASCEPA

5.2 Potential for Allergic Reactions in Patients with Fish Allergy

In pregnant rats given icosapent ethyl from gestation day 17 through lactation day 20 at 0.3, 3, 1 g/kg/day, no adverse maternal or developmental effects were observed. However, complete litter loss (not dose-related) was noted in 2/23 litters at the low dose and 1/23 mid-dose dams by post-natal day 4 at human exposures of a maximum dose of 4 g/day, based on body surface area comparisons across species.

In pregnant rats given oral gavage doses of 0.1, 0.3, 1, and 3 g/kg/day icosapent ethyl from gestation through organogenesis, a decrease in body weight and food consumption was observed at the high dose of 1 g/kg/day (5 times the human exposure at the maximum dose of 4 g/day, based on body surface area comparisons). Slight increases in resorbed and dead fetuses were noted in the 1 g/kg/day group, but these were not significantly different from the control group. There were no differences between the icosapent ethyl groups and control group as to the number of corpora lutea, number of implantations, number of surviving fetuses, sex ratio, body weight of female fetuses or placental weight. There were no treatment-related malformations or skeletal anomalies.

In pregnant rats given icosapent ethyl from gestation day 17 through lactation day 20 at 0.3, 1, 3 g/kg/day no adverse maternal or developmental effects were observed. However, complete litter loss (not dose-related) was noted in 2/23 litters at the low dose and 1/23 mid-dose dams by post-natal day 4 at human exposures of a maximum dose of 4 g/day, based on body surface area comparisons.

The effect of VASCEPA on the risk for pancreatitis in patients with severe hypertriglyceridemia has not been determined.

In clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

Cardiovascular Outcomes Trial

In a double-blind, randomized, placebo-controlled cardiovascular outcomes trial of 8,179 patients, 482 (12%) patients receiving VASCEPA experienced a bleeding event compared to 84 (2%) patients receiving placebo. Serious bleeding events occurred in 111 (3%) of patients on VASCEPA vs. 85 (2%) patients receiving placebo. The incidence of bleeding was greater in patients receiving concomitant antithrombotic medications, such as aspirin, clopidogrel, or warfarin.

6 ADVERSE REACTIONS

The following adverse reactions are described below and elsewhere in the labeling:

• Atrial Fibrillation or Atrial Flutter [see Warnings and Precautions (5.1)]
• Potential for Allergic Reactions in Patients with Fish Allergy [see Warnings and Precautions (5.2)]
• Bleeding [see Warnings and Precautions (5.3)]

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

Postmarketing Experience

Additional adverse reactions have been identified during post-approval use of VASCEPA. Because these reactions are reported voluntarily from a population of uncertain size, it is generally not possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

• Diarrhea
• Blood triglycerides increased
• Abdominal discomfort
• Pain in the extremities

7.2 Postmarketing Experience

Additional adverse reactions have been identified voluntarily from a population of uncertain size, it is generally not possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

The available data from published case reports and the pharmacoeconomics database on the use of VASCEPA in pregnant women are insufficient to identify a drug-associated risk for major birth defects, miscarriage or adverse maternal or fetal outcomes. In animal reproduction studies in pregnant rats, non-dose-related increases for some minor developmental findings were observed with administration of icosapent ethyl during organogenesis at exposures that were equivalent to the clinical exposure at the human dose of 4 g/day based on body surface area comparisons. In a study in pregnant rabbits orally administered icosapent ethyl during organogenesis, there were no clinically relevant adverse developmental effects at exposures that were 5 times the clinical exposure, based on body surface area comparisons (see Data).

The estimated background risk of major birth defects and miscarriage for the indicated population is unknown. All pregnancies have a background risk of birth defect, loss, or other adverse outcome. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2-4% and 15-20%, respectively.

8.2 Lactation

Risk Summary

Published studies have detected omega-3 fatty acids, including EPA, in human milk. Lactating women receiving oral omega-3 fatty acids for supplementation have resulted in higher levels of omega-3 fatty acids in human milk. There are no data on the effects of omega-3 fatty acid ethyl on the breastfed infant or on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for VASCEPA and any potential adverse effects on the breastfed child from VASCEPA or from the underlying maternal condition.

8.4 Pediatric Use

Safety and effectiveness in pediatric patients have not been established.

8.5 Geriatric Use

Of the total number of patients in well-controlled clinical studies of VASCEPA, 45% were 65 years of age and over. No overall differences in safety or effectiveness were observed between these patients and younger groups. Other reported clinical experience has not identified differences in responses between the elderly and younger patients.

8.6 Neonatal Impairment

In patients with hepatic impairment, alamine aminotransferase (ALT) and aspartate aminotransferase (AST) levels should be monitored periodically during therapy with VASCEPA.

17 PATIENT COUNSELING INFORMATION

Advise the patient to read the FDA-approved patient labeling before starting VASCEPA (Patient Information).

Inform patients that VASCEPA may increase their risk for atrial fibrillation or atrial flutter [see Warnings and Precautions (5.1)].

Inform patients with known hypersensitivity to fish and/or shellfish about the potential for allergic reactions to VASCEPA and advise them to discontinue VASCEPA and seek medical attention if any reactions occur [see Warnings and Precautions (5.2)].

Inform patients that VASCEPA may increase their risk for bleeding, especially if they are receiving other antithrombotic agents [see Warnings and Precautions (5.3)].

Advise patients to swallow VASCEPA capsules whole. Do not break open, crush, dissolve, or chew VASCEPA [see Dosage and Administration (2.2)].

Instruct patients to take VASCEPA as prescribed. If a dose is missed, patients should take it as soon as they remember. However, if they miss one day of VASCEPA, they should not double the dose when they take it.

For more information about VASCEPA, go to www.VASCEPA.com or call 1-855-VASCEPA (1-855-627-2372).

A VASCEPA® (icosapent ethyl) capsule contains omega-3 fatty acids that have demonstrated prolongation of bleeding time. The prolongation of bleeding time reported in those studies has not exceeded normal limits and did not produce clinically significant bleeding episodes. Fuller patients receiving VASCEPA and concomitant anticoagulants and/or antiplatelet agents for bleeding.
Pharmacist Burnout Reaches a Breaking Point

In the second month of 2022, and the country is besieged by more cases of COVID-19 than ever before. Pharmacists, pharmacy technicians, and other pharmacy professionals are busier than ever, administering record numbers of tests and thousands of vaccines. These numbers prompted the Board of Trustees of the American Pharmacists Association (APhA) to release a statement in late December acknowledging the very real workforce issues that have led to high levels of frustration and burnout in the pharmacy workforce. In their statement, the trustees acknowledged that these conditions have “pushed many pharmacists and pharmacy teams to the brink of despair,” creating a patient safety issue that can no longer be ignored.

They go on to lay out the root causes of these issues, including lack of provider status, payment issues driven by pharmacy benefit manager business models, and unrealistic performance metrics. Solutions—short and long term—are laid out as well, and include improving working conditions on an organizational level and closely examining staffing levels, performance measures, technology use, and administrative policies.

This statement is just the beginning. As a leading industry publication, Drug Topics® has a responsibility to shed light on these issues, elevating the voices of those on the ground who are working tirelessly to keep the public safe. We take that responsibility seriously and will be examining these issues more closely both in this issue and in the coming months.

Elsewhere in this month’s issue, we take a closer look at emerging treatments for COVID-19, where strides have been made in creating actionable clinical guidance for treating those hospitalized with severe illness. As more data emerge, we look forward to keeping our readers abreast of these changes, ensuring that pharmacists can continue to do their most important work.

As always, thank you for reading.

Mike Hennessy Jr
President and CEO
of MJH Life Sciences®

REFERENCES
SAVE THE DATE
for the next Total Pharmacy Solutions Summit

Explore, learn and earn up 1.75 LIVE CE credits!

Join us for an exciting virtual continuing education event featuring expert-driven practical and relevant business solutions tailored to drive success for independent community pharmacies.

Session Topics Including:
- Staffing & Retention
- POC Testing & Other In-Store Services
- Community Partnering Strategies
- Pharmacy Legal & Regulatory Review
- And much more!

Saturday, April 30th, 2022
9AM – 3 PM EST

In partnership with: Drug Topics
**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.

<table>
<thead>
<tr>
<th>Name</th>
<th>Title/Position</th>
</tr>
</thead>
<tbody>
<tr>
<td>LAKESHA M. BUTLER</td>
<td>PHARMD, Clinical Professor, Pharmacy Practice Director of Diversity, Equity and Inclusion, Southern Illinois University, Edwardsville, IL</td>
</tr>
<tr>
<td>JAMES JORGENSEN</td>
<td>MS, RPH, CEO &amp; Board Chairman, Visante, Inc., &amp; Visante Ltd., St. Paul, MN</td>
</tr>
<tr>
<td>JEFF LOMBARDO</td>
<td>PHARMD, BCOP, Research Assistant Professor, UB School of Pharmacy and Pharmaceutical Sciences, Buffalo, NY</td>
</tr>
<tr>
<td>MARK NEUENSCHWANDER</td>
<td>PHARMD, President, The Neuenschwander Company, Bellevue, WA</td>
</tr>
<tr>
<td>PERRY COHEN</td>
<td>PHARMD, FAMCP, Chief Executive Officer, The Pharmacy Group LLC, Irvine, CA</td>
</tr>
<tr>
<td>PAUL LOFHLOM</td>
<td>PHARMD, FACA, Owner, GoldenGate Pharmacy Services, San Rafael, CA</td>
</tr>
<tr>
<td>DAVID D. POPE</td>
<td>PHARMD, CDE, MBA, RPH, Director, Guidehouse LLC, Augusta, GA</td>
</tr>
<tr>
<td>DAVID J. FONG</td>
<td>PHARMD, Vice President, Pharmacy, Nurx Inc, a Telehealth Company, Danville, CA</td>
</tr>
<tr>
<td>LISA M. HOLLE</td>
<td>PHARMD, BCOP, FHOPA, FISOPP, Clinical Professor, University of Connecticut, School of Pharmacy, Storrs, CT</td>
</tr>
<tr>
<td>DEBBIE MACK</td>
<td>BS PHARM, RPH, Director, Pharmacy Regulatory Affairs, Omnicare, Cheshire, CT</td>
</tr>
<tr>
<td>GENET MEMOLI JR</td>
<td>RPH, FASCP, Owner, GoldenGate Pharmacy Services, San Rafael, CA</td>
</tr>
<tr>
<td>LUCY M. BUTLER</td>
<td>Clinical Professor, Pharmacy Practice Director of Diversity, Equity and Inclusion, Southern Illinois University, Edwardsville, IL</td>
</tr>
<tr>
<td>STUART R. INGUANTI</td>
<td>PHARMD, M.D., President, University of Minnesota, School of Pharmacy, Minneapolis, MN</td>
</tr>
<tr>
<td>MOHAMED A. JALLOH</td>
<td>PHARMD, Assistant Professor, College of Pharmacy, University of Minnesota, Minneapolis, MN</td>
</tr>
<tr>
<td>LAKESHA M. BUTLER</td>
<td>PHARMD, Clinical Professor, Pharmacy Practice Director of Diversity, Equity and Inclusion, Southern Illinois University, Edwardsville, IL</td>
</tr>
<tr>
<td>JAMES JORGENSEN</td>
<td>MS, RPH, CEO &amp; Board Chairman, Visante, Inc., &amp; Visante Ltd., St. Paul, MN</td>
</tr>
<tr>
<td>JEFF LOMBARDO</td>
<td>PHARMD, BCOP, Research Assistant Professor, UB School of Pharmacy and Pharmaceutical Sciences, Buffalo, NY</td>
</tr>
<tr>
<td>MARK NEUENSCHWANDER</td>
<td>PHARMD, President, The Neuenschwander Company, Bellevue, WA</td>
</tr>
<tr>
<td>PERRY COHEN</td>
<td>PHARMD, FAMCP, Chief Executive Officer, The Pharmacy Group LLC, Irvine, CA</td>
</tr>
<tr>
<td>PAUL LOFHLOM</td>
<td>PHARMD, FACA, Owner, GoldenGate Pharmacy Services, San Rafael, CA</td>
</tr>
<tr>
<td>DAVID D. POPE</td>
<td>PHARMD, CDE, MBA, RPH, Director, Guidehouse LLC, Augusta, GA</td>
</tr>
<tr>
<td>DAVID J. FONG</td>
<td>PHARMD, Vice President, Pharmacy, Nurx Inc, a Telehealth Company, Danville, CA</td>
</tr>
<tr>
<td>LISA M. HOLLE</td>
<td>PHARMD, BCOP, FHOPA, FISOPP, Clinical Professor, University of Connecticut, School of Pharmacy, Storrs, CT</td>
</tr>
<tr>
<td>DEBBIE MACK</td>
<td>BS PHARM, RPH, Director, Pharmacy Regulatory Affairs, Omnicare, Cheshire, CT</td>
</tr>
<tr>
<td>GENET MEMOLI JR</td>
<td>RPH, FASCP, Owner, GoldenGate Pharmacy Services, San Rafael, CA</td>
</tr>
<tr>
<td>LUCY M. BUTLER</td>
<td>Clinical Professor, Pharmacy Practice Director of Diversity, Equity and Inclusion, Southern Illinois University, Edwardsville, IL</td>
</tr>
<tr>
<td>STUART R. INGUANTI</td>
<td>PHARMD, M.D., President, University of Minnesota, School of Pharmacy, Minneapolis, MN</td>
</tr>
<tr>
<td>MOHAMED A. JALLOH</td>
<td>PHARMD, Assistant Professor, College of Pharmacy, University of Minnesota, Minneapolis, MN</td>
</tr>
</tbody>
</table>
Navigating a cancer diagnosis is hard. Navigating a cancer diagnosis as a transgender patient is even harder, according to Don S. Dizon, MD, medical oncologist, director of women’s cancers at Lifespan Cancer Institute in Rhode Island and associate professor of medicine at The Warren Alpert Medical School at Brown University.

“I think what people may not realize, particularly my colleagues, is that any person who identifies as gay or bisexual or trans...ever single time they meet a new doctor, there's that moment of anxiety of: Do I need to come out to this person? Are they going to ask me, and what’s going to be the repercussions if I do?” Dizon said.

Dizon sat down with Hayley Virgil, senior editor of OncologyLive®, a Drug Topics® sister publication, for a recent episode of Deep Dive, covering a wide range of topics, from the importance of society-published guidelines to how patients can be their own advocate.

“If a patient is not being cared for in an environment that they consider friendly, supportive, and equal—if it's hostile, and they're going in with increased anxiety—then I would encourage them...to state [their] experience,” Dizon said, adding that “I” statements—such as “I felt,” “I was,” and “I heard”—are powerful, “because no one can take that away from you.”

Even outside the oncology space, pharmacists play an important role on the multidisciplinary care team.

Providing “comprehensive, respectful, and gender-affirming support” to patients, as well as improving the physical pharmacy space and environment, can position pharmacists as trustworthy health care providers for transgender patients, wrote the authors of a 2019 study published in Transgender Health. Keeping principles of cultural competence—the ability to “understand, appreciate, and interact with people from cultures or belief systems different from one’s own”—in mind can go a long way toward ensuring that transgender patients are receiving the highest quality of care.

In 2021, the Human Rights Campaign and the American Pharmacists Association (APhA) partnered to create a guide for pharmacists on providing inclusive services for patients in the transgender and gender-diverse communities. Released on March 31 to mark International Transgender Day of Visibility, the guide is “an educational tool and a resource...on how to be inclusive to transgender, nonbinary, and gender-diverse patients,” said the organizations in a press release.

“The pharmacy profession holds itself to the highest standards of conduct,” said Ilisa Bernstein, PharmD, JD, FAPhA, senior vice president, pharmacy practice and government affairs, at APhA, adding that the guide promotes “treating patients that identify as transgender and gender-diverse with the utmost care and respect.”

For references, visit drugtopics.com.
OTC Update: Asthma Medications

When patients first experience asthma symptoms, their instinct may be to try an OTC bronchodilator. That these remedies are sold OTC may lead patients to believe that there are no contraindications—but that’s far from the case.

While OTC products may temporarily alleviate some asthma symptoms, the inflammation associated with repeated asthma attacks can permanently scar airways. Patients need to relieve symptoms, as well as a way to prevent future attacks. For that reason, asthma is best treated under medical supervision, and getting a professional diagnosis is an important first step.

“People with asthma strongly benefit from having an accurate diagnosis and a tailored treatment approach from an allergist, pulmonologist, or primary care provider,” said Melanie Carver, chief mission officer, Asthma and Allergy Foundation of America. “The [National Institutes of Health] Guidelines for the Diagnosis and Management of Asthma recommend the use of control medicines to reduce airway swelling and inflammation and quick-relief medicines to open the airways. These asthma guidelines do not recommend the use of OTC products.”

Approved treatment regimens can include a combination of short- and long-term bronchodilators, as well as oral medications, to prevent and treat asthma symptoms. While some OTC products are promoted as useful for mild, intermittent asthma, that recommendation is not necessarily echoed by medical professionals.

“According to national guidelines updated in December 2020, patients with very mild asthma would be on a short-acting bronchodilator,” said Rachel L. Miller MD, FAAAAI, system division chief, Division of Clinical Immunology, Icahn School of Medicine at Mount Sinai. “No [OTC] asthma medications are recommended for patients without physician evaluation.”

Primatene Mist HFA and Asthmanefrin are two OTC products currently available. Primatene Mist HFA is the only nonprescription inhaler approved by the FDA—but that approval comes with certain conditions.

“[OTC] products for asthma should only be used by people with a prior diagnosis of mild intermittent asthma,” Carver explained, and “should not be used by patients who have heart disease, high blood pressure, diabetes, thyroid disease, seizures, benign prostatic hyperplasia, or glaucoma.”

In 2011, Primatene Mist HFA was removed from pharmacy shelves due to the presence of chlorofluorocarbons (CFCs), a propellant banned by the EPA. The inhaler returned to the market in 2019 after CFCs were replaced with hydrofluoroalkane (HFA). However, medical professionals and health organizations have expressed concerns about the decision to return Primatene to shelves, citing a lack of efficacy and the potential for adverse effects. “Patients should not stop or switch their prescribed asthma medicines to use [OTC] options. If someone is experiencing asthma symptoms 2 or more times per week, they need medical care to assess their asthma severity and control,” said Carver.

Tommy Thompson, RPh, owner of Mechanicsville Drug Store in Mechanicsville, Virginia, believes OTC medications like Primatene have their place.

“They’re not widely used in my pharmacy because most of my customers have a relationship with a physician,” Thompson said.

Most patients who buy these OTC products have already seen a physician, said Thompson, but occasionally people will buy OTC medications because they are waiting to see their physician or cannot afford the visit.

“If someone is taking it for the wrong reasons, we are going to suggest that it won’t help,” Thompson said. “That’s why we keep it behind the counter—not because it’s being abused...but so that we can counsel patients about why they are using it.”

“People with asthma strongly benefit from having an accurate diagnosis and a tailored treatment approach.”

MELANIE CARVER, CHIEF MISSION OFFICER, ASTHMA AND ALLERGY FOUNDATION OF AMERICA

For references, visit drugtopics.com.
Multidisciplinary Lipid Management
FOR THE PREVENTION OF Cardiovascular Risks

In this Drug Topics® Around the Practice series, five experts share perspectives and insights on effective identification of high-risk patients, review treatment options and factors in their selection, examine new data advancing secondary prevention of atherosclerotic cardiovascular events, and review patient cases to improve real-world application.

“Multidisciplinary Approaches to Reducing CVD Risk”

WATCH EPISODE

“Strategies Used to Treat Hypercholesterolemia”

WATCH EPISODE

“Counseling Patients on CVD Risk Factors”

WATCH EPISODE

“Screening for Cardiovascular Disease”

WATCH EPISODE
Vaccines are a critical means of preventing disease-related morbidity and mortality, providing individual and herd immunity, and decreasing the burden of certain diseases. While vaccination is important at every age, it is especially important for older adults: As people age, their immune system weakens, making them more vulnerable to infections. Likewise, age-related comorbidities may increase the risk of complications from illnesses.

Preventive medicine is the most effective strategy to protect the health of older adults, and vaccination is one of the most feasible approaches. Read on for an overview of current vaccination recommendations for adults 65 years and older and strategies to ensure the effective vaccination of this population.

**Recommended Vaccines for Older Adults**

The CDC provides recommendations for immunization practices, which are available on the CDC website. Specific recommendations are made based on age group as well as on medical condition and other indications. A summary of the CDC recommendations for those 65 years and older is presented in the Table.

### COVID-19

The COVID-19 vaccine reduces the risk of contracting and spreading SARS-CoV-2 and decreases the risk of serious illness. The dosing regimen differs based on the specific product that is used. The CDC updated its recommendations in late December 2021 to include a clinical preference for the Pfizer-BioNTech or Moderna mRNA vaccines over the Johnson & Johnson vaccine. The CDC also recommends a single booster dose of the COVID-19 vaccine. At press time, individuals who received the Pfizer-BioNTech vaccine are eligible to receive a booster dose 5 months after their completed series, and those who received the Moderna vaccine, after 6 months. Individuals who received the Johnson & Johnson vaccine are eligible to receive a booster dose beginning 2 months after their initial vaccination.

Because of the uncertainty about the duration of protection and the emergence of new variants of the virus, recommendations for booster doses of the COVID-19 vaccine may change.

### Influenza

All individuals 65 years and older should receive an annual influenza vaccine, ideally by the end of October but no earlier than September because of concerns of waning immunity. During the 2017-2018 flu season, nearly 80% of influenza-related deaths were in individuals 65 years or older.

The CDC recommends the influenza inactivated vaccine (IIV) or the influenza recombinant vaccine (RIV4) in adults over 50 years; the influenza live attenuated vaccine (LAIV4) is not recommended in this population.

### Tetanus/Diphtheria/Pertussis

A tetanus and diphtheria (Td) booster, with or without pertussis, is recommended every 10 years. Individuals who have not been previously vaccinated with tetanus, diphtheria, and pertussis (Tdap) at or after the age of 11 should receive 1 dose of Tdap followed by Td or Tdap boosters every 10 years.

### Herpes Zoster (Shingles)

The risk for developing herpes zoster increases with age. As such, it is recommended that adults 50 years and older receive a 2-dose series of the recombinant zoster vaccine (Shingrix) spaced 2 to 6 months apart, regardless of previous herpes zoster infection or previous administration of a live zoster vaccine (Zostavax, ZVL).

### Pneumococcal

The overall case-fatality rate for pneumococcal bacteremia is about 20% among adults; this rate may be as high as 60% among older patients. The CDC currently recommends 1 dose of the pneumococcal polysaccharide vaccine (PPSV23) for all adults 65 and older. If PPSV23 was administered prior to age 65, the dose of PPSV23 should be administered at least 5 years after the previous dose. A dose of PCV13 may also be considered in addition to PPSV23 in those who did not receive PCV13 previously; a determination...
concerning its administration should be based on shared clinical decision-making. In patients requiring both vaccines, PCV13 should be administered first, at least 1 year before the PPSV23 vaccine.5

Other Vaccines
In addition to the aforementioned vaccines recommended for most adults 65 years and older, the CDC recommends other vaccines—including varicella, hepatitis A, hepatitis B, MenACWY (meningococcal A, C, W, Y), MenB (meningococcal B), and Haemophilus influenzae type b5—for those with certain risk factors or other indications.

Barriers to Vaccination
There are several reasons elderly adults may not be vaccinated according to CDC recommendations. Patient-related factors include lack of awareness of declining immunity or the importance of vaccines in this age group, lack of familiarity with vaccine recommendations, the belief that a healthy lifestyle can take the place of vaccines, worries about vaccine safety, underestimation of the impact of vaccine-preventable diseases on health, concerns about cost, and mobility issues preventing the individual from getting to a vaccination site.14,15

Provider-related issues and other systematic issues include lack of familiarity with vaccine recommendations, lack of promotion of vaccination to patients, limited access to immunization records, and availability of a vaccine at the provider’s practice site.5,16

Overcoming Barriers
Overcoming barriers to vaccination among older individuals means addressing patient-level, provider-level, and systematic issues. Key to the success of vaccination efforts is buy-in from the patient; effective patient education and encouragement can help facilitate this. Health care professionals should identify knowledge gaps and patient concerns, achieved via motivational interviewing that alleviates concerns. Inform patients that Medicare Part B covers influenza and pneumococcal vaccines, as well as other vaccines for those who are at increased risk. Vaccines may also be covered by Medicare Part D, Medicaid, or private insurers.15

At the provider level, attaining the proper education and training necessary to effectively address vaccination needs in the community can help. Keeping current with the CDC’s recommendations is essential. Providers must maintain complete and up-to-date patient records, ensure sufficient supply of properly stored vaccines. Providers must also be proactive in examining patient history and screening for immunization needs. Although this should be an ongoing process, it may be instrumental to designate a particular visit to ensure that an overall assessment of patient immunization status is performed.15

Pharmacists are uniquely positioned to play a significant role in vaccination efforts. Community pharmacies are convenient vaccination sites, staffed with trusted professionals who are knowledgeable and trained.17

On a systemic level, government and social agencies and the health care community should work to facilitate successful vaccination programs. Those who live in community-based group homes or who receive home health care should be included in vaccination outreach programs. Involving caregivers is also important. Vaccines should be offered at convenient locations: senior centers, community centers, or independent living facilities for older adults. Pay special attention to those who are homebound, and to people living in rural or remote areas. Lastly, create effective communication material specifically geared for this population; this is likely to be instrumental in maximizing the impact of these efforts.18

Conclusion
Older adults are among the most vulnerable populations. By leveraging expertise to advocate for and facilitate vaccine administration, pharmacists are poised to ensure widespread vaccination in this cohort.

For references, visit drugtopics.com.

### ROUTINE VACCINATIONS FOR INDIVIDUALS 65 YEARS AND OLDER

<table>
<thead>
<tr>
<th>VACCINE</th>
<th>PROTECTION</th>
<th>NUMBER OF DOSES ADMINISTERED</th>
<th>FREQUENCY OF ADMINISTRATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>COVID-19 vaccine</td>
<td>SARS-CoV-2</td>
<td>Initial dosing series (varies based on manufacturer) plus booster dose</td>
<td>Once</td>
</tr>
<tr>
<td>Influenza inactivated vaccine (IIV) or Influenza recombinant vaccine (RIV)</td>
<td>Influenza</td>
<td>1 dose</td>
<td>Annually</td>
</tr>
<tr>
<td>Tdap vaccine</td>
<td>Tetanus, diphtheria, and pertussis</td>
<td>1 booster dose</td>
<td>Every 10 years</td>
</tr>
<tr>
<td>Td vaccine</td>
<td>Tetanus and diphtheria</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Zoster vaccine (RZV)</td>
<td>Herpes zoster</td>
<td>2 doses</td>
<td>Once</td>
</tr>
<tr>
<td>Pneumococcal polysaccharide vaccine (PPSV23)</td>
<td>Pneumococcal disease</td>
<td>1 dose</td>
<td>Once</td>
</tr>
</tbody>
</table>

Key: Td, tetanus and diphtheria; Tdap, tetanus, diphtheria, and pertussis.
BECOME A CHAMPION FOR HEART HEALTH

American Heart Month is a great time for pharmacists to educate the public about their contributions to managing patients with cardiovascular disease.

By Jennifer Gershman, PharmD, CPh
through an interdisciplinary approach—administering and educating the public about the importance of vaccines, performing medication therapy management (MTM) services, offering counseling tips to improve outcomes, and recommending lifestyle modifications—pharmacists can make a significant difference for people living with CVD. Million Hearts 2022, a national initiative to prevent 1 million heart attacks and strokes within 5 years, focuses on evidence-based priorities to improve cardiovascular health—and evidence shows that pharmacist-led cardiovascular clinics improve patient health outcomes.

Vaccination and Heart Health

Patients with CVD are at an increased risk of complications from influenza and COVID-19, and pharmacists play a vital role in ensuring this population is vaccinated against these diseases. According to the CDC, patients with certain cardiovascular conditions—such as heart failure (HF), coronary artery disease (CAD), cardiomyopathies, and hypertension—are at a higher risk of severe COVID-19 that could result in hospitalization and death.

Andrea Levin, PharmD, BCACP, assistant professor, Department of Pharmacy Practice, Nova Southeastern University College of Pharmacy, Fort Lauderdale, Florida, shared the importance of COVID-19 boosters for patients with CVD. Everyone 18 years and older should be getting a COVID-19 vaccine.
If it has been at least 6 months after completing their second dose of Pfizer-BioNTech or Moderna (or) at least 2 months after a single dose of Johnson & Johnson, Levin said. This is an important counseling pearl that Levin provides to both her ambulatory care patients and her pharmacy students during their clinical rotations.

According to a study that evaluated over 80,000 adults in the United States hospitalized with influenza across 8 flu seasons, acute cardiovascular events occurred in 1 of every 8 patients, approximately 12%. Patients with CVD can receive any flu vaccine except the live attenuated influenza vaccine (nasal spray). And, Levin added, patients with CVD can receive their COVID-19 and influenza vaccines at the same time.

**MTM and Counseling Pearls**

Pharmacists can improve patient health outcomes by providing MTM services to patients with CVD. There are 5 core elements of MTM that can be implemented by pharmacist-led services: medication therapy review, personal medication record, medication-related action plan, intervention or referral, and documentation and follow-up. These services can include identifying uncontrolled hypertension or educating patients on CVD and other cardiac medication therapies, including anticoagulants like apixaban (Eliquis), rivaroxaban (Xarelto), and warfarin (Coumadin), which are typically used for atrial fibrillation and to prevent deep vein thrombosis and pulmonary embolism. Counseling points include monitoring for signs of bleeding and the importance of a consistent diet—as well as a reminder for patients taking warfarin to avoid consuming large amounts of foods that contain high quantities of vitamin K, such as spinach and kale.

Secondary prevention of atherosclerotic cardiovascular disease (ASCVD) should include 81 mg to 162 mg per day of aspirin. Recent guidelines from the American College of Cardiology (ACC) and the AHA indicate that aspirin therapy should not be routinely used for primary prevention of ASCVD because of the lack of benefit and an increased risk of bleeding (Table 2).

Pharmacists can educate patients based on risk factors to determine whether they would benefit from aspirin for primary prevention. Other antplatelet therapies such as clopidogrel (Plavix), prasugrel (Effient), and ticagrelor (Brilinta) are also used for secondary prevention. Prasugrel should be avoided in patients with a history of stroke or transient ischemic attack because of an increased risk of significant or fatal bleeding.

First-line pharmacologic therapy for hypertension typically includes thiazide diuretics (hydrochlorothiazide, chlorothalidone), angiotensin-converting enzyme (ACE) inhibitors (benazepril, enalapril), angiotensin II receptor blockers (ARBs; valsartan, irbesartan), and calcium channel blockers (CCBs; amlodipine). Pharmacists should recommend ACE inhibitors or ARBs for patients with diabetes because these agents can prevent nephropathy, CAD, and HF. Evidence suggests that taking ACE inhibitors and ARBs at bedtime, rather than in the morning, may result in better blood pressure control and a decrease in CVD events. Moderate- to high-intensity statin therapy (atorvastatin, simvastatin) to reach a low-density lipoprotein cholesterol goal of 50% reduction in patients with ASCVD can decrease the risk of CVD events. Pharmacists should ensure that patients who have experienced a myocardial infarction (MI) receive β-blockers (carvedilol, metoprolol), while atenolol therapy should be avoided because it has not been shown to improve outcomes after MI.

Primary prevention of CVD is also a critical component of patient care. Adults age 40 and 75 years who are being evaluated for CVD prevention should undergo a 10-year ASCVD risk estimation; pharmacists should educate these patients about pharmacological therapy including antihypertensives and statins, as well as the importance of lifestyle modifications such as diet and exercise.

**Blood Pressure Monitoring and Hypertension Management**

Pharmacists can become champions of hypertension control by performing blood pressure (BP) screenings at point of care and providing education about the importance of self-measured blood pressure monitoring (SMBP) at home. A tool kit provided by the Million Hearts initiative includes patient education resources to ensure that any SMBP monitoring product is a validated device through the American Medical Association—meaning that the device has been validated for clinical accuracy through an independent review process. Pharmacists can also educate patients about the importance of effectively controlling hypertension and the link between measuring BP and controlling high BP. This education can include SMBP device operation techniques and a suggestion to measure BP on the upper arm, which produces more reliable measurements than the wrist. Results are typically displayed digitally and some devices will store readings, calculate

**TABLE 1. ACC/AHA Aspirin Recommendations for Primary Prevention**

- Low-dose aspirin (75-100 mg) may be considered for the primary prevention of ASCVD in adults aged 40-70 years who are at higher ASCVD risk but not at an increased risk of bleeding.
- Low-dose aspirin should not be routinely given for primary prevention of ASCVD in adults > 70 years.
- Low-dose aspirin should be avoided for primary prevention of ASCVD in adults of any age who have an increased risk of bleeding.

Terms Key: ACC, American College of Cardiology; AHA, American Heart Association; ASCVD, atherosclerotic cardiovascular disease.
Pharmacists can become champions of hypertension control by performing blood pressure screenings at point of care and providing education about the importance of self-measured blood pressure monitoring at home.

Uncontrolled hypertension is a major problem among minority groups—in particular, non-Hispanic Black men. In 2018, data from the Los Angeles Barbershop Blood Pressure Study (NCT02321618) enrolled over 300 Black adult men with systolic BP greater than 140 mm Hg from 52 US barbershops. These barbershops became nontraditional health care settings: Each shop was assigned to a pharmacist-led intervention or the active control group.

In the control group, barbers encouraged lifestyle modifications and doctor’s appointments; in the intervention group, barbers encouraged meetings in their shops between customers and specialty-trained pharmacists who prescribed medication therapy through a collaborative practice agreement with the customers’ physicians.

At 6 months, the mean reduction in systolic BP was 21.6 mm Hg greater with the intervention (95% CI, 14.7-28.4). This study further highlights the importance of pharmacists in a nontraditional setting for managing patients with hypertension.

**Lifestyle Modifications**

Adults should participate in at least 150 minutes of moderate-intensity or 75 minutes of vigorous-intensity physical activity per week. Routine exercise can help lower BP, maintain healthy body weight, reduce diabetes risk, strengthen muscles, lower stress, and reduce inflammation. Pharmacists should encourage patients to begin by setting an attainable goal and increase exercise time as they get stronger, particularly if patients have been sedentary. Exercise can also be broken up throughout the day by taking 10-minute brisk walks.

Examples of moderate-intensity aerobic activities include brisk walking, water aerobics, dancing, gardening, tennis (doubles), and biking (< 10 miles per hour). Aerobic activities like hiking uphill with a heavy backpack, running, swimming laps, aerobic dancing, heavy yard work, tennis (singles), cycling (> 10 miles per hour), and jumping rope are considered vigorous intensity. Consuming a healthy diet that includes vegetables, fruits, nuts, whole grains, lean vegetable or animal protein, and fish, and minimizing the intake of trans fats, red meat, refined carbohydrates, and sweetened beverages is an important counseling point pharmacists should provide patients for primary and secondary prevention of CVD. Smoking cessation counseling is also important to prevent CVD complications, and pharmacists can assess patients’ willingness to quit smoking during MTM consults (Table 2).

Levin generally recommends “nicotine replacement therapy that consists of a long-acting formulation (a nicotine patch) and short-acting product (gum or lozenges). Combination therapy usually provides patients with the most success.”

For references, visit drugtopics.com.

Jennifer Gershman, PharmD, CPh, is a drug information pharmacist and medical writer residing in South Florida.

### TABLE 2. FIVE MAJOR STEPS TO INTERVENTION: “5 A’S”

<table>
<thead>
<tr>
<th>STEP</th>
<th>DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Ask</strong></td>
<td>Identify and document tobacco use at each MTM consult.</td>
</tr>
<tr>
<td><strong>Advise</strong></td>
<td>Urge patients in a strong and personal but nonjudgmental manner to quit smoking.</td>
</tr>
<tr>
<td><strong>Assess</strong></td>
<td>Determine whether the patient is willing to make a quit attempt.</td>
</tr>
<tr>
<td><strong>Assist</strong></td>
<td>Provide counseling on pharmacotherapy options for patients ready to quit.</td>
</tr>
<tr>
<td><strong>Arrange</strong></td>
<td>Schedule follow-up through a face-to-face or telephone consult within the first week after the quit date to check in on patients.</td>
</tr>
</tbody>
</table>

Terms Key: MTM, medication therapy management.
Managing Migraine: From Acute Treatment to CGRPs

Less than 5% of people with migraine have received an accurate diagnosis for this disabling—and painful—disease.  
By Karen Berger, PharmD

More than 37 million men, women, and children across the United States are affected by migraine. This translates to 1 in every 4 households, with higher rates of migraine among women. Roughly 3 of every 4 people living with migraine are women.1,2

“Because migraine has many different triggers, it is important to address prevention from multiple angles,” said Sara Crystal, MD, a neurologist and headache specialist and medical director of Cove, a digital health program that provides patients with expert care for migraine. “In addition to pharmacologic therapies, many nonpharmacologic treatments have been found to be effective for migraine.”

NONPHARMACLOGIC TREATMENTS
Crystal keeps the “SEEDS” mnemonic in mind when providing lifestyle recommendations: Patients should be encouraged to practice good sleep hygiene (prioritizing both quantity and quality of sleep), exercise 30 to 60 minutes 3 to 5 times per week, eat regular healthy meals, diary their migraine attacks on a calendar or in an app, and modulate stress through mindfulness, cognitive behavioral therapy, and biofeedback.2,3

For some, a supplement regimen that includes magnesium, riboflavin (vitamin B₂), and coenzyme Q10 may be effective. And according to a study published in BMJ,4 a diet high in omega-3 fatty acids can reduce migraine frequency. “[T]he study group that increased dietary omega-3, and reduced omega-6, had the greatest benefit—on average, a 4-day reduction in migraine frequency,” Crystal said.

Another dietary supplement of interest is feverfew, which may help reduce migraine frequency and symptoms, and should be avoided during pregnancy.5 Patients who ask about butterbur should be cautioned that the American Academy of Neurology stopped recommending butterbur in 2015 because of a risk of liver toxicity. Some butterbur products contain pyrrolizidine alkaloids that can damage the liver and lungs and impact blood circulation, as well as potentially cause cancer. Patients should use a butterbur product that is certified as pyrrolizidine alkaloid free.6

Methods like relaxation training, thermal biofeedback combined with relaxation training, electromyographic biofeedback, and cognitive behavioral therapy may also help migraine, according to the United States Headache Consortium.

PREVENTIVE PRESCRIPTIONS
When nonprescription measures aren’t enough, preventive treatment with prescription medications may be necessary.

When choosing preventive treatment for her patients, Crystal explained, “the most important [goal] is to establish realistic expectations.” Crystal teaches her patients that complete elimination of headaches is unlikely. “The goal of preventive therapy is a 50% reduction in migraine/headache days per month, in addition to decreasing the severity and duration of attacks and overall disability,” she said. Crystal cautions patients that it can take weeks to months to notice improvements from oral preventive drugs. “The migraine-specific anti–calcitonin gene-related peptide medications demonstrate faster onset, though,” she said.

Crystal turns to preventive medication in patients with 4 or more migraine days per month, or 2 or more migraine days if the headaches are disabling and don’t respond to acute treatments.

There are 3 classes of nonspecific migraine preventives; these medications were developed for other conditions and found to be effective for migraine prevention: blood pressure medications, antiseizure medications, and antidepressants.

“When choosing a preventive, we take into account the patient’s comorbidities and other medications, as well as [adverse] effects. A β-blocker may be a good choice for someone with hypertension and migraine, while a tricyclic antidepressant might be avoided in someone trying to lose weight,” Crystal explained. Her rule of thumb in terms of dosing is to start low and go slow. She starts the patient on a low dose and titrates slowly to the dose that is effective for the patient with minimal adverse effects.

These first-line prescription preventives include β-blockers.
(propranolol, metoprolol, and timolol), anticonvulsants (divalproex and topiramate). Antidepressants venlafaxine and amitriptyline are classified as “probably effective”; amitriptyline received this classification due to the adverse effect profile. Each of these drugs has been recommended by the American Headache Society and the American Academy of Neurology and are backed by high-quality evidence and established efficacy.

Botox is another effective migraine preventive, but only for those with chronic migraine; it is not effective for episodic migraine.

**MIGRAINE-SPECIFIC PREVENTIVE THERAPIES**

Calcitonin gene-related peptide (CGRP) antagonists are the first class of drugs developed exclusively for migraine prevention. CGRP is a neuropeptide in the nervous system released during migraine attacks, causing blood vessel dilation, and migraine pain. CGRP inhibitors can reduce migraine frequency, number of headache days, and medication usage.

Parenteral CGRP inhibitors are monoclonal antibodies and must be injected because of their large molecular size. Erenumab (Aimovig) works by binding to the CGRP receptor so that CGRP cannot attach to it. Fremanezumab (Ajovy), galcanezumab (Emgality), and eptinezumab (Vyepti) all bind to the CGRP molecule, preventing it from binding to the receptor.

Gepants are a class of CGRP antagonists that are smaller in molecular size and are dosed orally. They work by binding to CGRP receptors. These oral CGRP inhibitors include atogepant (Qulipta), rimegepant (Nurtec ODT), and ubrogepant (Ubrelvy). Both atogepant and rimegepant are indicated for the preventive treatment of episodic migraine in adults; rimegepant is also indicated for acute treatment of migraine with or without aura. Atogepant adverse effects include nausea, constipation, and fatigue, while common rimegepant adverse effects are nausea, abdominal pain, and indigestion. Ubrogepant is indicated for the acute treatment of migraine with or without aura in adults. Unlike atogepant and rimegepant, it is not indicated for preventive treatment of migraine. The most common adverse effects are nausea, drowsiness, and dry mouth.

**OPTIONS FOR ACUTE TREATMENT**

“While not all patients need a prescription migraine preventive treatment, all patients should be offered a migraine-specific acute treatment,” Crystal said of her view on acute treatment. “By the time someone is seeking care, they no doubt have tried over-the-counter medications and found them ineffective.”

Triptans are generally considered first-line treatment in patients without contraindications, with the caveat that patients with uncontrolled hypertension, cardiovascular disease or risk factors, cerebrovascular disease or stroke, or ischemia should not take triptans because of their effects on vessel constriction. They should be used cautiously in patients over 50 years—because of cardiovascular risk factors—and in patients with Raynaud phenomenon.

There are 7 triptans currently available: naratriptan (Amerge), almotriptan (Axert), frovatriptan (Frova), sumatriptan (Imitrex), rizatriptan (Maxalt), eletriptan (Relpax), and zolmitriptan (Zomig). Patients who experience significant nausea or vomiting, or who do not respond to oral triptans, may benefit from non-oral triptans, including nasal sprays and injectables. In her practice, Crystal assesses response to the acute medication after 2 attacks. If the drug is ineffective, she considers another class of medication or route of delivery.

The risk of serotonin syndrome is minimal, said Crystal, referring to a 2018 study published in JAMA Neurology. While serotonin syndrome is an important counseling point, the study concluded that “patients with coexisting affective disorders and migraine need not forgo management of one condition to treat the other.”

For acute prevention, the gepant class of drugs has several advantages over triptans. These small molecule CGRP receptor antagonists have “better tolerability/[adverse] effect profiles, and they do not cause vasoconstriction, so they should be safer in patients with stable cardiovascular disease,” Crystal said, but cautioned that there are drug interactions to consider: Rimegepant should not be administered concomitantly with strong cytochrome P450 (CYP) 3A4 inhibitors, strong and moderate CYP3A inducers, or inhibitors of P-gp or BCRP; ubrogepant should not be administered with strong CYP3A4 inhibitors; and lasmiditan (Reyvow), a serotonin (5-HT) 1F receptor agonist, should be used with caution in patients taking medications that lower heart rate and should not be used concomitantly with drugs that are P-gp or BCRP substrates.

There are also several noninvasive neuromodulation devices on the market that can offer a “nonmedication option and can be used in conjunction with medications,” said Crystal.

For references, visit drugtopics.com.
Joe Maki, PharmD, vice president of pharmacy at Novant Health in Winston-Salem, North Carolina, wanted to figure out why it was taking so long for pharmacy technicians to refill the medication cabinets in one of the health system’s emergency departments. After deploying Lean operations methodology and machine learning software, his team discovered that the busiest time in the emergency department was between 6 and 8 am.

During those early morning hours, pharmacy technicians were slowed by the steady flow of patient and staff foot traffic. Every time a nurse walked up to retrieve a medication from the cabinet, the technician had to step aside. As a result of the work by Maki’s team, pharmacy technicians now refill the medicine cabinets toward the end of the second shift—usually around midnight.

“We [now] have really efficient workflows in the pharmacy department,” Maki said. “That means that we’re touching the cabinets at the right time of the day.”

According to Purdue University, Lean tools are used to eliminate processes that don’t add value. Lean tools are often used along with the Six Sigma methodology, which attempts to reduce variation within a process. When Lean tools are used in concert with the Six Sigma methodology, they can reduce and manage various types of waste in organizations.¹

**TECHNOLOGY SUPPORTS PHARMACISTS PRACTICING “AT THE TOP OF THEIR LICENSE”**

According to Anita Jacobson, PharmD, clinical professor at the University of Rhode Island College of Pharmacy in Kingston, the goal of most pharmacy technology platforms is “to reduce the human touch aspect at different points in dispensing…and to increase patient safety.”

Pharmacists with a PharmD degree have 6 years of education in addition to experiential learning in a clinical setting, said Jacobson, who is also a pharmacist at Eleanor Slater Hospital in Cranston, Rhode Island. Her point: Technology can help pharmacists use their years of training, which includes “look[ing] for and prevent[ing] medication-related problems and for untreated or overtreated indications and [adverse] effects.”

Making routine tasks faster for pharmacists, pharmacy technicians, and clinicians is one reason Novant Health uses Lean methodology, machine learning, and other software solutions, said Maki. One of his priorities is to increase the amount of time nurses can spend at the patient bedside. But they can’t do that if they’re spending as much as 20% of their day at the nursing unit’s medicine cabinet, he said.

Results of a 2018 study showed that half of health system pharmacists self-identified as being at risk for burnout.² Using Lean methodology and technology to support pharmacy teams and clinicians throughout the health care system is in alignment with Maki’s mission to “remove ‘bottom of license’ tasks that overburden staff.”

“Look at the [typical] hospital pharmacist who spends a lot of time tracking down information in the medical record,” Maki said, “[or at] the time they’re using Excel and other manual ways to calculate the best use of drugs. They’re [working with] techs to track down a patient’s history.”

He doesn’t want Novant Health’s pharmacists spending time pulling up a patient’s lab values from the elec-
Making routine tasks faster for pharmacists, pharmacy technicians, and clinicians is one reason Novant Health uses Lean methodology, machine learning, and other software solutions.

Electronic health record (EHR) or another platform to calculate the right medication dose. Instead, he prefers that pharmacists rely on software that serves up that information with little human intervention.

Community pharmacies can also use automation to improve efficiency. Jacobson said. For example, automation can be used to keep track of the top 100 or 500 drugs and dispense them in the typical quantities of 30 or 90 days, she said.

Jacobson also pointed to technology platforms that allow a pharmacist to verify a photograph or barcode of a medication from a remote location. Using these tools allows community pharmacies to increase the capacity of their pharmacists.

**A HEALTHY MIX OF CAUTION AND OPTIMISM**

Still, Jacobson cautioned pharmacy leaders to be mindful when deploying technology. While the potential upside is that pharmacists have more time to counsel patients, the downside may be a dramatic increase in the number of prescriptions per day. At first blush, increasing the number of prescriptions dispensed in a day sounds like a good thing—but patient safety may be negatively impacted.

While connectivity between the EHR and pharmacy systems is generally considered positive, Jacobson also cautioned that without intervention, proactive communication, and education by a pharmacist or physician, it falls on the patient to understand the medications that they should be taking—a challenge when a new medication is prescribed, especially when that medication replaces a previous prescription, she said.

Refills are automatically generated for patients, who arrive to pick them up at the pharmacy. Jacobson explained. While automated refills are convenient and can help with medication adherence, prescriptions may be getting pushed out to patients who are taking as many as 15 medications each day. A new medication may only add to their confusion.

Jacobson cited an example of an older patient taking blood pressure medication. Because the previous medication was causing the patient’s heart rate to slow down too much, her physician prescribed a new one. If the physician or a pharmacist doesn’t take the time to educate the patient about the reason associated with the medication change, she may continue to take both medications.

Taking the scenario further, that same patient could fall because of her slow heart rate, breaking her hip or dying as a result, Jacobson explained. Access to the physician’s EHR can help, she added, because it gives the pharmacist access to the patient’s care plan and lab values.

An even better solution, said Jacobson, requires a technology that dates to 1876, the year that Alexander Graham Bell secured a patent for inventing the telephone. The solution? A simple phone call where the patient’s physician discusses the updated care plan with the pharmacist.

**THE FUTURE OF PHARMACY TECHNOLOGY**

Mark Sullivan, PharmD, BCPS, associate chief pharmacy officer for Vanderbilt University Hospital and Clinics in Nashville, Tennessee, looks toward future technology possibilities within the pharmacy department. He pictures, for example, the “autonomous hospital” where targeted therapies will be used to treat bone cancer, which is typically very painful for patients.

“Getting the pain medications based on an evidence-based algorithm that's physician-approved” can have a significant impact on the patient’s experience in the hospital, he said.

These autonomous hospitals put the patient in the driver’s seat, allowing them to use a tablet to communicate their pain score. From there, the appropriate medication and dose can be selected from the medication cabinet, confirmed by a clinician, and given to the patient to address their pain, Sullivan explained. “The nurse doesn’t have to do a (pain) assessment. The patient helps with that.”

**REFERENCES**


Interested in more content like this?

Subscribe to our newsletters!
It's no secret that the United States is facing an obesity epidemic. Over 40% of the adult population is living with obesity, which can increase the risk for a multitude of health conditions including heart disease, stroke, and type 2 diabetes. Besides its impact on quality of life, obesity can be a burden on both individual finances and the health care system. Can pharmacists—positioned as trusted health care professionals in the communities they serve—play a role in bringing weight loss programs to the public?

Meagen M. Rosenthal, PhD, associate professor, Department of Pharmacy Administration, University of Mississippi School of Pharmacy, has taken part in research investigating the role of pharmacists in weight loss programs, including a scoping review of literature on the topic and research into pharmacists' and patients' attitudes toward pharmacy-based weight loss programs. “We have community pharmacists who are interested in doing this kind of work, and we have patients who are willing to see community pharmacists to make this work happen, which to me is the perfect storm of opportunity to do more of this work,” she said. In small rural communities dealing with recent hospital closures, Rosenthal noted, community pharmacists can play an important role in improving health outcomes.

In a review of 9 studies of pharmacist-run weight loss programs published between 2010 and 2017, Rosenthal and her colleagues found that patients in these programs lost a mean 3.8 kg over the course of the programs which, she said, “translates to important clinical reductions in...glucose levels for people who have diabetes and blood pressure levels for folks who have hypertension.”

Kathy M. Campbell, PharmD, owner of Medicap Pharmacy in Owasso, Oklahoma, who has had over 300 patients complete her pharmacy-based weight loss program over the past 6 years, reported dramatic results over the course of the 12-week program in some patients, including reductions in glycated hemoglobin A1c from 13.5 to 6.5 and a 107-point reduction in low-density lipoprotein cholesterol.

Personalized Programming
In focus group interviews with potential participants, many highlighted their desire for programs that are tailored to their individual needs, with a mix of one-on-one and group counseling sessions. Instead of a program with a specific defined curriculum, Rosenthal noted, they wanted opportunities to say things like “I can exercise fine on my own, but what I really need to know more about is how to cook for myself.”

Campbell’s 12-week pharmacy-based weight loss program typically includes 6 half-hour individual counseling sessions, but also offers group activities such as cooking demonstrations. Some pharmacy-based weight loss programs feature pharmacists working in conjunction with other providers to manage patients who are taking weight loss drugs. Campbell takes a more biochemical view of weight loss, and incorporates a Mediterranean diet–based meal plan,
pharmaceutical-grade supplementation with multivitamins, omega-3 fatty acids, and vitamin D, as needed, and counseling on movement (“It doesn’t have to be formal exercise,” she emphasized), stress management, and sleep. “The biggest secret is that it’s not a weight loss program. It’s a health program; it’s a lifestyle program,” Campbell said. “The by-product of a healthy body is a healthy weight.”

In sessions with patients, Campbell assesses whether they have drug- or disease-induced nutrient deficiencies that may cause weight gain and can be corrected by diet and supplementation. In some cases, she may recommend that a patient switch to a different drug.

Desiree Gaines, PharmD, health and wellness director at Avant Pharmacy and Wellness Center in Charlotte, North Carolina, does lab work before and after her 12-week weight loss program, examining patients’ lipid panels as well as vitamin D, magnesium, vitamin B₁₂, and folate levels to identify potential chronic conditions that require further evaluation by a medical provider. Gaines also uses these data to give patients recommendations on supplements and nutrition education outside counseling sessions, and she offers an app that allows patients to contact the pharmacist with questions at any time.

Pharmacists have a unique perspective on weight loss, as they recognize not only the effects of prescription drugs on weight, but also the effects of weight on prescription drugs. Most of the patients Campbell works with are taking between 3 and 5 medications. She coaches patients on communicating with their providers so they can, for example, adjust the dose of their antihypertensive medications.

“Many supplements actually enhance the effects of our traditional medications. Eventually these patients are able to either lower their doses, or... come off some of their medications,” Gaines said.

**Money Matters**

As in so many areas of pharmacy practice, lack of insurance reimbursement for services is a major impediment. Campbell’s motto is “no margin, no mission,” and she has moved beyond the dispensing fee model to charge patients for counseling services. After a great deal of market research, she introduced her weight loss program with a price tag of $1000—which patients were willing to pay. She also offers related products for sale in her pharmacy, such as cast-iron cookware and microgreens, and has even started her own line of supplements.

Gaines offers weight-loss counseling packages tailored to patients’ needs for cash prices that can range from $199 to $1500. “We are working on trying to find grants that will cover the cost of this program for our community so that we can make this accessible to everyone,” she said.

There is room for pharmacy advocacy in this area, Rosenthal added, to convince payers that reimbursement for health and weight management education will yield tremendous savings in health care costs.

**Getting Started**

Gaines advises pharmacists who want to start a weight loss program to focus on their goals and training. Education on topics related to health and weight loss is important. One such source is a course that Campbell teaches through the National Community Pharmacists Association, but there are other avenues of education as well.

One major challenge is figuring out how to fit weight loss counseling into pharmacy workflow. Gaines began by offering these classes in the evenings and on weekends and, once she had built up enough business, designated 1 day a week when she does only counseling while another pharmacist handles dispensing.

Promotion can be done through a combination of word-of-mouth, point-of-sale, print, and online advertising. Gaines’ pharmacy uses social media and hosts free events where it gives out products and showcases its offerings to specific demographic groups.

“I think that the biggest thing with marketing is telling people what you can do for them and then doing it,” Campbell said.

“Reach out to other pharmacists who may be doing similar programs,” Gaines advised. As an individual who struggled with her own weight challenges before establishing a program to help others, she added, “Start your program with yourself, family members, and close patients that you feel comfortable with. This is a great way for you to tweak your program the way you feel is best for you and your patients.”

For references, visit drugtopics.com.
Tips for Managing Autoimmune Disease During Pregnancy

Managing autoimmune conditions like type 1 diabetes, rheumatoid arthritis, and lupus during pregnancy can present challenges for patients and physicians. By Aine Cryts

The most valuable advice pharmacists can give to women with autoimmune conditions who want to get pregnant is simple: Participate in preconception planning.

Beyond that general advice, understanding a woman’s “head-to-toe” health is important, explained Susan Lanni, MD, a professor in the Division of Maternal-Fetal medicine at Virginia Commonwealth University (VCU) School of Medicine’s Department of Obstetrics and Gynecology. Women with type 1 diabetes (T1D), for example, might have another autoimmune condition present, she explained.

Conditions such as a history of heart attack; underlying vascular disease, nephropathy, or retinopathy; or other autoimmune disorders can make the care of a woman with T1D more complex, said Lanni, who is also a women’s health provider at VCU Health in Richmond, Virginia.

It makes a big difference if a woman’s T1D is well managed, and the general rule with such patients is “no alteration whatsoever,” Lanni said. The only reason to change the woman’s insulin is to get her blood sugar level under control, she added, noting that surveillance for vascular disease is also important if the woman’s condition isn’t well managed.

For other autoimmune diseases, study results have shown that hydroxychloroquine, sulfasalazine, and azathioprine are safe for pregnant women, said Mary Temple-Cooper, PharmD, MS, BCPS, a clinical coordinator at Cleveland Clinic’s Hillcrest Hospital in Ohio who specializes in obstetrics. It is safe to use azathioprine in pregnant women who have rheumatoid arthritis (RA) or lupus, she said, but dosage is important: Try to maintain it at 2 mg/kg per day or less.

Hydroxychloroquine can be prescribed safely in pregnancy to treat RA, lupus, and other autoimmune diseases. Sulfasalazine, a disease-modifying anti rheumatic drug, is used to treat RA, inflammatory bowel disease, and other autoimmune conditions.

OTC treatments like nonsteroidal anti inflammatory drugs may cause the fetus to experience kidney problems, which can result in low levels of the amniotic fluid that supports the development of their lungs, digestive system, and muscles. According to Temple-Cooper, other treatments to steer clear of include methotrexate, which can take 4 months to clear from the body, and mycophenolate mofetil, which a woman should stop taking a minimum of 4 weeks before conception.

Methotrexate can result in miscarriage or birth defects affecting the brain and bones, while mycophenolate mofetil can cause miscarriage and have teratogenic effects. During the first 3 to 5 weeks of pregnancy, teratogens can lead to neural tube defects, such as spina bifida.

For those prescribed steroids, appropriate use of those treatments is another consideration. “Many women [with autoimmune disease] will have major flares during pregnancy. The goal is to get them treated,” said Temple-Cooper. “You may have to use a high-dose steroid for the shortest possible [time] and then get them on the lowest dose possible to control them. What [we] find is that if you don’t keep [women] controlled, the outcomes are usually a lot worse if you pull them off the steroids.”

For references, visit drugtopics.com.

“Many women [with autoimmune disease] will have major flares during pregnancy. The goal is to get them treated.” Mary Temple-Cooper, PharmD, MS, BCPS
Retail Pharmacy Has Reached the Breaking Point

By Christine Blank

Pharmacy workloads, corporate demands, and customer behavior have stretched an already thin pharmacy workforce to the breaking point.

Breaks were nonexistent. I would have to try to use the bathroom at the most convenient time to step away from the pharmacy. Often I would find myself saying, “I’m going to the bathroom,” and 2 hours later still needing to go.” This is the story that one former employee at a major retail pharmacy chain told Drug Topics.

The lack of breaks, hiring of new staff, organization of staff schedules, and managerial support was a problem at the pharmacy even before the COVID-19 pandemic began, the pharmacist said.

After community pharmacists began administering COVID-19 vaccines, pharmacy staff workloads increased, but help was not available “due to staff quitting and not being replaced,” the pharmacist added.

She is now working for an independent pharmacy and said her work experience is “much better.”

But that former retail pharmacist is not alone. Many pharmacists and pharmacy staff have told Drug Topics and other national news outlets that they are leaving retail pharmacy or have plans to make a change.

“Community pharmacy is hemorrhaging pharmacists currently,” said another PharmD who recently left their role at another retail pharmacy chain after 11 years.

The lack of well-trained staff was the pharmacist’s biggest challenge. “I had not had enough staff for 7 months. Having to do the work of multiple people for so long really took its toll,” she said.

“People come and go because they get overwhelmed without adequate training,” she added. “The job does not pay enough for the level of stress that technicians endure.”

Stress and burnout among pharmacists and pharmacy technicians are not new issues, nor are they limited to retail pharmacy. Some pharmacists and technicians are leaving the profession and encouraging high school graduates not to go into pharmacy, said Lucinda L. Maine, PhD, RPh, executive vice president and CEO of the American Association of Colleges of Pharmacy (AACP).

Still, chain pharmacy practices have the highest percentage of pharmacists whose scores indicate the risk of high distress in the American Pharmacists Association’s (APhA) Well-Being Index for pharmacy personnel, an online self-assessment tool measuring well-being and suicidal ideation, and other factors. Last July, the national distress percentage for pharmacists had reached 33.68%.

Initial findings from APhA and the National Alliance of State Pharmacy Association’s (NASPA) 2022 National Pharmacy Workplace Survey validate the many anecdotal stories heard through national and state pharmacy association members and pharmacy-specific social media,” the organizations said in a news release.

“The responses to this survey indicate that work environment factors contribute to pharmacy personnel’s difficulty in performing their clinical and nonclinical duties effectively,” the organizations said. “There is no open mechanism for pharmacists and pharmacy personnel to discuss workplace issues with supervisors and management; if they try, the discussion is not welcomed or heard. This is concerning because feelings of not being listened to or valued are risk factors that can cause stress leading to occupational burnout.”

The APhA/NASPA survey identified a number of factors that contribute to stress—and may lead to medication errors or near misses—a list that includes increased demands on pharmacy staff; harassment, and bullying by patients/consumers; insufficient and ill-trained staff; employer focus on production results; constant interruptions or calls to insurance companies; and the addition of services with inadequate support for these services. Additional comments from pharmacy staff included complaints about management’s focus on metrics. “Quotas always increase,” said one commenter. “This year, our region’s flu shot goal is 500% larger than last year. It’s ridiculous.”

According to survey respondents, other issues that impact the ability of pharmacy staff to provide optimal patient care include the following:

- “Not caring that employees are at their breaking points mentally and emotionally while still asking for us to do more.”

Pharmacy workloads, corporate demands, and customer behavior have stretched an already thin pharmacy workforce to the breaking point.
“People come and go because they get overwhelmed without adequate training. The job does not pay enough for the level of stress that technicians endure.”

A FORMER RETAIL CHAIN PHARMACIST

- “Imposing unrealistic workload by increasing COVID-19 vaccines while we try to maintain good and safe service to our customers.”

- “Employers are solely focused on the bottom line. Eliminating technician hours and pushing salaried pharmacists to work 60 to 80 hours weekly without paying overtime. The money is not what matters, but the detriment to patient care and well-being of the pharmacist is evident for every pharmacy you walk into.”

- “Conflicting messaging: Go as slow as you need to avoid errors/get the prescriptions done and out faster, you slow down the discharge process.”

Many pharmacy organizations are supporting the Pharmacist’s Fundamental Responsibilities and Rights, developed by APhA and NASPA, which outlines the fundamental principles enabling pharmacists to fulfill their professional obligations to patients. The National Association of Boards of Pharmacy (NABP) recently pledged its support of the document. “NABP recognizes that pharmacists have a primary role in the protection of public health and the provision of quality health care,” NABP said in a statement adding that “In support of this role, pharmacists must be given the opportunity to understand their rights and responsibilities and preserve patient safety without fear of intimidation or retaliation.”

Retail Responds
"We greatly appreciate and value our pharmacists and technicians who have been working diligently on the front lines during the pandemic,” said a spokesperson for Albertsons Companies. “[We are] committed to supporting their work and well-being, and we have several initiatives in place to provide additional staff, reduce workload, and provide access to training.”

Meanwhile, spokespersons for Walgreens—another retail chain at the center of the movement to improve pharmacist working conditions—and CVS told Drug Topics® that their organizations are committed to hiring additional staff and improving working conditions.

“We are taking several steps to mitigate current pharmacy staffing pressures, including hiring thousands of new pharmacy team members, offering bonuses for vaccination certifications, and adjusting our appointment availability and store hours as needed,” Fraser Engerman, senior director of external relations at Walgreens, told Drug Topics®. The company also increased shift breaks for team members to “provide needed rest,” Engerman said.

Walgreens has “continued to offer new roles to allow our pharmacists more time to spend with our patients,” Engerman added. For example, the company created a pharmacy operations manager position to reduce the administrative burden on the retail chain’s pharmacy managers. In May 2021, Walgreens gave a bonus of $1000 to full-time pharmacists and $700 to part-time pharmacists. In September 2021, the company gave additional bonuses of $1250 to full-time pharmacists and $1000 to part-time pharmacists.

As of October 2021, all Walgreens pharmacy technicians receive a starting salary of $15 per hour, which will be increased to $16 per hour later this year. In addition, new pharmacy technician hires receive a $1250 signing bonus.

At CVS, many stores have teams dedicated to administering vaccines and are not filling prescriptions or counseling patients, Matt Blanchette, manager of retail communications for CVS Pharmacy, told Drug Topics®.

“At pharmacies without vaccination teams, we’ve adjusted workflows, processes, and vaccine scheduling to provide pharmacists and other vaccinators with predictability and structure for their day-to-day activities,” Blanchette said. “Also, we’re rolling out an additional prescheduled daily break time to create a predictable and consistent daily pause while minimizing disruption to our patients.”

For references, visit drugtopics.com.

Like what you're reading? Subscribe to our newsletters! Using your smartphone camera, hover over the QR code.
As more research is completed, COVID-19 treatment recommendations evolve. Guidance has been published by several institutions for treatment of patients hospitalized with COVID-19, and their basic recommendations are very similar. Although a standard of care has been offered, treatment of patients severely ill with COVID-19 is heavily dependent on a patient’s health condition and comorbidities. Clinical judgment should be used on a case-by-case basis.

Agents Recommended for Use
Corticosteroids, remdesivir, tocilizumab, and baricitinib are pharmaceutical agents commonly recommended for treatment of patients hospitalized with COVID-19.

Corticosteroids
Systemic corticosteroid use can reduce 28-day mortality in patients receiving respiratory support through oxygen supplementation and invasive or noninvasive mechanical ventilation, but not among those not receiving respiratory support.

The immune response in patients with severe COVID-19 symptoms can cause lung injury and significant organ damage. Corticosteroids inhibit the inflammatory response, reducing cytokine release. This weakens the intensity of the immune response and lowers the severity of organ damage. Common adverse effects (AEs) of steroid use include hyperglycemia, adrenal suppression, and myopathy, if given in high doses for long periods of time. Psychiatric disturbances may also occur, and steroids may also cause perforation risk in patients with gastrointestinal disease.

Dexamethasone is the recommended corticosteroid. Other steroid equivalents can be substituted.

Dosing regimen: Dexamethasone 6 mg intravenously (IV) or orally, once daily for up to 10 days or until hospital discharge.

Remdesivir (Veklury)
As of press time, remdesivir (Veklury)—a nucleotide analogue RNA polymerase inhibitor—is the only FDA-approved agent indicated for patients in this setting. It was approved in October 2020 for the treatment of adults and pediatric patients 12 years and older who weigh more than 40 kg and who require hospitalization for COVID-19. Remdesivir has an emergency use authorization (EUA) for hospitalized pediatric patients younger than 12 years, weighing between 3.5 kg and 40 kg with suspected or laboratory-confirmed COVID-19.

Common AEs include nausea and increased liver enzymes.

Dosing regimen: 200 mg IV once, then remdesivir 100 mg IV once daily for 5 days or until hospital discharge.

Tocilizumab (Actemra)
Originally approved in 2010 for rheumatoid arthritis (RA), tocilizumab was issued an EUA for the treatment of COVID-19 in hospitalized adults and pediatric patients age 2 years and older who are receiving systemic corticosteroids and who require supplemental oxygen, noninvasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO).

Tocilizumab, a monoclonal antibody to the IL-6 receptor, is administered by IV infusion. Tocilizumab may affect the expression of multiple cytochrome P450 enzymes. The precise effects are unknown, but they may last for several weeks after stopping therapy.

Severe AEs include serious infections, gastrointestinal perforation, and hepatotoxicity. The most common AEs include upper respiratory tract infections, nasopharyngitis, headache, hypertension, increased alanine transaminase level, and injection site reactions.

Dosing regimen: Tocilizumab 8 mg/kg actual body weight (up to a maximum of 800 mg) is administered as a single IV dose. In clinical trials, one-third of participants received a second dose of tocilizumab 8 hours after the first if no clinical improvement was observed.
Baricitinib (Olumiant)

Another drug originally approved for RA, baricitinib has additional use in treating patients with COVID-19, and—at press time—is also under EUA in combination with remdesivir for those hospitalized with COVID-19.

Baricitinib is an oral Janus kinase inhibitor known to have anti-inflammatory effects. In the COV-BARRIER study (NCT04421027), baricitinib was found to have a safety profile similar to that of standard of care alone and was associated with reduced mortality in hospitalized adults with COVID-19. However, it did not show a significant reduction in the frequency of disease progression overall.5

Dose reductions should be considered when coadministered with strong OAT3 inhibitors (eg, probenecid).6,7

Serious AEs include serious infections or worsening of active infections; increased risk of cancers; and increased risk of major cardiovascular events, blood clots, and tears in the stomach or intestines (especially with concomitant use of NSAIDs, corticosteroids, or methotrexate). The most common AEs include upper respiratory tract infections, nausea, cold sores, and shingles.6

**Dosing regimen:** Baricitinib dose is dependent on estimated glomerular filtration rate (eGFR). Duration of therapy is up to 14 days or until hospital discharge.1

- eGFR at least 60 mL/min/1.73 m²: baricitinib 4 mg orally once daily
- eGFR 30 to less than 60 mL/min/1.73 m²: baricitinib 2 mg orally once daily
- eGFR 15 to less than 30 mL/min/1.73 m²: baricitinib 1 mg orally once daily
- eGFR less than 15 mL/min/1.73 m²: baricitinib is not recommended.7

**Treatment Recommendations**

COVID-19 treatment is differentiated based on illness severity, determined by oxygen requirements. Prior to beginning therapy, patients severely ill with COVID-19 should be assessed for possible organ dysfunction and other comorbidities that could complicate potential therapy.1

**Drug Considerations**

Tocilizumab may be preferred to baricitinib in patients who cannot take anything orally. However, baricitinib can also be administered via oral dispersion, gastrostomy tube, or nasogastric tube.6,7

**Fever Reduction**

Acetaminophen is recommended for fever reduction for all patients with COVID-19, rather than NSAIDs. However, patients on chronic NSAIDs for other conditions should not discontinue use.1

**Patients Who Do Not Require Oxygen Supplementation**

Patients who have an oxygen saturation greater than 95% on room air and who do not require oxygen supplementation above their baseline should receive supportive care and oxygen monitoring.1 They should be closely monitored for disease progression.1 In the case of high risk for disease progression, remdesivir may be appropriate.1

The National Institutes of Health COVID-19 Treatment Panel recommends against the use of corticosteroids in these patients.1

**For Patients Requiring Oxygen Supplementation**

Therapy for patients who are severely ill with COVID-19 with oxygen requirements above their baseline continues on the level of oxygen.

**For Patients Requiring Low-Flow Oxygen**

For these patients, low-dose dexamethasone and remdesivir are recommended. Baricitinib or tocilizumab therapy is recommended as an adjuvant to be added based on different conditions, such as elevation of inflammatory marker C-reactive protein level (>75 mg/L), increased oxygen requirements despite dexamethasone, and being within 96 hours of hospitalization.1

**For Patients Requiring High-Flow Oxygen**

For patients requiring noninvasive high-flow oxygen, low-dose dexamethasone is recommended within 24 to 48 hours of patient admission to an ICU. Baricitinib or tocilizumab should be considered in addition to dexamethasone; the addition of remdesivir should be made if supplies are available. Remdesivir is prioritized for patients who are on low-flow oxygen supplementation at baseline.1

**Patients Requiring Mechanical Ventilation or ECHo**

Low-dose dexamethasone is recommended within 24 to 48 hours of admission to an ICU and within 96 hours of hospitalization. Tocilizumab can be added to dexamethasone therapy if tocilizumab is not available. Baricitinib is a reasonable alternative.1

**Conclusions**

Corticosteroids, remdesivir, tocilizumab, and baricitinib are not the only pharmaceutical agents available for treatment of hospitalized patients. Numerous other agents are under investigation, or are used on a case-by-case basis. Treating hospitalized patients with COVID-19 requires professional clinical judgment, as COVID-19 treatment guidelines are constantly evolving and can change based on evidence from studies and clinical trials.1

Betsy Adegboriyo is a PharmD candidate at South College School of Pharmacy, anticipated to graduate in spring 2022.

Debra Lee, MBA, BA, is a PharmD candidate at Duquesne University School of Pharmacy, anticipated to graduate in spring 2022.

Jonathan Ogurchak, PharmD, CSP, is CEO and cofounder of STACK, a professional information management platform. He also serves as a preceptor at more than 15 schools of pharmacy for a virtual advanced pharmacy practice experiential rotation for specialty pharmacy, technology, and entrepreneurship.

For references, visit drugtopics.com.
Thinking About Selling Your Pharmacy?

Whether you are just getting started in the selling process or not sure where to begin, our team of pharmacy brokerage and valuation experts have you covered!

Reasons owners come to us when preparing to sell:

- To learn more about the process
- Because they are unsure of the market
- To find out what their pharmacy is worth
- Help finding & negotiating with buyers
- Our database of hundreds of qualified buyers
- To maintain confidentiality with potential buyers

FREE Consultation
FREE Pharmacy Selling Guide
Guaranteed Confidentiality

PRSRx.com
800-338-3688
Hayslip & Zost
Pharmacy Brokers LLC

Ernie Zost, RPH
727-415-3659
Ernie@RxBrokerage.com

Tony Hayslip, ABR/AREP
713-829-7570
Tony@RxBrokerage.com

Need Expert Help
Selling / Buying a Pharmacy?
Approached by a Chain to Sell?
Looking for an Independent Buyer?
Need a Valuation for Your Pharmacy?

MAXIMIZE your value
MINIMIZE your worry

HAYSLIP & ZOST
PHARMACY BROKERS, LLC
Contact Hayslip & Zost for All Your Answers
RxBrokerage.com 1.800.530.5650

Endorsed by
State Pharmacy Associations
NEW DRUG REVIEW

Paxlovid: Oral Antiviral for the Treatment of COVID-19

By Cassandra R. Doyno, PharmD, BCPS, BCCCP

On December 22, 2021, the FDA issued an EUA for nirmatrelvir copackaged with ritonavir (Paxlovid; Pfizer).1 Paxlovid is the first oral pill indicated for the treatment of mild to moderate COVID-19 for certain adult and pediatric patients 12 years and older, weighing at least 40 kg, who have a positive SARS-CoV-2 viral test, whose symptoms have been present for at least 5 days, and who are at high risk for progression to severe disease, including hospitalization or death. Paxlovid is not indicated for treatment in those requiring hospitalization for severe disease, as exposure prophylaxis, or for those with symptoms that have been present for more than 5 days.3,4

Cassandra R. Doyno, PharmD, BCPS, BCCCP, is an assistant clinical professor at the University of Connecticut School of Pharmacy in Storrs.

For references, visit drugtopics.com

Efficacy

The Paxlovid EUA came from a planned interim analysis of the EPIC-HR Trial (NCT04960202), a phase 2/3 randomized, double-blind, placebo-controlled trial.2 At randomization, the trial enrolled 2246 nonhospitalized, symptomatic (<5 days) adult patients 60 years or older with at least 1 risk factor for progression to severe disease. Patients with a history of COVID-19 infection or evidence of vaccination against the virus were not included.

The primary efficacy end point was the proportion of patients with COVID-19–related hospitalization or death from any cause through day 28. In a modified intention-to-treat analysis (n = 2085) of patients whose symptom onset was within 5 days and who were not expected to receive monoclonal antibody therapy, 8 patients in the Paxlovid group (n = 1039; 0.8%) and 66 patients (n = 1046; 6.3%) in the placebo group were hospitalized or died.2 This represented an 88% decreased risk of hospitalization or death in those treated with Paxlovid vs placebo (–5.62 reduction relative to placebo; 95% CI –7.21 to –4.03). This is an interim analysis; effectiveness continues to be evaluated.2

Safety

Initial safety data also come from the EPIC-HR Trial. Notable adverse effects in the Paxlovid group vs placebo included dysgeusia, diarrhea, hypertension, and myalgia.2 As stated in the EUA, rates of reactions observed may not reflect the rates observed in clinical practice and may become more apparent with widespread use. Health care providers and/or facilities are required to track all serious medication errors and adverse events that are considered related to the drug and must report them to both the FDA and Pfizer.

Dosing and Special Considerations

Paxlovid is supplied as two 150-mg tablets of nirmatrelvir copackaged with one 100-mg tablet of ritonavir. The current dosing recommendation is 300 mg/100 mg every 12 hours for 5 days. A dose adjustment to 1 tablet of nirmatrelvir (150 mg) plus ritonavir (100 mg) is recommended in moderate renal impairment (eGFR 30-60 mL/min). Pharmacokinetic or safety data are not available for severe renal or hepatic impairment and pregnancy; therefore, use is not recommended in these populations.2

Paxlovid (ritonavir component) inhibits cytochrome P450 3A4 metabolism pathways, and many potentially significant drug interactions may exist. Contraindications to use are any clinically significant hypersensitivity reactions to active drug components of Paxlovid. The Paxlovid Fact Sheet for Healthcare Providers provides an extensive and comprehensive list of potential drug interactions.2 Given the significant potential for many drug interactions, pharmacists should review all concomitant medications and monitor for any adverse events that may be associated.