RADAR on Specialty Pharmacy
Strategies and Analysis for Managing High-Cost Specialty Products

Collaboration Is Needed on COVID Vaccine Dosing, Specialty Drugs

Many people taking specialty medications, such as people with cancer, are immunocompromised, and specialty drugs themselves can cause drug-induced immunosuppression. As COVID-19 vaccines roll out, it may be unclear how those products could impact people taking specialty therapies. At least one medical society, however, has released a guidance summary, and industry experts say that all stakeholders, including specialty pharmacies, have a role to play in making sure people getting vaccinated do so in the most effective, safest way possible.

In February, the American College of Rheumatology (ACR) released its COVID-19 Vaccine Clinical Guidance Summary, which provides recommendations on vaccinating people with musculoskeletal, inflammatory and autoimmune diseases. A panel of nine rheumatologists, two infectious disease specialists and two public health experts developed the guidance through multiple meetings in December and January. The guidance was updated on March 4.

"Recommendations in the guidance should not replace clinical judgement, and decisions about individual patients should be made as part of shared decision-making with patients that considers their underlying health condition(s), disease activity level, current treatments, risk of exposure to SARS-CoV-2 and geography," says the ACR.

"Although there is limited data from large population-based studies, it appears that patients with autoimmune and inflammatory conditions are at a higher risk for developing hospitalized COVID-19 compared to the general population and have worse outcomes associated with infection," said Jeffrey Curtis, M.D., chair of the ACR COVID-19 Vaccine Clinical Guidance Task Force, in a press release unveiling the guidance. "Based on this concern, the benefit of COVID-19 vaccination outweighs any small, possible risks for new autoimmune reactions or disease flare after vaccination."

Dea Belazi, president and CEO of AscellaHealth, points out that clinical trials for the three vaccines with emergency use authorization in the U.S. "included patients with many types of underlying disease, including specialty drug conditions. Specific information on each of these disease subtypes has not been fully described, but the vaccines have been shown to be generally safe and effective at preventing COVID-19 for patients enrolled in the clinical studies."

The ACR guidance offers general considerations with COVID-19 vaccinations in people with these conditions, as well as recommendations for use of the vaccines and the timing and use of the vaccines and immunomodulatory therapies.

Among the immunomodulatory therapy recommendations with a moderate level of task force consensus are the following:

- Hold ***methotrexate*** one week after each vaccine dose "for those with well-controlled disease; no modifications to vaccination timing."
- Hold ***Janus kinase inhibitors*** one week after each vaccine dose, with "no modification to vaccination timing."
- Hold ***subcutaneous Orencia*** (abatacept) "both one week prior to and one week after the first COVID-19 vaccine dose" only, with no changes around the second dose.
- For ***intravenous Orencia***, "time vaccine administration so that the first vaccination will occur four weeks after abatacept infusion (i.e., the entire dosing interval), and postpone the subsequent abatacept infusion by one week (i.e., a 5-week gap in total); no medication adjustment for the second vaccine dose."

- For ***rituximab***, "assuming that patient's COVID-19 risk is low or is able to be mitigated by preventive health measures (e.g., self-isolation), schedule vaccination so that the vaccine series is initiated approximately 4 weeks prior to next scheduled rituximab cycle; after vaccination, delay RTX 2-4 weeks after 2nd vaccine dose, if disease activity allows."
- "No modifications to either immunomodulatory therapy or vaccination timing" are needed for many treatments, including ***tumor necrosis factor inhibitors***, ***Benlysta*** (belimumab) and ***interleukin-6R, IL-1, IL-17, IL-12/23*** and ***IL-23 inhibitors***.

There are other specialty drug-treated conditions where treatment regimens should be modified when people receive a COVID vaccine. For example, the National Comprehensive Cancer Network recommends delaying a COVID vaccine for three months after a hematopoietic cell transplant or treatment with a chimeric antigen receptor T cell (CAR-T) therapy, says Robert Kinyua, Pharm.D., clinical program development director at Prime Therapeutics LLC.

In addition, he says, people receiving a transplant usually require immunosuppressive therapies, which "may diminish the response of the COVID-19 vaccine; however, transplant centers do not currently recommend that these patients modify their medications before or after receiving the COVID-19 vaccine. Instead, they recommend patients wait at least one month after receiving a transplant before getting vaccinated."

People with hemophilia "usually have special considerations with all types of medical interventions," says Belazi. "Recent articles and commentaries published generally support the use of COVID-19 vaccines in these patients, particularly because the vaccination is administered intramuscularly and minimizes the chance of bleeding, but patients should be monitored and watched for signs of bleeding. Hemophilia patients should ensure that they consult with their treating physician prior to receiving the vaccine."

MDs Can Assess Patient-Specific Factors

"With any specialty drug-treated condition, it is important for the patient to work closely with his or her provider, who will assess the patient's risk factors, medications and condition to make the best decision possible," recommends Renee Baiano, Pharm.D., clinical program manager at AllianceRx Walgreens Prime.

"If a patient has an underlying medical condition, the patient should continue to follow their prescribed treatment plan," Belazi tells AIS Health. "This includes continuing their medicines and not changing the treatment plan without talking to their health care provider, including the addition of over-the-counter supplements. Also, they should not delay getting emergency care for their underlying medical condition."

For people with particularly complex conditions who are weighing the risks and benefits of getting vaccinated or not, providers "can request a consultation from CISA COVIDvax for a complex COVID-19 vaccine safety question that is about an individual patient residing in the United States or vaccine safety issue and not readily addressed by the CDC or Advisory Committee on Immunization Practices guidelines. This request can be made through CDC-INFO by calling (800) 232-4636 or submitting a request via the CDC-INFO website."

"The risk vs. benefit of receiving or not receiving the vaccine will vary from person to person," Kinyua tells AIS Health. "Both the provider and patient should rely on the most up-to-date vaccine information gathered from reputable sources," including the FDA, Centers for Disease Control and Prevention (CDC), Advisory Committee on Immunization Practices and National Institutes of Health.

The bottom line, though, is that except in people with a history of severe allergic reaction or severe allergic reaction to any ingredient in a COVID vaccine, "the CDC recommends that most people including those with preexisting conditions should receive the vaccine," he says. "The benefits of receiving the vaccine include protection from COVID-19 infection and severe COVID-19 illness if infected. The vaccine may also help slow or stop the spread of the virus."

Care Team Members Should Collaborate

With so many stakeholders involved in a person's care, a collaborative approach should help in finding out any recommended regimen changes.

"If available, the provider will consult with clinical guidelines to determine if any updates are needed for the patient's treatment regiments," says Baiano. "When no clinical guidelines are available, the provider and patient will take an individualized approach to weigh the risks and benefits to determine the best option."

"Manufacturers are under current obligations to advise the health care community regarding the ongoing safety and efficacy of their marketed drug products, including modifications based upon new or emerging clinical evidence," notes Belazi. "As validated and reported information becomes available due to the administration of the different vaccines to existing patients using marketed drug products, manufacturers need to provide timely and relevant information to all parties. As information is being collected by different stakeholders, all parties should contribute to information that may be pertinent to modifications in medication efficacy, safety and dosing recommendations."

Kinyua says that as far as manufacturers' responsibility to notify providers of recommended treatment modifications, it depends on the information being communicated. "The FDA may in certain instances require manufacturers to send out communications to providers especially if related to a significant safety concern. The FDA may also send out such communications. Otherwise, manufacturers are not obligated to notify providers of medication modifications such as those noted by" the ACR. "Most health care institutions including clinics and hospitals have processes in place to ensure their providers are educated on the most up-to-date clinical practice recommendations such as those from ACR."

Should Specialty Pharmacies Take Lead?

In the Feb. 23 Anton Rx Report, Executive Editor and longtime industry expert Bill Sullivan focused on the ACR task force's dosing recommendations. He asserted that "since virtually all specialty pharmacies are now accredited, it is incumbent on specialty pharmacies to develop such enhanced therapeutic protocols as new information becomes available." He advised specialty pharmacies to prepare protocols for "each therapeutic category you support including desktop workflows for patient coordinators and pharmacists to determine if a dosing schedule adjustment is warranted. Notes to the patient file should include patient status and follow-up to ensure that the specialty therapy resumes. A call to the treating physician may be required as well. Each manufacturer should be able to provide their dosing recommendation for their drug. Developing a full suite of protocols will be challenging but is essential to a high-quality therapeutic management program."

"In general, it is a provider's responsibility to ensure they are up to speed on all necessary clinical updates needed to take care of their patient," says Kinyua. "Pharmacists may not notify providers of modifications such as those noted in ACR since the recommendation may vary from patient to patient."

Specialty Pharmacists Can Offer Support

"Although the patient and the provider will decide the best course of action for them regarding getting the COVID-19 vaccine, the specialty pharmacy can help provide valuable insight," says Baiano. For example, AllianceRx Walgreens Prime has developed "disease-specific resources, based on clinical guidelines, for the pharmacists to consult while counseling patients on the COVID vaccine. For some medications, a therapy adjustment may be recommended, while it may not for other medications. The specialty pharmacist can help provide guidance on medication-specific updates."

She says that "specialty pharmacies should stay abreast of any updates and clinical guidelines or recommendations to best support the patient and provider decision-making. At AllianceRx Walgreens Prime, our specialty clinical team continuously provides updated research to our pharmacist teams. We review expert clinical guidelines for updates and recommendations, so our specialty pharmacists stay informed on the latest information."

Specialty pharmacies, says Belazi, "have the opportunity to engage with the patient and their caregivers outside of the traditional pharmacy setting. This unique practice setting expands their care delivery teams and allows for the opportunity for additional information exchange, especially for the complex specialty patients."

Pharmacists May Have Full Patient View

He maintains that "all parties involved in a patient's care should communicate the information on a patient's treatment regimen. In particular, pharmacists interact with patients very frequently, generally have a full view of the patient's entire medication profile and have an opportunity to take a lead role in coordinating this information for prescribers, patients and their support team."

"The management of the COVID-19 pandemic is an evolving situation with new information emerging. There has been significant progress made and, as a nation, we have come a long way in the one year since the outbreak began with not only different vaccines, but also the availability and efficacy of treatment options," Belazi says. "Dialogue among the patient, caregivers and health care team is essential to share information and clinical evidence to provide the highest quality of care and optimize the patient's drug treatment regimen."

View the ACR guidance summary at https://bit.ly/3wpvowt. Contact Baiano via Adrienne Foley, APR, at adrienne.foley1@alliancerxwp.com, Belazi via Caroline Chambers at cchambers@cpronline.com, Kinyua through Jenine Anderson at jenine.anderson@primetherapeutics.com and Sullivan at bsullivan0011@gmail.com.

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