Indication and Important Safety Information

Indication and Usage

FLUAD® QUADRIVALENT is an inactivated influenza vaccine indicated for active immunization against influenza disease caused by influenza virus subtypes A and types B contained in the vaccine. FLUAD QUADRIVALENT is approved for use in persons 65 years of age and older. This indication is approved under accelerated approval based on the immune response elicited by FLUAD QUADRIVALENT.

Important Safety Information

Contraindications

Do not administer FLUAD QUADRIVALENT to anyone with a history of severe allergic reaction (e.g. anaphylaxis) to any component of the vaccine, including egg protein, or to a previous influenza vaccine.

Warnings and Precautions

If Guillain-Barré syndrome (GBS) has occurred within 6 weeks of receipt of prior influenza vaccine, the decision to give FLUAD QUADRIVALENT should be based on careful consideration of the potential benefits and risks.

Appropriate medical treatment and supervision must be available to manage possible anaphylactic reactions following administration of the vaccine.

ADVERSE REACTIONS

The immune response to FLUAD QUADRIVALENT in immunocompromised persons, including individuals receiving immunosuppressive therapy, may be lower than in immunocompetent individuals.

Syncope (fainting) may occur in association with administration of injectable vaccines and may not reflect rates observed in clinical practice.

Vaccination with FLUAD QUADRIVALENT may not protect all vaccine recipients against influenza disease.

ADVERSE EVENTS

Local reactions in elderly subjects 65 years of age and older were injection site pain (16.3%), swelling (4.8%), redness (4.6%), tenderness (4.0%), and bruising (1.0%).

Solicited systemic reactions in the elderly subjects 65 years of age and older were fever ≥100°F (38°C) (1.2%), vomiting (1.5%), and diarrhea (4.1%). Swelling of the face and throat was uncommon (0.3%).

Unsolicited adverse events (AEs) were collected for all subjects for 21 days after vaccination. The most common (≥1%) unsolicited event reported in the elderly subjects 65 years of age and older was syncope (0.3%).

References


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FLUAD® QUADRIVALENT (Influenza Vaccine, Adjuvanted)
Injectable Emulsion for Intramuscular Use
2022-2023 Formula

BRIEF SUMMARY OF PRESCRIBING INFORMATION
Consult the full US Prescribing information for complete product information.

INDICATIONS AND USAGE
FLUAD QUADRIVALENT is an inactivated influenza vaccine indicated for active immunization against influenza disease caused by influenza virus subtypes A and types B contained in the vaccine. FLUAD QUADRIVALENT is approved for use in persons 65 years of age and older. This indication is approved under accelerated approval based on the immune response elicited by FLUAD QUADRIVALENT. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

For intramuscular injection only.

CONTRAINDICATIONS
Do not administer FLUAD QUADRIVALENT to anyone with a history of severe allergic reaction (e.g., anaphylaxis) to any component of the vaccine, including egg protein, or to a previous influenza vaccine.

WARNINGS AND PRECAUTIONS
Guillain-Barré Syndrome: If Guillain-Barré syndrome (GBS) has occurred within 6 weeks of receipt of prior influenza vaccine, the decision to give FLUAD QUADRIVALENT should be based on careful consideration of the potential benefits and risks. The 1976 swine influenza vaccine was associated with an elevated risk of GBS. (See Reference 1) Evidence for a causal relationship of GBS with other influenza vaccines is inconclusive; if an excess risk exists, it is probably slightly more than 1 additional case per 1 million persons vaccinated.

Preventing and Managing Allergic Reactions: Appropriate medical treatment and supervision must be available to manage possible anaphylactic reactions following administration of the vaccine.

Altered Immunecompetence: The immune response to FLUAD QUADRIVALENT in immunocompromised persons, including individuals receiving immunosuppressive therapy, may be lower than in immunocompetent individuals.

Syncpe: Syncope (fainting) may occur in association with administration of injectable vaccines including FLUAD QUADRIVALENT. Ensure procedures are in place to avoid injury from falling associated with syncope.

Limitations of Vaccine Effectiveness: Vaccination with FLUAD QUADRIVALENT may not protect all vaccine recipients against influenza disease.

ADVERSE REACTIONS
The most common (≥10%) local and systemic reactions in elderly subjects 65 years of age and older were injection site pain (16.5%), headache (10.8%) and fatigue (10.5%).

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

The safety of FLUAD QUADRIVALENT was evaluated in two clinical studies in ≥629 elderly subjects 65 years of age and older. Study 1 (NCT02557721) was a multi-center, randomized, observer-blind, non-influenza comparator-controlled efficacy and safety study conducted in 12 countries during the 2016-2017 Northern Hemisphere and 2017 Southern Hemisphere seasons. In this study, 3381 subjects received FLUAD QUADRIVALENT and 3380 subjects received a US-licensed non-influenza comparator vaccine (Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine, Boostrix® (GlaxoSmithKline Biologicals)).

The mean age of subjects at enrollment was 72 years. 62% were female, 48% White, 34% Asian, 16% Other, 2% American Indian/Alaska Native, and 18% of Hispanic/Latino ethnicity. Solicited local and systemic adverse reactions were collected for 7 days after vaccination in a subset of 665 subjects who received FLUAD QUADRIVALENT and 667 subjects who received the comparator vaccine. The percentages of subjects reporting solicited local adverse reactions are presented in Table 1a and systemic adverse reactions are presented in Table 1b. Onset usually occurred within the first 2 days after vaccination. The majority of solicited reactions resolved within 3 days.

Table 1a. Percentages of Subjects Reporting Solicited Local Adverse Reactions in the Solicited Safety Population within 7 Days of Vaccination (Study 1)

<table>
<thead>
<tr>
<th>Local (Injection site) Reactions</th>
<th>FLUAD QUADRIVALENT N=659</th>
<th>Non-Influenza Comparator Vaccine N=657-664</th>
</tr>
</thead>
<tbody>
<tr>
<td>Injection site pain</td>
<td>16.3</td>
<td>11.2</td>
</tr>
<tr>
<td>Swelling ≥25mm</td>
<td>3.8</td>
<td>1.6</td>
</tr>
<tr>
<td>Induration ≥20mm</td>
<td>4.0</td>
<td>2.6</td>
</tr>
<tr>
<td>Ecchymosis ≥25mm</td>
<td>0.5</td>
<td>0.7</td>
</tr>
</tbody>
</table>

Table 1b. Percentages of Subjects Reporting Solicited Systemic Adverse Reactions in the Solicited Safety Population within 7 Days of Vaccination (Study 1)

<table>
<thead>
<tr>
<th>Systemic Reactions</th>
<th>FLUAD QUADRIVALENT N=659-659</th>
<th>Non-Influenza Comparator Vaccine N=657-664</th>
</tr>
</thead>
<tbody>
<tr>
<td>Headache</td>
<td>10.8</td>
<td>8.3</td>
</tr>
<tr>
<td>Fatigue</td>
<td>10.5</td>
<td>8.6</td>
</tr>
<tr>
<td>Myalgia</td>
<td>7.7</td>
<td>6.1</td>
</tr>
<tr>
<td>Arthralgia</td>
<td>7.3</td>
<td>6.6</td>
</tr>
<tr>
<td>Chills</td>
<td>5.0</td>
<td>3.9</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>4.1</td>
<td>3.0</td>
</tr>
<tr>
<td>Nausea</td>
<td>3.6</td>
<td>2.3</td>
</tr>
<tr>
<td>Loss of appetite</td>
<td>3.6</td>
<td>3.6</td>
</tr>
<tr>
<td>Fever ≥100.4°F (38°C)</td>
<td>1.7</td>
<td>1.2</td>
</tr>
<tr>
<td>Vomiting</td>
<td>0.8</td>
<td>1.1</td>
</tr>
</tbody>
</table>

Study 1: NCT02557721
Abbreviation: N-number of subjects with solicited safety data
Non-Influenza Comparator Vaccine = combined Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine, Boostrix® (GlaxoSmithKline Biologicals)
All solicited adverse events reported within 7 days of vaccination are included

* Solicited Safety Population: all subjects in the exposed population who received a study vaccine and provided post-vaccination solicited safety data.

** Seven reactions of each type were reported in 1.1% or fewer subjects receiving FLUAD QUADRIVALENT. Seven reactions of each type were also reported in the comparator group at similar percentages. Seven definitions: Nausea, Fatigue, Myalgia, Arthralgia, Headache, and Chills = prevents daily activity. Loss of appetite = not eating at all; Vomiting = 6 or more times in 24 hours or requires intravenous hydration; Diarrhea = 6 or more loose stools in 24 hours or requires intravenous hydration; Fever = ≥100.4°F (38°C).

Unsolicited adverse events (AEs) were collected for all subjects for 21 days after vaccination.

Related unsolicited AEs were reported by 30.3% (9/30) and by 26.1% (7/27) of the subjects for the FLUAD QUADRIVALENT and Boostrix, respectively. For FLUAD QUADRIVALENT, injection site pain and influenza-like illness were the only unsolicited adverse reactions reported in ≥ 1% of subjects (1.7% and 1.5%, respectively).

Serious adverse events (SAEs) and potentially immune-mediated adverse events of special interest (AESIs) were collected up to 366 days after vaccination. SAEs were reported by 23.8% (70/30) FLUAD QUADRIVALENT recipients and 234 (6.9%) comparator recipients. There were no SAEs, AESIs or deaths in this study that were related to FLUAD QUADRIVALENT.

Study 2 (NCT03314662) was a multicenter, randomized, double-blind, comparator-controlled study conducted during the 2017-18 Northern Hemisphere influenza season. In this study, 888 subjects received FLUAD QUADRIVALENT, 444 subjects received the licensed adjuvanted Influenza vaccine (Fluad®) and 444 subjects received an adjuvanted Influenza vaccine with an alternate B strain (Fluad-2). The mean age of subjects at enrollment who received FLUAD QUADRIVALENT was 72.5 years. Female subjects represented 56.6% of the study population and the racial distribution of subjects was 91.8% Caucasian, 7.0% Black or African American, and ≤ 1% each for Asian, Native Hawaiian or Pacific Islander, American Indian or Alaska Native or Other.

Solicited and unsolicited adverse reactions were collected for 7 days after vaccination were similar to those reported for Study 1. Unsolicited AEs were collected for 21 days after vaccination. Related unsolicited AEs were reported by 39 (4.4%) and by 17-19 (3.8%-4.3%) of subjects administered FLUAD QUADRIVALENT or aTIV, respectively. For FLUAD QUADRIVALENT, injection site bruising (1.0%) was the only unsolicited adverse reaction reported in ≥ 1% of subjects.

Serious AEs and AESIs were collected up to 181 days after vaccination. Within 6 months after vaccination, 37 (4.2%) FLUAD QUADRIVALENT recipients and 18-28 (4.1%-6.3%) aTIV recipients experienced an SAE. There were no SAEs, AESIs or deaths in this study that were related to the study vaccine. There were no AEs leading to withdrawal from the study.

Postmarketing Experience: There are no postmarketing data available for FLUAD QUADRIVALENT. However, the postmarketing experience with FLUAD (irritant formulation) is relevant to FLUAD QUADRIVALENT because both vaccines are manufactured using the same process and have overlapping compositions. Because these events 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.

Blood and lymphatic system disorders: Thrombocytopenia (some cases were severe with platelet counts less than 5,000 per µm³), lymphadenopathy

General disorders and administration site conditions: Extensive swelling of injected limb lasting more than one week, injection site cellulitis-like reactions (some cases of swelling, pain, and redness extending more than 10 cm and lasting more than 1 week)

Immune system disorders: Allergic reactions including anaphylactic shock, anaphylaxis, and angioedema
Musculoskeletal and connective tissue disorders: Muscular weakness
Neurological disorders: Convulsions, encephalitis, Guillain-Barré syndrome, encephalopathy, myelitis, neurologic disorder, paralysis, headache, facial nerve palsy, peripheral neuropathy, cerebrovascular disease, peripheral nerve disorder, neurodegeneration, myasthenia gravis
Skin and subcutaneous tissue disorders: Generalized skin reactions including erythema multiforme, urticaria, pruritus or nonspecific rash
Vascular disorders: Vasculitis, renal vasculitis

DRUG INTERACTIONS
Concomitant Use With Other Vaccines: No clinical data on concomitant administration of FLUAD QUADRIVALENT with other vaccines is available.

If FLUAD QUADRIVALENT is given at the same time as other injectable vaccine(s), the vaccine(s) should be administered at different injection sites.

Do not mix FLUAD QUADRIVALENT with any other vaccine in the same syringe.

 Concurrent Use With Immunosuppressive Therapies: Immunosuppressive or corticosteroid therapies may reduce the immune response to FLUAD QUADRIVALENT.

USE IN SPECIFIC POPULATIONS
Pregnancy

Risk Summary
FLUAD QUADRIVALENT is not approved for use in persons < 65 years of age. There are insufficient human data to establish whether there is a vaccine-associated risk with use of FLUAD QUADRIVALENT in pregnancy.

There were no developmental toxicity studies of FLUAD QUADRIVALENT performed in animals. A developmental toxicity study has been performed in female rabbits administered FLUAD (trivalent formulation) prior to mating and during gestation. A 0.5 mL dose was injected on each occasion (a single human dose is 0.5 mL).

Lactation

Risk Summary
FLUAD QUADRIVALENT is not approved for use in persons < 65 years of age.

No human or animal data are available to assess the effects of FLUAD QUADRIVALENT on the breastfed infant or on milk production/excretion.

Pediatric Use
Safety and effectiveness of FLUAD and FLUAD QUADRIVALENT (same manufacturing process and overlapping composition with FLUAD) were evaluated in clinical trials conducted in children 6 months to <72 months of age. Data from these trials are inconclusive to demonstrate the safety and effectiveness of FLUAD QUADRIVALENT in children 6 months to <72 months of age. The safety and effectiveness of FLUAD QUADRIVALENT in infants less than 6 months of age and in children older than 72 months of age have not been evaluated.

Geriatric Use
Safety and immunogenicity of FLUAD QUADRIVALENT have been evaluated in adults 65 years of age and older.

REFERENCE

To report SUSPECTED ADVERSE REACTIONS, contact Seqirus at 1-855-368-8966 or VAERS at 1-800-822-7967 or www.vaers.hhs.gov.
As summer starts winding down, parents begin turning their thoughts to back-to-school season. This year, a COVID-19 vaccine may be included on parents’ back-to-school shopping lists, along with notebooks, crayons, and a new pair of sneakers.

On June 17, 2022, the FDA authorized the Moderna and Pfizer-BioNTech COVID-19 vaccines for children 6 months to 5 years of age—the final group of individuals awaiting vaccination. Endorsement by the Advisory Committee on Immunization Practices and recommendation by the CDC followed, and distribution of these pediatric vaccines began immediately.

Pharmacists should be prepared for a potential influx of families with preschool- or kindergarten-aged children seeking vaccination. If you’re unsure of the latest guidance, turn to page 10, where we share the most recent interim immunization schedule from the CDC, as well as information on the COVID-19 vaccine products currently approved for use in the United States.

Elsewhere in the issue, we look ahead toward the 2022-2023 flu season, with the latest updates on flu vaccines, including the selected strains, changes in recommendations, and forthcoming vaccine options for patients.

As always, thank you for reading.

Mike Hennessy Jr
President and CEO of MJH Life Sciences®

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Looking to the Future of Independent Pharmacy

Don Arthur, RPh, owner of Black Rock Pharmacy in Buffalo and Brighton Eggert Pharmacy in Tonawanda, New York, discusses what clinical care may look like in the future and the biggest challenges ahead for independent pharmacies.

Behind the Science™: Behind Burnout

Two experts detail the history of burnout, its manifestations, and treatments.

Second Opinion™: Pediatric COVID-19 Vaccines

Where should the youngest patients receive their COVID-19 vaccines? A pharmacist and a pediatrician come together to discuss who should administer vaccines to this vulnerable population.

Notable Quotables

“There are a lot of competitors, a lot of big chains. It’s really a testament to our customers who have stuck with us for years and years; they didn’t have to come to us [and] we wouldn’t be here without them.”

—MARK SZILAGYI, RPH
co-owner and pharmacist at Gateway Pharmacy, on the customers in his Phoenixville, Pennsylvania community.
Opioid use disorder (OUD) and overdose deaths are an epidemic. During the COVID-19 pandemic, opioid overdose deaths in the United States soared by 45%—up to 107,622 drug overdose deaths in 2021, according to the CDC. 

Despite these high numbers, when individuals with OUD or their caregivers ask their pharmacist for help, the answer all too often is “I can’t.”

“The barriers to patient access to medication for opioid use disorder (MOUD) are decades old, entrenched in our clinics, our regulations, and our attitudes that stigmatize OUD and (individuals) who have OUD,” said Anna Legreid Dopp, PharmD, CPHQ, senior director of clinical guidelines and quality improvement at American Society of Health-System Pharmacists in Washington, DC. “But the evidence is there that MOUD reduces mortality and facilitates recovery, and we are seeing change.”

There are decades of data supporting the effectiveness of naltrexone, buprenorphine, and methadone to treat OUD, and nearly as many decades of legal and regulatory restrictions on their use. Naloxone—used to reverse acute opioid overdose—is the 1 clear success in the continuing battle against opioid fatalities, said Anne Burns, RPh, vice president of professional affairs for the American Pharmacists Association in Washington, DC. Although naloxone saves lives, it does not treat OUD.

Naltrexone, a complete opioid blocker, is most commonly formulated as an injectable and is seldom used for MOUD due to inconvenience of routine injections and unwelcome adverse effects, including headache, fatigue, joint and muscle pain, loss of appetite, and vomiting. Methadone is a complete opioid agonist dispensed in pharmacies for analgesia but can be used for MOUD only in federally approved opioid treatment programs.

Buprenorphine, a partial opioid blocker, is also dispensed for analgesia. As a schedule III narcotic, it can be prescribed and titrated by pharmacists if the state practice act allows. However, prescribing or titrating the same buprenorphine for MOUD is restricted to clinicians who hold a waiver under the Drug Addiction Treatment Act of 2000 (DATA 2000).

These waivers, sometimes called X waivers, were originally restricted to physicians meeting specific training requirements. Subsequent legislation extended waivers to physician assistants and nurse practitioners—but not to pharmacists.

“Regulations that would allow for patients to receive the appropriate level of care where and when they need it, so [patients] could potentially receive methadone and buprenorphine in community pharmacies—and having pharmacists be able to prescribe or order these medications where it is part of their scope of practice—could go a long way to expanding access,” said Bethany DiPaula, PharmD, BCPP, FASHP, who is part of a primary care practice focused on substance use disorders in Baltimore, Maryland.

She is also a professor and the director of the Pgy2 Psychiatric Pharmacy Residency Program at the University of Maryland School of Pharmacy. “I can enter buprenorphine prescriptions in our electronic order entry system, but they are actually prescribed by a practice physician, not by me,” she said. “That’s an extra step, an additional barrier, to providing treatment that works. Internationally, pharmacists provide MOUD in the community pharmacy setting, and there have been studies about expanding MOUD in community pharmacies in this country. DATA 2000 is the big hang-up.”

However, that could change. A coalition of pharmacy, medical, and other groups have been pushing both to expand DATA 2000 waivers to pharmacists and eliminate waiver requirements altogether. In June, the United States House of Representatives passed HR 7666, the Restoring Hope for Mental Health and Well-Being Act of 2022. The bill would eliminate the need for pharmacists and other clinicians to obtain a DATA 2000 waiver to administer MOUD but would continue current training requirements. “Patients in need must have...”
access, but this well-established solution is hindered by unnecessary and unproven bureaucratic processes,” said Timothy D. Fensky, RPh, DPh, president of the National Association of Boards of Pharmacy in 2021 in Suffolk County, Massachusetts. “Pharmacists are well positioned to help eliminate barriers and allow more patients with OUD to access the treatment they need.”

**Facing the Stigma**

Only approximately 20% of individuals who could benefit from MOUD actually get it, Burns noted. Stigma in the community, from law enforcement, government, and the health care industry, gets in the way.

“There are pharmacists who feel that if they dispense buprenorphine, [they are] trading one addiction for another,” Burns said. “Some addiction specialists say it is being diverted onto the street, which is probably a good thing. If someone uses buprenorphine vs heroin or fentanyl, it is very unlikely they are going to overdose. MOUD requires a different mindset.”

Of this mindset, some in law enforcement are taking note. “The chief barriers to expanding MOUD access...are often based on misguided stereotypes and stigmas about the treatment and diversion concerns,” wrote Assistant United States Attorneys David Sinkman, of the Eastern District of Louisiana, and Gregory Dorchak, of the District of Massachusetts in the *Department of Justice Journal of Federal Law and Practice* in 2020. “Equating the prescription use of MOUD with addiction overlooks the fact that any woman trying to get oral contraceptives when they first came out. The stigma and judgment that any woman trying to get that prescription filled at the pharmacy (faced) was almost overwhelming. It’s the same kind of situation for patients [with substance use disorder] trying to get their medications.”

**Regulation and Reimbursement**

It’s not just individual pharmacists prejudging patients, Allen noted that some pharmacy chains discourage outlets from accepting patients who need MOUD or from filling MOUD prescriptions. “Wholesalers have certain controlled substance dispensing patterns they expect to see, and chains don’t want to lose their ability to purchase,” she said. “It’s terrifying to think you could be cut off from ordering medications because you don’t fit an algorithm that doesn’t take substance use disorder medications into account.”

In turn, wholesalers are trying to avoid attention from the Drug Enforcement Administration (DEA), which has cracked down on opioid sales in recent years. It is unclear how the DEA views MOUD dispensing. The agency touted steps taken to expand access to MOUD in a March 2022 press release, a list that includes “engaging in regular outreach with pharmacists and practitioners to express support for the use of medication-assisted treatment for those suffering from substance use disorder.”

But what that outreach has accomplished is unclear. “DEA is hearing from a lot of advocacy groups, including ASHP,” Dopp said. “There is positive momentum with other stakeholder groups to try to educate and advocate within the DEA to create change.” Ongoing discussions with the agency have brought no discernable changes in policy or enforcement, she added.

“It’s a tangled web of barriers for pharmacists who want to take care of patients,” said Hannah Fish, PharmD, CPHQ, director of strategic initiatives for the National Community Pharmacists Association in East Greenwich, Rhode Island. “All these regulations effectively limit access to care rather expanding access.”

On top of navigating these barriers, MOUD can also be a financial strain, as it is a time-intensive, high-touch practice. Few payers adequately reimburse pharmacists for the time involved. “[When] treating [patients with] substance use disorder, you have to think back on why you got into pharmacy,” Allen said. “When you see in real life how these people have turned their lives around with good care and the right medication at a pharmacy that doesn’t give them a hard time about filling their prescriptions, it reminds you why you got into this practice in the first place.”

For references, visit drugtopics.com.
On June 17, 2022, the FDA authorized the Moderna and Pfizer-BioNTech COVID-19 vaccines for use in children 6 months to 5 years of age, and many parents and caregivers across the country breathed a sigh of relief. Endorsement by the Advisory Committee on Immunization Practices (ACIP) and the CDC followed, and distribution of these vaccines across the United States began immediately.

The authorization of the vaccine for this final group means that COVID-19 immunizations are available for individuals age 6 months and older. This month, Drug Topics® is providing an overview of the latest interim guidance, direct from the CDC, on administering these vaccines.

---

**TABLE 1** IMMUNIZATION SCHEDULE FOR INDIVIDUALS 18 YEARS OF AGE

<table>
<thead>
<tr>
<th>TYPE</th>
<th>PRODUCT*</th>
<th>RECIPIENT AGE</th>
<th>FOR MOST PEOPLE</th>
<th>THOSE WHO ARE MODERATELY OR SEVERELY IMMUNOCOMPROMISED</th>
</tr>
</thead>
<tbody>
<tr>
<td>mRNA vaccine</td>
<td>Moderna</td>
<td>18 years and older</td>
<td>Total number: 3 or 4 doses</td>
<td>Total number: 5 doses</td>
</tr>
<tr>
<td></td>
<td>(Red vial cap with a blue-bordered label)</td>
<td>Dose 1 to 2</td>
<td>at least 3 to 8 weeks</td>
<td>Dose 1 to 2</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Dose 2 to 3</td>
<td>at least 8 weeks</td>
<td>Dose 2 to 3</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Dose 3 to 4</td>
<td>at least 4 months for persons aged 50 years and older</td>
<td>Dose 3 to 4</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Dose 4 to 5</td>
<td>at least 4 months</td>
<td>Dose 4 to 5</td>
</tr>
<tr>
<td>mRNA vaccine</td>
<td>Pfizer-BioNTech</td>
<td>18 years and older</td>
<td>Total number: 3 or 4 doses</td>
<td>Total number: 5 doses</td>
</tr>
<tr>
<td></td>
<td>(Purple vial cap with a purple-bordered label or gray vial cap with gray-bordered label)</td>
<td>Dose 1 to 2</td>
<td>at least 3 to 8 weeks</td>
<td>Dose 1 to 2</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Dose 2 to 3</td>
<td>at least 4 months for persons aged 50 years and older</td>
<td>Dose 2 to 3</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Dose 4 to 5</td>
<td>at least 4 months</td>
<td>Dose 4 to 5</td>
</tr>
<tr>
<td>Protein subunit vaccine</td>
<td>Novavax</td>
<td>18 years and older</td>
<td>Total number: 2 doses</td>
<td>Total number: 2 doses</td>
</tr>
<tr>
<td>Viral vector vaccine</td>
<td>Janssen*</td>
<td>18 years and older</td>
<td>Total number: 2 or 3 doses</td>
<td>Total number: 4 doses</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Dose 1 to 2</td>
<td>at least 8 weeks</td>
<td>Dose 1 to 2</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Dose 2 to 3</td>
<td>at least 4 months for persons aged 50 years and older (mRNA vaccine)**</td>
<td>Dose 2 to 3</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Dose 3 to 4</td>
<td>At least 4 months (mRNA vaccine) §</td>
<td>Dose 4 to 3</td>
</tr>
</tbody>
</table>

* More detailed information can be found on the CDC’s website at https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html or by scanning the QR code.
**TABLE 2**

IMMUNIZATION SCHEDULE FOR CHILDREN 6 MONTHS THROUGH 17 YEARS OF AGE

<table>
<thead>
<tr>
<th>TYPE</th>
<th>PRODUCT*</th>
<th>RECIPIENT AGE</th>
<th>FOR MOST PEOPLE</th>
<th>THOSE WHO ARE MODERATELY OR SEVERELY IMMUNOCOMPROMISED</th>
</tr>
</thead>
<tbody>
<tr>
<td>mRNA vaccine</td>
<td>Moderna (Blue vial cap with magenta-bordered label)</td>
<td>6 months through 5 years</td>
<td>Total doses: 2 doses</td>
<td>Total doses: 3 doses</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Dose 1 to 2</td>
<td>at least 4 to 8 weeks&lt;sup&gt;‡&lt;/sup&gt;</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Dose 2 to 3</td>
<td>at least 4 weeks</td>
</tr>
<tr>
<td></td>
<td>Moderna (Blue vial cap with purple-bordered label)</td>
<td>6 through 11 years</td>
<td>Total doses: 2 doses</td>
<td>Total doses: 3 doses</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Dose 1 to 2</td>
<td>at least 4 to 8 weeks&lt;sup&gt;‡&lt;/sup&gt;</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Dose 2 to 3</td>
<td>at least 4 weeks</td>
</tr>
<tr>
<td></td>
<td>Moderna (Red vial cap with blue-bordered label)</td>
<td>12 through 17 years</td>
<td>Total doses: 2 doses</td>
<td>Total doses: 3 doses</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Dose 1 to 2</td>
<td>at least 4 to 8 weeks&lt;sup&gt;‡&lt;/sup&gt;</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Dose 2 to 3</td>
<td>at least 4 weeks</td>
</tr>
<tr>
<td></td>
<td>Pfizer-BioNTech (Maroon vial cap with maroon-bordered label)</td>
<td>6 months through 4 years</td>
<td>Total number: 3 doses</td>
<td>Total number: 3 doses</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Dose 1 to 2</td>
<td>at least 3 to 8 weeks&lt;sup&gt;‡&lt;/sup&gt;</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Dose 2 to 3</td>
<td>at least 8 weeks</td>
</tr>
<tr>
<td></td>
<td>Pfizer-BioNTech (Orange vial cap with orange-bordered label)</td>
<td>5 through 11 years</td>
<td>Total number: 3 doses</td>
<td>Total number: 4 doses</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Dose 1 to 2</td>
<td>at least 3 to 8 weeks&lt;sup&gt;‡&lt;/sup&gt;</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Dose 2 to 3</td>
<td>at least 5 months</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Dose 2 to 3</td>
<td>at least 4 weeks</td>
</tr>
<tr>
<td></td>
<td>Pfizer-BioNTech (Purple vial cap with a purple-bordered label or gray vial cap with gray-bordered label)</td>
<td>12 years through 17 years</td>
<td>Total number: 3 doses</td>
<td>Total number: 5 doses</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Dose 1 to 2</td>
<td>at least 3 to 8 weeks&lt;sup&gt;‡&lt;/sup&gt;</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Dose 2 to 3</td>
<td>at least 5 months</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Dose 2 to 3</td>
<td>at least 4 weeks</td>
</tr>
</tbody>
</table>

---

**Key to Table 1**

- Complete the primary series with same product. If the vaccine product previously administered cannot be determined or is no longer available, any age-appropriate mRNA COVID-19 vaccine product may be administered at least 28 days after the first dose. Any COVID-19 vaccine product (age appropriate) may be administered for a booster dose. It does not need to be the same product used for the primary series. An mRNA COVID-19 vaccine is preferred.

° Persons with a recent SARS-CoV-2 infection may consider delaying a primary series or booster dose by 3 months from symptom onset or positive test (if infection was asymptomatic).

‡ Some studies in adolescents and adults have shown the small risk of myocarditis associated with mRNA COVID-19 vaccines might be reduced and peak antibody responses and vaccine effectiveness may be increased with an interval longer than 4 weeks. An 8-week interval may be optimal for people who are not moderately or severely immunocompromised and ages 6 months–64 years, especially for males ages 12–39 years.

§ Age-appropriate mRNA COVID-19 vaccines are preferred over the Janssen COVID-19 vaccine for all vaccine doses for all vaccine-eligible people 18 years of age and older. Janssen COVID-19 vaccine should only be used in limited situations. See: www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html

¶ mRNA vaccine must be used.

** People ages 18–49 years: Those who received Janssen COVID-19 vaccine as both their primary series dose and booster dose may receive a second booster dose using an mRNA COVID-19 vaccine at least 4 months after the Janssen booster dose.
**COVID-19 Vaccination Schedules**

Use the schedules below to determine how many total COVID-19 vaccine doses are recommended based on primary series product, age, and immune status. This schedule does not include clinical details necessary for administering COVID-19 vaccines. For clinical details, see the resources at the end of this document.

**COVID-19 Vaccination Schedule for Most People**

Number and intervals of COVID-19 vaccine doses  
Source: CDC

---

**Moderna (ages 6 months – 17 years)**

- Dose 1 (primary) → Dose 2 (primary) → Dose 3 (booster*) → Dose 4 (second mRNA booster*)

In 4-8 weeks

People aged 50 years and older should get a second booster.

---

**Moderna (ages 18 years and older)**

- Dose 1 (primary) → Dose 2 (primary) → Dose 3 (booster*)

In 4-8 weeks → In at least 5 months → In at least 4 months

†Second booster dose for some groups

People aged 50 years and older should get a second booster.

---

**Novavax (ages 18 years and older)**

- Dose 1 (primary) → Dose 2 (primary)

In 3-8 weeks

---

**Pfizer-BioNTech (ages 6 months – 4 years)**

- Dose 1 (primary) → Dose 2 (primary) → Dose 3 (primary) → Dose 4 (second mRNA booster*)

In 3-8 weeks → In at least 8 weeks → In at least 4 months

People aged 50 years and older should get a second booster.

---

**Pfizer-BioNTech (ages 5 years and older)**

- Dose 1 (primary) → Dose 2 (primary) → Dose 3 (booster*)

In 3-8 weeks → In at least 5 months → In at least 4 months

People aged 50 years and older should get a second booster.

---

**Janssen (J&J) (ages 18 years and older)**

- Dose 1 (primary) → Dose 2 (booster*)

In at least 2 months → In at least 4 months

People aged 50 years and older should get a second booster.

---

* Age-appropriate mRNA COVID-19 vaccines are preferred over Janssen COVID-19 vaccine for primary and booster vaccination. Janssen COVID-19 vaccine should only be used in limited situations. See: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interimconsiderations-us.html#considerations-Janssen.
COVID-19 Vaccination Schedule for People Who Are Moderately or Severely Immunocompromised

Number and intervals of COVID-19 vaccine doses  
Source: CDC

For more specific clinical guidance, see:
- Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States
- Interim COVID-19 Immunization Schedule

cdc.gov/coronavirus
RESPIRATORY

2022-2023 Flu Season Updates

Learn about the selected strains for this year’s flu season, flu vaccine recommendation changes, and newly licensed and forthcoming vaccine options  By Sandra Fyfe

Now more than ever, it's essential for patients—particularly those who are at risk—to be vaccinated against influenza. Adults 65 and older, individuals with comorbidities, people of color, and individuals of lower socioeconomic status are at higher risk of illness. Getting vaccinated helps protect these vulnerable populations.

The 2022-2023 Flu Season

What strains have been chosen for this season's vaccines?

On February 25, 2022, the World Health Organization (WHO) announced the strains selected for the 2022-2023 flu season vaccines after reviewing the data of circulating virus (see sidebar, left).1 On March 3, 2022, the FDA’s Vaccines and Related Biological Products Advisory Committee voted to approve the strains selected by WHO.2

What are the new recommendations for the current flu season?

At a meeting in June 2022, the Advisory Committee on Immunization Practices recommended that adults 65 and older receive high-dose influenza vaccine for better protection.3 These vaccines include quadrivalent adjuvanted inactivated influenza vaccine (aIIV4), quadrivalent

For egg-based, quadrivalent vaccines, the World Health Organization (WHO) recommended an A/Victoria/2570/2019 (H1N1)pdm09-like virus; an A/Darwin/9/2021 (H3N2)-like virus; a B/Austria/1359417/2021 (B/Victoria lineage)-like virus; and a B/Phuket/3073/2013 (B/Yamagata lineage)-like virus.

For recombinant-based or cell culture quadrivalent vaccines, WHO recommended an A/Wisconsin/588/2019 (H1N1)pdm09-like virus; an A/Darwin/6/2021 (H3N2)-like virus; a B/Austria/1359417/2021 (B/Victoria lineage)-like virus; and a B/Phuket/3073/2013 (B/Yamagata lineage)-like virus.

For trivalent, egg-based vaccines, WHO recommended an A/Victoria/2570/2019 (H1N1)pdm09-like virus; an A/Darwin/9/2021 (H3N2)-like virus; and a B/Austria/1359417/2021 (B/Victoria lineage)-like virus.

For recombinant-based or cell culture trivalent vaccines, WHO recommended an A/Wisconsin/588/2019 (H1N1)pdm09-like virus; an A/Darwin/6/2021 (H3N2)-like virus; and a B/Austria/1359417/2021 (B/Victoria lineage)-like virus.
DrugTopics® August 2022

2022-2023 FLU SEASON UPDATES / RESPIRATORY

high-dose inactivated influenza vaccine (HD-IIV4), or quadrivalent recombinant influenza vaccine (RIV4). 3

New and Forthcoming Vaccines
In May 2021, the FDA approved the cell-based vaccine Flucelvax (Seqirus). 4 This extends the age of coverage of the vaccine to children 6 months and older. A phase 3 clinical study supported this approval, showing that the vaccine's safety and immunogenicity was equivalent to that of other standard quadrivalent vaccines for children of ages 6 months to 5 years. 4 These data, presented at the Pediatric Academic Societies 2021 Virtual Meeting on May 1, 2021, represent the first US phase 3 study of a cell-based influenza vaccine in this population,” the press release noted. 4

Moderna is conducting ongoing clinical trials for its mRNA-1230 combination vaccine, which is designed to protect against influenza, COVID-19, and respiratory syncytial virus using the company's mRNA platform. In a press release distributed ahead of the company’s annual Vaccines Day— held this year in March 2022—Stephen Hoge, MD, president of Moderna, said, “We are pleased to add a combination respiratory vaccine candidate against 3 of the leading causes of respiratory disease in older adults, and a vaccine against all 4 of the endemic human coronaviruses as part of our strategy to address the substantial global burden of respiratory infections...Our goal is to develop vaccines to address respiratory infections and eventually combine many into a single annual booster vaccine, with the aim of reducing the significant morbidity and mortality caused by these viruses.” 5

On July 1, 2022, the FDA approved the license for Sanofi's Fluzone High-Dose Quadrivalent, Flublok Quadrivalent, and Fluzone Quadrivalent influenza vaccines for the 2022-2023 season. Fluzone and Flublok are the only influenza vaccines proven by randomized controlled trials to prevent more cases in older adults, according to Sanofi’s press release. 6 Sanofi said Fluzone has 10 years of evidence in protecting adults 65 and older from flu-related hospitalizations.

In a clinical study, Flublok Quadrivalent is the first and only recombinant influenza vaccine for adults 18 [and older] that was proven to be 30% more effective than a standard-dose vaccine at preventing flu infection in over 9000 adults 50 [and older]. In adults 50 [and older], the most common [adverse] effects were tenderness and/or pain at the injection site, headache, and tiredness,” the press release stated. 6

Finally, Novavax, Inc, is developing a COVID-19–influenza combination vaccine. In April 2022, Novavax reported the vaccine was well tolerated and immunogenic, and that the phase 2 confirmation trial will begin toward the end of 2022. 7 In the news release, Gregory M. Glenn, MD, president of research and development at Novavax, said the company is continuing “to evaluate the dynamic public health landscape and believes there may be a need for recurrent boosters to fight both COVID-19 and seasonal influenza. We’re encouraged by these data and the potential path forward for a combination COVID-19 influenza vaccine (and) stand-alone vaccines for influenza and COVID-19.” 7

For references, visit drugtopics.com.

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Like what you’re reading? Subscribe to our newsletters!
Using your smartphone camera, hover over the QR code to log in.
Pharmacists’ body of knowledge is crucial in helping pediatric and adult patients select the right medication to treat their ADHD.

By Christine Blank

or years, Ritalin was the go-to methylphenidate to treat attention deficit hyperactivity disorder (ADHD). In recent years, several new intermediate- and extended-release (IR; XR) versions of the drug have come on the market, providing a variety of time-release options and easier routes of administration for patients and making pharmacists’ knowledge of these newer medications more essential than ever for their pediatric and adult patients.

These new products include methylphenidate for extended-release oral suspension and methylphenidate (Quillivant XR); extended-release chewable capsules such as methylphenidate HCl (QuilliChew ER); methylphenidate hydrochloride extended-release capsules (Aptensio XR); methylphenidate extended-release orally disintegrating tablets (XR-ODT, NT-0102, and Cotempla); and Oradour-Methylphenidate (once-daily tamper-resistant formulation).1

“When I started, we had methylphenidate [Ritalin] and [amphetamine/dextroamphetamine (Adderall)]. Now, there are upwards of 10 formulations,” Megan Ehret, PharmD, MS,
ADHD in Adults

Although pediatric attention deficit hyperactivity disorder garners more media attention, ADHD in adults—both patients diagnosed for the first time and those who were not properly diagnosed in childhood—is increasing.

“Adult ADHD is definitely an under-served area. We thought in the past that [pediatric patients] would outgrow it. Over half of these people who are diagnosed as kids continue to have symptoms in adulthood;” said Megan Ehret, PharmD, MS, BCPP, of the University of Maryland School of Pharmacy in Baltimore.4

“Pharmacists could be helpful, with their understanding of the formulations, [in selecting] the best medication that could be most effective” for these adult patients.

The prevalence of persistent adult ADHD was an estimated 2.58%—or nearly 140 million—of the global population—and symptomatic adult ADHD was an estimated 6.76% (366.33 million) of the global population in 2020, according to a study published in the Journal of Global Health.5

However, most ADHD treatment guidelines don’t specifically address adults and are focused on children, Ehret said. The most recent available guideline that includes adults is “Attention Deficit Hyperactivity Disorder: Diagnosis and Management,” published by the National Institute for Health and Care Excellence in the United Kingdom in 2018 and updated in 2019.6

New flavored IR products allow ease of administration for those who struggle with swallowing medications. Medications such as methylphenidate HCl XR capsules (Ritalin LA), Aptsensio XR, and Focalin release a larger portion of their IR component in the morning, which can be beneficial for patients with more early-morning symptoms, while Cotempla XR-ODT and Adhansia XR provide a larger medication release later in the day, which can be helpful for those whose symptoms may extend into later in the day, Ehret explained.

“Determine the symptoms where the patient is having the most struggle,” she advised. “Do they have the most symptoms in the morning? Can we get by with some medication in the morning, or is the afternoon a struggle so we need something that lasts?” The timing of administration must be correct, so the patient can still get to sleep that night.

Sandra Mullen, PharmD, BCPP, clinical pharmacy specialist, child and adolescent psychiatry, and clinical assistant professor at Virginia Commonwealth University (VCU) School of Pharmacy and VCU School of Medicine in Richmond, agreed that pharmacists need to ask patients about their most troublesome symptoms and the timing of their day.

“In adult patients, a lot of times we see more lack of attention, rather than impulsive [symptoms],” Mullen explained. “Talk to patients about what their day looks like…and how quickly they need the medication to work,” Mullen said. “It is also about minimizing how many times a day they need to take it; for some [medications], you have to take them 3 to 4 times a day.”

Determining the best formulation must also take into account adverse effects, such as decreased appetite, and patients’ sleep schedules. “If they have a weekend [when] they are not doing anything and they sleep in, we need to be cognitive of how many [times a day] they take the medication.” Taking the medication too late in the day, she explained, means that it works later into the night and will impact sleep.

Patients also need to be aware of potential adverse effects of stimulant medication, such as increased blood pressure. “If patients feel like their heart is racing too much, make sure they see their physician to determine whether it is because of the medication or the medication has uncovered symptoms [of a heart or blood pressure condition],” Mullen said.

Insurance Coverage Decisions

As with other medical conditions, pharmacists’ knowledge of the various formulations of methylphenidate and dexamethylphenidate is crucial for appropriate medication selection for control of ADHD symptoms, according to an article Ehret penned, published in the American Journal of Health-System Pharmacy.2 “Knowledge of differences between release mechanisms and the pharmacokinetic properties is essential for appropriate use of these products.”

New flavored IR products allow easier administration, and delayed-release capsules, administered by the patient the night before, both increase patient adherence. Ehret noted. And, different durations of action allow for individualization of dosing regimens for patients based on the symptoms they are experiencing.

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treatment decisions are never based solely on formulation alone—but are often determined by the ever-changing costs of various products, Ehret said. Some of the newer formulations, such as orally dissolving tablets or transdermal patches, are often not covered by insurance, according to Ehret and Mullen. “There is always a concern with getting the newer medications for our patients,” Mullen said. “Most insurance companies prefer Adderall or Ritalin.”

Pharmacists often need to obtain prior authorizations from the patient’s physician stating that the patient has already tried the covered medication and is not able to take it. For pediatric patients who have a difficult time taking medications, Mullen recommends crushing the generic Adderall or Ritalin, then mixing it in applesauce or pudding. “If it is still a barrier, then we move to newer agents that are more expensive (such as orally disintegrating tablets). You need to show the insurance company that you have tried it [the covered medication],” Mullen said.

There may also be additional hurdles to clear for both pediatric and adult patients. For example, some insurance companies require annual urine drug screening for certain ADHD drugs. However, many physicians’ offices’ software systems do not have automatic reminders to provide the lab order for patients to get the urine screening, Mullen noted.

“You get a call from the pharmacy that you have to go back and do the labs and update the charts. The providers are not happy all the time... because there is a delay in treatment.”

**The Challenges and Benefits of ADHD Patches**

In March 2022, the FDA approved a second patch to treat ADHD, dextro-amphetamine (Xelstrym). However, Ehret has not seen much uptake of that medication—nor of the methylphenidate stimulant patch (Daytrana) that was cleared by the FDA in 2006.

Insurance often doesn’t cover patch versions, Ehret explained. “Due to the cost, for our state’s Medicaid the provider will have to fill out a prior authorization form with the medical rationale about why they are doing the patch vs something that is capable of prescribing orally.” Ehret said.

“Xelstrym takes effect after 2 hours and is applied for up to 9 hours, according to the manufacturer, Noven.” As a once-daily transdermal patch, Xelstrym provides clinicians and their patients, many with varying daily schedules, the ability to share in the decision-making process of determining when to apply and subsequently, when to remove the patch to optimize the desired benefit of individualized treatment, said Greg Mattingly, MD, associate clinical professor of psychiatry at the Washington University School of Medicine in St Louis, Missouri, in a statement from Noven.3

And although patches are a convenient option for adults—and patients of all ages who are unable to swallow medications—patch options can pose challenges for younger children. “If you have kids who are struggling to take pills, the patch offers another option,” Ehret acknowledged. “However, I don’t know if I would send my 6-year-old to school with it, wondering if he would take it off—or if someone else would. There are a lot of risks with kids, including swimming, heat...a lot of unknowns.”

Another concern for children is that the patch has a 2-hour delayed onset and a 2-hour delayed offset, Mullen explained. “A parent would need to put it on their child at 6am, so it is working when they start school at 8am,” Mullen said.

Another reason for not using patches is that there are so many good oral medication options, according to Ehret. “We have extended-release tablets and now we have a liquid [Quillivant XR] that lasts just as long.”

For references, visit drugtopics.com.

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When AmerisourceBergen established Good Neighbor Pharmacy in the 1980s as a franchise program for independently owned pharmacies, the primary focus of community pharmacy was dispensing medications. Although some pharmacies specialized in home health care needs, such as durable medical equipment, others in the space focused purely on retail.

“Especially in the ‘60s, ‘70s, and early ‘80s, chain [pharmacies] weren’t as prevalent,” Brian Nightengale, president of community and specialty pharmacy and long-term care at AmerisourceBergen, told Drug Topics®. “The independents were the main thing you saw in terms of pharmacies; chains were more regional and smaller—certainly not the large national presence they have now.”

As the role and influence of chain pharmacies began to evolve, Nightengale explained, the impetus for Good Neighbor Pharmacy, or GNP, was born.

“When it was founded in the early ‘80s, it was to create a national brand [with] national support to compete with the expansion of the chains,” he said. “As we got into the mid- to late 90s, the substantial growth in chains and the rapid expansion was part of the growth of Good Neighbor Pharmacy.”

Over the past 2.5 decades, Nightengale has had a front-row seat to the growth and expansion of Good Neighbor Pharmacy, formerly serving as the president of the Good Neighbor Pharmacy Network. However, despite the changes across the industry—ranging from drug coverage and reimbursement models in the early 2000s to the COVID-19 pandemic in 2020—the Good Neighbor Pharmacy mission has stayed true.

“We’ve remained consistent in our mission over the past 40 years to rally together independent pharmacies, to support them in driving care and services in their communities that are much needed, and to give them a more powerful voice and presence in the industry,” he said. Although the Good Neighbor Pharmacy services have evolved over time, “our sense of purpose in supporting and using our scale, scope, and expertise…has not changed,” Nightengale said.

Jenni Zilka, the current president of Good Neighbor Pharmacy, agreed.

“It’s such a journey we’ve been on with our pharmacy owners and, as importantly, their patients,” she said. “Our initial focus when we started Good Neighbor Pharmacy was on buying power [and] brand awareness. The goal was to feel more like a chain for our independent pharmacies—focused on signage, rugs, striping, and the Good Neighbor Pharmacy brand. As consumer and patient needs and requirements have shifted, our pharmacies have continued to evolve with those changing needs.”

In 2008, Zilka began building the AmerisourceBergen business coaching program, an initiative that focused on helping independent...
pharmacy members grow and optimize their businesses. When the program kicked off, Zilka explained, it was run by a team of 2. Today, there are nearly 40 coaches working with Good Neighbor Pharmacies across the country.

Part of that work has involved maintaining a line of sight into pharmacists’ continually evolving needs. Even a decade ago, a pharmacy owner wouldn’t have needed to concern themselves with digital advertising or social media marketing. “[Today], we’re focused on so much more,” Zilka said. That “more” includes assisting pharmacy owners with the digital transformation necessary to thrive in today’s business environment. 

Good Neighbor Pharmacy supports owners with digital marketing through Facebook and Google, the latter of which was just expanded to include Google Shopping Ads, which will enable pharmacies to attract more front-end shoppers by making pharmacy inventory available to the community when they search for products near them. GNP also provides front-end support, which since January 2020, has included addressing the disruption and challenges faced by every member of the health care industry during the COVID-19 pandemic. 

“This is my favorite topic right now, because our independent pharmacy owners are really truly heroes in terms of how they stepped up during the COVID-19 pandemic,” Zilka said. “Not only from having to shift their business model from walk-ins to drive-through, curbside service, or even delivery, [but] they also organized food drives, grocery delivery, and so many things within their communities to help.”

And, she added, “we would be remiss if we didn’t talk about their vaccine efforts and the important role they played throughout the vaccine process. They had to evolve on the fly.” Good Neighbor Pharmacy worked quickly to establish a federal network partnership with the CDC on behalf of independent pharmacies, providing stores with much-needed vaccines for their communities. In early April 2022, Good Neighbor Pharmacy officially surpassed 5 million vaccine doses sent to participating independent pharmacy members.

In part, this success was fueled by tireless advocacy work from the larger Good Neighbor Pharmacy team. “A lot of the focus in advocacy [up until the COVID-19 pandemic] was at the federal level,” Nightengale explained. “We started out needing to educate federal regulators and legislators in Congress about the pharmacy business model, the value of community pharmacy, and [about] some of the challenges that, quite frankly, laws and regulations were creating, preventing pharmacists and pharmacies from...
providing the level of care that they can.”

One such example, Nightengale noted, is the work Good Neighbor Pharmacy and AmerisourceBergen have done to address direct and indirect remuneration (DIR) fees. Nightengale recalls spending up to 2.5 years trying to educate members of Congress and their staff on what DIR fees were, what they stood for, and what exactly it represented in the larger Medicare ecosystem. Once accomplished, that work was able to shift toward addressing more specific issues, including “the problems [DIR fees] cause, how it increases patient out-of-pocket costs, and specific legislation that’s required for reform,” Nightengale said.

“That’s just 1 example of the evolution of education into real recommendations and action,” he said. “One of the biggest results of that is finally, we have legislation that has a real chance of moving forward to radically transform DIR fees.”

But despite all that Zilka, Nightengale, and Good Neighbor Pharmacy have accomplished, the work is far from done. The pharmacy landscape is constantly in motion, and even more changes are on the horizon.

“As I think about our pharmacies and how they’ve evolved over the past 40 years, there’s so much to be proud of,” said Zilka, “but we also still have so much work to do. Most importantly, we [must] continue to advocate and evolve the model of pharmacy as a recognized and meaningful extension of the whole health care system and as an essential access point for those who need the most care.”

Nightengale agreed, expressing his hopes that the very public response by independent pharmacies to the COVID-19 pandemic can create an opportunity for the profession. “My hope is that through this advocacy momentum we have through increased awareness, people all across this country recognize the value of pharmacy and the abilities pharmacies have to provide care for [patients] and their families, and that they can benefit from the incredible accessibility, expertise, and personalized care the community pharmacies and their staff provide.”

Looking forward to next year, Zilka anticipates Good Neighbor Pharmacy will “double down on the advocacy. We’re truly at an inflection point as a profession,” she explained, “and I think we [must] continue to share the important story of the role pharmacies played throughout the COVID-19 pandemic and the important role they can play going forward.” The organization will also be investing in future independent pharmacy owners by increasing access to education through a new scholarship program funded in partnership between Good Neighbor Pharmacy and the AmerisourceBergen Foundation. The Good Neighbor Pharmacy Scholarship Program will support Black and African American students pursuing a doctor of pharmacy degree at a historically Black college or university. This scholarship highlights the rewarding career of community pharmacy and underscores the importance of diverse representation in the pharmacy industry.

“It’s really easy to get up every morning and champion [our] independent pharmacy owners,” Zilka said. “Their resilience is second to none, and the care they provide to their patients and communities is phenomenal. We’ve been able to help them grow and evolve as the industry and patient needs evolve around them…leading us toward the ability to increase access, equity, and the services they’re able to provide patients.”

For references, visit drugtopics.com.

Scan the QR code to learn more about Good Neighbor Pharmacy’s 40th anniversary.
Technology is reshaping the way that health care is delivered. From the physician's office to the pharmacy, a slew of innovative ideas and solutions are poised to change the way pharmacies interact with their customers and patients.

Drug Topics® sat down with Eric Lindsay, MBA, vice president of product management at OmniSYS, to discuss some of these solutions.

Drug Topics®: Can you provide an overview of technologies available that can help pharmacies and pharmacists manage compliance? What are the challenges with these technologies, if any?

Eric Lindsay: The area of compliance is both complex and multifaceted, so I will focus on the most pressing aspects to your readers.

Pharmacist credentialing: The growing movement related to pharmacists as a care provider increases the need for pharmacists to be credentialed for certain clinical services and—as a result—increases the demand for related information technology services. This is challenging for both pharmacies and pharmacists, because of the relative newness of this need, and hastens the need for pharmacists to partner with a knowledgeable technology vendor.

Some pharmacies may want to outsource the credentialing process to third parties based on resource constraints and areas of expertise. If this is the path taken, a system is needed to facilitate items such as information gathering, status tracking, and error correction.

Taken one step further, consider the following patient experience scenario: A patient searches to find which pharmacy locations provide a service they need, and arrives at the pharmacy only to find that a credentialed pharmacist is unavailable at the time of the patient visit. Pharmacies need a solution to ensure that when patients look up locations for specific services, the location presented has the right credentialed pharmacist available. Although this seems somewhat straightforward, practically there is added complexity. Think about a pharmacy that offers various services by different credentialed pharmacists; those pharmacists and services may only be delivered during specific hours. That information is critical to present to patients during their service and location search. Purpose-built technology that addresses these nuances is vital to delivering on the promise of an exceptional patient experience.

Medication adherence: Medication adherence can be viewed as a patient need based on implications to clinical outcomes as well as financial repercussions to the pharmacy. Pharmacists are well positioned to impact behaviors in this area, based on their status as trusted care providers and the breadth

Become the Pharmacy of the Future With Technology Solutions

Technology can help manage every aspect of the pharmacy.

by Lauren Biscaldi

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.
of available information technology solutions.

Some of the types of information technology solutions that pharmacists can use to impact medication adherence include:

- **Patient communication solutions** that drive medication adherence through patient refill reminders, notifications when it is time to pick medications up, and related educational materials
- **Solutions that group prescriptions** so that they can be picked up on the same day to greatly improve patient convenience
- **Analytical tools** that can be used to identify nonadherent or at-risk patients with whom pharmacists may want to personally call, or otherwise engage that patient’s physician
- **Data visualization capabilities** that provide actionable trends and reporting for prescribers, clients, and payers
- **Interoperable or integrated pharmacy and laboratory solutions** that support the exchange of laboratory testing results to monitor medication adherence, help guide patient care, and modify treatment plans or confirm clinical impressions

Solutions of this nature can be found from a variety of vendors, ranging from those who provide just some of these specialized services, to larger enterprise solution vendors. There are a few services purpose-built for pharmacy solution providers who are better positioned to address the nuances of pharmacy and their rapidly evolving business models that are underway.

Pharmacies across all markets should strategically be thinking about how their technology stack and partners are aligned with their future state so that they can determine the platform and partner that are the best fit for their business now and in the future.

### What are the top considerations that a pharmacist/pharmacy should make when deciding what technology to implement into their practice?

The process of selecting an appropriate technology vendor for pharmacists and their staff will vary based on their unique needs. There are, however, some common considerations across pharmacies, including:

- **Strategic direction**: Is there alignment between the pharmacist/pharmacy and vendor regarding industry direction and, therefore, how the solution needs to progress?
- **Proven solution**: Does the technology vendor have a proven track record of success?
- **Expertise and advocacy**: Beyond the technology provider, are they experts in your business and advocating for your industry with government, payers, associations, and other key stakeholders?
- **Operational fit**: Does the solution fit with how your pharmacy provides care and have the necessary integration into your existing workflow?
- **Return on investment**: Which vendor provides maximum return either through driving growth or reducing costs, and how long will it take to achieve this return?
- **Partnership considerations**: Can the vendor address your partnership needs, such as support hours, service level agreements, system integration, data encryption, and more?

### What are some of the most common workflow issues pharmacists face, and how can technology address these? How does bringing technology into the pharmacy workflow address pharmacist burnout?

Pharmacists and pharmacy staff, across practice settings, are feeling tired or burned-out because of staff shortages, professional demands, and the realities surrounding COVID-19. Although many may feel that adding new technology into the system simply means that there’s more to learn, we’ve seen the opposite of this when the technology is the right fit. Technology can, and should, meaningfully improve the pharmacy team’s workflow efficiency and enable the pharmacist and their teams to spend more time serving patients. Technology solutions can also result in additional benefits, such as improving medication adherence, reducing risk, driving revenue, and improving customer convenience or experience.

Some typical solutions that follow the flow of a prescription and improve workflow efficiencies, separate from the pharmacy management system, include:

- **Inventory management solutions** that automate the prescription filling process and reduce administrative tasks.
- **U&C price setting solutions** that run automatically on a set schedule, addressing staffing constraints while maximizing third-party reimbursement by lowering paid at U&C events.
- **Patient communication solutions** that automate inbound and outbound communications (eg, refill reminders, will-call alerts, store hours, and more).
- **Clinical documentation solutions** that support the expanding role of pharmacies as providers.
- **Immunization registry reporting solutions** that automate the process of submitting immunization claims to state registries and facilitate a means to easily correct errors.

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**Eric Lindsay**, MBA, is vice president of product management at OmniSYS.
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Diarrhea is a common adverse effect of antibiotics, affecting 11% to 40% of children treated with broad-spectrum antibiotics. Antibiotic-associated diarrhea (AAD) may occur when antibiotics disrupt the normal balance of the gut flora, causing harmful bacteria to multiply and destroy the gut microflora. Probiotics restore the natural balance of gut flora through the introduction of nonpathogenic bacterial or yeast microbiota and have been used in clinical trials and in practice to manage AAD in children. Probiotics are generally well tolerated in healthy children, with minor adverse effects being dyspepsia, abdominal pain, nausea, and bloating. Probiotics should be avoided in children who are immunocompromised or severely debilitated. Likewise, probiotics must be used with caution in specific populations such as premature infants, critically ill patients, and patients with a central venous catheter, cardiac valvular disease, and short-gut syndrome. Although evidence supporting a clinically meaningful interaction between probiotics and antibiotics is lacking, the use of antibiotics could theoretically eradicate the microorganisms contained in the probiotics. Therefore, it has been suggested to space the administration of probiotics from antibiotics by 2 hours.

Because antibiotics are commonly used in the pediatric population, we sought to examine the evidence concerning the use of probiotics for the prevention of pediatric AAD. After applying search criteria, 7 relevant articles were identified, which are summarized below.

**Clinical Data**
Shan et al described an open label, randomized, controlled trial involving 333 hospitalized children who were being treated with intravenous antibiotics. The study’s objective included an assessment of the efficacy of *Saccharomyces boulardii*, dosed at 500 mg per day, for the prevention of AAD. Patients were followed during and 2 weeks after antibiotic therapy. The primary outcomes related to the prevention of AAD were the frequency and duration of AAD. In this study, the use of *S. boulardii* resulted in statistically significant fewer occurrences of AAD. The investigators concluded that using *S. boulardii* was effective for the prevention of AAD in children.

Georgieva et al described a randomized, controlled study that examined the efficacy of *Lactobacillus reuteri* for the prevention of AAD. In this study, 100 hospitalized children aged 3 to 12 years were randomly assigned to receive a probiotic tablet containing 1 × 10⁸ colony-forming units (CFU) *L. reuteri* or placebo once daily during the antibiotic treatment period and for an additional 7 days. The primary study end point was the incidence of diarrhea during and up to 21 days post antibiotic treatment. The investigators found no statistically significant difference between the 2 groups but noted that because of the low incidence of AAD in both groups, no conclusion can be made about the efficacy of *L. reuteri* for the prevention of AAD.

Fox et al described a randomized, double-blind, placebo-controlled study that examined the efficacy of a yogurt containing probiotics (*Lactobacillus rhamnosus GG*, *Bifidobacterium lactis*, and *Lactobacillus acidophilus*) for the prevention of AAD. In this study, 72 outpatients aged 1 to 12 years were randomly assigned to receive active yogurt or pasteurized yogurt (placebo) for the duration of...
A LITERATURE REVIEW / IN MY VIEW

Although evidence supporting a clinically meaningful interaction between probiotics and antibiotics is lacking, the use of antibiotics could theoretically eradicate the microorganisms contained in the probiotics. Therefore, it has been suggested to space the administration of probiotics from antibiotics by 2 hours.

their antibiotic treatment. The primary outcome was stool frequency and consistency. There were significantly fewer occurrences of diarrhea in the children who were given the probiotic-rich yogurt as compared with those receiving placebo. Also, more adverse events, including abdominal pain, loss of appetite, and nausea, were reported in the placebo group compared with the active group. The investigators concluded that the specific probiotic-rich yogurt used in the trial was an effective intervention for reducing the incidence of antibiotic-associated gastrointestinal disturbance in children.

Olek et al described a randomized, double-blind, placebo-controlled study that examined the efficacy of probiotics for the prevention of AAD in 438 outpatient children aged 1 to 11 years. Patients were assigned to receive a probiotic capsule containing 1 × 10^8 CFU L plantarum or placebo once daily for the duration of antibiotic therapy and for 1 week after completion of treatment. The primary outcome was the incidence of antibiotic-associated loose/watery stools; the investigators found no statistically significant differences between the groups regarding this outcome. Furthermore, the incidence of children with at least 1 adverse event was significantly higher in the placebo group compared with the probiotic group. The investigators concluded that there was no beneficial effect of Lactobacillus plantarum for the prevention of AAD in children.

Kołodziej and Szajewska assessed the efficacy of L reuteri for the prevention of diarrhea and AAD in hospitalized children. The investigators randomly assigned 250 children younger than 18 years to receive L reuteri 2 × 10^8 CFU or placebo twice daily for the duration of antibiotic treatment. Primary outcome measures were the occurrences of diarrhea and AAD. The investigators found no statistically significant differences between the 2 groups in the primary outcome measures. Additionally, there were no statistically significant differences in adverse effects. The investigators concluded that the study provided no evidence to support the use of L reuteri for the prevention of AAD in children.

Wronowski et al described a prospective, randomized, double-blind, placebo-controlled study in a pediatric hospital. In this study, 156 children aged 1 to 18 years were randomly assigned to receive 100-mg bovine lactoferrin or placebo twice daily for the duration of antibiotic therapy. The primary outcome was the occurrence of AAD during treatment and up to 2 weeks after antibiotic therapy. The investigators found no statistically significant benefit for the probiotic and concluded that bovine lactoferrin was not effective for the prevention of AAD.

Esposito et al described a placebo-controlled study designed to evaluate the effectiveness of L rhamnosus GG for the prevention of AAD in children receiving antibiotic therapy postoperatively. The study consisted of 3 groups (probiotic, no treatment, and placebo), with 30 boys in each group. The overall incidence of AAD was statistically significantly lower in the probiotic group compared with the other groups. Also, the duration of AAD was statistically significantly longer in the control groups than the probiotic group. The investigators concluded that the use of L rhamnosus GG significantly reduced the incidence and duration of AAD in children.

Summary

Clinical trials evaluating the use of probiotics for the prevention of AAD in children yielded varying results. A systematic review that assessed the results of 33 randomized, controlled studies concluded that probiotics produced a moderate reduction in the incidence of pediatric AAD, with a larger effect noted with high-dose probiotics (≥ 5 billion CFUs/day). Furthermore, probiotics reduced the duration of diarrhea by almost 1 day. Among the various probiotics evaluated, L rhamnosus (eg, Culturelle) or S boulardii (eg, Florastor) at 5 to 40 billion CFUs per day appeared to be most appropriate for preventing AAD in children. The authors of the systematic review also stated that it is premature to draw firm conclusions about other probiotic agents.

Notably, there does not seem to be a consensus concerning the use of probiotics to prevent AAD in children as a standard of care. When making recommendations concerning the use of probiotics, pharmacists should follow evidence-based practices.

For references, visit drugtopics.com.
IN MY VIEW / DISPENSED AS WRITTEN

By Peter A. Kreckel, RPh

Pendulum Ping-Pong

As a young pharmacist in 1982, I dispensed conjugated estrogens (Premarin) by the thousands. We bought Premarin 0.625 mg and 1.25 mg in bottles of 1000 and moved them over the course of 3 or 4 weeks. Every woman was on this medication. We sold 100 tablets for approximately $15, and my customers seemed happy. Today, a bottle of 100 conjugated estrogens tablets, at any strength, is over $600 direct cost. The pendulum has swung the other direction for use of estrogen, as my fellow seasoned pharmacists can attest to: two trials—HERS1 (NCT00319566) and WHI2 (NCT00000611)—essentially pushed the pendulum to where it is today. Even I have shouted from the lecture halls of St Francis University that “estrogens should be only used for relief of vasomotor symptoms, at the lowest dose for the shortest duration.”

Another pendulum that has shifted is the prescribing of opioids. Back in my younger days, it was rare to see an oxycodone/acetaminophen (Percocet) prescription for 60 tablets. Thanks to the explosion of oxycodone (Oxycontin) in the mid-1990s, providers became too comfortable prescribing opioids, and the opioid pendulum swung wildly. However, approximately 10 years ago, the pendulum slowly moved back toward the center, as the opioid dispensing rate declined from 81.3 to 43.3 per 100 persons today. The subsequent crisis of heroin addiction was addressed by the Drug Addiction Treatment Act of 2000, with waivers that allowed physicians to write buprenorphine (Suboxone) prescriptions following an 8-hour training, then dispensed in community pharmacies. This change was made to avoid the stigma of standing in line at a methadone clinic and was intended to help our citizens living with opioid addiction. We’re told buprenorphine is a partial agonist, with less potential for euphoria, and that naloxone helps decrease the abuse potential. Buprenorphine has a morphine milligram equivalent (MME) factor of (x30). The buprenorphine/naloxone combo (8 mg/2 mg) dosed twice daily is equivalent to 480 mg of morphine, or oxycodone 80 mg dosed 4 times daily. I know opioid experts who would disagree on some of these points.

Every day, we community pharmacists see the benefits of prescribing buprenorphine. Patients come in for their 2- or 4-week supply after a day spent working as mechanics, plumbers, roofers, or mothers. I also know of many pharmacists who will not dispense buprenorphine because they don’t want “those people” in their stores. However, these pharmacists dispense oxycodone, hydrocodone, oxymorphone, and fentanyl—likely not realizing “those people” are already in their stores.

When I check the prescription drug monitoring program, the MMEs for buprenorphine are no longer there. At one time, the 480 MME was listed, but I’ve been told this was removed to avoid stigma. When a new patient comes to the pharmacy, I outfit them with a naloxone rescue kit and a pamphlet describing the MMEs of buprenorphine. In response, many patients tell me it’s the first time they have been treated with respect. I’ve studied this disease enough to understand it truly is a mental health disorder, usually stemming from childhood trauma. It has been postulated that 75% of women abusing alcohol and drugs were victims of sexual abuse; it’s not in my wheelhouse to determine who deserves compassionate care—all my patients do.

Pharmacies frequently get calls from their warehouses, questioning their buprenorphine purchases. Wholesalers do this at the behest of the Drug Enforcement Administration, as the big 3 wholesalers have been slapped around for opioid sales in the past. Pharmacists are cognizant of the microscopic analysis of their buprenorphine purchases, whereas the Department of Health and Human Services wants to see more buprenorphine prescribers. I, for one, do not want to see my brethren in the profession stigmatized for providing such lifesaving medications, including buprenorphine, to people with substance use disorder. Pharmacists are not riding a pendulum; we are more like a Ping Pong ball getting slapped back and forth between government agencies.

“I, for one, do not want to see my brethren in the profession stigmatized for providing such lifesaving medications, including buprenorphine, to people with substance use disorder.”

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

For references, visit drugtopics.com
Vivjoa Approved for Recurrent Vulvovaginal Candidiasis

Oteseconazole is a treatment option for those living with a previously unmet medical need.

Egla Hasimllari, PharmD Candidate; Cassandra R. Doyno, PharmD, BCPS, BCCCP

On April 26, 2022, the FDA approved oteseconazole (Vivjoa), an oral azole antifungal indicated to reduce the incidence of recurrent vulvovaginal candidiasis (RVVC) in women with a history of RVVC who are not of reproductive potential. Oteseconazole is an azole metalloenzyme inhibitor that targets CYP51 and is available as a single-drug regimen or in combination with fluconazole. Antifungal therapy may be instituted before the results of the cultures are known and adjusted accordingly when results become available.

EFFICACY

The first 2 clinical trials (NCT03562156 and NCT03561701) included a total of 656 adults and postmenarcheal pediatric women with RVVC who were randomly assigned to receive either oteseconazole only or placebo. A third trial (NCT03840616) evaluated safety of oteseconazole vs fluconazole and placebo in 219 adults and postmenarcheal pediatric women with RVVC.

OSESCEONAZOLE-ONLY REGIMEN

Trials 1 and 2 each included an open-label induction phase and an 11-week maintenance phase. During the induction phase, participants received 3 sequential doses of fluconazole 150 mg every 72 hours on days 1, 4, and 7. At 14 days following the first fluconazole dose, if the acute VVC episode was resolved, participants were randomly assigned 2:1 to receive either oteseconazole 150 mg or placebo for 7 days, followed by 11 weekly doses during the maintenance phase; 326 and 330 patients, respectively, entered this phase. Primary efficacy end points were the proportion of patients with greater than or equal to 1 culture-verified acute VVC episode during the maintenance phase through week 48. The average percentage of patients with an acute VVC episode was lower in the oteseconazole group vs the placebo group in both trials (6.7% vs 42.8% and 3.9% vs 39.4%, respectively).
NEW DRUG REVIEW

OTESECONAZOLE AND FLUCONAZOLE REGIMEN

Trial 3 evaluated the efficacy and safety of oteseconazole vs fluconazole and placebo. This trial also included induction and maintenance phases. Participants received a total dose of oteseconazole 150 mg over 2 days (600 mg [4 × 150 mg] on day 1 and 450 mg [3 × 150 mg] on day 2) or 3 sequential doses of fluconazole 150 mg every 72 hours on days 1, 4, and 7. Patients returned 14 days after the first dose and moved to the maintenance phase if the acute VVC episode was resolved. During the maintenance phase, patients received oteseconazole 150 mg or placebo weekly for 11 weeks.5 The primary efficacy end point was the proportion of patients with greater than or equal to 1 culture-verified acute VVC during the maintenance phase or who failed to clear their infection during the induction phase. The average percentage of patients with greater than or equal to 1 culture was lower in the oteseconazole group vs the fluconazole and placebo group (10.3% vs 42.9%, respectively).2

SAFETY

The most frequently reported adverse events were headache (7.4%) and nausea (3.6%). One patient discontinued therapy because of allergic dermatitis. Because of the risk of embryo-fetal toxicity, oteseconazole is contraindicated in women of reproductive potential and in women who are pregnant or lactating. Medication administration in conjunction with a high-fat, high-calorie meal increased concentrations, but no significant differences were observed with a low-fat, low-calorie meal.2

DOSSING AND SPECIAL CONSIDERATIONS

The oteseconazole-only dosage regimen is initiated as a 600-mg capsule on day 1 and 450 mg on day 2, each as a single dose. The next dose is administered on day 14 as a 150-mg capsule once weekly for 11 weeks. The fluconazole/oteseconazole dosage regimen is initiated with fluconazole 150 mg orally on days 1, 4, and 7, followed by oteseconazole 150 mg once daily for 7 days, starting on day 14 through day 20. After day 20, the next oteseconazole dose is administered on day 28 as a 150-mg capsule once weekly for 11 weeks. Oteseconazole must be taken with food.2

Egla Hasimllari is a fourth-year pharmacy student at the University of Connecticut in Storrs. She is currently completing her advanced pharmacy practice experiences. She will graduate with a doctor of pharmacy degree in May 2023.

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

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