The High-Quality CBD You Can Trust

Forth™ CBD is third-party lab tested for quality and purity. Our full-spectrum CBD Lotions and Tinctures Drops provide all the benefits of the hemp plant without forfeiting quality—helping to relieve unwanted tension, improve recovery times from physical activities, and provide a sense of relaxation.

*Tincture Drops available in 10mg and 20mg of CBD per serving

For more details: ForthCBD.com/Contact-Us
Community Pharmacies Can Make a Difference As Health Hubs

Independent community pharmacy represented 35% of all retail pharmacies in the United States in 2019, according to the National Community Pharmacists Association’s 2020 NCPA Digest report.1 Particularly in rural and underserved areas, independent pharmacies have become the health care hubs for their communities, making them ideally positioned to bridge gaps in health care access. While the coronavirus disease 2019 (COVID-19) underscored disparities regarding access to care, supplies, and mortality in minority communities, pharmacy has only scratched the surface in addressing the factors that lead to these disparities.

On page 14, our cover story delves into how pharmacy professionals are serving minority populations to address these health care disparities and improve outcomes. In a series of interviews, we learn from pharmacy owners about what it means to provide culturally competent care and build trust with members of minority communities.

As Drug Topics’® Editorial Advisory Board member Lakesha Butler, PharmD, BCPS, says in this month’s issue: “Patient-provider trust is critical when serving communities of color.”

Additionally, February is American Heart Month. Individuals with diabetes are especially at greater risk of developing heart disease. On page 20, Jennifer Gershman, PharmD, discusses the prevention of heart disease and how pharmacists, as part an interdisciplinary team, can play an important role in helping patients with prediabetes or diabetes reduce their risk. You can also read more on this topic in our dedicated Heart Health resource center on drugtopics.com.

Immunizations are at the forefront of everyone’s mind. The COVID-19 pandemic has ushered in a renewed interest in vaccinations. This issue also discusses how pharmacies can effectively promote their immunization programs for important non-COVID vaccinations, as well as leveraging social media.

For health-system pharmacists, we dive into some of the top COVID-19–related medication safety errors occurring in hospitals amid the pandemic. The Institute of Safe Medication Practices offers best practice recommendations around potential risks associated with infusion pumps, drug shortages and importation, and drug labeling changes. Turn to page 30 to learn more.

Continue to visit drugtopics.com for up-to-date information and timely pharmacy news.

Thank you for reading,

Mike Hennessy Sr  
Chairman and Founder of MJH Life Sciences™
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.
Visit drugtopics.com for an

Get easy access to news, information, practical solutions, trusted perspectives through peer-based forums and opinions.

View in-depth interviews with industry experts.

Find therapeutic and condition-specific information for optimal patient care.

Medical World News®
Discover the 24-hour news channel for #healthcareprofessionals, by health care professionals.

Website Enhancements
• Streamlined navigation, so it is more user-friendly
• Improved mobile compatibility, so it is easier to read on your phone
• Increased responsiveness, so you can find what you are looking for
Enhanced Website Experience

Use our improved navigation and search.

Sign up to receive e-newsletters and the print publication.

Read keynote highlights, industry trends and policy updates.

Customize content specific to your needs.
A survey from the American Pharmacists Association (APhA) reported that more than 9 in 10 pharmacists plan to or have received the coronavirus disease 2019 (COVID-19) vaccine. The survey of 570 pharmacists was conducted from January 9-16, 2021. The respondents work in a broad range of practice settings, with a majority of respondents in community-based settings. Of the pharmacists who plan to or have been vaccinated, 51% said they received 1 dose, 10% received 2 doses, and 31% planned to get as soon as it is available.

Additionally, the survey results also showed that 95% of pharmacists reported confidence in addressing patient concerns about the vaccine, and 79% reported adequate staffing in their pharmacy for offering the vaccine.

According to APhA, this is the third survey of pharmacists that the organization has conducted about the COVID-19 vaccine. In each successive survey, an increasing number of pharmacists indicated plans to be immunized, manage the logistics of handling the vaccine, and administer it to their patients.

The Institute for Safe Medication Practices (ISMP) identified the most commonly reported errors or hazards associated with the administration of new coronavirus disease 2019 vaccines.

The most common mistakes identified in the reports included:
- dilution errors,
- vaccine and monoclonal antibody mix-ups,
- waste of doses,
- administration to wrong age groups,
- second dose scheduling errors, and
- allergic reactions.

Other reported errors include a misspelling in an email address that resulted in the patient not receiving information on an appointment to receive a second dose, the vaccination of underage patients, and serious but not life-threatening allergic responses.

To help reduce risk, ISMP offered several recommendations for health care organizations, which included best practices on vaccination site selection, dispensing of pharmacy-prepared syringes, independent double-checking, plans for leftover vaccine, and more.
In this episode of Over the Counter, Ryan Marable, PharmD, president of the National Pharmaceutical Association (NPhA), and Lakesha Butler, PharmD, BCPS, immediate past president of NPhA, shared insights on health disparities and social determinants of health (SDOH).

Marable and Butler both tackle SDOH, improving access to health care, and the pharmacist’s role in addressing these disparities to improve care for diverse populations.

"I think the first step is that interpersonal work: truly finding ways to educate ourselves on what might be contributing factors to these decreased health outcomes," Butler said in the episode.

Study: Patients Report Worse Migraine Symptoms During Pandemic

Patients with migraines reported more frequent and severe migraines during the coronavirus disease 2019 (COVID-19) pandemic, according to a study published in the Journal of Headache and Pain. Many also reported an overuse of analgesics.

Study investigators administered an online, self-reported survey that included demographic, migraine-related, COVID-19-specific, and overall psychosocial variables between July 15 and July 30, 2020.

In comparison with prepandemic period, approximately 60.0% of patients reported an increase in migraine frequency. 16.0% reported a decrease in frequency and 10.3% reported developing chronic migraine. Sixty-four percent of patients reported that their migraine severity increased during the pandemic. Most (61.5%) did not communicate with their neurologists. Additionally, nearly half (46.9%) reported adherence to treatment. However, 58.7% said they overused analgesic treatments. Sixty-six percent were negatively affected by Botox injection cancellations.

Long-term strategies should be validated and implemented to deliver quality care for patients with migraine, with an emphasis on psychosocial well-being, the investigators concluded.

64% of patients reported an increase in migraine severity during the pandemic, according to the study.

Study: Blood Pressure Medications Are Safe for Patients With COVID-19

Results of a recent study led by University of Pennsylvania investigators showed no risk for patients continuing their blood pressure medications while hospitalized with coronavirus disease 2019 (COVID-19).

The REPLACE COVID trial (NCT04338009), which was published in The Lancet Respiratory Medicine, compared outcomes among individuals with COVID-19 and diabetes by either continuing or discontinuing renin-angiotensin-converting enzyme inhibitors (ACEIs) or angiotensin receptor blockers (ARBs).

A total of 152 adult patients who had been admitted to the hospital with clinical presentation of COVID-19 and were prescribed either ACEI or ARB outpatient therapy prior to admission were included in the study.

Between March 31 and August 20, 2020, study participants were randomized to either stop or continue taking their blood pressure medications. Results demonstrated that continuation of ACEI or ARB therapy among hospitalized patients with COVID-19 had no overall effect on severity of infection and are consistent with previously published observational studies and unpublished trial evidence.

ThoughtSpot Series

Closing the Health Care Gap

In this episode of Over the Counter, Ryan Marable, PharmD, president of the National Pharmaceutical Association (NPhA), and Lakesha Butler, PharmD, BCPS, immediate past president of NPhA, shared insights on health disparities and social determinants of health (SDOH).

Marable and Butler both tackle SDOH, improving access to health care, and the pharmacist’s role in addressing these disparities to improve care for diverse populations.

"I think the first step is that interpersonal work: truly finding ways to educate ourselves on what might be contributing factors to these decreased health outcomes," Butler said in the episode.

This podcast episode was hosted by Brian Nightengale, PhD, RPh, president of Good Neighbor Pharmacy.

To listen to this podcast and others, visit www.drugtopics.com/podcasts.
Educating patients about the healing properties of lavender oil and reminding them to get flu vaccinations are 2 examples of advice that pharmacists can share on social media. But before doing so, securing buy-in from top management is essential, said Joey Mattingly, PhD, PharmD, an associate professor at University of Maryland School of Pharmacy in Baltimore.

Mattingly, who has 15 years of experience engaging in social media in the pharmacy field, was a pharmacy technician early in his career. A director-level leader at a large for-profit company near his employer didn’t like one of Mattingly’s social media posts about health policy and tried to get him fired. Mattingly emphasized that he wasn’t blogging on behalf of his employer and didn’t mask his identity online. He also kept his job, because of a leader in his organization who helped guide Mattingly in his career.

Pick the Right Social Media Platforms

Choosing the right online platforms for engagement is a good first step, said Mattingly, who added that Facebook is a great tool for a variety of audiences.

Mattingly advises pharmacies to be mindful of patient privacy. Although a patient can send tweets or post publicly to the pharmacy about medical history, the pharmacy must respond off-line, he explained. He recommends that patients call the pharmacy instead.

Keep It Simple

Joe Moose, PharmD, a clinical pharmacist and co-owner of Mount Pleasant, North Carolina–based Moose Pharmacy, tells pharmacies to use Hootsuite, a software program that allows users to schedule posts and push them out to multiple social media platforms. He hires young people—some are high school students—to post on the pharmacy’s social media account. They understand the technology, he explained.

Creating a content calendar helps, added Moose. Still, he tells employees at Moose Pharmacy’s 8 locations to watch for special moments to capture for social media. For example, a customer came in praising the pharmacy for saving her cat. That’s a perfect story for social media, said Moose.

Hire an Agency

Theresa Tolle, BPharm, FAPhA, a pharmacist and owner of Bay Street Pharmacy in Sebastian, Florida, recently chose to work with an agency to develop her social media strategy. The agency is well established in the pharmacy field, and she learned about its work at an industry trade show. Tolle also checked references among the agency’s current clients.

One thing that persuaded her to work with the agency was that it sent her free material for social media posts. For example, some posts helped remind customers to wear masks during the coronavirus disease 2019 (COVID-19) pandemic, said Tolle. The agency also helps craft posts to timely events relevant to patients, such as open enrollment periods, and national awareness days like World Diabetes Day (November 14), and even World Kindness Day (November 13) and National Nachos Day (November 6).

Focus on Established Science; Avoid Politics

Pharmacies should focus on using social media to share evidence-based information.

For example, although wearing a mask to prevent the spread of COVID-19 has become politicized in some parts of the country, Moose insists that pharmacies should use social media to dispel myths about mask wearing and urge patients to follow these guidelines. “Wearing masks saves lives,” he said.

If a patient disagrees in a post on the pharmacy’s Facebook page, the best way to handle it is to respond like this, said Moose: “Thanks for your response. We want to keep our community healthy. We think masks are a way to do that.”

Social Media for Your Pharmacy

Pharmacists share tips for engaging with patients online. By Aine Cryts
In the pivotal clinical trials, the most common solicited adverse reactions observed were pain, redness, and swelling at the injection site, myalgia, fatigue, headache, shivering, fever, and gastrointestinal symptoms.

'Data from the phase 3 ZOE-50 (≥50 years of age) trial and pooled data in individuals ≥70 years of age from the phase 3 ZOE-50 and ZOE-70 trials. See study designs on the next page for more details.'

**Indication**

SHINGRIX is a vaccine indicated for prevention of herpes zoster (shingles) in adults aged 50 years and older.

SHINGRIX is not indicated for prevention of primary varicella infection (chickenpox).

**Important Safety Information**

- SHINGRIX is contraindicated in anyone with a history of a severe allergic reaction (eg, anaphylaxis) to any component of the vaccine or after a previous dose of SHINGRIX
- Review immunization history for possible vaccine sensitivity and previous vaccination-related adverse reactions. Appropriate medical treatment and supervision must be available to manage possible anaphylactic reactions following administration of SHINGRIX

Please see additional Important Safety Information throughout and Brief Summary of Prescribing Information for SHINGRIX on the previous pages.
SHINGRIX DELIVERED >90% EFFICACY AGAINST SHINGLES REGARDLESS OF AGE IN THOSE 50 YEARS AND OLDER

<table>
<thead>
<tr>
<th>AGE</th>
<th>50-59†</th>
<th>60-69†</th>
<th>70-79†</th>
<th>≥80†</th>
</tr>
</thead>
<tbody>
<tr>
<td>Efficacy</td>
<td>96.6%</td>
<td>97.4%</td>
<td>91.3%</td>
<td>91.4%</td>
</tr>
<tr>
<td>(95% CI)</td>
<td>(89.6, 99.3)</td>
<td>(90.1, 99.7)</td>
<td>(86.0, 94.9)</td>
<td>(80.2, 96.9)</td>
</tr>
<tr>
<td>Shingles cases (n) in SHINGRIX group (N)</td>
<td>3 (3492)</td>
<td>2 (2141)</td>
<td>19 (6468)</td>
<td>6 (1782)</td>
</tr>
<tr>
<td>Shingles cases (n) in placebo group (N)</td>
<td>87 (3525)</td>
<td>75 (2166)</td>
<td>216 (6554)</td>
<td>68 (1792)</td>
</tr>
</tbody>
</table>

*Data from the phase 3 ZOE-50 (≥50 years of age) trial and pooled data in individuals ≥70 years of age from the phase 3 ZOE-50 and ZOE-70 trials in subjects who received 2 doses of SHINGRIX (N=7344 and 8250, respectively) or placebo (N=7415 and 8346, respectively) and did not develop a confirmed case of herpes zoster within 1 month after the second dose.*

**Study 1 Design:** Data from ZOE-50—a placebo-controlled, observer-blind, phase 3 trial conducted in 18 countries, in which subjects ≥50 years old were randomized to receive 2 doses (0 and 2 months) of either SHINGRIX (N=7698) or placebo (N=7713). A total of 7344 and 7415 subjects who received SHINGRIX and placebo, respectively, were included in the modified Total Vaccinated Cohort (mTVC) analysis.1,2

**Study 2 Design:** Data from ZOE-70—a placebo-controlled, observer-blind, phase 3 trial conducted in 18 countries, in which subjects 70 years old were randomized to receive 2 doses (0 and 2 months) of either SHINGRIX (N=8250) or placebo (N=8346). A total of 6541 and 6622 subjects who received SHINGRIX and placebo, respectively, were included in the mTVC analysis.1,3

1 Data from ZOE-50 phase 3 trial.1
2 Pooled data from ZOE-50 and ZOE-70 phase 3 trials.1
3 CI=confidence interval; n=number of subjects having at least 1 confirmed herpes zoster episode; N=number of subjects in each group.

The primary efficacy analysis (mTVC) in Studies 1 and 2 included all subjects who did not develop a confirmed case of HZ within 1 month after the second dose.1

**Pooled Analysis:** Data from ZOE-50 and ZOE-70 were combined in a pre-specified pooled analysis. A total of 8250 and 8346 subjects ≥70 years of age who received SHINGRIX and placebo, respectively, were included.1

The studies excluded subjects who were immunocompromised, had a previous history of HZ, were previously vaccinated against varicella or HZ, and patients whose survival was not expected to be at least 4 years, or with conditions that might interfere with study evaluations.1

**Important Safety Information (cont’d)**

- Solicited local adverse reactions in subjects aged 50 years and older were pain (78.0%), redness (38.1%), and swelling (25.9%).
- Solicited general adverse reactions in subjects aged 50 years and older were myalgia (44.7%), fatigue (44.5%), headache (37.7%), shivering (26.8%), fever (20.5%), and gastrointestinal symptoms (17.3%).
- SHINGRIX was not studied in pregnant or lactating women, and it is unknown if it is excreted in human milk. Therefore, it cannot be established whether there is vaccine-associated risk with SHINGRIX in pregnant women or if there are effects on breastfed infants or milk production/excretion.

To see the CDC Recommendations about vaccination, visit us at AgingSHINGRIX.com.

**References:**
2. Prescribing Information for SHINGRIX.
**SOLICITED ADVERSE REACTIONS**

<table>
<thead>
<tr>
<th>LOCAL ADVERSE EVENTS*</th>
<th>SHINGRIX (N=4884)</th>
<th>Placebo (N=4880)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain</td>
<td>78.0%</td>
<td>10.9%</td>
</tr>
<tr>
<td>Pain, Grade 3†</td>
<td>6.4%</td>
<td>0.3%</td>
</tr>
<tr>
<td>Redness</td>
<td>38.1%</td>
<td>1.3%</td>
</tr>
<tr>
<td>Redness, Grade 3‡</td>
<td>2.9%</td>
<td>0%</td>
</tr>
<tr>
<td>Swelling</td>
<td>25.9%</td>
<td>1.0%</td>
</tr>
<tr>
<td>Swelling, Grade 3‡</td>
<td>1.0%</td>
<td>0%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>GENERAL ADVERSE EVENTS*</th>
<th>SHINGRIX (N=4876)</th>
<th>Placebo (N=4881)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Myalgia</td>
<td>44.7%</td>
<td>11.7%</td>
</tr>
<tr>
<td>Myalgia, Grade 3†</td>
<td>5.1%</td>
<td>0.7%</td>
</tr>
<tr>
<td>Fatigue</td>
<td>44.5%</td>
<td>16.5%</td>
</tr>
<tr>
<td>Fatigue, Grade 3‡</td>
<td>5.3%</td>
<td>1.0%</td>
</tr>
<tr>
<td>Headache</td>
<td>37.7%</td>
<td>15.5%</td>
</tr>
<tr>
<td>Headache, Grade 3§</td>
<td>3.3%</td>
<td>0.7%</td>
</tr>
<tr>
<td>Shivering</td>
<td>26.8%</td>
<td>5.8%</td>
</tr>
<tr>
<td>Shivering, Grade 3§</td>
<td>4.1%</td>
<td>0.3%</td>
</tr>
<tr>
<td>Fever†</td>
<td>20.5%</td>
<td>3.0%</td>
</tr>
<tr>
<td>Fever, Grade 3‡</td>
<td>0.3%</td>
<td>0.2%</td>
</tr>
<tr>
<td>Gastrointestinal Symptoms*</td>
<td>17.3%</td>
<td>8.7%</td>
</tr>
<tr>
<td>Gastrointestinal Symptoms, Grade 3§</td>
<td>1.4%</td>
<td>0.6%</td>
</tr>
</tbody>
</table>

*Main safety pooling analysis, ZOE-50 and ZOE-70 studies. Incidence of solicited general symptoms reported during the 7-day (i.e., day of vaccination and subsequent 6 days) post-vaccination period, overall/subject (Total vaccinated cohort with 7-day diary card; subjects ≥50 YOA).

†Significant pain at rest; prevented normal everyday activities.

‡Temperature ≥99.5°F (≥37.5°C).

§Including nausea, vomiting, diarrhea, and/or abdominal pain.

N=number of subjects with at least 1 documented dose; YOA=years of age.

To see the CDC Recommendations about vaccination, visit us at AgingSHINGRIX.com

**Important Safety Information (cont’d)**

• Vaccination with SHINGRIX may not result in protection of all vaccine recipients

Please see additional Important Safety Information throughout and Brief Summary of Prescribing Information for SHINGRIX on the previous pages.


Trademarks are owned by or licensed to the GSK group of companies.

©2020 GSK or licensor.

SGX:RNA200009 August 2020

Produced in USA.
The reported frequencies of specific solicited local adverse reactions and general adverse events (overall per subject), by age group, from the 2 studies are presented in Table 1:

Table 1. Percentage of Subjects with Solicited Local Adverse Reactions and General Adverse Events within 7 Days of Vaccination in Adults Aged 50 to 59 Years, 60 to 69 Years, and 70 Years and Older* (Total Vaccinated Cohort with 7-Day Diary Card)

<table>
<thead>
<tr>
<th>Aged 50-59 Years</th>
<th>Aged 60-69 Years</th>
<th>Aged ≥70 Years</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>SHINGRIX%</td>
<td>Placebo%</td>
</tr>
<tr>
<td>Local Adverse Reactions</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain</td>
<td>n=1,315</td>
<td>n=1,312</td>
</tr>
<tr>
<td>Pain, Grade 3</td>
<td>10.3</td>
<td>0.5</td>
</tr>
<tr>
<td>Redness</td>
<td>38.7</td>
<td>1.2</td>
</tr>
<tr>
<td>Swelling</td>
<td>30.5</td>
<td>0.8</td>
</tr>
<tr>
<td>Swelling, &gt;100 mm</td>
<td>1.1</td>
<td>0.0</td>
</tr>
<tr>
<td>General Adverse Events</td>
<td>n=1,315</td>
<td>n=1,312</td>
</tr>
<tr>
<td>Myalgia</td>
<td>56.9</td>
<td>15.2</td>
</tr>
<tr>
<td>Myalgia, Grade 3</td>
<td>8.9</td>
<td>0.9</td>
</tr>
<tr>
<td>Fatigue</td>
<td>57.0</td>
<td>19.8</td>
</tr>
<tr>
<td>Fatigue, Grade 3</td>
<td>8.5</td>
<td>1.8</td>
</tr>
<tr>
<td>Headache</td>
<td>50.6</td>
<td>21.6</td>
</tr>
<tr>
<td>Headache, Grade 3</td>
<td>6.0</td>
<td>1.7</td>
</tr>
<tr>
<td>Shivering</td>
<td>35.8</td>
<td>7.4</td>
</tr>
<tr>
<td>Shivering, Grade 3</td>
<td>6.8</td>
<td>0.2</td>
</tr>
<tr>
<td>Fever</td>
<td>27.8</td>
<td>3.0</td>
</tr>
<tr>
<td>Fever, Grade 3</td>
<td>0.4</td>
<td>0.2</td>
</tr>
<tr>
<td>GI</td>
<td>24.3</td>
<td>10.7</td>
</tr>
<tr>
<td>GI, Grade 3</td>
<td>2.1</td>
<td>0.7</td>
</tr>
</tbody>
</table>

Total vaccinated cohort for safety included all subjects with at least 1 documented dose (n).

* 7 days included day of vaccination and the subsequent 6 days.

** Data for subjects aged 50 to 59 years and 60 to 69 years are based on Study 1. Data for subjects 70 years and older are based on pooled data from Study 1: NCT01165177 and Study 2: NCT01165229.

Paragraph continues on the next page.
The incidence of solicited local and general symptoms was lower in subjects aged 70 years and older compared with those aged 50 to 69 years.

The majority of solicited local adverse reactions and general adverse events seen with SHINGRIX had a median duration of 2 to 3 days.

There were no differences in the proportions of subjects reporting any or Grade 3 solicited local reactions between Dose 1 and Dose 2.

Headache and shivering were reported more frequently by subjects after Dose 2 (28.2% and 21.4%, respectively) compared with Dose 1 (24.4% and 13.8%, respectively). Grade 3 solicited general adverse events (headache, shivering, myalgia, and fatigue) were reported more frequently by subjects after Dose 2 (2.3%, 3.1%, 3.6%, and 3.5%, respectively) compared with Dose 1 (1.4%, 1.4%, 2.3%, and 2.4%, respectively).

Unsolicited Adverse Events

Unsolicited adverse events that occurred within 30 days following each vaccination (Day 0 to 29) were recorded on a diary card by all subjects. In the 2 studies, unsolicited adverse events occurring within 30 days of vaccination were reported in 50.5% and 32.0% of subjects who received SHINGRIX (n = 14,645) and placebo (n = 14,660), respectively (Total Vaccinated Cohort). Unsolicited adverse events that occurred in >1% of recipients of SHINGRIX and at a rate at least 1.5-fold higher than placebo included chills (3.5% versus 0.2%), injection site pruritus (2.2% versus 0.2%), malaise (1.7% versus 0.3%), arthralgia (1.7% versus 1.2%), nausea (1.4% versus 0.5%), and dizziness (1.2% versus 0.8%).

Gout (including gouty arthritis) was reported by 0.18% (n = 27) versus 0.05% (n = 8) of subjects who received SHINGRIX and placebo, respectively, within 30 days of vaccination; available information is insufficient to determine a causal relationship with SHINGRIX.

Serious Adverse Events (SAEs)

In the 2 studies, SAEs were reported at similar rates in subjects who received SHINGRIX (2.3%) and placebo (2.2%) from the first administered dose up to 30 days post last vaccination. SAEs were reported for 10.1% of subjects who received SHINGRIX and for 10.4% of subjects who received placebo from the first administered dose up to 1 year post last vaccination. One subject (<0.01%) reported lymphadenitis and 1 subject (<0.01%) reported fever greater than 38°C; there was a basis for a causal relationship with SHINGRIX.

Optic ischemic neuropathy was reported in 3 subjects (0.02%) who received SHINGRIX (all within 50 days after vaccination) and 0 subjects who received placebo; available information is insufficient to determine a causal relationship with SHINGRIX.

Deaths

From the first administered dose up to 30 days post last vaccination, deaths were reported for 0.04% of subjects who received SHINGRIX and 0.05% of subjects who received placebo in the 2 studies. From the first administered dose up to 1 year post last vaccination, deaths were reported for 0.8% of subjects who received SHINGRIX and for 0.9% of subjects who received placebo. Causes of death among subjects were consistent with those generally reported in adult and elderly populations.

Potential Immune-Mediated Diseases

In the 2 studies, new onset potential immune-mediated diseases (pIMDs) or exacerbation of existing pIMDs were reported for 0.6% of subjects who received SHINGRIX and 0.7% of subjects who received placebo from the first administered dose up to 1 year post last vaccination. The most frequently reported pIMDs occurred with comparable frequencies in the group receiving SHINGRIX and the placebo group.

Dosing Schedule

In an open-label clinical study, 238 subjects 50 years and older received SHINGRIX as a 0- and 2-month or 0- and 6-month schedule. The safety profile of SHINGRIX was similar when administered according to a 0- and 2-month or 0- and 6-month schedule and was consistent with that observed in Studies 1 and 2.

6.2 Postmarketing Experience

The following adverse reactions have been identified during postapproval use of SHINGRIX. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to the vaccine.
CULTURALLY COMPETENT CARE FIGHTS HEALTH DISPARITIES
Pharmacy professionals serving minority populations aim to bridge gaps in health care access.

By Frieda Wiley, PharmD

Miguel Oseguera, CPhT, got his start in pharmacy by sweeping floors. Although he worked his way up to becoming a pharmacy technician, the first-generation Mexican American never envisioned owning his own pharmacy, let alone bridging the gap in culturally competent health care. But that is what happened in summer 2019, when he opened the doors to Familia Farmacia, which serves the Hispanic community of Modesto, California.

Entrepreneur Invests in His Community

Oseguera saw an opportunity to fill a void when the only independent pharmacy in the South Modesto neighborhood closed after 34 years. The area, in California’s Central Valley nearly 100 miles from San Francisco, has a largely Mexican and Mexican American population.

“Let’s face it: No chain pharmacies or other big businesses were going to come to this area,” he said. “Most of the businesses here are independently owned.”

Oseguera’s pharmacy has features that attract Hispanic patients, one being its location in their neighborhood. In addition, the staff provides service in English and Spanish, something Oseguera emphasized is essential in establishing strong patient rapport.

“Speaking the language is enough already,” he said. “But it’s also an important way to develop a sense of trust that helps your patients relate to you.”
Oseguera, a Modesto-area native, said his cultural ties give him another advantage. "I was born here and raised with Mexican values so that I can relate to the people here," he said.

Not only are most of Oseguera's patients Mexican or Mexican American, but many hail from the same region as his family, Michoacán. He equates the high concentration of immigrants from Michoacán in the Modesto area with those from Ireland, Italy, or Asian countries moving to specific regions.

The pharmacy's inventory and layout reveal another draw for Oseguera's patients: One wall houses a vast collection of prepackaged herbs used in traditional home remedies in the Mexican culture.

Oseguera's initiatives are logical and appropriate to address health challenges in diverse populations, according to Drug Topics® Editorial Advisory Board Member Lakesha Butler, PharmD, BCPS, clinical professor of pharmacy practice at Southern Illinois University Edwardsville.

Members of minority populations "understand the history of medical racism and mistreatment of people of color in this country, enduring it ourselves," said Butler, who is African American. "This understanding often translates to providing compassionate care and advocating for minoritized communities."

"I try to connect with folks on social media and establish a rapport so I can direct them to health care services provided by people who look like them."

FRANK NORTH, PHARMD, MPA

Frank North, PharmD, MPA, president-elect of the National Pharmaceutical Association and founder of Frank North and Associates, has dedicated his career to addressing disparities in the African American community. His family history—North's father was among the first African American students to earn a PhD from the University of Colorado in Boulder—and professional goals illustrate a principle of cultural competency: valuing diversity. "Many think all people of African descent have the same culture, but African Americans have their own subcultures within their families and throughout different regions of the United States," North said. "Also, African American culture differs from Africans' culture from other countries such as Ghana or [European countries]."

As a clinical pharmacist for the Rowe Network, a company founded by Tisha Rowe, MD, North uses social media to reach out to African American patients. The company engages patients using a telemedicine network called RoweDocs. North addresses access and adherence issues. He also directs users to other health care providers.

"I try to connect with folks on social media and establish a rapport so I can direct them to health care services provided by people who look like them," North said.

Social media is hugely influential in the Black community. According to a 2020 report from Pew Research, 8 of every 10 Black social media users consider it an effective platform for raising awareness of social and political issues. Seven of 10 Black social media users view it as a useful tool in influencing decisions. The statistics in Hispanic and Asian communities are similar, and White social media users trail by roughly 10% in each category.

RoweDocs also disseminates information regarding health initiatives such as diabetes month, breast cancer awareness, and the American Heart Association’s Go Red for Women. Prospective patients visiting the website may subscribe to the company’s newsletter, watch videos, and read blogs. The website also encourages users to leave comments—a feature North said creates opportunity for additional interaction.

Improving Health Literacy

Donney John, PharmD, uses his role as executive director of NOVA ScriptsCentral, a nonprofit pharmacy in Falls Church, Virginia, to improve health literacy in non-English-speaking communities. As with other charitable pharmacies across the nation, NOVA ScriptsCentral's mission is to help underserved populations.

John's organization is predominantly grant funded and focuses on providing uninsured patients prescriptions at little to no cost.

NOVA ScriptsCentral site users can choose to have the web copy...
translated from English into Spanish, Portuguese, Chinese, French, Hindi, or Vietnamese. The pharmacy’s efforts to connect with these patient populations do not stop there.

This year marks the launch of NOVA ScriptsCentral’s Diabetes Access Pilot Initiative 2021. NOVA ScriptsCentral will offer free insulin to uninsured patients who receive care at any of the 16 clinics with which the pharmacy partners in northern Virginia.

“Virginia passed a law where the maximum co-pay for insulin is $50,” John told Drug Topics®. “This does nothing for people who have no insurance because they always pay cash.”

In addition to generating revenue from donors, NOVA ScriptsCentral is registered as a pharmacy allowed to accept old medications patients bring in and dispense them to others in need. John referenced a charitable pharmacy in California that dispenses medications it has repackaged from physician samples. However, he said, such a practice is illegal in many states. Other states observe a Good Samaritan law that allows them to engage in such activities to improve medication access for patients in need.

John traces his mission to his childhood, growing up among diverse cultures in New York, New York. Eventually, he would practice as a pharmacist working with underserved communities at a federally qualified health center in Boston, Massachusetts. These experiences helped him recognize cultural nuances among minority communities.

“If people of color don’t have access to the right medical care or understand their health, they’ll never improve their health,” he said. “To change their behavior, you must first understand the people and where they’re coming from.”

**Looking Ahead**

Despite the efforts of Oseguera, North, and John, and other like-minded pharmacy professionals, Butler said pharmacy practice has yet to master authentic cultural competence.

“Unfortunately, cultural competency in pharmacy has only scratched the surface in addressing the pertinent factors contributing to health disparities,” she said. “There has been a significant gap in addressing racism in pharmacy and health care, resulting in health inequities that persist.”

For example, the coronavirus disease 2019 pandemic challenged many aspects of the health care system while magnifying disparities regarding access to care, supplies, and mortality in minority communities.

“You see a level of disbelief about the coronavirus and the hesitancy around getting the vaccine that’s more prominent in communities of color—especially in African American communities,” North said. “Minority groups tend to respond better to health care providers who look like them, have their best interest at heart, and are able to break down barriers.”

Unfortunately the odds that a minority patient can navigate the health care system by only interacting with minority professionals belonging to their communities is statistically impossible. Consequently, all health care providers and clinicians must improve their skills in serving patients outside their own communities.

Butler emphasized the importance of building trust when bridging cultural gaps, regardless of whether the health care professional shares the same background.

“Patient-provider trust is critical when serving communities of color.”

For more information on cultural competency and the pharmacies mentioned in this story, please see the following resources:

- https://ncc.georgetown.edu/
- http://www.hpoe.org/Reports-HPOE/becoming_culturally_competent_health_care_organization.PDF
- https://www.remedichain.org
- https://rowedocs.com/
- https://novascriptscentral.org
- https://familiafarmacia.business.site/
Immunization is one of the most familiar pharmacy clinical services; approximately 77% of community pharmacies offer flu vaccines and 73% provide other immunizations, according to the National Community Pharmacists Association (NCPA). All 50 states have had authorized pharmacists to immunize patients in some form since 2010, but promoting such services also is necessary to achieve results.

Beverly Schaefer, RPh, has been starting immunization conversations at Katterman’s Sand Point Pharmacy in Seattle, Washington, for more than a decade. She is co-owner and evangelist-in-chief for a program that delivered over 4000 influenza immunizations from September 1 to October 10, 2020, even amid store closures for Sundays and Labor Day weekend.

Promoting immunization services is more about generating questions and providing information than about selling, she said. Something as simple as a countertop card asking “Have you had your shingles vaccine yet?” can be highly effective. Patients see the sign while they’re doing something else, such as having a prescription filled, asking a question, or looking for an OTC product, Schaefer explained.

“If they know about shingles vaccine, they think, ‘Oops, I need to get that done,’” she said. “If they don’t know about it, they ask what it is. Either way you started that first conversation that leads to immunization. And because they asked the question, you’re providing information they can use, not trying to sell them some product they may or may not want.”

The scenario is different for severe acute respiratory syndrome coronavirus 2 vaccines. The coronavirus disease 2019 (COVID-19) pandemic itself is starting vaccine conversations around the world.

“Vaccine demand greatly exceeds supply right now,” said John Vinson, PharmD, CEO of the Arkansas Pharmacy Association. Community pharmacies have been the primary distribution point for COVID-19 immunizations in Arkansas since the first doses were delivered in late December 2020.

“Anytime demand greatly exceeds supply, you don’t have to do a lot of marketing,” Vinson said. “But you do have to do a lot of planning to get that vaccine into as many people as possible, as fast as you can.”

Expand Your Program
Planning is part of any successful immunization program. Under normal circumstances, state laws and regulations govern pharmacy immunization programs.

“Some states have [been] pretty liberal with vaccine authority;” noted John Beckner, RPh, NCPA senior director of strategic initiatives. “Others are still pretty restrictive, whether it’s limited pharmacists to certain vaccines or certain age groups.”

Pharmacists must tailor their immunization programs to meet state requirements. That could mean not providing pediatric immunizations or providing only select vaccines such as influenza, shingles, or measles-mumps-rubella.

In Wisconsin, however, changes to the state pharmacy act that took effect in early 2020 allow pharmacists to prescribe and administer any vaccine approved by the FDA as recommended by the CDC. Pediatric vaccines must be reported within 7 days.

Wisconsin’s broad immunization authority was no accident. The Pharmacy Society of Wisconsin (PSW) actively promoted pharmacy-based immunization to expand vaccine access.

“We worked with other health care providers to expand immunization...
authority for pharmacists and to get more patients into pharmacies to get vaccines,” said Sarah Sorum, PharmD, PSW executive vice president and CEO. “It started with a formal survey that documented what we knew, that other providers recognize pharmacists as fully competent to provide vaccines, and that pharmacists are more accessible than any other providers. We went to the state as a group saying that better vaccine uptake is better health care regardless of who administers it.”

COVID-19 gives pharmacies nationwide similar authority. The US Department of Health & Human Services (HHS) promulgated rules under the public health emergency (PHE) declaration allowing pharmacists to administer any FDA-approved vaccine. While the PHE continues, HHS rules override state regulation to give pharmacists broad immunization authority.

“Pharmacy is taking on a much more active role, making sure that children as well as adults aren’t falling behind in their immunizations,” said Michael Hogue, PharmD, FAPhA, FNAP, president of the American Pharmacists Association and dean and professor at Loma Linda University School of Pharmacy in California. “And with kids, pharmacists are strengthening their connections to pediatricians to refer for developmental checks and well-child visits that are usually tied to childhood immunizations. That’s the kind of thing too many people don’t realize pharmacists are doing.”

The Million-Dollar Move

Many pharmacists have been too busy providing immunization services to talk about it. “Pharmacists get into this business to help people, to serve our patients,” said Hannah Fish, PharmD, associate director of strategic initiatives at NCPA. “We don’t always remember that we have to promote ourselves and our services to better care for patients.”

That’s where sparking that initial conversation about immunization matters. Countertop signs can start the conversation for patients who are already in the pharmacy. Sidewalk signs are just as effective at bringing in drive-by traffic.

“They don’t suddenly swerve into the parking lot asking for a shingles shot or FluMist,” Schaefer said. “But when you see that sign every day when you drive by, it has a cumulative effect. One day people stop in and the conversation starts.”

Word of mouth and social media can be more effective over a broader area. Schaefer used Twitter to spread the word about appointment-only flu vaccinations. The problem wasn’t publicity, but staff time.

It takes at least 10 minutes to enter new patient information for an influenza vaccine. That’s no problem for the occasional walk-in patient, but for 4000 new flu vaccine immunizations, 10-minute periods add up. Schaefer expects to administer 7000 to 10,000 COVID-19 immunizations during the next few months.

“That kind of time takes some modification to workflow,” she said. “When you start promoting immunizations and ramping up your program, you have to take staff time into consideration.”

Beyond COVID-19

Pharmacies nationwide should be preparing to modify their workflow for COVID-19 immunizations, talking with patients about vaccines in general and COVID-19 in particular.

“Community pharmacies are the key distribution point for COVID-19 vaccines for the CDC,” Hogue said. “They are expecting that community-based pharmacies will pick up the yeoman’s work in administering vaccines in local communities. Having adequate staffing is going to be key to success in this.”

Trust and information are also key. Vaccine misinformation has been growing for years, noted Anna Dopp, PharmD, senior director of clinical guidelines and quality improvement for the American Society of Health-System Pharmacists.

“Vaccine choices often come down to a one-on-one interaction between the patient and the pharmacist,” Dopp said. “That relationship, that trust, will likely be the driver for someone to access care and get a vaccine from there.”

Arkansas pharmacies are adapting familiar onsite clinic models to promote and deliver COVID-19 vaccines. In the initial rollout to long-term care facilities, community pharmacies vaccinated 100% of residents and staff within 72 hours, Vinson reported. Similar onsite delivery by chain providers in the state took about 30 days.

Immunizing about 300 million individuals against COVID-19 could be the beginning of greater pharmacy involvement. State and national pharmacy groups built on the success of pharmacy-based novel influenza A vaccines to expand immunization authority for pharmacy. COVID-19 could provide a similar boost.

“COVID-19 is absolutely transformational for the profession,” Vinson said. “Pharmacists are not only the prescribers of the vaccine; they’re also the educators, counselors, and providers.”

For references, visit drugtopics.com.

February 2021
Atherosclerotic cardiovascular disease (ASCVD) is the leading cause of morbidity and mortality, both globally and in individuals with type 2 diabetes (T2D). 1

Individuals with diabetes are at greater risk of developing CVD, with common risk factors including high blood pressure (BP), abnormal cholesterol levels and high triglycerides, obesity, physical inactivity, poorly controlled blood sugars, and smoking. Pharmacists, as part of an interdisciplinary team, can play an important role in helping patients with prediabetes or diabetes reduce their risk of CVD through education, medications for risk reduction, and lifestyle modifications.

Prediabetes and Prevention of T2D
Approximately 88 million adults in the United States have prediabetes, and about 84% of those individuals do not realize they have it and are at risk of developing T2D and CVD. 2

According to the American Diabetes Association (ADA), individuals who meet any 1 of the following criteria have prediabetes:

- fasting plasma glucose level of 100 mg/dL to 125 mg/dL,
- 2-h plasma glucose level during 75-g oral glucose tolerance test of 140 mg/dL to 199 mg/dL, or
- glycated hemoglobin (A1C) level of 5.7% to 6.4%. 1

The ADA recommends annual monitoring for the development of T2D in patients with prediabetes. 3 Pharmacists can also screen patients for risk of developing T2D during medication therapy management consults using the 60-second ADA risk test. 4 This tool is available electronically and in print, and the results can be emailed to the patient. Individuals who score 5 or higher may have prediabetes, and these results along with lab work can serve as an important counseling and referral tool. 4

Patients with prediabetes should be referred to an intensive lifestyle behavior program known as the National Diabetes Prevention Program (DPP) to achieve and maintain a 7% loss of initial body weight and increase moderate-intensity physical activity to at least 150 minutes each week. 5 The National DPP was developed in 2010 by the CDC along with other organizations to prevent T2D in the United States, and patients must meet certain eligibility criteria to enroll (see Table). 6 The 1-year lifestyle change program is one of the key components of the National DPP for patients to reduce their risk of developing T2D, and it includes a CDC-approved curriculum (approximately 24 hours of instruction), a lifestyle coach, and a support group. 7 Evidence has shown that the National DPP reduces the risk of developing T2D by up to 58% (71% for those over 60 years of age) in participants who lost 5% to 7% of their body weight and added 150 minutes of exercise per week. 5

Metformin pharmacotherapy for the prevention of T2D should be considered in patients with prediabetes, especially in the following individuals: those with a body mass index greater than or equal to 35 kg/m², individuals under 60 years of age, and women with prior gestational diabetes mellitus. 3 Patients should have their vitamin B12 levels monitored because long-term metformin therapy may cause vitamin B12 deficiency. 3

Pharmacists can promote awareness about prediabetes and educate patients at risk about the National DPP. 8 Additionally, evidence demonstrates that more pharmacy sites are offering the program. 9 Administering a blood glucose test is a great way to identify patients with prediabetes and pharmacists should communicate this information to the primary care physician or refer individuals to a health care provider. Pharmacies can also deliver the National DPP by applying to become
CDC recognized, and pharmacy residents, students, and technicians can help to support the program.4

CVD Risk Reduction Strategies
The American College of Cardiology (ACC) and American Heart Association (AHA) recommend a team-based approach for the prevention of CVD.1

Adults should consume a healthy diet that includes vegetables, fruits, nuts, whole grains, lean vegetable or animal protein, and fish. Additionally, the diet should minimize the intake of trans fats, processed red meats, refined carbohydrates, and sweetened beverages.1 Evidence demonstrates that dietary sodium consumption of less than 1500 mg/d and reduced alcohol intake (men ≤ 2 drinks daily and women ≤ 1 drink daily) are non-pharmacological ways to reduce BP1

Individuals who are overweight or obese should receive counseling on caloric restriction to reduce their risk of CVD. Adults should also engage in at least 150 minutes per week of moderate-intensity physical activity or 75 minutes per week of vigorous-intensity physical activity.1 Patients should also be assessed at every health care visit for tobacco use, and those who are smokers should receive smoking cessation support through a combination of behavioral interventions and pharmacotherapy (eg, nicotine replacement therapy).1

Individuals aged 40 to 75 years being assessed for CVD should routinely undergo the 10-year risk of ASCVD assessment, and adults aged 20 to 39 years should be assessed every 4 to 6 years.1 The ASCVD risk estimator is available as a free app that health care professionals can use at the point of care to help guide clinical decisions.6 The 10-year risk for ASCVD is categorized as the following: low risk, less than 5%; borderline risk, 5% to 7.4%; intermediate risk, 7.5% to 19.9%; high risk, greater than or equal to 20%.6 Most adults with diabetes have a 10-year ASCVD risk of greater than or equal to 10%.

Statin therapy is considered first-line treatment for primary prevention of ASCVD in patients with elevated low-density lipoprotein cholesterol levels (≥ 190 mg/dL), those with diabetes, individuals aged 40 to 75 years, and those determined to have a sufficient ASCVD risk.7 The ACC/AHA guidelines discuss that aspirin should not be routinely used for the primary prevention of ASCVD in adults at any age who are at increased risk of bleeding.8 Also, low-dose aspirin should not be given for the primary prevention of ASCVD in adults 70 years and older. Low-dose aspirin may be considered for the primary prevention of ASCVD among certain adults aged 40 to 70 years who are at higher risk of ASCVD but not at increased risk of bleeding.9 Pharmacists can play an important role in counseling patients and educating other health care professionals about these new aspirin recommendations.

The ADA recommends that patients with diabetes have individualized BP goals.11 If individuals with diabetes and hypertension are at higher risk of ASCVD or have a 10-year ASCVD risk greater than or equal to 15%, a target BP level of less than 130/80 mm Hg may be appropriate. Patients at lower risk for CVD (10-year ASCVD risk <15%) should receive anti-hypertensive treatment to a target BP of less than 140/90 mm Hg.11 Evidence demonstrates that angiotensin-converting enzyme inhibitors, angiotensin receptor blockers, thiazide-like diuretics, and dihydropyridine calcium channel blockers can all reduce cardiovascular events in patients with diabetes, and any of these drug classes can be utilized as initial treatment for hypertension.11

The Community Preventive Services Task Force recommends tailored pharmacy-based interventions to enhance adherence in patients with CVD risk factors.3 Evidence demonstrates that pharmacist interventions in the community and hospital settings increase medication adherence through pill boxes, medication cards, calendars, medication refill synchronization, and follow-up.3 Additionally, improved medication adherence results in health care cost savings.13 Pharmacists can communicate interventions with the patient’s primary care provider as an interdisciplinary approach to CVD prevention.13

For references, visit drugtopics.com.

<table>
<thead>
<tr>
<th>TABLE</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>National Diabetes Prevention Program Eligibility Criteria</strong>6</td>
</tr>
<tr>
<td>□ At least 18 years of age</td>
</tr>
<tr>
<td>□ BMI &gt; 25 or &gt; 23 if Asian</td>
</tr>
<tr>
<td>□ Not pregnant</td>
</tr>
<tr>
<td>□ No previous diagnosis of type 1 or type 2 diabetes</td>
</tr>
<tr>
<td>□ Prediabetes blood test results within the past year:</td>
</tr>
<tr>
<td>□ A&lt;sub&gt;1c&lt;/sub&gt; level of 5.7% to 6.4% or,</td>
</tr>
<tr>
<td>□ FPG level of 100-125 mg/dL or,</td>
</tr>
<tr>
<td>□ 2-hour PG (after a 75-gm glucose load) of 140-199 mg/dL</td>
</tr>
<tr>
<td>□ Previous clinical diagnosis of gestational diabetes or high risk for type 2 diabetes results from prediabetes risk test</td>
</tr>
<tr>
<td>□ Medicare beneficiaries are required to have a blood test within the past year to qualify</td>
</tr>
</tbody>
</table>

A<sub>1c</sub> glycated hemoglobin; BMI, body mass index; FPG, fasting plasma glucose; PG, plasma glucose.
Pandemic Precautions Lead to Low Incidence of Flu

Preventive efforts and renewed interest in vaccinations drive milder flu season. By Jill Sederstrom, contributing editor

Pharmacists across the country are seeing a milder flu season this year, thanks in part to the precautions put in place to prevent coronavirus disease 2019 (COVID-19), but many are also seeing increases in the number of flu vaccinations administered at their stores. The COVID-19 pandemic has ushered in a greater focus on health and prevention efforts, which has led to fewer cases of the flu this season than in past years. “This flu season, we have seen lower incidences of flu compared to an average season, which may be due to our shift in behavior to reduce the spread of COVID-19,” said Tasha Polster, BSPharm, vice president of pharmacy quality, compliance, and patient safety for Walgreens. “For example, more people are social distancing, wearing face masks, hand washing, and forgoing travel.”

According to the CDC, laboratory-confirmed cases of the flu remain “low at this time.” Additionally, reported deaths due to COVID-19 remain higher than for influenza, according to recent National Center for Health Statistics (NCHS) mortality surveillance data. For the data available on January 7, 2021, the NCHS reported that 14.5% of deaths occurring during the week ending January 2, 2021, were from pneumonia, influenza, and COVID-19 (PIC). However, of the 2150 deaths from PIC reported in that week, 1496 had COVID-19 listed as an underlying or contributing cause of death, whereas only 2 listed influenza.

Rite Aid and CVS officials also reported decreased numbers in flu incidence this year among patients. “As a general trend, people are more aware of health and immunity than perhaps ever before, which fits into our purpose to become a neighborhood destination for whole being health, including traditional medicine like vaccinations and alternative remedies and supplements that may help boost immunity or reduce stress,” said Jocelyn Konrad, BSPharm, executive vice president and chief pharmacy officer for Rite Aid.

Moreover, the number of Americans receiving the flu vaccine is on the rise this season. The CDC led a push to encourage more individuals to get their vaccinations to avoid illness or hospitalizations that could tax an already overworked health care system.

“During the COVID-19 pandemic, reducing the overall burden of respiratory illnesses is important to protect vulnerable populations at risk for severe illness, the health care system, and other critical infrastructure,” the CDC said in its pandemic guidance released to the public. The push—and greater concerns about health among Americans—resulted in a significant increase in the number of individuals who have received vaccinations to date. According to the CDC, by December 19, 2020, an estimated 46.9 million adult flu vaccinations had been administered in pharmacies, compared with 32.9 million at the same time in 2019, representing a 43% increase. An additional 28.9 million adult flu vaccinations were administered in physician medical offices.

Although last year 32.1 million individuals turned to physicians’ offices to receive vaccinations—about the same number as those who went to a pharmacy setting in 2019—this year to date there has been a significant increase in those seeking immunizations at pharmacies rather than at their physicians’ offices (46.9 million vs 28.9 million, respectively).

These trends seem to match what pharmacists are seeing in stores. “This flu season we anticipate administering nearly 20 million vaccines, which is more than double last year, so the demand to be vaccinated has certainly increased,” said Ryan Rumbarger, BSPharm, senior vice president of retail store operations for CVS Pharmacy.

Polster said Walgreens has seen “double-digit growth” in the number of flu vaccinations administered this year at its stores compared with this time last year. The company has also seen seniors 65 or older—who are
particularly at risk for COVID-19—getting flu vaccinations in higher numbers and earlier in the flu season than in past years.

“Our marketing mix is consistent with previous flu seasons; however, understanding the importance of flu shots amid the COVID-19 pandemic, we wanted to ensure we reached our customers to raise broad awareness far earlier this flu season, and ramped up our flu messaging beginning in August,” Polster said. The organization continued its Flu Fighter campaign this year, emphasizing that getting a flu vaccination “not only helps protect you, but those you love—your crew,” she said.

According to the CDC, by December 19, 2020, an estimated 46.9 million adult flu vaccinations had been administered in pharmacies.3

Konrad said Rite Aid’s messaging focused on communicating the importance of getting a vaccination “as a way to prevent a possible ‘twindemic’ that some experts feared could result from the collision of flu season and the COVID-19 pandemic.”

To date, it appears that concern has failed to come to fruition, but flu season is not over, and experts and the CDC said the community needs to remain vigilant in the months ahead. “We’ve continued to remind people it’s never too late to get your flu shot,” Rumbarger said. “We’ve also increased access to flu shots for communities in need.”

Brian Caswell, RPh, National Community Pharmacists Association president and owner of Wolkar Drug in Baxter Springs, Kansas, said that although he hasn’t necessarily seen an increase in the number of flu vaccinations administered at his pharmacy this season, he has seen more interest from patients who may have declined vaccinations in past years.

“I have not talked to anyone who said that they are going to forgo their flu shot because of what’s going on, but I have talked to a few people who’ve said, ‘You know, I haven’t had a flu shot ever’ or ‘I haven’t had a flu shot in the last 2 years and with everything going on, I thought I better go ahead and get it this year,’” he said.

Although the COVID-19 pandemic appears to have motivated many Americans to seek out flu vaccinations, it has also presented challenges to pharmacies in terms of marketing and logistics. Caswell said his pharmacy was forced to close its lobby twice during the pandemic and had to rely more heavily on communicating with patients through word of mouth and social media outlets like Facebook. It also switched to an appointment-based approach to vaccinations to minimize the number of individuals in the store at any given time.

“I thought moving over to an appointment model was going to be a problem. It hasn’t been a problem,” he said. “People were willing to do it, and I think they didn’t want to be hanging around a lobby with sick people either.”

Caswell said he had expected the pharmacy’s home delivery services to rise during the pandemic but was surprised to find the biggest growth was in drive-through use. “I think people still wanted to get out,” he said.

Rumbarger said CVS also amplified its digital experience within its mobile app and expanded home delivery options, like DoorDash and Instacart, to reach patients during the pandemic. “Before and during the pandemic we’ve deployed a diverse marketing strategy to meet people where they are—in our pharmacies, in the community, in the home or in the palm of their hand,” he said, adding that officials will continue to revise strategies based on patient feedback.

Konrad said Rite Aid’s marketing messages have focused on how the pharmacy chain is still able to serve patients amid the pandemic and the increased safety precautions in place. “We’ve worked hard to provide essential pharmacy services, including vaccinations, despite the need to socially distance and protect customers and associates from COVID-19 transmission,” she said. “From enhanced cleaning and sanitation protocols to [personal protective equipment] and social distancing, we’ve made sure our customers can safely visit their neighborhood Rite Aid, whether to get a flu shot, get tested for COVID-19, or pick up medications and immunity-boosting supplements.”

Polster said pharmacies are expecting the COVID-19 vaccine to be more broadly available toward the end of the flu season. There will be high demand for COVID-19 vaccinations, but even with help on the horizon, pharmacies will need to encourage patients to remain as healthy as possible.

“It’s going to take time for a COVID-19 vaccine to be available to the general population, so we encourage everyone to get vaccinated against the flu to avoid 2 respiratory illnesses circulating at the same time and reduce the burden on our strained health care system,” Polster said.

For references, visit drugtopics.com.

DrugTopics.com
A Primer on Atopic Dermatitis

Pharmacists can advise patients on how to control symptoms and reduce exacerbations. By Hiba Takieddin, PharmD

Atopic dermatitis (AD) is a chronic, inflammatory skin condition with symptoms ranging from dry, itchy skin to painful rashes that interfere with sleep and daily activities. It usually starts in early childhood; however, cases also are diagnosed in some adults. It is estimated that 25% of children in the United States have AD compared with 10% of adults. Study results have shown that African American and Asian populations are more likely to develop the disease. Patients with AD can develop other autoimmune conditions; for example, asthma and hay fever are reported in more than half of children with eczema.

Pharmacists can play a major role in educating patients on how to manage flare-ups and take preventive measures. The goal of the treatment is to enhance patients’ quality of life by reducing outbreaks, controlling symptoms, and lowering the risk of infection.

Patients should stay hydrated and apply moisturizer at least twice daily. Pharmacists should help patients learn to identify triggers that can cause skin irritations. Keeping a list of such triggers can help patients reduce skin flare-ups and better manage symptoms. Some triggers include stress, dry skin, detergent, fragrance, dye, and other chemicals.

The first-line treatment for mild AD is a topical steroid (eg, hydrocortisone) that can be applied twice daily during flare-ups. Hydrocortisone is safe to use for patients 2 years and older. However, if symptoms have not been controlled within 7 days of treatment, seeing a dermatologist is recommended. Topical hydrocortisone is available over the counter at 1% strength. It can be used on almost all body areas for a short time. Oral first-generation antihistamine (eg, diphenhydramine) can help reduce itching.

Some remedies for adults and children include the following:

- Take a warm bath for no more than 10 minutes
- Use a mild, fragrance-free cleanser
- Pat skin gently to dry and apply petroleum jelly–based moisturizer after bathing
- Trim fingernails to avoid scratching and skin infection
- Keep room temperature at a comfortable level

For severe cases, a dermatologist may recommend phototherapy, which includes using UV light 2 to 3 times per week for a few weeks or months. Another option that a physician may recommend for moderate to severe eczema is the wet wrap therapy. Wet wrap therapy can help calm the skin and reduce itching and scratching.

For references, visit drugtopics.com.
A content source designed specifically for pharmacy industry professionals practicing in (or interested in moving to) an independent pharmacy. Total Pharmacy® provides trusted resources and actionable business solutions to effectively maximize profitability, minimize costs and improve patient experience.

Total Pharmacy® features:

**Business Strategies**
Gain insight into potential challenge areas, innovative solutions, and opportunities to expand your pharmacy services.

**Customer Experience**
Receive information to help you enhance overall customer experience and build additional revenue streams in your pharmacy.

** Buyers’ Exchange**
Access resources to better maintain front- and back-end stock, including inventory management strategies, seasonal buying guides and product categories to consider carrying at your location.

Look for Total Pharmacy® in the March 2021 issue of Drug Topics® and at www.TotalPharmacy.com!
Limitations Persist in Growth of Precision Medicine

Despite breakthroughs for personalized medicine, barriers still exist in real-world application. By Phil Huber, PharmD Candidate and Jonathan Ogurchak, PharmD, CSP

In recent years, breakthroughs and advances have led to wider adoption of genomic and precision medicine. Yet there remains an abundance of unrealized potential in personalized medicine, raising the question: What boundaries still exist in providing more individualized care? This article will discuss current applications of precision medicine and what limitations persist.

In the past few years, the realities of personalized medicine have become increasingly evident. In 2016, the Precision Medicine Initiative (PMI) launched by the National Institutes of Health propelled expansion of precision medicine. Initially announced in 2015, the PMI mission was to enable a new era of medicine through research, technology, and policies to develop more individualized care. In more recent years, breakthroughs and advances in the technology and availability have led to wider adoption of genomic medicine. The primary disease states involved in the expansion of precision medicine include oncology, immunology, central nervous system disorders, and respiratory disorders. The growth of precision medicine has also boosted growth of the specialty and rare drug industry. Specialty pharmacies continue to grow and adjust to provide a higher level of care for patients with individual disease states.

In 2019, the precision medicine market size exceeded $57 billion and was estimated to grow to $119 billion by 2026. Some of the drivers behind this growth include advances in cancer biology and targeted therapies, increased global adoption of gene therapy, and increased usage of data analytics in precision medicine. Alongside the development of targeted therapies themselves, the diagnoses of genetic diseases or genetic targets had growth as well. The availability of these tests has also played a role in the advancement of precision medicine. One of the main pitfalls include the high cost associated with precision medicine, fear of genetic discrimination, misinterpretation of genetic and health data, access and availability of genetic testing, and a relatively unprepared primary care workforce.

High Cost of Precision Medicine
The high cost associated with precision medicine comes from not only the research and development but also diagnostic methods and genetic testing. However, the long-term benefits to patients can offset the up-front costs of precision medicine. One way that has been proposed to mitigate cost to a patient would be outcomes-based rebate arrangements, in which the manufacturer would provide a rebate if prespecified therapeutic outcomes are not achieved. Another proposed payment approach would be annuity payments or annual fees, which would be made as long as the therapeutic effect persists. There needs to be a development of health-plan payment systems in which risk adjustment and reinsurance can be utilized for smaller disease states that can be treated by personalized therapies to give insurers incentive to efficiently manage care and control spending.

Alongside tackling the high cost of therapies, the testing and diagnoses of potential targets are often associated with high costs as well. One way to prove cost-effectiveness would be to ensure that genetic tests are both clinically appropriate and billed correctly. Having genetic counselors to review test orders could potentially allow health systems and providers to find ways to cut expenses and decrease genetic testing costs. The ability to invest in genetic expertise and claims may allow health plans to manage the costs associated with genetic innovation more effectively. This may be an area where pharmacists can increase their availability to determine the cost benefit and effectiveness of targeted drug therapy.

Handling Genetic Information and Data Collection
Genetic information is defined as information about an individual’s genetic tests or the genetic tests of an individual’s family members, and the indication of a condition in their family members. Under the Genetic Information Nondiscrimination Act (GINA) of 2008, it is illegal to discriminate against employees or health insurance applicants because of genetic information. But the battle of GINA continues today and still...
excludes other forms of insurance outside health insurance, including life insurance, long-term care insurance, and disability insurance. Being able to eliminate the risk of genetic discrimination and protect the privacy of an individual’s genetic information still remains an issue in the realm of precision medicine. One major success came in July of 2020 when Florida became the first state to enact a DNA privacy law. Florida’s House Bill 1189: Genetic Information for Insurance Purposes prohibits life, disability, and long-term care insurance companies from using genetic tests for coverage purposes. The law blocks companies from requiring or soliciting genetic information from individuals and forbids DNA testing companies from providing genetic information to insurers without their permission. This bill should serve as a model for other states and future legislation to help eliminate the risks of genetic discrimination.

In addition to handling genetic information, access to real-world data and patient outcomes is of equal importance. The momentum of personalized medicine relies heavily on developing genetically targeted therapies based on large populations of data. Forming collaborative networks to share patient data while also maintaining patient privacy is needed to deliver widespread therapeutic advancements. Pharmacies can play a role in sharing patient data and outcomes to advance precision medicine.

Preparing Primary Care Workforce

With the advancement and availability of genetic testing and an increased number of medications with genetic considerations comes the need to prepare primary care providers and workers for the role of precision medicine in broader populations. To prove valuable, pharmacogenomics and personalized medicine would need to be implemented on a wider scale. Creating appropriate teachable moments and training for health networks and providers to implement could create better genomics-based prescribing practices. Furthermore, establishing better precision medicine practices would help health care providers adapt to the growing market for genetically guided therapy. Precision medicine had historically been considered too complex, expensive, and inaccessible to underserved populations; therefore, it was hard to find a place for it in primary care. Now that precision medicine is becoming increasingly incorporated into evidence-based treatments, it is time to adapt and adjust practice patterns. Pharmacists can advance their knowledge in pharmacogenomics and precision medicine by taking certificate programs provided by the American Society of Health-System Pharmacists or National Association of Chain Drug Stores and applying these concepts and principles to their practice sites.

Takeaways

Precision medicine is here to stay. Although advances and breakthroughs in the realm of personalized medicine have been bountiful, barriers still exist. The obstacles discussed in this article are only a few areas that pharmacists and other health care professionals can look to in the coming years to expand the practice of precision medicine.

For references, visit drugtopics.com.

Phil Huber is a PharmD candidate at Duquesne University School of Pharmacy, anticipated to graduate in spring 2021.

Jonathan Ogurchak, PharmD, CSP, is the CEO and cofounder of STACK, a pharmacy information management platform, and serves as preceptor for a virtual Advanced Pharmacy Practice Experiential Rotation for specialty pharmacy, during which this article was composed.
Pharmacy Benefit Changes Are Coming for Medi-Cal Beneficiaries

An update for pharmacy on the transition to the new fee-for-service program in California for Medi-Cal.  

By Keith Loria

Last year, California Gov Gavin Newsom announced the state would transition the pharmacy benefit for Medi-Cal beneficiaries from managed care plans to a fee-for-service (FFS) program, bringing approximately 13 million Medi-Cal beneficiaries to a new pharmacy program by January 2021.

Because of the ongoing challenges and evolving health care landscape associated with the coronavirus disease 2019 pandemic, the Department of Health Care Services (DHCS) has delayed implementation until April 1, 2021.

This change was implemented pursuant to an executive order, as opposed to legislative efforts. It reflects patient dissatisfaction with the performance of the Medi-Cal managed care organizations when it comes to pharmacy services and medication access, as well as state concerns about a system that was failing to control prices.

Ken Thai, PharmD, CEO of 986 Degrees Corporation, said the extension to April was welcomed because some details of the rollout needed to be finalized. He noted that during the last few months of 2020, more pharmacists voiced concerns that reimbursements were going from bad to worse—and independent pharmacies were hit especially hard.

“I think there’s optimism that this Medi-Cal FFS program changing back to the state will be very positive for the most part; however, there are concerns about the transition,” Thai said. “With 13 million lives being taken back on, there are some hiccups expected.”

Other concerns he has heard involve how this structure will apply to higher-cost drugs such as HIV or mental health medications. “I do expect this to be easier for patients who didn’t really understand how the Medi-Cal system worked previously,” Thai said.

Lucas W. Morgan, an attorney in Frier Levitt’s life sciences department, explained that DHCS will reimburse pharmacies based on a combination of their actual drug acquisition cost and preestablished fees (eg, dispensing fees).

Magellan Medicaid Administration, Inc, will be the sole pharmacy benefit manager (PBM) responsible for administering the program and was awarded a 5-year contract on December 12, 2019, with 5 optional 1-year extension periods.

The executive order states that California’s “spending on prescription drugs has increased at an unsustainable rate, including hikes of approximately 20% per year since 2012, constituting a substantial fiscal drain.”

“The stated goal of the executive order is to achieve cost savings for California’s spending on prescription drugs,” Morgan said. “A relatively small subset of high-cost drugs accounts for a disproportion-
ate amount of spending, with the 25 most expensive drugs accounting for approximately half of the state prescription drug expenditures. The executive order states that a major cause of skyrocketing prescription drug prices is unequal bargaining power, by which the pharmaceutical industry—often wielding monopoly power—is left unchecked in the absence of a strong counterparty at the bargaining table. The language of the executive order and other related commentary suggests that this unequal bargaining power is related to drug manufacturers,” Morgan said. “While manufacturers certainly play a role in this, it is important to note the critical role PBMs have played in the rising costs of prescription drug prices.”

Impact on Pharmacies
Harry Nelson, JD, managing partner of Nelson Hardiman, a health care law firm in Los Angeles, California, said this change will expand dramatically the number of pharmacies able to participate in dispensing outpatient prescription medications to the 14 million Medi-Cal members in California without the challenge of being part of the Medi-Cal managed care networks, which had been a barrier to patient access and a regulatory burden for pharmacies.

“Instead, pharmacies can directly enroll in Medi-Cal with DHCS and bill claims, which will be managed by a single, centralized pharmacy benefit manager,” Nelson said. “My sense is that the majority of pharmacies see this as a positive change, particularly given that Medi-Cal has become the single biggest payer in the state, with almost 36% of state residents and growing.”

Because there will be a single payer for California’s pharmacy benefit, Morgan said this is in stark contrast with previous arrangements in which multiple PBMs managed the pharmacy benefit with varying reimbursement benchmarks.

“The FFS model will likely eliminate any meaningful challenges. Therefore, more pharmacies will likely be able to participate in California Medicaid.”

Impact on Patients
One of the primary benefits of the new program will be increased access and freedom for patients to choose pharmacy providers because there likely will be more pharmacies able to participate in California Medicaid.

According to DHCS, “the vast majority of the state’s pharmacies” will be included in California Medicaid’s pharmacy network—citing 94% at last report. “Patients were restricted to a relatively smaller number of pharmacies that contracted with the 2 dozen or so Medi-Cal managed care organizations,” Nelson said. “After the carve-out, patients will be able to obtain their medications through most pharmacies that will participate in ‘straight’ Medi-Cal [without the managed care organizations]. This is likely to benefit pharmacies focused on Medi-Cal populations, including pharmacies contracted to support federally qualified health centers through the 340B program.”

Once enacted, this will be good for all parties going forward, he said. “The big attraction for Medi-Cal patients is the ability to go to almost any pharmacy in the state and have instantaneous processing thanks to the technology that allows PBMs to provide convenience for patients with private insurance,” he said. “For the state, centralizing drug rebates and having a single PBM utilizing a cost-based model holds out the potential for savings that did not materialize” in the current managed care organization-negotiated model.”

For references, visit drugtopics.com.

“For the state, centralizing drug rebates and having a single PBM utilizing a cost-based model holds out the potential for savings that did not materialize” in the current managed care organization-negotiated model.”

Lucas W. Morgan

“For references, visit drugtopics.com.”

February 2021 DrugTopics.com

During the presentation, Christina Michalek, BS, RPh, FASHP, medication safety specialist and administrative coordinator for the Medication Safety Officers Society at ISMP, discussed top COVID-19–related medication safety issues in 2020.

Repositioning Infusion Pumps
At the start of the pandemic, many hospitals employed strategies to preserve personal protective equipment and limit staff exposure to COVID-19. “Some of the choices that were made really affected safe medication practices,” Michalek said.

One of these choices involved moving infusion pumps outside the critical care rooms of patients with COVID-19, according to Michalek. However, she noted several challenges and risks associated with this strategy:
- Supply availability of extensions sets
- Mechanical issues, such as delayed occlusions alarms
- At low flow rates, more frequent alarms at high flow rates, and affected flow rate accuracy
- Need for increased priming volume because of length of tubing
- Effects on barcode scanning and double-checks

“This definitely presented some challenges,” Michalek said. “Throughout, ISMP tried to represent the risks so that everybody could make the best and most informed decisions.”

Drug Shortages and Importation
Although a long-standing issue, drug shortages have presented even more intense challenges during the pandemic. “We had many more critically ill patients, which really led to shortages of every drug that we use in mechanically ventilated patients,” Michalek said.

To combat some of these challenges, the FDA allowed importation of some medications. One of them was propofol. “Typically, in the United States, we use propofol as a 1% solution, and the FDA allowed us to import a 2% solution,” Michalek said. Because of shortages of propofol 1%, Fresenius Kabi received an emergency use authorization to bring in propofol 20 mg/mL (Fresenius Propoven 2%).

“If the double concentration of this imported product is overlooked, we could have an overdose in patients,” Michalek said.

Absence of Cap Warnings on Vials of Neuromuscular Blocking Agents
Because of a shortage, Gland Pharma Ltd was allowed to manufacture and market vecuronium and rocuronium vials without the usual required labeling on the vial cap: “Warning: Paralyzing Agent.” The rest of the labels remained unchanged, but the caps were allowed to be marketed without the warning.

With the unlabeled caps, “it can be very easy for practitioners to mistake them for a normal medication,” Michalek said.

“We know with neuromuscular blockers, these are one of those high-alert medications that are so likely to be linked to harm in situations where they’re mistaken for another product.”

Pharmacists can also visit ISMP.org for additional strategies on medication safety best practices.

According to Michalek, ISMP recommends that hospitals:
- Alert providers to the double concentration.
- Post wall charts and distribute fact sheets.
- Apply warning stickers to individual vials and cartons.
- Update drug databases and smart pump libraries, and
- Affix a barcode if the international barcode does not scan.
Advocate for Your Pharmacy Staff

“If some among you fear taking a stand because you are afraid of reprisals from customers, clients, or even government, recognize that you are just feeding the crocodile hoping he’ll eat you last.”
– Ronald Reagan

R

o

ald Reagan was the most quotable president of my lifetime. The above quote truly resonates with me, especially when dealing with patients. I never use the term customer when they are at the prescription counter. They are here for health care, not just for making purchases.

Readers have heard me sing the praises of pharmacy technicians I’ve worked with. These technicians have allowed me to provide optimal patient care and ensure that the pharmacy is run efficiently.

For example, Darlene worked as my technician for 24 years. She is highly organized and efficient, and a pharmacist’s best friend. Brad was my technician for the past 12 years. He started while in high school and learned the ever-cumbersome pharmacy software we used. He was a rock star at processing prescriptions and allowing me time to handle patient consultations, comprehensive medication reviews, and interventions that proved financially beneficial for my employer. The efficiency of the store didn’t depend on the pharmacist but on whether Brad was there.

I currently have 2 excellent technicians, Hunter and George. I’ve been on the new job for only 4 months so I can’t take credit for their hiring or training. Both are whizzes with the operations of the system. Doing the paperwork and processing orders are their greatest strengths. Both are very capable data entry technicians as well. They are guiding me, the 62-year-old “new kid” on the block, through the challenges of working for a new employer.

What frustrates me is when I go to several general merchandise stores and I see signs saying, “The customer is always right.” If the customer is always right, then who is always wrong? Talk about throwing your employees under the bus. If they are always right, my staff and I are always wrong. If I were an employee for that organization, I’d feel insulted every time I walked past such a sign. If patients tell me their physicians said there are refills on an oxycodone prescription, are they always right?

Of all the giants in the grocery store business, none shines as brightly as Wegmans. Their employees are always happy and helpful. They greet you with a genuine smile and a most caring attitude. Their attitude is their highly trained employees are always right.

“Our employees are our No. 1 asset, period,” Kevin Stickles, the company’s senior vice president for human resources, told the Atlantic in 2012. “The first question you ask is ‘Is this the best thing for the employee?’ That’s a totally different model.”

I can assure Hunter and George that I will use my 40 years’ experience on the bench to guide them so they can have fulfilling careers like Darlene and Brad. As the sun begins to set on my career, I can assure my staff I will never “feed them to the crocodile.” We owe it to our pharmacy technicians to be their strongest advocates.

Peter A. Kreckel, RPh, practices community pharmacy in Pennsylvania.

Peter A. Kreckel, RPh, practices community pharmacy in Pennsylvania.

IN MY VIEW / DISPENSED AS WRITTEN
By Peter A. Kreckel, RPh

Advocate for Your Pharmacy Staff

“The first question you should ask is ‘Is this the best thing for the employee?’ That’s a totally different model.”
Belantamab Mafodotin-blmf for Relapsed or Refractory Multiple Myeloma

Ryan Nolan, 2021 PharmD candidate; and Lisa M. Holle, PharmD, BCOP, FHOPA, FISOPP

On August 5, 2020, the FDA granted accelerated approval to belantamab mafodotin-blmf (Blenrep; GlaxoSmithKline). Belantamab mafodotin-blmf is now indicated for adult patients with relapsed or refractory myeloma who have received at least 4 prior therapies including an anti-CD38 monoclonal antibody, a proteasome inhibitor, and an immune modulating agent. Belantamab mafodotin-blmf is a first-in-class, anti–B-cell maturation antigen (BCMA) immunoconjugate with afucosylated, humanized immunoglobulin G1 anti-BCMA monoclonal antibody conjugated by a protease-resistant maleimidocaproyl linker to a microtubule-disrupting agent, monomethyl auristatin F (MMAF). This conjugated drug allows delivery of cytotoxic MMAF to BCMA-expressing multiple myeloma cells, causing apoptosis and tumor lysis through antibody-dependent cellular cytotoxicity and antibody-dependent cellular phagocytosis.

**EFFICACY**

Accelerated approval of belantamab mafodotin-blmf stemmed from the results of the multicenter open-label, phase 2 DREAMM-2 (NCT03525678) study. The study enrolled patients with relapsed or refractory multiple myeloma with disease progression after 3 or more lines of therapy and who were refractory to immunomodulatory drugs and proteasome inhibitors, and refractory or intolerant to an anti-CD38 monoclonal antibody. The primary end point of patients achieving a partial response or better occurred in 31% (97.5% CI, 20.8-42.6) of patients in the 2.5-mg/kg cohort. Another key secondary end point was probability of having a duration of response 4 months or longer, which was estimated by the Kaplan Meier curve to be 78% (95% CI, 57-89) in the 2.5-mg/kg cohort.

**SAFETY**

The most common adverse effects (AEs) were keratopathy (71%), decreased visual acuity (53%), nausea (24%), blurred vision (22%), pyrexia (22%), infusion-related reactions (21%), and fatigue (20%). The most common grade 3 or 4 laboratory abnormalities were decreased platelet count (21%), decreased lymphocytes (22%), decreased hemoglobin level (18%), decreased neutrophils (9%), increased creatine level (5%), and increased γ-glutamyltransferase (5%). Because of the risks of ocular toxicity, the medication is restricted under the Risk Evaluation and Mitigation Strategy (REMS) program. Prescribers must be certified with the Blenrep REMS program. Patients must be enrolled in the program and adhere to monitoring. This medication also carries a black box warning: Corneal epithelium changes can occur, resulting in alteration in vision, including severe vision loss and corneal ulcer, and symptoms such as blurred vision and dry eyes. Ophthalmic examinations should occur at baseline (3 weeks prior to the first dose), prior to each dose (at least 1 week after previous dose and within 2 weeks prior to next dose), and promptly for worsening symptoms. Patients should be advised to use preservative-free lubricant eye drops at least 4 times per day starting with the first infusion and continuing until end of treatment, to avoid contact lens use, and to use caution when driving. Complete blood counts should occur at baseline and as clinically indicated thereafter. If applicable, patients should use contraception while on this medication because of the potential of embryofetal toxicity. Female patients of reproductive potential should talk to their physician about the use of contraceptive methods during treatment and for 6 months after the last dose. Male patients with female partners of reproductive potential should use contraception for 6 months after the last dose.

**DOsing**

The recommended belantamab mafodotin-blmf dose is 2.5 mg/kg as an intravenous infusion over approximately 30 minutes once every 3 weeks. For AEs requiring dose reductions, decrease to 1.9 mg/kg intravenously once every 3 weeks.
Help your eligible commercially insured patients get Aimovig® for as little as a $5 copay per month*†

In order to remain eligible for the Copay Offer, commercially insured patients must re-enroll every 12 months by visiting aimovigaccesscard.com or by calling 833-AIMOVIG (833-246-6844)

Remind patients to re-enroll using the information on their existing Aimovig Ally™ Access Card

Terms and Conditions for Bridge to Commercial Coverage Offer (“Bridge Offer”):

• A patient who enrolls before or by December 31, 2020 can receive Aimovig® free for up to 12 doses over 24 months (whichever occurs first) from the first prescription filled under the Bridge Offer. Ongoing eligibility requires that patient has a prior authorization or medical exception denied within 90 days of first use of offer.

• A patient who enrolls on or after January 1, 2021 can receive Aimovig® free for up to 3 doses over 90 days (whichever occurs first) from the first prescription filled under the Bridge Offer. Available if patient has a prescription, is commercially insured, and 18 years or older. This offer is not valid if patient is uninsured or receiving prescription reimbursement under any federal-, state-, or government-funded healthcare program, such as Medicare, Medicare Advantage, Medicare Part D, the Retiree Drug Subsidy Program, Medicaid, Medigap, Veterans Affairs (VA), the Department of Defense (DoD), or TRICARE or where prohibited by law. Cash Discount Cards and other noninsurance plans are not valid as primary under this offer. If at any time patient begins receiving coverage under any such federal-, state-, or government-funded healthcare program, patient will no longer be able to use this offer and patient must call 833-AIMOVIG to stop participation. By participating in this offer, patient acknowledges intent to pursue insurance coverage for Aimovig® with their healthcare provider. Once insurance approval is obtained, patient is no longer eligible for this offer. No purchase necessary. This is not health insurance. Participation is not a guarantee of insurance coverage. Valid in the United States, Puerto Rico, and the US territories. Other restrictions may apply. This offer is subject to change or discontinuation without notice.

Terms and Conditions for Copay Offer: Pay as little as a $5 copay per month, up to an annual maximum benefit. Available if patient has a prescription, is commercially insured, and 18 years or older. This offer is not valid if patient is uninsured or receiving prescription reimbursement under any federal-, state-, or government-funded healthcare program, such as Medicare, Medicare Advantage, Medicare Part D, the Retiree Drug Subsidy Program, Medicaid, Medigap, Veterans Affairs (VA), the Department of Defense (DoD), or TRICARE or where prohibited by law. Cash Discount Cards and other noninsurance plans are not valid as primary under this offer. If at any time patient begins receiving coverage under any such federal-, state-, or government-funded healthcare program, patient will no longer be able to use this offer and patient must call 833-AIMOVIG to stop participation. Patient may not seek reimbursement for value received from this offer from any third-party payers, including flexible spending accounts or healthcare savings accounts. This is not health insurance. Participation is not a guarantee of insurance coverage. Valid in the United States, Puerto Rico, and the US territories. Other restrictions may apply. This offer is subject to change or discontinuation without notice. If you become aware that your health plan or pharmacy benefit manager does not allow the use of manufacturer copay support as part of your health plan design, you agree to comply with your obligations, if any, to disclose your use of the card to your insurer. This offer is ongoing and in order to remain eligible, patient must re-enroll every 12 months by visiting www.aimovigaccesscard.com or by calling 833-AIMOVIG (833-246-6844).

* If Aimovig® is approved by the patient’s health plan, a patient pays as little as a $5 copay per month up to an annual maximum benefit. This applies to patient out-of-pocket costs, including deductible, co-insurance, and copayments for Aimovig®. Patient is responsible for costs above the annual maximum. Terms and conditions apply. See below for the full Terms and Conditions.

† If the patient’s health plan does not cover Aimovig®, or requires a prior authorization, the patient can qualify for the Bridge to Commercial Coverage Offer and receive Aimovig® free for up to 3 doses, while pursuing approval from their health plan. No purchase necessary. Terms and conditions apply. See below for the full Terms and Conditions.
Selling Your Pharmacy?

Maximize Your Value

Minimize Your Worry

HAYSLIP & ZOST

Pharmacy Sales Experts Ready to Help You!

www.RxBrokerage.com

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

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

Call Hayslip & Zost Pharmacy Brokers LLC for a free consultation. We have helped hundreds of independent pharmacy owners nationwide get the maximum value for their pharmacies. For more information about us, please visit our website.

MARKETPLACE CAN WORK FOR YOU!

DrugTopics.com February 2021 DrugTopics® 33