FLU SEASON AHEAD

OPPORTUNITIES ABOUND FOR TESTING AND VACCINATIONS
DON’T BE OUT OF THE LOOP ON OUT-OF-POCKET COST

LET PATIENTS KNOW THE AVERAGE OUT-OF-POCKET COST MAY BE LESS THAN THEY THINK

SHINGRIX
(ZOSTER VACCINE RECOMBINANT, ADJUVANTED)

LESS THAN*

$5

*Average out-of-pocket cost for commercially insured patients.1

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
• In a postmarketing observational study, an increased risk of Guillain–Barré syndrome was observed during the 42 days following vaccination with SHINGRIX
• 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

References:
1. Data on file, GSK.
2. SHINGRIX.com
When it comes to healthcare, coverage and cost are often big concerns for patients. But as you’ll see, cost doesn’t need to be an obstacle to receiving quality care. In fact, for most commercial plans, the out-of-pocket cost to patients is usually minimal.

Nationally, payers covering 96% of commercial medical benefit enrollees cover SHINGRIX.

96%

The Affordable Care Act (ACA) requires all Health Insurance Marketplace plans and most other private health insurance plans to cover all Advisory Committee on Immunization Practices (ACIP)-recommended vaccines, including SHINGRIX, with no cost sharing (deductibles, copayments or coinsurance) if administered in-network.

90%

90% of privately insured patients pay no or limited out-of-pocket cost with the average cost being less than $5 per dose.

Individual access may vary by geography and plan benefit design.

What you need to know:

Coverage, coding, cost to patient, reimbursement amount for product, and administration fee will vary by payer, plan, patient, professional setting, or services rendered and are subject to change without notice. Cost to patients may vary. Coverage and reimbursement decisions are made by individual payers following receipt of claims from providers. Providers must follow payer documentation and billing requirements.

*SOURCE: Managed Markets Insight & Technology, LLC, Database as of June 2021. “Coverage” is formulary access without restrictions, which means reimbursement from a health plan with no accompanying step edits or prior authorizations. Veterans Affairs (VA) and Indian Health Service (IHS) lives have been omitted when calculating the percentage of lives for this geography.

Important Safety Information (cont’d)

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


You are encouraged to report vaccine adverse events to the US Department of Health and Human Services. Visit www.vaers.hhs.gov to file a report, or call 1-800-822-7967.

Please see Brief Summary of Prescribing Information for SHINGRIX on the following pages.

To see additional information about cost and coverage go to CoverageSHINGRIX.com

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SGXJRNA210005 April 2021

Produced in USA.
BRIEF SUMMARY

SHINGRIX (Zoster Vaccine Recombinant, Adjuvanted)

The following is a brief summary only; see full prescribing information for complete product information.

1 INDICATIONS AND USAGE

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

Limitations of Use:

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

2 DOSAGE AND ADMINISTRATION

2.1 Administration Instructions

For intramuscular injection only.

After reconstitution, administer SHINGRIX immediately or store refrigerated between 2° and 8°C (36° and 46°F) and use within 6 hours. Discard reconstituted vaccine if not used within 6 hours.

2.2 Administration Instructions

For intramuscular injection only.

After reconstitution, administer SHINGRIX immediately or store refrigerated between 2° and 8°C (36° and 46°F) and use within 6 hours. Discard reconstituted vaccine if not used within 6 hours.

2.3 Dose and Schedule

Two doses (0.5 mL each) administered intramuscularly according to the following schedule: A first dose at Month 0 followed by a second dose administered anytime between 2 and 6 months later.

4 CONTRAINDICATIONS

Do not administer SHINGRIX to anyone with a history of a severe allergic reaction (e.g., anaphylaxis) to any component of the vaccine or after a previous dose of SHINGRIX [see Description (1) of full prescribing information].

5 WARNINGS AND PRECAUTIONS

5.1 Preventing and Managing Allergic Vaccine Reactions

Prior to administration, the healthcare provider should review the 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.

5.2 Guillain-Barré Syndrome (GBS)

In a postmarketing observational study, an increased risk of GBS was observed during the 42 days following vaccination with SHINGRIX [see Adverse Reactions (6.2)].

6 ADVERSE REACTIONS

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a vaccine cannot be directly compared with rates in the clinical trials of another vaccine and may not reflect the rates observed in practice. There is the possibility that broad use of SHINGRIX could reveal adverse reactions not observed in clinical trials.

Overall, 17,041 adults aged 50 years and older received at least 1 dose of SHINGRIX in 17 clinical studies.

The safety of SHINGRIX was evaluated by pooling data from 2 placebo-controlled clinical studies (Studies 1 and 2) involving 29,305 subjects aged 50 years and older who received at least 1 dose of SHINGRIX (n = 14,645) or saline placebo (n = 14,660) administered according to a 0- and 2-month schedule. At the time of vaccination, the mean age of the population was 69 years; 7,286 (24.9%) subjects were aged 50 to 59 years, 4,488 (15.3%) subjects were aged 60 to 69 years, and 17,531 (59.8%) subjects were aged 70 years and older. Both studies were conducted in North America, Latin America, Europe, Asia, and Australia. In the overall population, the majority of subjects were white (74.3%), followed by Asian (18.3%), black (1.4%), and other racial/ethnic groups (0.6%); 58% were female.

6.2 General Adverse Reactions

In Studies 1 and 2, data on solicited local and general adverse events were collected using standardized diary cards for 7 days following each vaccine dose or placebo (i.e., day of vaccination and the next 6 days) in a subset of subjects (n = 4,886 receiving SHINGRIX; n = 4,881 receiving placebo with at least 1 documented dose). Across both studies, the percentages of subjects aged 50 years and older reporting each solicited local adverse reaction and each solicited general adverse event following administration of SHINGRIX (both doses combined) were pain (78.0%), redness (38.1%), and swelling (25.9%) and myalgia (44.7%), fatigue (44.5%), headache (37.7%), shivering (26.8%), fever (20.5%), and gastrointestinal symptoms (17.3%), respectively.

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>Adverse Reaction</th>
<th>Aged 50-59 Years</th>
<th></th>
<th>Aged 60-69 Years</th>
<th></th>
<th>Aged ≥70 Years</th>
</tr>
</thead>
<tbody>
<tr>
<td>SHINGRIX</td>
<td>Placebo*</td>
<td></td>
<td>SHINGRIX</td>
<td>Placebo*</td>
<td>SHINGRIX</td>
</tr>
<tr>
<td>n=1,311</td>
<td>n=1,312</td>
<td></td>
<td>n=1,311</td>
<td>n=1,305</td>
<td>n=2,258</td>
</tr>
<tr>
<td>Pain</td>
<td>86.4</td>
<td>14.4</td>
<td>82.8</td>
<td>11.1</td>
<td>69.2</td>
</tr>
<tr>
<td>Fatigue</td>
<td>57.0</td>
<td>19.8</td>
<td>45.7</td>
<td>16.8</td>
<td>36.6</td>
</tr>
<tr>
<td>Headache</td>
<td>50.6</td>
<td>21.6</td>
<td>39.6</td>
<td>15.6</td>
<td>29.0</td>
</tr>
<tr>
<td>Shivering</td>
<td>38.8</td>
<td>12.0</td>
<td>38.4</td>
<td>1.6</td>
<td>37.7</td>
</tr>
<tr>
<td>Fever</td>
<td>27.8</td>
<td>3.0</td>
<td>23.9</td>
<td>3.4</td>
<td>14.3</td>
</tr>
<tr>
<td>GI</td>
<td>24.3</td>
<td>10.7</td>
<td>16.7</td>
<td>8.7</td>
<td>13.5</td>
</tr>
</tbody>
</table>

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

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

b 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.

c Placebo was a saline solution.

d Grade 3 pain: Defined as significant pain at rest; prevents normal everyday activities.

e Grade 3 myalgia, fatigue, headache, shivering, GI: Defined as preventing normal activity.

f Fever defined as ≥37.5°C/99.5°F for oral, axillary, or tympanic route, or ≥38°C/100.4°F for rectal route; Grade 3 fever defined as >39.0°C/102.2°F.

g GI = Gastrointestinal symptoms including nausea, vomiting, diarrhea, and/or abdominal pain.

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 (continued on next page))
second dose administered anytime between 2 and 6 months later. The reported frequencies of specific solicited local adverse reactions symptoms (17.3%), respectively. (37.7%), shivering (26.8%), fever (20.5%), and gastrointestinal (both doses combined) were pain (78.0%), redness (38.1%), and and older reporting each solicited local adverse reaction and each Across both studies, the percentages of subjects aged 50 years 6 days) in a subset of subjects (n = 4,886 receiving SHINGRIX, In Studies 1 and 2, data on solicited local and general adverse events were female. Latin America, Europe, Asia, and Australia. In the overall population, administered according to a 0- and 2-month schedule. At the time 1 dose of SHINGRIX (n = 14,645) or saline placebo (n = 14,660) 29,305 subjects aged 50 years and older who received at least 1 dose of SHINGRIX in 17 clinical studies. The safety of SHINGRIX was evaluated by pooling data from 2 • SHINGRIX is not indicated for prevention of primary varicella Limitations of Use: SHINGRIX is a vaccine indicated for prevention of herpes zoster vaccine and may not reflect the rates observed in practice. There is cannot be directly compared with rates in the clinical trials of another vaccinereactions not observed in clinical trials. • SHINGRIX is not indicated for prevention of primary varicella • SHINGRIX is not indicated for prevention of primary varicella SHINGRIX 5.2 Guillain-Barré Syndrome (GBS) After reconstitution, administer SHINGRIX immediately or store 6.1 Clinical Trials Experience for each solicited local adverse reaction and each 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 recorded 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 39°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. General Disorders and Administration Site Conditions Decreased mobility of the injected arm which may persist for 1 or more weeks. Immune System Disorders Hypersensitivity reactions, including angioedema, rash, and urticaria. Nervous System Disorders Guillain-Barré syndrome. Postmarketing Observational Study of the Risk of Guillain-Barré Syndrome following Vaccination with SHINGRIX The association between vaccination with SHINGRIX and GBS was evaluated among Medicare beneficiaries aged 65 years or older. Using Medicare claims data, from October 2017 through February 2020, vaccinations with SHINGRIX among beneficiaries were identified through National Drug Codes, and potential cases of hospitalized GBS among recipients of SHINGRIX were identified through International Classification of Diseases codes. The risk of GBS following vaccination with SHINGRIX was assessed in self-controlled case series analyses using a risk window of 1 to 42 days post-vaccination and a control window of 43 to 183 days post-vaccination. The primary analysis (claims-based, all doses) found an increased risk of GBS during the 42 days following vaccination with SHINGRIX, with an estimated 3 excess cases of GBS per million doses administered to adults aged 65 years or older. In secondary analyses, an increased risk of GBS was observed during the 42 days following the first dose of SHINGRIX, with an estimated 6 excess cases of GBS per million doses administered to adults aged 65 years or older, and no increased risk of GBS was observed following the second dose of SHINGRIX. These analyses of GBS diagnoses in claims data were supported by analyses of GBS cases confirmed by medical record review. While the results of this observational study suggest a causal association of GBS with SHINGRIX, available evidence is insufficient to establish a causal relationship. 7 DRUG INTERACTIONS 7.1 Concomitant Vaccine Administration For concomitant administration of SHINGRIX with inactivated influenza vaccine [see Clinical Studies (14.5) of full prescribing information]. 7.2 Immunosuppressive Therapies Immunosuppressive therapies may reduce the effectiveness of SHINGRIX. 8 USE IN SPECIFIC POPULATIONS 8.1 Pregnancy There are no available human data to establish whether there is vaccine-associated risk with SHINGRIX in pregnant women [see Use in Specific Populations (8.1) of full prescribing information]. 8.2 Lactation It is not known whether SHINGRIX is excreted in human milk. Data are not available to assess the effects of SHINGRIX on the breastfed infant or on milk production/excretion [see Use in Specific Populations (8.2) of full prescribing information]. 8.5 Geriatric Use Of the total number of subjects who received at least 1 dose of SHINGRIX in the 2 efficacy trials (n = 14,645), 2,243 (15.3%) were aged 60 to 69 years, 6,837 (46.7%) were aged 70 to 79 years, and 1,921 (13.1%) were 80 years and older. There were no clinically meaningful differences in efficacy across the age groups or between these subjects and younger subjects [see Clinical Studies (14.1, 14.2, 14.3) of full prescribing information]. The frequencies of solicited local and general adverse events in subjects aged 70 years and older were lower than in younger adults (aged 50 through 69 years) [see Adverse Reactions (6.1)]. 17 PATIENT COUNSELING INFORMATION • Inform patients of the potential benefits and risks of immunization with SHINGRIX and of the importance of completing the 2-dose immunization series according to the schedule. • Inform patients about the potential for adverse reactions that have been temporally associated with administration of SHINGRIX. • Provide the Vaccine Information Statements, which are available free of charge at the Centers for Disease Control and Prevention (CDC) website (www.cdc.gov/vaccines). Storage: Store vials of Lyophilized gE Antigen and Adjuvant Suspension Components refrigerated between 2° and 8°C (36° and 46°F). Protect vials from light. Do not freeze. Discard if the vials have been frozen. Trademarks are owned by or licensed to the GSK group of companies. 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CHAIRMAN’S LETTER

Upcoming Influenza Season Is a “Big Question Mark”

We’re coming up on another influenza season. Although there’s reason to believe this year will be different than 2020, experts don’t know what to expect.

Last year, pharmacists were gearing up for influenza season as COVID-19 surges sparked concerns about a dual epidemic. The CDC reported just 2038 influenza cases in the United States between September 2020 and April 2021. To put that in perspective, approximately 35.5 million individuals were sick with influenza during the 2019-2020 season.1,2

However, there were minimal cases compared with previous years, which was likely due partly to the preventive measures taken amid the pandemic. The CDC reported just 2038 influenza cases in the United States between September 2020 and April 2021. To put that in perspective, approximately 35.5 million individuals were sick with influenza during the 2019-2020 season.1,2

Now, after several months of administering COVID-19 vaccines, pharmacists are preparing for influenza season by stocking inventory and getting ready to ramp up vaccinations. However, because there were so few incidents of influenza last year, the upcoming season is “a big question mark,” Ann Philbrick, PharmD, FCCP, BCACP, BCPS, associate professor in the Department of Pharmaceutical Care & Health Systems at the University of Minnesota Medical School, said in this month’s cover story. Still, as many individuals return to their normal activities, with or without masks, and many schools reopen for in-person instruction, getting the public vaccinated against influenza is critical.

Pharmacists can help quell myths and misinformation surrounding all vaccines, in general, to ensure all of their patients receive their necessary immunizations—whether it’s for influenza, COVID-19, or other vaccine-preventable diseases. Beyond promoting and administering vaccinations, pharmacists also can leverage opportunities in point-of-care (POC) testing services. Our cover story on page 16 dives into how pharmacists are getting ready for an unpredictable influenza season, including preparing for an influx of vaccinations and best practices for POC testing.

And for independent pharmacists looking to expand their clinical service offerings, our Total Pharmacy section offers the final installment of our medication management services (MMS) toolkit. On page 22, you’ll find more information on delivering effective MMS to patients. Read all 3 parts of this article series at totalpharmacy.com.

You’ll also find in this issue great insights into innovative health system telepharmacy models, best practices for educating patients on naloxone, and tips for psoriasis management. In the month ahead, keep an eye out for our coverage of the National Association of Chain Drug Stores Total Store Expo, being held virtually August 23-25, on drugtopics.com.

Thank you for reading.

Mike Hennessy Sr
Chairman and Founder of MJH Life SciencesTM

REFERENCES

4 DrugTopics® August 2021
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*All data sourced from Brightfield Group.
Finerenone Is Approved for Chronic Kidney Disease Associated With Type 2 Diabetes  By Marissa Fox

On July 9, 2021, the FDA approved finerenone (Kerendia; Bayer) tablets to reduce complications in adults with chronic kidney disease (CKD) and type 2 diabetes. Finerenone is the first and only nonsteroidal mineralocorticoid receptor antagonist approved for adults with CKD associated with type 2 diabetes. It can slow CKD progression and reduce the risk of kidney failure, heart attack, heart failure hospitalization, and cardiovascular death.

The effectiveness of finerenone in preventing kidney and heart complications was studied in the randomized, multicenter, double-blind, placebo-controlled phase 3 FI-DELIO-DKD (NCT02540993) trial. Included in the study were 5674 adult patients with CKD associated with type 2 diabetes. Patients were randomly assigned to receive either finerenone or a placebo. The investigators studied the 2 groups for the number of patients whose disease progressed to a combined end point: at least 40% reduction in kidney function, progression to kidney failure, or kidney death. The results of this study showed that 504 of the 2833 patients taking finerenone experienced 1 of the events in the combined end point. This was compared with 600 of the 2841 patients who received a placebo.

The investigators further examined the number of patients who experienced cardiovascular death, a nonfatal heart attack, nonfatal stroke, or hospitalization for heart failure. The results showed that 367 of the 2833 patients taking finerenone had at least 1 of the events in the combined end point compared with 420 of the 2841 patients who received a placebo.

For references, visit drugtopics.com
The FDA granted priority review to AstraZeneca’s biological license application (BLA) for tezepelumab for the treatment of severe, uncontrolled asthma.

Tezepelumab is the first biologic to show a reduction in asthma symptoms, according to phase 3 study results. Tezepelumab is a potential first-in-class human monoclonal antibody that inhibits the action of thymic stromal lymphopoietin (TSLP), a key epithelial cytokine that sits at the top of multiple inflammatory cascades. TSLP is critical in the initiation and persistence of the types of airway inflammation associated with severe asthma.

The BLA was based on the results of the PATHFINDER clinical trial program, including the phase 3 NAVIGATOR (NCT03347279). In clinical trials, tezepelumab demonstrated superiority across every primary and key secondary end point when compared with placebo in a broad population of patients with uncontrolled asthma. Participants received tezepelumab in addition to standard-of-care treatment with medium- or high-dose inhaled corticosteroids plus at least 1 additional controller medicine with or without oral corticosteroids.

Tezepelumab was granted priority review by the FDA due to its advantages over current options in the areas of safety improvement, preventing serious conditions, and enhancing patient compliance. The agency has set a regulatory decision date during the first quarter of 2022.

A meta-analysis in JAMA Pediatrics looks at whether vaccines can prevent rotavirus gastroenteritis. Investigators searched the databases Embase, PubMed, the Cochrane Library, and Web of Science using terms such as “rotavirus” and “vaccin*.” Cohort and case-control studies as well as randomized clinical trials that enrolled more than 100 children younger than 5 years were included in the meta-analysis if they reported information on effectiveness, safety, or immunogenicity. The primary outcomes included rotavirus gastroenteritis, severe rotavirus gastroenteritis, and rotavirus gastroenteritis hospitalization. Outcomes for safety included serious adverse events, mortality, and intussusception.

A total of 58 studies met the criteria—20 randomized clinical trials and 38 case-control studies. The studies showed that rotavirus vaccine, live, oral suspension (Rotarix; GlaxoSmithKline) led to a significant reduction in rotavirus gastroenteritis and rotavirus gastroenteritis hospitalization risk in children who were fully vaccinated. The rotavirus vaccine, live, oral, pentavalent (RotaTeq; Merck) showed similar outcomes in fully vaccinated children. The vaccines also showed high protection against severe rotavirus gastroenteritis.

The investigators concluded that the high efficacy and safety profiles of rotavirus vaccines highlighted the importance of providing the vaccine to children everywhere. The similar profiles of both vaccines can make selection easier for public health authorities.

For reference, visit contemporarypediatrics.com.
How to Tactfully Handle Naloxone Counseling

Naloxone education often requires difficult but necessary conversations with patients. By Karen Berger, PharmD

Pharmacists can save lives by counseling patients on naloxone use, although it may be a difficult topic to address. If you are not experienced in naloxone counseling, where do you begin?

Drug Topics interviewed experts on how to best approach patients about naloxone, an opioid antagonist medication that is used to reverse an opioid overdose.

Put Patients At Ease
Ellen R. Cohn, PhD, CCC-SLP, AAS-HA-F, who is an adjunct professor of communications at the University of Pittsburgh in Pennsylvania and an adjunct professor at the University of Maryland Global Campus, reminds pharmacists to maintain eye contact, convey caring, and be direct and calm.

She suggests telling the patient: “The medication you are taking could put you at risk. It would be good to have an antidote on hand.” If the pharmacist is anxious about discussing this sensitive topic, the patient can pick up on their anxiety, she said. Cohn acknowledges that the topic may be difficult, but it will become second nature over time. “The more one delivers the message, the easier it will be,” she said.

Amanda McQuillan, PharmD, BCPS, BCPP, is a pharmacist in Pittsburgh. “You have to approach the subject like any other,” she said. “For example, does it make you feel awkward counseling a [patient with diabetes] on healthy food options or educating someone on an EpiPen? If you feel uncomfortable, they obviously will, too. Your anxiety about the topic will come across as being judgmental, and that never goes well when counseling a patient,” she said.

In a situation where she thinks the patient may feel offended, McQuillan reviews all the possible ways the patient can accidentally overdose, such as when starting a new medication or when they have an acute respiratory illness. She also asks if the patient has any children in their home who could accidentally ingest the patient’s medication. “It’s really a public safety measure for everyone,” she said.

Rebecca Bouse, PharmD, pharmacy manager at Walmart Pharmacy in Newcastle, Oklahoma, approaches counseling with an “open mind and one of care to the patient and their family, [including] children and pets,” who may accidentally ingest the patient’s medication.

After introducing herself, Bouse lets the patient know that she would like to discuss safe medication use and risk. “I also ask permission to speak openly and candidly. Empathy is key, and I place myself in their shoes and think about how difficult it must be to have to take opiate medication for their health condition,” she said.

Bouse suggests listening with an open mind and letting the patient talk freely. “There is already a stigma attached to opiates, and often patients feel judged [about their] treatment with opiate medications even before the conversation starts,” she said.

Bouse then offers to check the price of naloxone HCl nasal spray (Narcan; Emergent BioSolutions) with insurance or a discount card. Bouse and her colleagues document conversations in the patient profile. “We never force a patient to obtain Narcan. It’s always a choice. And more times than not, they opt out. It’s not a failure. It just may take several times or talking to various family members for the justification to make sense,” she said.
Elizabeth VanSlyke, PharmD, BCPS, begins naloxone counseling by saying, "We have an initiative to provide naloxone to any patient on opioids—no matter the dose—and this is a standard of care."

By starting this way, "I think this helps, so people don't feel singled out," she said.

VanSlyke encourages the patient to bring their spouse or another close friend or family member for training. She finds that using the word “poisoning” is better accepted by patients than “overdose.”

VanSlyke emphasizes that the risk of overdose or poisoning is present and possible. “I normally tell patients that typically the naloxone never gets used, [it] expires, and they dispose of it and get a new one, but it is a protective factor that we would much rather have in place and available on the small chance it is needed, versus needing it and not having it,” she said.

**Tailor Counseling Points to the Patient**

Crystal D. Choi, PharmD, MS, MEd, is a pharmacist at CVS in Las Vegas, Nevada. She reminds pharmacists that many patients who take opioids are older adults, so there could be polypharmacy and drug interactions. "Mix-ups are a distinct possibility. If the patient, or someone else, takes the opiate medication by accident, or maybe they double a dose because they forgot they already took it, having the naloxone gives them a layer of protection," she explained.

Choi also considers younger patients who have children in the home. "For those patients, I point out that if a child takes their medication, naloxone could prevent an accidental overdose. This line of reasoning is effective for parents picking up prescriptions for teen and young adult children, as well," she said. "I also bring up the potential for drug interactions... and remind them that having it in the home is just a precaution. I let them know that naloxone is like an EpiPen. They can use it to save another person who needs it if the situation arises."

**Communicate the Need**

McQuillan compares naloxone to a fire extinguisher. "Noboy anticipates setting a fire, but if there is one, you definitely want a fire extinguisher; you want to know where it is located and how to use it, and, naturally, you are also going to call for help by calling 911," she explained.

Bouse uses an open-ended style of questioning. She asks patients questions such as, "What risks do you think there are with taking opiates medications?" and "What are the risks associated with adding other medications that can have additive depressant effects or adding medications that have a stimulant effect?"

She acknowledges to the patient that all the various medications have a valid place in therapy. However, there are also risks associated with each treatment that can cause unexplained respiratory depression, up to and including sudden death in extreme cases. Bouse tries to avoid the word “overdose,” as most patients will automatically assume that it would never happen to them. She also compares taking opioids to driving a car—each has inherent risks. "Those risks go up with speeding, taking benzodiazepines, and so on," she said.

**Ensure Proper Use**

When a patient gets naloxone, Choi takes it out of the box and shows the patient how to use it and where the directions are. She suggests that the patient teach other adults in the home. “It’s just like CPR [cardiopulmonary resuscitation] or the EpiPen—a life-saving measure—and they should be familiar with it before actually facing a situation where they have to use it," Choi said.

VanSlyke reminds patients to always carry naloxone, "just like an EpiPen, because if the naloxone is at home and the patient is not and something happens, it isn’t going to do any good.”

VanSlyke also tells patients that more than 1 dose of naloxone may be needed. And if the patient regains consciousness, caregivers should stay with the patient until help arrives—do not cancel the ambulance.
More than 7.5 million individuals in the United States have psoriasis, according to the National Psoriasis Foundation (NPF). Psoriasis is a chronic, inflammatory autoimmune disease characterized by raised, red, scaly patches. The majority of patients with mild to moderate psoriasis can control symptoms with topical medications. However, individuals with moderate to severe psoriasis likely will require systemic medications and biologics. Pharmacists can educate patients on treatments and lifestyle modifications, address expected drug-related adverse effects (AEs), and improve medication adherence.

Nonprescription Treatment Options

OTC Products

The NPF and the American Academy of Dermatology have issued joint guidelines for managing psoriasis. OTC products are effective for mild psoriasis, and ingredients such as coal tar and hydrocortisone are commonly included. Pharmacists can recommend products that have the NPF Seal of Recognition, which means they have proven to be nonirritating and safe. Coal tar is available in shampoos, creams, ointments, and bath solutions. It works by decreasing itching and flaking; reducing redness, swelling, and scaling; and slowing rapidly growing skin cells. Hydrocortisone creams and ointments reduce itching and inflammation. If patients have cracked or bleeding skin, hydrocortisone ointments may feel better than creams and cause less irritation.

Moisturizer helps seal water in the skin to relieve dryness. When selecting a moisturizer, look for a fragrance-free heavy cream, ointment, or oil. Patients should apply moisturizer within 3 minutes of bathing and after washing their hands. Scale softeners or scale lifters containing salicylic acid remove and soften scales and reduce swelling; they are commonly used to manage scalp psoriasis. Ingredients commonly found in scale lifters include lactic acid, urea, and phenol.

Lifestyle Modifications

Lifestyle modifications can reduce psoriasis flares, reduce the number of medications, and enhance the efficacy of treatments. Taking daily lukewarm baths with colloidal oatmeal and Epsom salts can help remove scales. Pharmacists should educate smokers on the importance of quitting for health benefits and to prevent psoriasis flares. Patients should also limit alcohol consumption because alcohol can decrease the efficacy of treatments. Maintaining a healthy diet and exercising can reduce the risk of developing diseases linked to psoriasis such as diabetes.

Prescription Treatment Options

Topical Therapies

Topical medications are the most common treatments for mild to moderate psoriasis and are typically used as adjunctive therapies for patients taking systemic or biologic agents. Topical corticosteroids are classified into 7 classes that range in strength from ultrahigh (class 1: clobetasol propionate 0.05%) to low (class 6 and 7: triamcinolone acetonide 0.025%, methylprednisolone acetate 0.25%). Topical calcineurin inhibitors such as tacrolimus and pimecrolimus can be used as an off-label treatment for psoriasis, and they are especially useful on thinner skin areas (eg, around the eyes) as steroid-sparing agents for prolonged use (> 4 weeks). Calcipotriene and calcitriol are vitamin D analogs that slow skin cell growth. They can also be used in combination with topical corticosteroids. Tazarotene is a topical retinoid that is more effective when used in combination with topical corticosteroids.

Systemic Nonbiologic Treatments

Systemic medications are used to treat moderate to severe psoriasis. Methotrexate (Trexall; AstraZeneca) is taken weekly by oral administration. Apremilast (Otezla; Amgen) is an oral medication that does not require laboratory monitoring. Cyclosporine is an immunosuppressant taken orally for severe psoriasis, but it is generally not used long term due to the risk of serious AEs. Acitretin (Soriatane; Stiefel) is an oral retinoid that typically takes 3 to 6 months to see the full benefits, and it is less effective than other systemic therapies.

By Jennifer Gershman, PharmD, CPh
Biologic Therapies

There are 11 FDA-approved biologics for the treatment of psoriasis:

**TNF-α inhibitors**
- Etanercept (Enbrel; Amgen)
- Infliximab (Remicade; Janssen Biotech)
- Adalimumab (Humira; AbbVie)
- Certolizumab pegol (Cimzia; UCB)

**IL-12/IL-23 inhibitor**
- Ustekinumab (Stelara; Janssen Biotech)

**IL-17 inhibitors**
- Secukinumab (Cosentyx; Novartis)
- Ixekizumab (Taltz; Eli Lilly and Company)
- Brodalumab (Siliq; Valeant Pharmaceuticals)

**IL-23 inhibitors**
- Guselkumab (Tremfya; Janssen Biotech)
- Tildrakizumab (Ilumya; Sun Pharma)
- Risankizumab (Skyrizi; AbbVie)

Biologic agents are administered by injection or intravenous infusion and can be used as monotherapy or combined with topical or nonbiologic systemic medications for the treatment of moderate to severe psoriasis. Response to treatment (positive or negative) with TNF-α inhibitors generally occurs after 12 to 16 weeks of continuous therapy except for infliximab which should be assessed after 8 to 10 weeks. Patients should be evaluated after 8 weeks of treatment with ustekinumab, IL-17 inhibitors, or IL-23 inhibitors. Individuals who have partially responded to biologic therapies may have their doses increased, and other drugs, such as topical corticosteroids, can be added to their regimen.

There are also novel treatments on the horizon for psoriasis that have completed phase 3 trials (see Table 9,10).

### Counseling Pearls

Pharmacists play an important role in increasing adherence and monitoring for AE in patients taking psoriasis therapies. It is critical to account for patient preferences and daily routines to promote adherence. Patients who would like to avoid injections can receive oral therapies. The NPF is working to help pass legislation for step therapy reform and to reduce out-of-pocket costs for patients, which can improve medication adherence and access to care.

Patients should be empowered to be educated consumers and question their pharmacist and physician about psoriasis treatments. Pharmacists can take the following steps to ensure optimal use of these medications:

- Counsel patients to give their treatments time, as biologics take approximately 12 weeks to see the full benefits.
- Provide patients with clear written and verbal directions on how to use the medications. Discuss the expected AEs and how to manage them.
- Conduct follow-up phone calls and visits (in person or through telehealth) to assess for adherence and address patients’ concerns.
- Encourage patients to set medication reminders, which also can improve adherence.

Because coal tar can irritate the skin, it is important to test the product on a small area before applying it to regions affected with psoriasis. Patients should use salicylic acid products according to the instructions, as too much can worsen psoriasis. Using moisturizers along with anti-itch products can help prevent skin irritation.

Lower-potency corticosteroids should be used on the face, intertriginous areas, and regions that are susceptible to thinning of the skin (eg, forearms). Tazarotene should not be used during pregnancy, and women of childbearing age should have a negative pregnancy test 2 weeks before starting the medication. Folic acid or folinic acid supplementation is recommended in combination with methotrexate to reduce gastrointestinal and hepatic AEs.

Patients taking cyclosporine should have their renal function checked and monitor their blood pressure at home. Acitretin is contraindicated in pregnancy because it can cause fetal harm. Biologics can increase the risk of infection, and tuberculosis screening is required before initiating therapy.

The IL-17 inhibitor brodalumab carries a boxed warning regarding rare cases of suicide that have occurred during treatment; patients with a history of suicidal behavior should not receive this medication. Brodalumab is only available through restricted access known as the Siliq Risk Evaluation and Mitigation Strategy program.

For references, visit drugtopics.com.

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

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**TABLE. PIPELINE DRUGS FOR PSORIASIS**

<table>
<thead>
<tr>
<th>MEDICATION</th>
<th>MANUFACTURER</th>
<th>MECHANISM OF ACTION</th>
<th>STATUS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bimekizumab</td>
<td>UCB</td>
<td>First-class biologic that is a monoclonal antibody and IL-17A and IL-17F inhibitor</td>
<td>BLA has been submitted to FDA for review for the treatment of moderate to severe psoriasis. Two phase 3 studies (BE VIVID [NCT03370133] and BE READY [NCT03410992]) have demonstrated positive efficacy and safety data.</td>
</tr>
<tr>
<td>Deucravacitinib</td>
<td>Bristol Myers Squibb</td>
<td>First-class oral selective tyrosine kinase 2 inhibitor that inhibits IL-12, IL-23, and type 1 IFN pathways</td>
<td>Two phase 3 studies demonstrated deucravacitinib was superior to placebo and apremilast for moderate to severe psoriasis with a positive safety profile.</td>
</tr>
</tbody>
</table>

BLA, Biologics License Application; IFN, interferon.
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FLU SEASON IS APPROACHING,
BUT EXPERTS DON’T KNOW WHAT TO EXPECT

Although COVID-19 safety measures helped squash the number of influenza cases last season, pharmacists are revving up vaccination programs and testing. By Aine Cryts
Despite early concerns of a dual epidemic of influenza and COVID-19, last year’s flu season produced a dramatically minimal amount of cases compared with previous years, which was likely the result of precautionary measures taken amid COVID-19 surges. Now, as most pandemic restrictions have been lifted, pharmacists are preparing for flu season by stocking inventory and getting ready to ramp up vaccinations.

According to Ann Philbrick, PharmD, FCCP, BCPS, BCACP, an associate professor in the Department of Pharmaceutical Care & Health Systems at the University of Minnesota in Minneapolis, the upcoming season may be “a big question mark.” Because there were so few incidents of the flu last year, it’s “really hard to make recommendations….It’s even possible that the flu vaccines won’t match the flu [strains] very well.”

The CDC reported 2038 flu cases in the United States between September 2020 and April 2021. In contrast, approximately 35.5 million individuals were sick with the flu during the 2019-2020 season, which the federal agency describes as “moderate severity.”

Flu Vaccine Options for the 2021-2022 Season

According to the CDC, health care providers can choose any licensed, age-appropriate vaccine with no preference for any vaccine over another. For the 2021-2022 flu season, the vaccine options include as follows:

- standard-dose flu shots;
- high-dose shots for individuals aged 65 and older;
- shots made with adjuvant for individuals aged 65 and older;
- shots made with virus grown in cell culture—eggs are not involved in the vaccine’s production;
- shots made using vaccine production technology—specifically, a recombinant vaccine that doesn’t require having a candidate vaccine virus sample to produce; and
- live attenuated flu vaccine, which is made with attenuated (or weakened) live virus and administered by nasal spray.

Manufacturers estimate that between 194,000,000 and 198,000,000 doses of flu vaccine will be available for the upcoming flu season, according to the CDC. This is more than the 175,000,000 dose record set during the 2019-2020 flu season, the CDC noted.

Administering Vaccines for COVID-19 and Flu

Jason Mallada, PharmD, BCPS, BCIDP, a clinical pharmacy specialist in infectious diseases and internal medicine at Newton-Wellesley Hospital in Boston, Massachusetts, agreed that it’s almost impossible to predict the rate of flu infections during the upcoming season.

That said, communities are opening up and COVID-19 restrictions are starting to go away, which could mean Americans are at greater risk for both COVID-19 and flu if they’re not vaccinated, Mallada said. As a result, pharmacists and other health care providers have to be prepared with vaccination programs, in addition to testing, for both flu and COVID-19, he said.

The CDC’s Advisory Committee on Immunization Practices also recently announced that COVID-19 vaccines can be given to patients at the same time as other vaccines. Health care providers should be mindful of the possibility of increased adverse reactions.

In May, Reuters reported that COVID-19 vaccine manufacturers are developing and testing booster shots for new variants of the virus; it’s at the discretion of governments around the world as to whether the booster shots are purchased and offered to residents in those countries.

The news service also reported that the CDC is creating a risk assessment framework to determine the required evidence to recommend a modified vaccine. Both the CDC and other US health agencies are studying ways to assess vaccine efficacy. Top of mind are the effectiveness of the vaccine among older populations and children and the impact of new variants.

The CDC hasn’t officially decided yet whether the US population will need a booster to the COVID-19 vaccine. But Mallada thinks a booster is likely, which means pharmacists need
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to be prepared to counsel and provide educational materials on COVID-19 and flu vaccines throughout the 2021-2022 flu season.

In addition, Mallada anticipates increased demand for flu vaccines. To prepare, pharmacies have a sufficient inventory of personal protective equipment and swabs, in addition to vaccines for flu and COVID-19, he said.

Ordering Vaccines and Planning Ahead

Cleveland Clinic has ordered 2 different flu vaccines for its patients, according to Allison Riffle, PharmD, associate chief pharmacy officer. One vaccine is for patients aged 6 months to 64 years, whereas the second vaccine is for patients 65 years and older. “Standardizing in this way was a safety decision. It minimizes errors in helping ensure providers, pharmacists, and caregivers select the appropriate vaccine.”

Riffle added that Cleveland Clinic uses a multidose vial presentation in ambulatory settings, which offers significant cost savings compared with a prefilled syringe.

Theresa Tolle, BPharm, FAPhA, owner of Bay State Pharmacy in Sebastian, Florida, plans to start outreach to local employers to educate them about her pharmacy’s testing and vaccination capabilities for flu, just as she did for COVID-19 testing and vaccinations. During the upcoming flu season, Tolle expects to recruit retired nurses who can help vaccinate patients and other community members for patient intake, if needed.

Otherwise, she will prepare for the upcoming flu season the same way she has in the past. That includes promoting the flu vaccine through partnerships with senior centers and churches.

Tolle started prebooking vaccine orders in January with 5 different suppliers. She plans to have a high-dose flu shot for patients aged 65 and older and a standard-dose shot for her younger customers.

Best Practices for Point-of-Care Testing

Philbrick has 2 best practices for pharmacies that want to provide point-of-care testing for flu:

1. Ensure that there’s a private area for testing in the pharmacy.

2. Assume that the patients who enter the pharmacy for testing are infected; that means patients and pharmacy employees should wear masks and use hand sanitizer.

In addition, pharmacies can participate in collaborative practice agreements, which requires planning, Philbrick said. These agreements are beneficial for patients who test positive for flu because antivirals, such as oseltamivir (Tamiflu; Roche), which require a prescription, must be taken within 48 hours of the onset of symptoms to be effective.

Alternatively, pharmacies can set up referrals for video-based consultations with physicians who can prescribe oseltamivir, according to Philbrick.

Although it’s more work for her employees, Tolle plans to do flu testing on patients in their cars. It takes approximately 20 minutes to get a result, she said. The patient calls the pharmacy from the parking lot, an employee goes out to do the test, and the patient receives the test result.

Florida is a “test-and-treat” state, which means pharmacists can treat patients who test positive for flu with oseltamivir. Pharmacists participating in “test-and-treat” in Florida must complete a 20-hour course approved by the board of pharmacy and carry liability insurance coverage of at least $250,000.

The Future for Pharmacists and Public Health

Tolle points to the role of community pharmacies in West Virginia in bolstering COVID-19 vaccination rates as proof that pharmacists can have a meaningful impact on public health. By January 2021, almost 90% of the state’s vaccine inventory had been used, NPR reported in March. At the same time, some states had only used 30% to 50% of their doses. West Virginia continued to outpace other states that month.

West Virginia had delivered its vaccine supply to 250 pharmacies; most of the pharmacies were small, independent stores; chain stores such as CVS and Walgreens aren’t common in the state, according to NPR.

West Virginia was successful because many of its long-term care sites already were partnered with local pharmacies for vaccines and other medicines, in addition to regular COVID-19 testing for residents and staff. The state leveraged those existing partnerships, which helped West Virginia get “an early jump on most other states,” said Krista Capehart, PharmD, BCACP, director of professional and regulatory affairs for the state’s board of pharmacy and chief architect of its COVID-19 vaccination distribution plan, in an interview with NPR.

“The big picture is that this experience [with COVID-19 vaccines] elevated the importance of pharmacy leaders in primary care in our communities,” Tolle said. “A leader in a state allowed the independent pharmacists to step up…This is a great case model for how to do [vaccines] well.”

For references, visit drugtopics.com.
Each year, Pharmacy of the Year is awarded to 1 Good Neighbor Pharmacy member community pharmacy that has displayed excellence in patient care, community outreach, and innovative pharmacy practices.

The 2021 top contenders were Magnolia Pharmacy of Magnolia, Texas; Rogers Drug Store of Modesto, California; and Mahaska Drug of Oskaloosa, Iowa. Drug Topics® interviewed the owners of the 3 finalists to learn more about what separates them from the pack, the challenges and opportunities experienced amid the COVID-19 pandemic, and their inspirational outlooks on the future of pharmacy.

Magnolia Pharmacy of Magnolia, Texas
Since Magnolia Pharmacy opened its doors in 2002, pharmacist and owner Steve Hoffart, PharmD, has been growing his store and prioritizing the needs of his community in eastern Texas. What began as a small store supported by a staff of 3—himself, a technician, and a customer service representative—has grown to more than 30 employees and a bustling business.

Magnolia Pharmacy is unique from its competitors in that it provides a holistic look at a patient’s health. “We don’t just fill prescriptions,” Hoffart said. “We look at other aspects that can improve the health and wellness of our patients.” Clinical services include diabetes and hypertension management. They also analyze factors such as hormone levels and gut health. Customizing care has been key for Magnolia Pharmacy for the past 19 years.

Hoffart believes the COVID-19 pandemic has placed pharmacies in the spotlight as an essential mainstay of their communities. “When you look back at the past year and a half and see the full scope of the role pharmacies played across communities large and small, it’s refreshing to see independent pharmacy get the recognition we deserve. We hope to step into an even larger role in the health and wellness ecosystem in order to better serve our patients.”

As a member of the Community Pharmacy Enhanced Services Network (CPESN), Hoffart gained early insight into managing a scheduling system to handle the surge of vaccinations. “It was the craziest thing. We booked 500 appointments in less than 10 minutes,” he said. His pharmacists administered their first batch of COVID-19 shots through New Year’s weekend, and patients were eager to express their gratitude. Hoffart recalled an interaction with one woman in particular. “She said, ‘I just want to tell you that you changed my life. I am so looking forward to getting to see my grandkids.’ And we just melt. I have never felt so appreciated in my life.”

Magnolia Pharmacy also partnered with a local charity organization and pharmacy technician school to set up a COVID-19 clinic for seniors and low-income communities that lack reliable internet access. Staff and volunteers were available to help individuals book their appointments.

Looking ahead, Hoffart hopes that the pharmacy industry capitalizes on these pandemic efforts to enhance the profession, including legislative changes. “I’ve been very involved with the National Community Pharmacists Association. We know the value a pharmacist can bring. We want to work collaboratively with all of health care to provide access to patients and communities. That’s what a community pharmacy is all about,” Hoffart said.
patients about the effectiveness and Prasad made sure to educate his cant obstacle to the vaccination effort, Vaccine hesitancy has been a signifi - unsure of the safety of the vaccine. patients coming into the pharmacy were vaccinating in February, many pa- through their past collaboration with the county’s public health department. Furthermore, across the street from Rogers Drug Store is a parent re- source center that supports young and single mothers. “We help them with fundraising and anything they need to help the mothers they support; we also support the organization with pharmacy and other health care services,” Prasad explained.

Even before the SARS-CoV-2 virus hit the United States, Rogers Drug Store was preparing for a pos- possible crisis. Prasad was able to gain early insight into the pandemic from the county’s public health department through their past collaboration with health fairs. “And we kept our doors open. The business slowed down, ob- viously, but we kept moving and we never went back,” Prasad said.

When Rogers Drug Store began vaccinating in February, many pa- tients coming into the pharmacy were unsure of the safety of the vaccine. Vaccine hesitancy has been a signifi- cant obstacle to the vaccination effort, and Prasad made sure to educate his patients about the effectiveness and safety of COVID-19 vaccines and address all questions.

For Prasad, this nomination is heartening evidence that pharma- cists do make a difference in their pa- tients’ lives. “You know, we’re here just doing our work, this is what we do. The whole community recognizing what we’re doing, to me, was the big- gest thing. And that was very satisfying,” he said.

Rogers Drug Store supports the needs of its community through partnerships with local leaders and nonprofit organizations. Prasad vol- unteers on a medical team of a local outreach program to offer free health care services to underserved patients. Furthermore, across the street from Rogers Drug Store is a parent re- source center that supports young and single mothers. “We help them with fundraising and anything they need to help the mothers they support; we also support the organization with pharmacy and other health care services,” Prasad explained.

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Delivering clinical services doesn’t start with the patient walking into the pharmacy or talking with the pharmacist. Clinical care begins long before. Existing programs such as medication synchronization and Medicare Part D’s Medication Therapy Management (MTM) can help.

Medication synchronization serves 2 purposes. Enrolling 30% to 50% of chronic patients in an appointment-based refill program frees up a significant amount of pharmacist time compared with walk-in refills, according to Cody Clifton, PharmD, director of clinical services at Duvall Family Drugs in Duvall, Washington, and director of practice transformation and clinical programs for Community Pharmacy Enhanced Services Network (CPESN).

“Regular, scheduled follow-ups then pave the way for other clinical services. Reaching out to patients 7 to 10 days in advance of every refill lets you take services to the next level by asking straightforward questions about medication changes, changes in health, vaccinations, testing, and all the other ways we can help,” Clifton said.

Many independent pharmacies use OutcomesMTM’s standalone Part D MTM program. The program boosts nondispensing cash flow and can help identify patients who need more than a comprehensive medication review (CMR).

“We sometimes use that CMR to identify patients [who] could benefit from other services,” said Tripp Logan, PharmD, vice president of SEMO Rx Pharmacies, which has pharmacies across 3 counties in southeast Missouri. “From a value standpoint, we don’t see a ton of clinical value in 1 visit because these patients are complex enough that they need more than 1 intervention a year. That CMR is an index intervention that we can leverage to help move them to where they really need to be.”

Pharmacies that are part of a network with existing payer contracts such as CPESN or PrescribeWellness, part of Tabula Rasa HealthCare, can easily identify clinical needs. The payer or network can forward patient contacts or selection criteria directly.

“Our program identifies patients who are part of a certain health plan, have disease states within certain date ranges, or [have] other criteria,” explained Farah Madhat, PharmD, executive vice president at PrescribeWellness. “We try to empower community pharmacies to run their own clinical programs. And once you’ve identified that population through software, you can send out singular communications to only those select patients.”

Make the Contact

Other pharmacies use social media to drive demand. Traditional media can also be effective, depending on cost.

“We do a lot of social media and radio advertisements for the pharmacy,” said Martika Martin, PharmD, MBA, director of clinical services at Danhauer Drugs in Owensboro, Kentucky. “We mostly use Facebook, which is hugely successful in our area. Our pharmacy has been here since 1904, so people are

Synchronization, Communication, Staff Participation Boost Sales and Help Patients

The final installment of this 3-part series on medication management services delves into the process of providing clinical care in the pharmacy. by Fred Gebhart

A content source designed specifically for pharmacy industry professionals practicing in (or interested in moving to) an independent pharmacy. TotalPharmacy® provides trusted resources and actionable business solutions to effectively maximize profitability, minimize costs and improve patient experience.
used to coming to the pharmacist with questions. And when they're asking questions, they are asking you to help make their lives better.”

How to follow up on those initial contacts depends as much on the pharmacist as it does on patients. Some pharmacists would rather spend time calling patients directly rather than using robocalls, as some patients dislike prerecorded calls.

However, Madhat said Prescribe-Wellness metrics suggest that phone messages recorded by the local pharmacist with follow-up by text messaging can be highly effective in bringing potential patients into the pharmacy and reminding them of existing appointments. Email is generally less effective.

“We already have the phone number from the health plan, and a voice message really reinforces that connection and drives them to come in,” she said. “We've started using texting for intake components, texting them a link to provide some of the information before they ever come in. And in the pharmacy, they can scan a QR code and do some of the preconditioning work. It saves everyone time.”

**Involve Staff**

Support staff also play key roles in clinical work by identifying patients due for refills, consults, vaccinations, or other services; making phone calls; retrieving patient files; and watching for opportunities.

“If you have good communication with your staff and they have a clear understanding of your clinical vision, they can help,” said Tammy Bullock, PharmD, BCACP, clinical pharmacy coordinator for Osterhaus Pharmacy in Maquoketa, Iowa. “They can spot a MedWise patient or an OutcomesMTM opportunity and alert the pharmacist.

A growing number of states allow certain technicians to administer vaccines, a move that accelerated during COVID-19.

“When you get vaccinated in a physician's office, who provides that vaccine?” asked Josh Howland, PharmD, MBA, vice president of clinical strategy at PioneerRx. “It's the medical assistant, maybe the nurse. It's crazy to pay your most expensive resource to provide a vaccine. So if your state allows, make sure your techs are certified to administer immunizations and let them do it. Everyone in the pharmacy—you, the techs, other support staff—should be practicing at the very top of their license.”

**Involve Patients**

Providing clinical services takes time, which is why appointment-based scheduling matters. A scheduled visit gives the pharmacist time to review the patient file, gather any educational materials, and prepare for the encounter. But convincing patients to make and then keep appointments can be challenging.

“(COVID-19) has made that easier. People were asking, ‘Exactly what time do you want me in the pharmacy?’ That experience helped change attitudes about making pharmacy appointments,” Martin said.

Osterhaus Pharmacy tries to arrange appointments but also builds time into pharmacists' schedules just in case.

“We ask if they have a few minutes to talk, and most of the time, they do,” Bullock said. “If not, we ask about a more convenient time or offer to call them at home at a specific time. Having that flexibility to sit down for 15 minutes is a priority in our workflow and our staffing plans. That's why MedSync is so important to clinical workflows. If I know this patient is coming in tomorrow, I can prepare my action plan ahead of time.”

**COVID-19 Pandemic Takeaways**

COVID-19 has been a stress test for health care, and pharmacy is showing solid results.

“We vaccinated the first health care professionals in our country along with the hospital,” Bullock said. “We talk with physicians on the phone all the time, but they almost never step into the pharmacy. Being on the receiving end of services helped them see why we are so different.”

Kentucky is one of the states requiring pay parity with other providers.

“[COVID-19] blew the door open on clinical services in pharmacy.” Josh Howland, PharmD, MBA

“[COVID-19] was a catalyst for passing provider status in Kentucky,” Martin said. “Commercial insurers are now required to pay the pharmacy the same for services that they would pay any other provider. That's a real boost for patient care.”

The critical takeaway from COVID-19 is that pharmacists have the flexibility and training to provide direct patient care, track their interventions, and deliver solid clinical outcomes. All they need are regulatory approval and assured reimbursement.

“[COVID-19] blew the door open on clinical services in pharmacy” Howland said. “Pharmacists showed they are the one provider in the country willing and able to mobilize quickly to provide services at scale. It’s up to pharmacists to walk through that door now before it shuts.”
What Pharmacist eCare Plan Really Can Do for You

The Pharmacist eCare Plan greatly increases dispensing productivity and metrics reporting, but it’s just not built for billing. by Fred Gebhart

Pharmacist eCare Plan (PeCP) is one of the hottest buzzwords in pharmacy. Proponents call the PeCP the greatest innovation in pharmacy technology since electronic prescribing.

However, “there is a lot of confusion around the Pharmacist eCare Plan,” said Shelly Spiro, RPh, FASCP, executive director of the Pharmacy Health Information Technology Collaborative. “It’s not a clinical care system or a billing document. It’s a standard for the way data [are] sent from 1 health care provider or system to another. It’s a way to leverage technology that can help every pharmacist be more productive.”

How much more productive? Spiro recalled switching from payer-specific dispensing claim forms to the Universal Claim Form and seeing dispensing productivity shoot up by approximately 300%. Dispensing productivity received another boost from electronic prescribing. Both were based on newly developed data export standards that vendors, payers, and pharmacists turned into new productivity tools to standardize and streamline the dispensing workflow.

PeCP is on the same track to standardize and streamline the clinical workflow. A few early adopters are billing through the PeCP with more users focusing on clinical care documentation and quality measures.

An Unintended Platform

“If my patient has an outcome of interest, say blood pressure or A1c [glycated hemoglobin], I can use my pharmacy management software to collect and manage that data,” said Benjamin Jolley, PharmD, owner of Jolley’s Compounding Pharmacy in Salt Lake City, Utah.

“All my interventions are coded using SNOMED terminology, just like a physician or any other provider. All that information—baseline patient status, interventions, outcomes—is all in a structured, standard format. You can use it if you’re audited, you can use it to demonstrate quality of care, you can even use it to generate payment if you have a contract,” he said.

Jolley said clinical documentation collected by his PeCP-compliant pharmacy management system vendor is valuable for patient counseling and reinforcing medical-legal protections when dispensing controlled substances. But payer contracts remain scarce.

Spiro likened the adoption of PeCP to that of electronic prescribing. The National Council for Prescription Drug Programs adopted the first version of SCRIPT, the data standard for e-prescribing, in 2008. But vendors were slow to turn the new standard into viable electronic prescribing systems that streamlined pharmacy workflows. Early e-prescribing was more of a pain than a benefit.

“Pharmacists spent years printing out electronic scripts so someone could enter them manually because the interfaces weren’t there,” Spiro explained. “That’s where we are with eCare Plan. We have the standard to export clinical data, but we don’t yet have the systems or the connections to make it part of the regular workflow.”

The PeCP became a billing platform by default, not by design.

“It’s not intended to be a billing platform,” said Matthew Webber, PharmD, director of value-based contracting for PioneerRx. PioneerRx was an early pharmacy system vendor to support the PeCP.

Pharmacy claims typically involve product dispensing. Specific pharmacy locations are credentialed by payers; individual pharmacists are not. Claims are usually routed through a pharmacy benefit manager using the Universal Claim Form and paid through pharmacy benefits.

Clinical services are typically paid through medical benefits. Claims are usually routed through medical intermediaries using the X12N 837P form and procedural terminology (CPT) codes. Pharmacy systems focused on dispensing do not include medical claim forms, CPT codes, or interfaces to medical intermediaries or directly to payers.

And although pharmacies are credentialed by pharmacy payers, individual providers are credentialed by medical payers using the providers’ National Provider Identifier (NPI) numbers. Howland said relatively few pharmacists have NPI numbers, although the number has increased as more pharmacists and pharmacy technicians began providing immunizations.

CONTINUED ON PAGE 26 >
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During the COVID-19 pandemic. “There is a whole world of providers, say Blue Cross or UnitedHealthcare, [with] no idea how to credential pharmacists,” Howland said. “They’ve just never done it. In order for medical billing to be real, we have 200,000 pharmacists who need to credential themselves with every payer. The industry is going to have to figure that out, whether individually or some kind of mass credentialing.”

As payer and pharmacy groups work on pharmacist credentials, other organizations are tackling billing barriers.

**Early Adopters**
In 2014, Community Care of North Carolina created CPESN, initially funded by a grant from the Centers for Medicare & Medicaid Services Innovation Center. The network adopted an earlier version of PeCP and helped develop the standard. “We started down the eCare Plan path because we wanted to document the care and the value we were providing,” Webber explained. “And not just prove our interventions and outcomes to payers, but [we wanted] to prove to our fellow pharmacists. When you join a network, you are basically linking arms with a bunch of pharmacists you may not know. Every pharmacy in the network wants [to] feel confident that all the other pharmacies are meeting the standards, and, frankly, [they want] to kick out the nonperformers.”

CPESN became the intermediary between network pharmacies and medical benefit payers. For lack of an alternative, PeCP became the de facto billing tool for participating pharmacies. CPESN is the only clinically integrated network of community pharmacists in the United States. The network contracts with payers, which typically are multistate or national insurers.

**Typical services documented in the eCare Plan include as follows:**

- Blood pressure or A1c monitoring;
- Vaccine administration;
- Disease and medication management for asthma, heart failure, hypertension, hyperlipidemia, and other conditions; and
- Medication review and management services for specific populations.

Local CPESN pharmacies provide the services and document their interventions and outcomes using PeCP. CPESN translates clinical services documented in the PeCP into an X12 or other billing document and sends it to the payer.

“Two years ago, pharmacies didn’t have this capability,” said Kim Roberts, PharmD, lead for pharmacy informatics partnerships and innovations at CPESN. “This helps pharmacists rely more on their clinical skills because, from the community perspective, the financials are just not there to rely on dispensing medications.”

The PeCP also can report quality metrics.

“Because lab values, vitals, medications, therapy problems, and interventions can all be embedded in each eCare Plan, that solves a growing need for quality reporting,” said Sam Anderegg, PharmD, MS. Anderegg is CEO of clinical management system DocStation, another early PeCP supporter. “Information about what’s going on with the patient and my role in achieving those outcomes is a huge value for me or any provider,” he said.

Anderegg sees a long-term benefit in clinical documentation and quality reporting via PeCP. He’s less confident about PeCP as a billing vehicle.

“We are... in a situation where pharmacies bring their own way of doing things that deviate from the industry standard,” Anderegg cautioned. “That might create problems in the long term.” DocStation and CPESN see the PeCP as a temporary solution until system vendors roll out modules to give pharmacies direct access to medical billing resources. The ideal is a pharmacy system that documents both dispensing and clinical workflows, automatically generates the appropriate Universal Claim Form for pharmacy benefits or X12 for medical benefits, updates other providers on patient status, and accepts updates from other providers.

That system doesn’t exist—yet—but it’s coming. Spiro reported that the latest version of PeCP based on Fast Healthcare Interoperability Resources standard successfully transmitted clinical information to an Epic electronic medical record.

“We have dispensing systems [and] medical systems that are evolving their technologies,” said Hannah Fish, PharmD.

**Hannah Fish, PharmD**

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**Hannah Fish, PharmD**
By Peter A. Kreckel, RPh

Pharmacy Students Need More Real-world Experience

Five-week rotations don’t give students enough exposure to workforce realities.

My 5-year-old grandson has the same aspirations as many children his age. He wants to be a fireman or bulldozer operator. When observing excavators working at a job site, a lot of adults may wish they were in that cab. The urge to feel the power of moving mountains makes us want to run heavy equipment. However, it’s not all it’s cracked up to be when you actually do it.

In 1979, I ran heavy equipment while working at a paper mill. I worked most of the summer running a log carrier and a front-end loader. After an 8-hour shift of moving logs around the wood yard or hauling chips to the bin, I felt more motivated than ever to study when I went back to school in the fall.

After performing poorly on a pharmacognosy test, I questioned, “Is this worth all of the effort?” A couple of days later, I received a letter from my father. It was a thick envelope stuffed with wood chips and a handwritten note that read, “Do you want to make these the rest of your life?”

I think many students enter our profession with the same feeling I had when I saw heavy equipment running at the paper mill. They are drawn to the power of the machines, the ability to use their strengths to get the job done, and—best of all—a good paycheck. However, as it does when running a front-end loader, the glitz of the profession wears off quickly. The only way that anyone gets a real taste of this profession is to be fully immersed, which takes more than 5 weeks.

I believe schools of pharmacy should rethink the 5-week advanced pharmacy practice experience rotations. The first week you’re too busy learning the employee’s names and where the bathroom is, and by the fifth week you’re already wrapping up. Most students really only get about 3 out of 5 weeks of concentration in that rotation.

Most schools of pharmacy offer 8 of these 5-week rotations. In the physician assistant (PA) curriculum, they spend their last year on rotations, similar to pharmacy students. However, their family practice rotation consists of 12 weeks. Many PA students end up in primary care, so it is prudent to spend a large block in that discipline. Pharmacy students often end up in community practices, so a 10- to 12-week assignment in 1 community pharmacy site would make more sense. If the purpose of these rotations is to expose the student pharmacists to “real life,” 5 weeks seems insufficient.

Many students seem to be deluded as to the realities of the profession. As the glut of pharmacists and the job shortages continue, the chains and hospitals know that they can pay less, understaff pharmacies, and make excessive demands on pharmacists, knowing they probably will leave. The chains know there will be another pharmacist looking for a job to take their place.

I know several young pharmacists who have left the profession because they “have had enough.” Schools of pharmacy need to better prepare these students by showing them the real world through longer rotations.

My 5-year-old grandson just had a change of heart. He wants to be a policeman because he had a tour of a West Virginia police barracks and a police car. He wants to blow the siren, turn on the lights in the police car, chase down the bad guys. The brief encounter my grandson had with a police career seems similar to the amount of exposure many student pharmacists get to our profession.

Peter A. Kreckel, RPh, practices pharmacy in Lemont Furnace, Pennsylvania.

The only way that anyone gets a real taste of this profession is to be fully immersed.

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During the COVID-19 pandemic, many hospitals and health care services teams turned to telepharmacy to reduce delays in providing medications to patients while social distancing practices were in place.

Hospitals quickly found that telepharmacy benefited pharmacy services by providing patients with more efficient access to medical care and reducing costs. Thus, hospitals were able to focus more on patient care and less on logistics, which led to higher turnaround times and increased patient satisfaction.

Benjamin Kornitzer, MD, chief medical and quality officer of agilon health, noted that telepharmacy and meeting patients where they are can lead to higher-quality health care. “During the pandemic, we saw how challenging it was for a face-to-face encounter, and telepharmacy was a tremendous opportunity to continue offering these vital services to our patients, greatly increasing access to medications and medication adherence,” he said.

Expanding Access Takes Telepharmacy to the Next Level

Increases in service hours, programs, and locations lead to higher patient satisfaction, lower costs  By Keith Loria

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Gerwitz

Randy Gerwitz, RPh, is pharmacy executive director at Vizient, a health care services company based in Irving, Texas. He notes that telepharmacy has expanded access to pharmacy services for patients, which is why hospital pharmacy teams benefit from implementing telepharmacy models into their workflows. “There is a well-established history of operational benefits from these technologies remotely supporting common tasks such as prescriber order verification and the monitoring and verification of IV (intravenous) room production activities,” he said.

More recent efforts have focused on direct-to-patient and clinical services, including patient education, monitoring, and adherence support, as well as antimicrobial and opioid stewardship programs. “These types of enhanced clinical offerings improve patient safety and allow [pharmacists] to reach patients that they may not have otherwise been able to care for,” Gerwitz said.

Ann Phan, PharmD, BCGP, manager of clinical programs for L.A. Care Health Plan in Los Angeles, California, said that telepharmacy in the inpatient setting allows a hospital’s pharmacy services to extend coverage, both temporally and geographically. “In this sense, rural and small-volume hospitals with limited resources could especially benefit from telepharmacy,” she said. “The benefits of telepharmacy can lead to expansion of service hours if [a location is] not already providing around-the-clock coverage, more available clinical pharmacy services, and improved safety and overall patient care.”

According to Seun Bammeke, managing director of PharmaServe in Winnipeg, Manitoba, telepharmacy can increase patients’ medication adherence. Additionally, these services allow an external licensed pharmacist to review and double-check the prescription to ensure it is correct, which can ease the workload of busy hospital pharmacists. He added that telepharmacy needs to be thought about from a return on investment (ROI) perspective as well, with plenty of savings available. “Hospital pharmacies would require fewer pharmacists and technicians as a lot of the duties will be outsourced to the telepharmacy,” Bammeke said. “Plus, by using a JIT (Just In Time) system, the hospital can maintain less stock of medications [that] are not used on a daily basis, knowing they will arrive the next day. This prevents medications from expiring [or] being stolen, and [means] less work in process inventory, which frees up their finances to be used on things that are more needed.”

Pros and Cons

Eric Morožka, PharmD, senior director of the Center on Pharmacy Practice Advancement at the American Society of Health System Pharmacists (ASHP), said telepharmacy has grown

Expanding Hours, Locations

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exponentially over the past year. “We see it as an opportunity to improve patient outcomes, expand access to health care—whether it’s an acute or ambulatory care setting—and find that it’s also a way to enhance patient safety. It could in many ways achieve more effective delivery of care as well,” he said.

According to Maroyka, hospital pharmacy teams can benefit from implementing telepharmacy models into their workflows for medication selection order review. Dispensing the IV admixture verification can be done remotely. For instance, if you have a technician in a clean room, there could be a pharmacist who is working remotely to help with that verification process.

Then there are patient monitoring and counseling benefits. Maroyka explained that health systems that employ clinical pharmacy specialist can have them reach out to smaller facilities to provide patient counseling or consultations and real-time monitoring through telehealth services.

“It’s a solution for order review and verification in tertiary medical centers when staffing—particularly in specialty areas [such as] oncology or pediatrics—is limited and provides a mechanism for health systems to provide enterprise-level pharmacy services throughout the system, even when those pharmacies may not operate 24/7,” he said.

It also provides a tool for virtual monitoring, assessment, detection, and decision-making for adverse drug reaction prevention and management. One major advantage, Phan noted, is the positive ROI produced by telepharmacy in decreasing pharmacy operating costs and repurposing pharmacists to other clinical services to improve patient outcomes, such as discharge medication counseling or antimicrobial stewardship.

Another advantage is increased accessibility. For instance, Gerwitz explained that telepharmacy allows the pharmacist to provide services in locations that are inefficient, impractical, or unfeasible. “This is particularly true for services provided to at-risk populations and in rural or remote areas where distance and population density would make it impossible to provide care in a way that is convenient for the patient and financially sustainable for the health care organization,” he said.

A disadvantage is patients’ dependence on technology and broadband access. As many learned and experienced during the pandemic, technologies and the internet services that support them are not always perfect. Gerwitz said glitchy connections, lag, and bandwidth challenges can at times cause frustration.

During the pandemic, the industry saw more widespread adoption of regulations that allow and even encourage the use of telemedicine and telepharmacy, but challenges still exist. “The lack of a standardized regulatory environment and limitations on what pharmacy technicians can do under remote supervision in many states will continue to act as an obstacle to optimization of these technologies,” Gerwitz said.

Innovative Technology

There are plenty of new technologies available to help with a smoother transition and workflow. Video conferencing has become a standard tool for telepharmacy to provide discharge medication counseling and medication therapy management. “Thankfully systems have dramatically improved in recent years. Further maturation of technology and expanded access to broadband will continue to push the boundaries for telepharmacy, particularly in rural areas that struggle with access to health care. “Certainly, video conferencing has existed for some time, but not always in a secure and compliant environment that was appropriate for the health care environment,” Gerwitz said. “[Video communication] is especially beneficial when supporting patients on highly specialized therapies such as those seen in posttransplant care and oncology but can be very helpful as well in the setting of postdischarge medication reconciliation and home care.”

A graduate of the University of Miami, Keith Loria is a D.C.-based, award-winning journalist who has been writing for major publications for close to 20 years.

Eric Maroyka, PharmD

We see it as an opportunity to improve patient outcomes, expand access to health care—whether it’s an acute or ambulatory care setting—and find that it’s also a way to enhance patient safety.
NEW DRUG REVIEW

New Prodrug for ADHD in School-aged Children

By Andre S. Wang, PharmD; and Kevin W. Chamberlin, PharmD, FASCP

Attention-deficit/hyperactivity disorder (ADHD) affects 11% of school-aged children, and more than 75% of these cases will continue into adulthood.1 Without proper diagnosis and treatment, ADHD can lead to serious consequences, including school failure, social difficulties, depression, substance abuse, or job failure. Extensive clinical research has led to well-developed diagnostic criteria and multiple treatment options for ADHD. Serdexmethylphenidate and dexmethylphenidate (Azstarys; Corium), also called ser/dex, is a dexmethylphenidate-based prodrug for ADHD in patients 6 years and older.

Serdexmethylphenidate

Although the mechanism of action for serdexmethylphenidate is not well understood, investigators believe it is mostly converted to dexmethylphenidate in the lower gastrointestinal tract. The combination of immediate-release dexmethylphenidate and slow-absorbed serdexmethylphenidate allows a quick onset and all-day effect.

Efficacy

A 4-week randomized, double-blind, placebo-controlled, parallel-group, classroom study (NCT03292952) evaluated the efficacy of ser/dex versus placebo for the treatment of ADHD in 150 patients aged 6 to 12 years. Study results showed a statistically significant lowering of the primary efficacy end point, which was the mean change from baseline of the Swanson, Kotkin, Agler, M-Flynn, and Pelham-Combined (SKAMP-C) scores averaged across the test day. Patients underwent a 5-day washout period, then a 3-week open-label dose-optimization period followed by a 1-week randomized, double-blind treatment phase. Assessments were conducted at 0.5, 1, 2, 4, 8, 10, 12, and 13 hours post dose. The overall mean change in SKAMP-C score from baseline in the ser/dex arm was −4.87 and 0.54 for the placebo arm, which was statistically significant.2

Safety

The most commonly reported adverse effects (AEs) were headache (5.41%), upper abdominal pain (4.05%), pharyngitis (2.7%), and insomnia (2.7%). There were no serious AEs, nor all-cause mortality reported. Ser/dex is a controlled substance, central nervous system (CNS) stimulant, methylphenidate-containing product, and amphetamine, so there is a boxed warning for a high potential for abuse and dependence. As with many CNS stimulants, there is potential for serious cardiovascular reactions, increased blood pressure and heart rate, psychiatric AEs, peripheral vasculopathy, and long-term growth suppression.

Ser/dex has not been studied in pregnant women; animal embryo-fetal development studies conducted in rats and rabbits showed no malformations. No data are available on the presence of serdexmethylphenidate in human breast milk, effects on the breastfed infant, or effects on milk production. There is limited published literature on dexmethylphenidate present in human breast milk, which resulted in infant doses of 0.16% to 0.7% of the maternal weight-adjusted dosage and a milk/plasma ratio ranging between 1.1 and 2.7. There are no reports of AEs on the breastfed infant and no effects on milk production. Ser/dex has not been studied in individuals 65 years and older.3

Dosing

The recommended dose for patients 6 to 12 years old is a starting dosage of 39.2 mg/7.8 mg orally once daily in the morning. The dosage may be increased to the maximum dose of 52.3 mg/10.4 mg daily or decreased to 26.1 mg/5.2 mg daily after 1 week. For adults and patients 13 to 17 years old, the recommended starting dosage is 39.2 mg/7.8 mg orally once daily in the morning. The dosage can be increased after 1 week to 52.3 mg/10.4 mg once daily. Ser/dex can be administered without regard to food, and patients can swallow capsules whole or open and sprinkle onto applesauce or add to water. To avoid substitution errors and overdosage, do not substitute for other methylphenidate products on a milligram-per-milligram basis.3

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