



Expert: Psilocybin Treatment May Support Patients With Obesity Who Have Tried Everything, Need Further Support

July 19, 2021



Clive Ward Able, MD, BPharm, president of Clintell, consultant to NeonMind Inc, and a trained pharmacist and physician, discusses his research into the use of psychedelic compounds to treat obesity.

Clive Ward Able Interview Seg 1



Pharmacy Times interviewed Clive Ward Able, MD, BPharm, president of Clintell, consultant to NeonMind Inc, and a trained pharmacist and physician, on his research into the use of psychedelic compounds to treat obesity and optimize human health.

Ward Able noted that the use of psychedelic medicine to treat obesity has 2 potential mechanisms of approach. The first is by giving a psychedelic compound as part of psychotherapy, such as psilocybin, at a psychedelic dose—this approach is called drug-enhanced psychotherapy. At this dose, it works as an agonist against serotonergic receptors, and, specifically, the 5-HT2A receptors.

“What that does is it gives you the psychedelic event, which seems to be able to help along with psychotherapy,” Ward Able said. “Secondly, it also has effects on the 5-HT2C receptors, which are very much related to satiety or hunger and the control of hunger. So there, we can look at a different formulation where we use a much lower dose, probably 10% to 15% of what would normally be used for a psychedelic dose, but you do that on a daily or 4 times a week dosing.”

patient to be less hungry, according to Ward Able. Additionally, it has the potential to give the patient a sense of well-being.

However, to date, there's been no clinical research done on the effects of psychedelic medicine on obesity, but there have been promising in-vitro pre-clinical studies on rats. In these pre-clinical trials, the rats were fed a highly palatable, high calorie diet in which they could eat as much as they liked. They were then treated with 2 different doses of psilocybin—a high dose that would be equivalent to a human psychedelic dose—and a lower dose that would target the 5-HT_{2C} receptors.

“What was found with those is that both the high dose and the low dose led to less weight gain in both of those arms that were treated with the psilocybin,” Ward Able said. “The decrease in the weight gain gives us a very good, strong signal that this actually is working the way we expect it to work. Now we've got to translate this into clinical studies, and that's what we're going to be doing next in our proof of concept study.”

Ward Able explained that before he began working on research in the psychedelic medicine field, he had thought it was a very contained, small group of researchers working in the field.

“But actually, there's a lot of work that's been going on, and we have to tip a hat to a lot of researchers who worked under a really strict regulatory environment, and still managed to continue some of this research, despite it being completely closed down in the 60s and 70s,” Ward Able said. “One of the things that NeonMind Inc. looked at was obesity, because it's a pandemic now, not just an epidemic within the North American region, but a pandemic worldwide.”

The health implications of the global pandemic of obesity are significant, not only for the patient, but for every health care system and the country as a whole, Clive Ward Able explained.

However, he noted that not every patient who is obese is dissatisfied with their weight or finds that it poses a problem in their life. In light of this, a potential psychedelic medicine treatment for obesity would provide an option for patients who are interested in losing weight and keeping it off, something that they have not been effectively able to do in the past.

“The idea is that this has to come from the patient. If the patient wants help for it, this will be able to help them get to a place where they really want to be,” Ward Able said. “But I'm not talking about every single obese patient, because there are a lot of obese patients who are happy the way they are, and they don't necessarily want to lose weight. But there's a large component of those, such as in depressed patients, who have certain triggers that get them to overeat or not to exercise, etc.”

Ward Able noted that the target of obesity treatment is not necessarily to bring every patient under a body mass index of 25. Instead, this treatment can hopefully allow patients to get to a healthier weight and maintain it, with an added sense of wellbeing that they may desire after losing weight.

ward Able said. “Psychotherapies are being used for the treatment of obesity or weight management, but people tend to fall back into their old behaviors again, although they do work. What I'm calling drug enhanced psychotherapy or psilocybin-assisted psychotherapy adds another facet to that psychotherapy, which should be able to instill much longer lasting positive behaviors, such as an improved diet, whether that's quantity or quality, or within expenditure of energy, such as increasing your amount of exercise.”



Related Content:
[Mental Health](#) | [Retail](#) | [Weight Management](#)

- [The Reasons Behind Bipartisan Support for Granting Pharmacists Provider Status for Medicare Part B](#)
- [Despite Pandemic Challenges, Positive Health Effects Observed for Diabetes Patients Using Telehealth](#)
- [Leveling Up for Flu Season in the COVID-19 Era: How One Pharmacy Is Rising to the Challenge](#)

The Reasons Behind Bipartisan Support for Granting Pharmacists Provider Status for Medicare Part B

July 21, 2021



Ken Perez, MBA, vice president of healthcare policy and government affairs at Omnicell, outlined what has led to legislation granting pharmacists provider status gaining bipartisan support.

Pharmacy Times interviewed Ken Perez, MBA, vice president of healthcare policy and government affairs at Omnicell, on the House and Senate bills, HR2759 and S1362 respectively, intended to grant pharmacists provider status for Medicare Part B.

In this discussion, Perez breaks down the potential causes for these bills receiving support from both parties in the House of Representatives and the Senate. He highlighted how the pandemic revealed systemic coverage gaps and how pharmacists have played a key role in filling those gaps.

Related Content:

[Leveling Up for Flu Season in the COVID-19 Era: How One Pharmacy Is Rising to the Challenge](#)

[July 2021 Generic Product News](#)

[Tip of the Week: Performance Appraisal and Feedback](#)



Despite Pandemic Challenges, Positive Health Effects Observed for Diabetes Patients Using Telehealth

July 21, 2021

[Skylar Kenney,, Assistant Editor](#)



The shift to telemedicine for patient care for individuals with diabetes showed little negative impact on the metabolic health of these patients.

The COVID-19 pandemic shifted telemedicine from a peripheral aspect of therapy to one of the main health care delivery methods.¹ Though there were concerns initially as to how this change in care practices would impact patients with type 1 (T1DM) and type 2 diabetes (T2DM), early studies suggest the metabolic control of patients with diabetes actually improved over the course of quarantine.²

Although the pandemic necessitated the expansion of telemedicine services, its use in diabetes care is not only established, it has also been recommended as an effective alternative method for health care delivery as early as 2015.³ A retrospective chart review of 32 patients with T1DM conducted from June 2014 to October 2016 found that specialty diabetes care delivered via telemedicine was safe, effective, and associated with time savings, cost savings, high appointment adherence rates, and high patient satisfaction.⁴ Further, experts in the field of telemedicine research have found that those who receive care via telemedicine are very likely to continue using it.⁵

“Patients who use telemedicine—gain experience with it—are overwhelmingly more likely to try it again,” said Mary Reed, DrPH, research scientist at Kaiser Permanente, in an interview with *Pharmacy Times*. “So, I’m actually really hopeful that in the long run, our advances in experience with telemedicine are going to support our ongoing use of it.”⁵

A 2015 metanalysis of 16 studies on the use of telemedicine in diabetes care, published in the *Telemedicine Journal and E-Health*, found that health effects seen in patients were positive and remarkably consistent, with desirable outcomes seen across the metrics of glycemic level, blood pressure, low-density lipoprotein cholesterol levels, and body weight.³

Studies from the pandemic era of telemedicine have continued to reinforce this positive assessment. A review of the HbA1c levels between the 6 months preceding and the 6 weeks following the COVID-19 lockdown showed that HbA1c levels pre- and post-lockdown were 7.7% and 7.4%, respectively, translating into a significant reduction of – 0.1% ($P < .0001$).²

pandemic,” Reed said. “I think some sort of interest and organizational will to continue those things is pretty crucial to continue these advancements. Both patients and clinicians really need to continue to work out, in a non-emergency setting, which clinical and personal situations might be well-addressed by telemedicine.”⁵

Adults with diabetes weren’t the only patients benefitting from online health services. The pandemic required diabetes education for children with T1DM to shift online, resulting in a study of whether online education was able to effectively improve the quality of life (QoL) for children with T1DM and their parents during the pandemic. The investigators found that the QoL of all children ($P=.011$), all parents ($P=.001$), and parents and children as a combined group ($P=.002$) showed significant improvement after the treatment.⁶

Although the news is broadly positive, not every adjustment to the pandemic was fully effective in achieving its goals. A study published in *BMC Public Health* found that lifestyle change programs (LCPs), modeled after the Diabetes Prevention Program and hosted online, resulted in limited meaningful weight loss. Adults referred to an online LCP were more likely to enroll in the program, but less likely to engage. According to the investigators, it is currently unclear how to optimize the online delivery of LCPs when the reach and efficacy is considerably lower.⁷

Further, despite the positive results seen in studies of the effectiveness of telemedicine, access to telemedicine still remains a critical issue moving forward.⁸ Though the pandemic was observed to have had no major impact on the metabolic control of patients with T1DM and T2DM, only 32.1% of the patients in the study used teleconsultation services, and 49.4% went without consulting their general practitioner at all.²

“It’s not necessarily doable for all patients—in [Kaiser Permanente’s] system or in our country—to participate fully in digital aspects of their health care,” Reed said. “I suppose that sort of speaks to the importance of supporting low-tech options. Obviously, in-person health care services are needed, but also a low-tech option, like a telephone option. We found in our system, there are a lot of health care situations that can be handled via phone, and so supporting options like telephones are important.”⁸

Conclusion

Though there are valid concerns as to the effectiveness of certain virtual programs⁷ and accessibility,⁸ the evidence suggests that the necessary shift to telemedicine for the health care needs of patients with diabetes was largely successful. Metabolic control improvements over the course of the pandemic² and QoL improvements for children with T1DM⁶ suggest that in-person visits may not always be necessary for proper diabetes care to be delivered.

“I’m pretty hopeful that patients, clinicians, and health systems learn some lessons about what’s feasible, what’s the clinical value [of telemedicine], how convenient these tools might be,” Reed said. “Ideally, we can integrate those in the long term in ways that weave into patients’ ongoing clinical care and their ongoing patient-physician relationships.”⁹



1. How the Shift to Telehealth Affected Health Care Methods for Patients With Diabetes. Pharmacy Times; July 9, 2021. Accessed July 16, 2021. <https://www.pharmacytimes.com/view/how-the-shift-to-telehealth-affected-health-care-methods-for-patients-with-diabetes>
2. Ludwig L, Scheyer N, Remen T, Guerci B. The Impact of COVID-19 Lockdown on Metabolic Control and Access to Healthcare in People with Diabetes: the CONFI-DIAB Cross-Sectional Study [published online ahead of print, 2021 Jul 9]. *Diabetes Ther.* 2021;1-15. doi:10.1007/s13300-021-01105-y
3. Bashshur RL, Shannon GW, Smith BR, Woodward MA. The empirical evidence for the telemedicine intervention in diabetes management. *Telemed J E Health.* 2015;21(5):321-354. doi:10.1089/tmj.2015.0029
4. Xu T, Pujara S, Sutton S, Rhee M. Telemedicine in the Management of Type 1 Diabetes. *Prev Chronic Dis.* 2018;15:E13. Published 2018 Jan 25. doi:10.5888/pcd15.170168
5. The future of telemedicine as the COVID-19 pandemic wanes. Pharmacy Times; July 20, 2021. Accessed July 20, 2021. <https://www.pharmacytimes.com/view/the-future-of-telemedicine-as-the-covid-19-pandemic-wanes>
6. Rochmah N, Faizi M, Hisbiyah Y, et al. Quality of Life Differences in Pre- and Post-Educational Treatment in Type 1 Diabetes Mellitus During COVID-19. *Diabetes Metab Syndr Obes.* 2021;14:2905-2911. Published 2021 Jun 28. doi:10.2147/DMSO.S313575
7. Golovaty I, Wadhwa S, Fisher L, et al. Reach, engagement and effectiveness of in-person and online lifestyle change programs to prevent diabetes. *BMC Public Health.* 2021;21(1):1314. Published 2021 Jul 5. doi:10.1186/s12889-021-11378-4
8. Challenges faced by providers during the shift to online care. Pharmacy Times; July 13, 2021. Accessed July 16, 2021. <https://www.pharmacytimes.com/view/challenges-faced-by-providers-during-the-shift-to-online-care>
9. Changes in health care practices to retain as the pandemic wanes. Pharmacy Times; July 12, 2021. Accessed July 16, 2021. <https://www.pharmacytimes.com/view/changes-in-health-care-practices-to-retain-as-the-pandemic-wanes>

Related Content:
[Retail](#) | [Diabetes](#) | [Weight Management](#)

| | | |
|--|---|--|
| July 2021 Generic Product News | Tip of the Week: Performance Appraisal and Feedback | Biomarkers in the Brain May Predict ADHD Diagnosis With 99% Accuracy |
|--|---|--|

Leveling Up for Flu Season in the COVID-19 Era: How One Pharmacy Is Rising to the Challenge

July 21, 2021
[Kevin Day, PharmD](#)

Supplements, Influenza Guide for Pharmacists July 2021 ,



Kevin Day, PharmD, president of Day's Miami Heights Pharmacy in Cincinnati, Ohio, discusses how his independent pharmacy is gearing up for influenza season while continuing to deliver COVID-19 vaccines safely.

Recently, an editor from Pharmacy Times sat down with Kevin Day, PharmD, president of Day's Miami Heights Pharmacy in Cincinnati, Ohio, to discuss how his independent pharmacy is gearing up for influenza season while continuing to deliver COVID-19 vaccines safely.

immunization programs at your pharmacy:

Day: In our pharmacy we have a clerk who works at the front register, right inside the door when someone walks in. That person is responsible for starting the process and identifying that a customer is there for a vaccine, whether they have an appointment or just walk in. There is a notification process for us in the pharmacy to know there's a vaccine appointment or a vaccine walk-in ready for us. Then we generally use either a technician or a pharmacy intern to check in the person and complete any required paperwork or documentation, which varies by vaccine. With COVID-19 vaccines, the process is online; with most of the other vaccines, it's still a paper process.

[With this process,] all the paperwork is completed by a team member; the pharmacist goes into the vaccine room exclusively to answer any questions and to administer the vaccine. This helps keep the pharmacist in workflow and allows customers to build relationships with other staff members.

Pharmacy Times: Could that process be easily extrapolated to a [retail] chain pharmacy?

Day: I think it can certainly be. It's probably harder in a busy chain because it depends on how many [customers] are in that space. The person toward the front of the store—the patient services advocate—tends to be free [at our facility]. It's not [often] that they have 6 people waiting in line. They can step away momentarily to welcome someone. I can see at a large chain pharmacy where that same person might regularly have 4 or 5 people in line, and their job is to get those people through the line efficiently so stepping away might not be an option. And in a supermarket, where someone coming through the front door might be 300 yd away from where [they are] going to get the vaccine, that conversation is going to be a little bit different. But the mentality of getting other people involved in doing some of the steps that have to get done for every person, using more than the pharmacist, is critical to scaling up a vaccine program [without putting] more pressure on the pharmacist.

Pharmacy Times: How do you disseminate information to both patients and pharmacy staff about the available vaccination options?

Day: At my store, the pharmacist is the one who provides information to the patient. We have a de facto system where the pharmacist counsels every patient. Ninety-plus percent of the time, the pharmacists are the ones handing the medication to the patient at the counter and dispensing, and we use that opportunity to talk with the patient, [not only when there's a] dedicated campaign.

When there is a campaign—for example, [when] we were promoting the shingles vaccines—we identified everyone over the age of 50 and asked them if they had received a shingles vaccine. We're in that same mode right now, in early May, about the COVID-19 vaccines; we are checking to ensure that the people who are standing in front of us have been vaccinated. Then we are able to answer [any] questions because we have the licensure and the training to do so. It's just part of a natural flow for us as pharmacists.

meet regularly and [use] team emails to talk about what is going on and what's available. We communicated a lot about the COVID-19 vaccines because information was updated week after week.

Pharmacy Times: Do you have a designated education champion or someone who is providing the information to the patient services advocates?



Day: That is one difference between a small pharmacy vs a big one: I am the pharmacist in charge of providing education to the team. My pharmacy [has] 14 or 15 different names on payroll—that includes the patient services advocates, delivery drivers, everyone. A large, busy chain pharmacy location may have 30 to 50 people, so they may need more infrastructure around what the education model looks like, in addition to making sure everyone is on the same page.

I was at my pharmacy earlier today, on an off day, to see a few people whom I do not generally interact with on my team and ensure that they are on the same page as far as what we are doing for COVID-19 vaccines for this week and next. On Thursdays, when I am scheduled [to work] as a pharmacist, that just becomes part of my process: to ensure that the people who are around me are on the same page. If I were in a much bigger location, I would be doing this with a combination of online communication, ...such as an email or a message board, and a team huddle, such as a 5-minute discussion on where we are right now. Especially with COVID-19-specific learning, it makes sense [to have this type of training] when information changes on a weekly basis. People on your team need to have the most up-to-date information, particularly now that we are moving into flu season, too.

I love those 5-minute huddle models. They can feel forced early on, but oftentimes, once you get a couple weeks into it, they become a useful and usual part of the process, to get that quick check-in to see what's going on.

Pharmacy Times: How have the responsibilities or time management of pharmacy staff shifted to accommodate the new tasks?

Day: Not much has changed for the patient services advocates. Welcoming the person who walks in the door and helping them find what they need or pointing them in the right direction has always been a part of their responsibilities. In this case, they are identifying that the person walked in the door for a vaccine. We have 3 waiting areas for social distancing purposes, so they can run that process pretty easily. If a person walks in and drops off a few prescriptions and wants to wait for them, the time management shifts a little bit. Filling those prescriptions takes priority over whatever else has to be done in the pharmacy over the next hour. If the person who walks in has a vaccine appointment or someone walks in for a vaccine without an appointment, then they are next in line. It takes about the same amount of time to check a few scripts as it does to give a vaccine, especially if you have a process in place [and] someone else is helping take care of the paperwork.

and others on the team. If the data entry technician is typing out or an autofill queue, they are going to stop that process and take over to type for the vaccinator; that becomes top priority. Similarly, if the tech is the one who is responsible in that moment to check in that vaccine, they are going to stop what they're doing and check in that person for the vaccine. The process fits fairly naturally into that workflow that exists in most pharmacies, in my experience.



Pharmacy Times: You talked about spacing needs for social distancing requirements. What spacing and equipment needs must a pharmacy take into account to ensure the safe storage and delivery of vaccines?

Day: Social distancing definitely made the process more difficult. We took down almost 20 ft of shelving units in the pharmacy to create new areas where patients can wait and to add tables and chairs. Many pharmacies have waiting areas already: that was part of how they were built. However, ours was not built that way. That's a feature of being a small pharmacy that tends not to have a lot of people waiting around very often, [but with] social distancing that has to be a consideration.

It can be simple: if there are 3 chairs in a waiting area, take out the middle one and move the other 2 chairs 6 ft apart. We use a lot of signage to help keep people separated. For the vaccine administration itself, it was really important that we had a private space to do that and so we built it ourselves. It is not terribly hard to put up a few walls, and I promise you that you have someone in your life who owns a nail gun, or you can rent one and learn how to use it. Two-by-fours are still fairly cheap, and drywall is relatively easy and cheap. You can manage this if you want to. For a few hundred dollars we were able to create a private space with a door that patients feel comfortable in.

Pharmacy Times: As a pharmacy, you have commitments to suppliers and the signage required for some products. How did you decide to remove some to create more space?

Day: That is another advantage to owning my own pharmacy: I didn't have to ask for permission from anyone about what I was doing. It was about making smart choices, though. If there is no inventory on the shelves, you cannot sell as much. However, in every pharmacy there is inventory that never sells. Learning what that is, running reports to identify it, and making decisions can be challenging....We used to have almost 200 running feet—or 20 linear feet—of shelving of greeting cards and 45 running feet of school and office supplies. We only have about 500 to 600 running feet of total shelf space. For a long time, about 30% to 40% of our pharmacy housed school and office supplies and greeting cards. When I bought the store, I made a conscious choice that I wanted it to be a health care destination and not an "everything store." I had the ability to make that choice.

Obviously, though, there are many environments [in which] people do not have the ability to make the choice themselves. However, I would challenge any of them to look into it. As pharmacies get bigger, they also get better data from sales and inventory management. I would challenge them to run those reports and identify the 4-ft, 8-ft, 12- and 16-ft sections that aren't

[them] out. If you think about the pharmacy or a retail space as an apartment complex, you have penthouse suite locations: Some of the products just move quickly. Those 4-ft sections are paying rents double or triple what the going “rent” might be. Conversely, there are also [locations] that haven’t paid rent in 25 years....Put on your landlord hat and kick those [products] out! You have better things to do with [that space], including either putting out new products that can pay rent or, in our case, taking the shelves down to create more space where everyone is more comfortable.

It also makes the store feel bigger. We have had an incredible response to it. Do people sometimes ask for a hot glue gun? Absolutely. But if you sell hot glue guns twice in a 2-year period and make \$1 each time, [it doesn’t come close to] your inventory costs.

Pharmacy Times: Could this model theoretically be utilized in either a parking lot-extended pharmacy or an off-site vaccination clinic? How would that look?

Day: We’ve done quite a few vaccine clinics off site. I know pharmacies have been doing that for a long time. If the pharmacy is located in a part of the country [where it’s] doable, with ample parking spaces outside, great! There is an opportunity to administer many vaccines in a short period of time if you do leave the 4 walls of the pharmacy. An off-site model can be designed around the flow you need for vaccines, whereas inside the pharmacy you must adapt to the space you have.

Some pharmacies have a board requirement that prohibits leaving the pharmacy with vaccines. For example, some of the COVID-19 vaccines are in that [category]. There are also some logistical aspects, [such as] items that are easy to access inside the pharmacy that might not be easily accessible outside. These items include things as simple as trash cans and sharps containers, as well as more complex aspects such as what to do with documentation and tasks that are normally done in real time, electronically. If you’re taking computers [off site], consider how they are going to be powered and how you are ensuring HIPAA [Health Insurance Portability and Accountability Act] and HITECH [Health Information Technology for Economic and Clinical Health Act] protections. In addition, we almost exclusively offer a single [type of] vaccine, such as influenza vaccines, pneumonia, or COVID-19; we do not take multiple vaccine [types].

Generally, when we go off site, we have a “check-in” person and multiple vaccinators. The check-in process off site is different from in the pharmacy. We already know this person has come to receive a vaccine. The off-site process is to ensure we have the right information on the person, such as their demographic information, allergies, and insurance.

For COVID-19 vaccines, we also take a person who will monitor patients for 15 minutes after they have been vaccinated, which occurs after any vaccination. The monitoring person helps direct traffic to go from the checkin to the vaccinator.

any questions the patient might have and then administering the vaccine and giving instructions about follow-up, if there are any. All that happens at the point of vaccination, and the patient moves from that spot. That's really important from a flow perspective, to keep them moving somewhere else. That's where gyms, churches, and parking lots are helpful.

Pharmacy Times: How do you keep track of the patients? Is it done on paper or through a web portal?

Day: If you were to have asked me that question a year and a half ago, I would have said it was all paper. Sometimes we had the information in advance from the patients and had profiles built the morning of, say, an afternoon vaccine clinic. Then we brought the paper back to the pharmacy and performed the data entry at that point. That task does not have to be completed immediately. It might take several days to get all the information uploaded, which can work, as long as all the forms are dated on the day the vaccine was administered, in addition to the billing date, and ensuring that the origin code dates are all the same for the date the vaccine was administered.

At our pharmacy, we do not yet take enough technology with us to be able to bill or document on-site; however, for COVID-19 vaccines, our state has a system for scheduling first and second doses. Thus, all the documentation goes into that site.

Pharmacy Times: How does a pharmacy account for the cost of vaccination supplies and inventory?

Day: That is going to be pharmacy specific. At our pharmacy, we have a store-use document to track all the things we use in the store, from supplies for reconstitutions to paper towels, Lysol wipes, and hand sanitizer. We try to [do the same for] vaccine supplies. For my business, we performed a projection model: For example, for every 100 vaccines these are the associated costs, such as a Band-Aid for each one, which equals a box of Band-Aids, and then alcohol swabs, etc. There's a syringe, and for shingles vaccines, for example, there are 2 different needles as we change needles in between. From there you calculate that out to say, "For every 100 vaccines, this is what the cost is to the pharmacy side." We know if we make on a revenue perspective or on gross profit perspective, X number of dollars on 100 vaccines, that the hard costs associated with that are a certain number.

Pharmacy Times: In terms of billing, what channels are available to pharmacists regarding vaccination reimbursement and insurance coverage?

Day: For most small pharmacies and community pharmacies, it is likely either an all-pharmacy benefit model or potential cash pay. The cash pay model for vaccines is fairly small because most vaccines are fairly expensive, other than maybe flu shots. You're not likely to convince someone to pay out of pocket for a shingles vaccine at about \$400 for a 2-shot series. For my pharmacy, and many pharmacies like mine, we do not have access to medical billing outside of Medicare Part B; we're exclusively

it's the exact same way that you bill everything else. Overall it just becomes very routine.

There are many pharmacies that do have medical billing contracts; some are built into the pharmacy dispensing system. It's fairly similar to typing a regular prescription, but adjudication is going somewhere else. Diagnosis codes are needed, but those are often built into the system. Medicare tends to [pay for] flu vaccines, pneumonia vaccines, and COVID-19 vaccines under Medicare Part B; however, the pharmacy needs to have an accreditation for that. Again, most [chain] pharmacies have that already within the system. Independent pharmacies likely have one too; whether they use it or not, it's likely assigned to them. They need to make sure they know what this is and that it's built into their system. However, Medicare Advantage plans, third-party insurance plans for commercial insurance, and Medicaid plans for the most part all [pay for vaccines as] a normal prescription, and it is fairly simple to take advantage of that.

The cash pay model is competitive. It's less how about how to do it and more about how to set the pricing. For example, travel vaccines, which regularly are not covered by insurance, may be cash pay. If a person is going to go spend a month in South America, they might need 5 or 6 different vaccines and they may be willing to pay directly for that as part of their travel expenses. The competitor for those vaccines is unlikely to be the pharmacy across the street. The real competitor is a travel-specific company, which may offer those vaccines at a higher cost compared with the acquisition costs of vaccines. If you are in a position where you can choose how much you bill for a vaccine, especially for travel, then those are the places to compare with.

***Pharmacy Times:* How can pharmacies review their location demographics to determine which vaccines to stock?**

Day: That's a great question. The pharmacy is embedded in the community it's located in. To me, every pharmacy across the country can succeed with flu, pneumonia, shingles, and tetanus vaccines. If the pharmacy offers anything beyond that, it is going to get a bit subjective as to what you're interested in, who your relationships are with, and the providers in your area as well as within the community itself.

For example, our pharmacy did well offering hepatitis A vaccines about a year and a half ago because there was a hepatitis A outbreak in our neighborhood. It was [therefore] easy to articulate the value of the vaccine. If you don't have hepatitis A in your county, then you're never going to get someone to agree to pay for a vaccine to reduce their very small risk.

For me the decision stems from relationships. The pediatricians on my side of town are incredible. They take really good care of the community. I don't want to step on their toes, so we'll work collaboratively with them in building a plan for pediatric vaccines so that we're helpful for their practices and the families.

The same goes for meningitis if you are located in a town with a private college, for example. [That provider visit] at 17 years of age may be the last time a student sees a health care provider until they turn 30. You don't

we can bring value in addition to what others may bring to the team.

At this point in 2021, pharmacies have been giving vaccines broadly for almost 15 years. Providers in the area are going to expect pharmacies to give vaccines. If you do not have a relationship with a doctor, you're possibly stepping out of line. Don't step on toes that you don't need to step on.



Pharmacy Times: How do you reach all the members of a certain age group for a given vaccine? Are you doing phone calls, text alerts, emails?

Day: A program we did for shingles vaccination was very successful: We would place little paper flags on prescriptions for pickup with a patient over 50, and that would transition at various times [to talking about] a vaccine. We do have programs to send text messages or to send automated voice calls as well; however, our business model is built on personal relationships, and an automated phone call does not fit into the brand that we live and breathe. Thus, we have conversations at the point of dispensing and on the phone. And we encourage patients to tell their friends, particularly after every COVID-19 vaccination.

Pharmacists are masters at building a good rapport. Asking patients to tell their friends is important for encouraging vaccine-hesitant individuals. We want people to be vocal about it and say, 'Yes, I got my vaccine today. It was a great experience, it was super easy, and it didn't even hurt!' That is wonderful, because the person who they said that to might be on the fence about getting a vaccination. [Hearing something positive from their friend] might be the trigger that gets them to change their mind. That worked at our pharmacy with shingles vaccines. The friends came from all over; no amount of text messages or phone call campaigns would ever have found those people.

Pharmacy Times: How are you handling vaccine fatigue, both for patients and pharmacy staff?

Day: [Vaccine fatigue] has the potential to be a fairly big problem coming into this fall, and a lot of it's going to have to do with what happens around the success of the COVID-19 vaccines and the durable immune response to them. A situation [in which] a person is trying to get a flu shot while also thinking about getting a COVID-19 booster can be difficult. We are going to learn how to approach this from experience and talking to patients and seeing what resonates and what doesn't. Many patients likely will try to skip flu shots this fall if they have to get a COVID-19 booster. From the pharmacy and pharmacy team's perspective, if we get instruction that we need to use COVID-19 vaccine boosters in a November to February time frame, it's going to be really hard to get through the flu shot frenzy of September and October and directly into COVID-19 and organizing the two. That's a challenge we don't have the answer to yet.

Pharmacy Times: What else should pharmacies be thinking about going forward?

pneumonia vaccine percentages are pretty dismal across the country, and they have not really changed for a while. A program to improve that makes sense. Similarly, HPV [human papillomavirus] is estimated to cause more than 40,000 cancer cases a year.¹ It's not a small cancer, yet only about half of teens have been fully vaccinated against HPV.² The first step...is getting you and your team educated about the vaccine and the virus that can cause it so you can speak eloquently about the benefits of vaccination. To have it in stock, to know what the schedules are, to be able to speak about the benefits, and then to build relationships with providers about how to target those populations, that makes a ton of sense. There's so much opportunity in that regard from a public health perspective.

REFERENCES

1. HPV-associated cancer statistics. CDC. Updated September 3, 2020. Accessed June 10, 2021.
<https://www.cdc.gov/cancer/hpv/statistics/index.htm>

2. Elam-Evans LD, Yankey D, Singleton JA, et al. National, regional, state, and selected local area vaccination coverage among adolescents aged 13-17 years — United States, 2019. MMWR Morb Mortal Wkly Rep. 2020;69(33):1109-1116. doi:10.15585/mmwr.mm6933a1



[Download Issue : Influenza Guide for Pharmacists July 2021](#)

Related Content:
[Flu](#) | [Coronavirus](#) | [Retail](#)

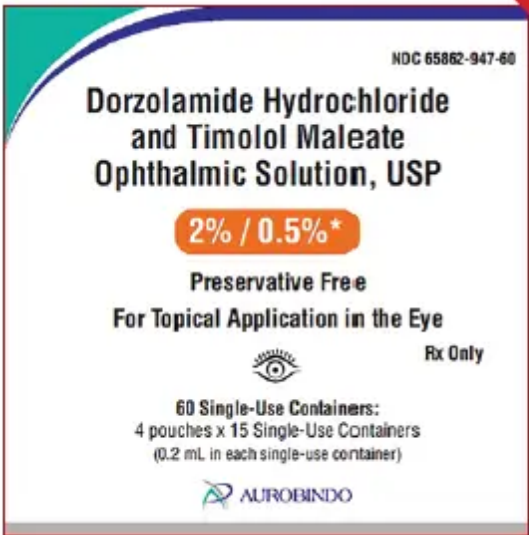
| | | |
|---|--|--|
| Tip of the Week: Performance Appraisal and Feedback | Biomarkers in the Brain May Predict ADHD Diagnosis With 99% Accuracy | Positive Headline Results Reported From 5 Studies of Daprodustat in Patients with Anemia From Chronic Kidney Disease |
|---|--|--|

July 2021 Generic Product News

July 21, 2021
Pharmacy Times, July 2021,



This month's featured products include an ophthalmic solution, darifenacin ER tablets, and more.



Dorzolamide Hydrochloride, Timolol Maleate Ophthalmic Solution, 2% and 0.5%

Marketed by Alembic Pharmaceuticals

Compare to: Cosopt

FDA officials recently approved Alembic’s generic dorzolamide hydrochloride (2%) and timolol maleate (0.5%) ophthalmic solution. It is indicated for the reduction of elevated intraocular pressure in patients with ocular hypertension and open-angle glaucoma who are insufficiently responsive to β -blockers. Common adverse effects include cloudy or double vision, sensitivity to light, temporary blurred vision, and watery eyes. The ophthalmic solution had a market value of approximately \$80 million for the 12 months ending in December 2020, according to data from IQVIA.

For more information: alembicpharmaceuticals.com



Darifenacin ER Tablets

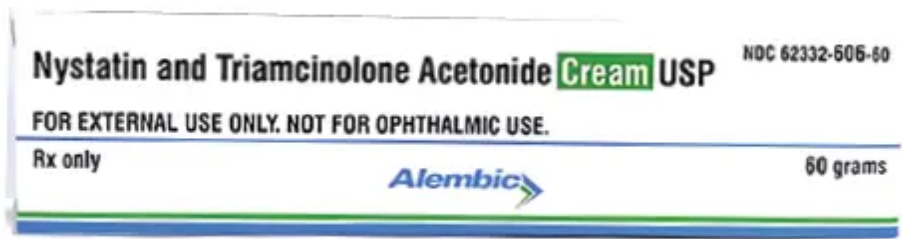
Marketed by Xiromed

Compare to: Enablex

Patients with an overactive bladder have a new option to manage symptoms, including frequency, urgency, and urinary incontinence, with the recent introduction of Xiromed’s generic darifenacin extended-release tablets. The drug relaxes muscles in the bladder and improves patients’ ability to control their urination. Common adverse effects include blurred vision, constipation, dizziness, dry mouth, nausea, and weakness.

market value of \$11.2 million for the 12-month period ending in February 2021.

For more information: xiromed.com



Nystatin and Triamcinolone Acetonide Cream

Manufactured by Alembic Pharmaceuticals

Compare to: Taro Pharmaceuticals Nystatin and Triamcinolone Acetonide Cream

Alembic is launching nystatin and triamcinolone acetonide cream in 100,00 units/gram and 1 mg/gram dosages for the treatment of cutaneous candidiasis. Cutaneous candidiasis typically occurs in areas exposed to moisture for long periods of time, and symptoms can include a red rash. Nystatin works to stop the growth of fungi, whereas triamcinolone acetonide works by reducing itching, redness, and swelling. Common adverse effects include burning, drying, and skin irritation, although these effects should lessen in a few days as the skin adjusts to the medication.

For more information: alembicpharmaceuticals.com



Erythromycin Tablets

Manufactured by Teva Pharmaceuticals

Compare to: Erythrocin

Teva's generic erythromycin tablets soon will be available in dosage strengths of 250 and 500 mg for managing a wide array of bacterial infections and preventing initial or recurrent attacks of rheumatic fever in patients allergic to penicillin. As a macrolide antibiotic, erythromycin works by stopping the growth of bacteria. Adverse effects include diarrhea, loss of appetite, nausea, stomach cramping or pain, and vomiting. Erythromycin oral tablets had a market value of more than \$49 million as of January 2021, according to data from IQVIA.

For more information: tevapharm.com



Related Content:

[Retail](#)

[Biomarkers in the Brain
May Predict ADHD
Diagnosis With 99%
Accuracy](#)

[Positive Headline Results
Reported From 5 Studies
of Daprodustat in Patients
with Anemia From Chronic
Kidney Disease](#)

[Congress Introduces Bill
to Legalize Ingestible CBD](#)



Tip of the Week: Performance Appraisal and Feedback

July 21, 2021
[Shane Desselle, RPh, PhD, FAPhA](#)



Despite their importance, formal performance appraisal systems are often lacking.

One of the most difficult responsibilities that managers face is appraising the performance of employees. Pharmacists could potentially be placed in a position of pharmacist-in-charge, supervisor, or manager very soon after graduating, and even if they are not formally designated as a manager, pharmacists will have technicians and clerical staff who report to them.

Performance appraisals are difficult because we are providing feedback to people we probably know pretty well, and there could be much at stake in the review. There are a number of biases inherent to conducting a performance appraisal, such as the tendency to evaluate everyone similarly (central tendency), or too leniently (lenience), or around just 1 or 2 characteristics of the employee without considering the totality of their performance. But conducting formal appraisals is important to communicate the organization’s mission and performance standards while giving employees something to aim for and letting them know that their contributions are, or at least could be, of significant value, all while promoting equity and fairness.

A study by Siaw et al found performance feedback critical to the success of the Diabetes Multidisciplinary Experiential program, in order to establish collaboration between pharmacists and other members of the diabetes care team.¹ The feedback provided consistent counseling opportunities as well as interdisciplinary collaboration.¹

Despite their importance, formal performance appraisal systems are often lacking. Jee et al found that personnel in independent pharmacies as well as part-time pharmacists in larger organizations were seldom evaluated.² When evaluations were carried out, they were often conducted by someone other than a pharmacist and were focused almost entirely on business targets. They also found that current performance systems are not useful in helping pharmacy personnel self-develop and improve their job performance.²

and deficiencies in fulfilling the important managerial role of performance evaluation. Inadequate or infrequent performance evaluations can result in poor employee performance, poor work attitudes, and failure to communicate the organization's mission. Managers adept at conducting performance reviews might position themselves for even further career advancement.

Additional information about Performance Appraisal Systems can be found in [Pharmacy Management: Essentials for All Practice Settings, 5e](#).

Shane P. Desselle, RPh, PhD, FAPhA, is a professor of social/behavioral pharmacy at Touro University in Vallejo, California.

REFERENCES

Siaw MYL, Ang SW, Lee JY. Evaluation of the Diabetes, Multidisciplinary, Experiential (DIAMANTE) program for retail pharmacists: A mixed-method study. J Contin Educ Health Prof. 2017;37:116-122.

Jee SD, Jacobs S, Schafeutle EI, Elvey R, Hassell K, Noyce PR. Res Social Adm Pharm. 2013;9:155-165.

Related Content:
[Pharmacy Management](#) | [Retail](#) | [Hospital](#)

- [Positive Headline Results Reported From 5 Studies of Daprodustat in Patients with Anemia From Chronic Kidney Disease](#)
- [Congress Introduces Bill to Legalize Ingestible CBD](#)
- [Pharmacy Quiz: Test Your Knowledge on Heart Failure Treatment](#)

Biomarkers in the Brain May Predict ADHD Diagnosis With 99% Accuracy

July 21, 2021
[Skylar Kenney, Assistant Editor](#)



Specific communication among different brain regions, known as brain connectivity, could potentially serve as a biomarker for attention-deficit hyperactivity disorder (ADHD), according to a study published in Frontiers in Physiology.

Specific communication among different brain regions, known as brain connectivity, could potentially serve as a biomarker for attention-deficit hyperactivity disorder (ADHD), according to a study published in *Frontiers in Physiology*. The investigators used machine-learning classifiers to identify adults who had received a childhood diagnosis of ADHD with 99% accuracy.

According to the researchers, these findings have implications not only for increasing the ease with which ADHD is diagnosed, but also for assisting clinicians in properly targeting treatments to address each patient's specific needs.

understanding the different types of ADHD can help inform decisions about one medication versus others,” said Chris McNorgan, PhD, in a press release.

Identifying and diagnosing ADHD is often difficult, despite being the most commonly diagnosed psychological disorder among school-aged children. Diagnostics are complicated by multiple subtypes of the disorder and a clinical diagnosis of ADHD may change when the same patient returns for follow-up evaluations.

“A patient may be exhibiting behavioral symptoms consistent with ADHD one day, but even days later, might not present those symptoms, or to the same degree,” McNorgan said in the release. “It could just be the difference between a good day and a bad day. But the brain connectivity signature of ADHD appears to be more stable. We don't see the diagnostic flip-flop.”

The investigators used archival fMRI data gathered from 80 adult participants who had been diagnosed with ADHD as children. The researchers then applied machine learning classifiers to 4 snapshots of activity, taken while the participants were performing a task designed to test the subject's ability to inhibit an automatic response. The collective analysis approached 99% diagnostic accuracy, with focused analysis of individual runs reaching 91%.

“It's by far the highest accuracy rate I've seen reported anywhere—it is leagues beyond anything that has come before it, and well beyond anything that has been achieved with a behavioral assessment,” McNorgan said in the release. “Many factors likely contributed towards our superior classification performance.”

This unique accuracy may be attributable to the application of deep learning networks, which are far more capable of detecting conditional relationships than direct linear classification, according to the researchers. Because the current study was designed to predict ADHD based on the patterns of communication between groups of brain areas, and these connections often require the consideration of multiple factors as opposed to linear correlation, the use of deep learning classifiers may have strongly contributed to the success of this diagnostic model, according to the authors.

REFERENCE

Detecting ADHD with near perfect accuracy [news release]. EurekAlert; January 27, 2021. Accessed July 13, 2021.
https://www.eurekalert.org/pub_releases/2021-01/uab-daw012721.php

Related Content:
[Retail](#) | [ADHD](#)

- [Congress Introduces Bill to Legalize Ingestible CBD](#)
- [Pharmacy Quiz: Test Your Knowledge on Heart Failure Treatment](#)
- [The Future of Telemedicine as the COVID-19 Pandemic Wanes](#)

Studies of Daprodustat in Patients with Anemia From Chronic Kidney Disease

July 21, 2021

Skylar Kenney, Assistant Editor



Five studies from the phase 3 ASCEND program showed positive headline results in evaluating the efficacy and safety profile of daprodustat (GlaxoSmithKline). The drug is an investigational oral hypoxia-inducible factor prolyl hydroxylase inhibitor (HIF-PHI) for patients with anemia due to chronic kidney disease (CKD).

CKD, characterized by progressive loss of kidney function, is a growing global health concern. Risk factors include hypertension, diabetes, obesity, and primary renal disorders, and CKD is itself an independent risk factor for cardiovascular disease. Anemia is a frequent complication from CKD, but it is often poorly diagnosed and undertreated in patients with early-stage CKD who are often not on dialysis. Anemia from CKD is associated with poor clinical outcomes when left untreated.

According to the investigators, daprodustat met its primary efficacy endpoint in each study, demonstrating an improvement in hemoglobin (Hgb) levels in untreated patients. Daprodustat also maintained Hgb levels in patients treated with an erythropoietin-stimulating agent (ESA), a standard treatment option for patients with anemia from CKD. Further, studies for non-dialysis (ASCEND-ND) and dialysis patients (ASCEND-D) demonstrated that daprodustat was non-inferior when compared to an ESA in the risk of major adverse cardiovascular events (MACE), the primary endpoint of both studies.

The ASCEND program also included studies focused on incident dialysis, for patients just starting dialysis (ASCEND-ID); quality of life measures (ASCEND-NHQ); as well as 3-times weekly dosing regimens (ASCEND-TD), each of which met its respective primary or co-primary endpoints.

“I am particularly pleased with the results from the ASCEND-ND and ASCEND-D studies given the importance of managing cardiovascular outcomes for patients who are currently suffering from anemia due to chronic kidney disease, as well as the need to provide a convenient, oral treatment option,” said Hal Barron, MD, chief scientific officer and president of R&D at GSK, in a press release “We will continue to analyze the data from the robust phase 3 ASCEND program and look forward to working closely with regulators as we plan for our submissions.”

Across all of the ASCEND trials, daprodustat was generally well tolerated in both non-dialysis and dialysis patients. Treatment-emergent adverse events (AEs) were similar in incidence rate between treatment groups and the nature of reported events was consistent with the underlying patient population. The most frequently reported AEs for the patients receiving daprodustat across the ASCEND program included hypertension, diarrhea, dialysis hypotension, peripheral edema, and urinary tract infection.



GSK announces positive headline results from five Phase 3 studies of daprodustat for patients with anaemia due to chronic kidney disease [news release]. GSK; July 16, 2021. Accessed July 20, 2021.
<https://www.gsk.com/en-gb/media/press-releases/gsk-announces-daprodustat-phase-3-headline-results/>

Related Content:

[Retail](#) | [Hospital](#) | [Chronic Kidney Disease](#)

[Pharmacy Quiz: Test Your Knowledge on Heart Failure Treatment](#)

[The Future of Telemedicine as the COVID-19 Pandemic Wanes](#)

[Finerenone Receives FDA Approval for Treatment of Chronic Kidney Disease Associated with Type 2 Diabetes](#)