Evolving Population Health Strategies for an Expanding Treatment Spectrum

A Q&A With Sheila M. Arquette, RPh

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***AJMC®*: In recent years, the treatment spectrum for follicular lymphoma has evolved significantly. Can you talk about the managed care implications of the rapidly growing treatment armamentarium?**

ARQUETTE: There are many implications, including determining which medications managed care organizations will cover. Are you going to cover all of them, and, if so, in what sequence? With respect to oncology, we are learning more each day about the human genome, which enables us to better determine which medications patients will and will not respond to. This is changing the way patients are treated and managed. Historically, managed care operated by the 80/20 rule: Formularies were designed to include medications that were most clinically appropriate and expected to produce optimal therapeutic outcomes for about 80% of the patient population. The remaining 20% required consideration of alternatives on a case-by-case basis predicated on their clinical presentation and treatment course. Now it is a much more personalized, precision-[focused] approach to care for all. The challenge is the selection and sequencing of the treatment regimens based on the patient's clinical presentation, treatment course, and genetic composition and considering what they have responded to previously as well as what their genetic profile predicts they will respond to. Working with the oncologist, considerations include the patient's genetic testing results, tumor DNA, if available, the National Comprehensive Cancer Network [NCCN] guidelines, the applicable compendia, and the clinical studies and trial data. In the past, certain agents that were therapeutically equivalent to others in the same class, expected to produce comparable outcomes in a majority of patients but whose manufacturers offered a deeper discount, were preferred. The newer treatment options carry a very high price tag but are so individualized and patient specific that the former approach to managing coverage may no longer be a viable option. So the challenge is how to balance optimal clinical patient management and drug formulary design while simultaneously providing coverage and care that is clinically appropriate, evidenced based, and affordable?

***AJMC®*: Could you discuss some factors beyond cost when it comes to weighing outcomes and treatment value?**

ARQUETTE: [It is key to engage] your prescriber community and the oncology healthcare professionals that support the oncologists. What are they comfortable with? What are their perceptions and thoughts about the drugs that are available? What has been their experience? What are they learning from other patients who are taking these medications? Have they participated or been an investigator in some of the clinical trials? You must engage the oncologist, but you also must review the drug's efficacy and safety profile and how the drug is administered. Does one drug offer an advantage over another? In reviewing the discontinuation rate, what are the common reasons for discontinuation? Is it based on tolerability issues or the [adverse] effect profile? At what point in the patient journey is this medication typically prescribed, and is that a contributing factor to discontinuation? You need to take into account all factors, especially if you have multiple

drugs available for use with the same mechanism of action and for the same indication.

With this in mind, you may be able to prefer one product over another and work with the manufacturer to garner discounts. However, before making a final decision, it is important to look at all factors associated with the drug. Does one drug require an FDA-approved genetic test, whereas the others do not? Is there additional monitoring or a specific type of monitoring required with one of the drugs, despite having a similar or identical mechanism of action? Are there factors that may affect the patient's ability to safely self-administer the medication or may impact compliance and adherence and, ultimately, the outcome achieved? These are all factors that must be considered.

***AJMC®*: What factors should be considered for drugs that fall outside the preferred spectrum?**

ARQUETTE: It is essential to work with prescribers to educate and outline specifically what information is needed to consider an exception to the preferred products on the formulary in order to make an appropriate and educated clinical decision. The health plan must learn more about the patients who fall "outside the box." Specifically asking the prescriber why they do not believe the preferred drug is going to work for this particular patient is important. Why do they feel the drug they are requesting is more appropriate? What evidence can they provide to support their assertion? When the prescriber submits an evidence-based rationale for why an alternate is more appropriate, the payer must have the clinical resources, the expertise, and the guidance to evaluate the request and make a sound decision.

***AJMC®*: What is the role of treatment guidelines from a payer perspective?**

ARQUETTE: This continues to be a challenge. I used to remind my [physician assistant] team and my leadership that although it's a science, medicine is still being practiced. Often when you push the boundaries, a new treatment discovery is made. However, the cost to the system and price sensitivity must be considered, especially when employer groups as the customers of the health plans are responsible for paying for treatments without any associated evidence. [Therefore,] sometimes you find yourself stuck in the middle. As a clinician you want to help patients and do everything possible; however, as stewards of ensuring premium dollars are used for the greatest common good, you simply cannot pay for everything, especially in the absence of evidence-based medicine and clinical study data. Guidelines are essential and serve as a foundation for payers, who use them to different degrees based on their mission and vision. Some payers will only accept category 2A evidence and above. Others will consider a wide range of evidence evaluating compendia citations, [like] peer-reviewed, published clinical literature and the treatment guidelines and position statements of the NCCN, the American Society of Clinical Oncology, and/or the American Society of Hematology.

The line of business also determines the role treatment guidelines play in the decision-making process. During my tenure at the health plan, we had a rapidly growing self-funded business. The self-funded employer assumes financial responsibility for all costs associated with their employees' health care. They are also afforded much more discretion as to what they will and will not cover. Many would not cover anything off label, regardless of the level of evidence. If it was not studied, evaluated for safety and efficacy, and vetted via the FDA-approval process, coverage was not provided; you had to incorporate that into your decision-making process when reviewing authorization and exceptions requests. Often a challenge is educating your medical directors on the nuances of the line of business-dictated constraints and requirements and why certain coverage decisions can and cannot be made. They, of course, are trained to heal and cure patients. However, the fiduciary responsibility must be considered in tandem with the clinical. Much of the decision-making process is dictated by the self-funded customer. Medicare, Medicaid, commercial plans, and self-funded plans all have different requirements, and payers are responsible for making decisions based not only on the available evidence but also in accordance with plan benefit design.

***AJMC®*: What are some factors you consider when attempting to balance the fiduciary elements, individual patient needs, and population health strategies?**

ARQUETTE: You have to manage your entire formulary. We [are] always looking for opportunities and categories of drugs that we could pare down and streamline while still providing optimal clinical and economic value to our members, providers, and customers. You are looking for cost containment strategies that will allow you to minimize the premium impact of covering the more personalized, precision therapies that are now being approved. Balancing clinical efficacy and safety with cost-effectiveness and affordability inundates the thought process of the pharmacy department and medical directors. I would try to look at the overall picture, keeping in mind [that] not all drugs have to be covered in a preferred position on the formulary. An established exception process [is in place] for patients who, for some reason, cannot take a specific medication or who try everything on the formulary and do not respond. We can steer utilization across the entire formulary to products that we feel are most clinically appropriate, produce the best outcomes, and are the most cost-effective. [That] helps to provide some "wiggle room" when

the more personalized products are approved. Though personalized therapies may only be indicated for a handful of patients, you want to ensure you are able to treat that handful of patients. It requires a very judicious approach and an appreciation of the entire formulary design and the drugs that you're covering, evaluating the categories and drug classes, what has changed, and staying abreast of any updates to the treatment guidelines. Are the treatment algorithms different than they were a year ago? Just because we decided to cover the drug 1 year, 2 years, and 5 years ago, does it still make sense today? Are there new innovations or available treatment options to consider? Is drug B now a better option than drug A? What changes, if any, are necessary to ensure that we are providing appropriate and affordable coverage to as many patients as possible?

***AJMC®*: How can and how should the managed care spectrum evolve along with clinical innovations and developments, which may be rapid in a particular disease state?**

ARQUETTE: We must be better at balancing the application of population health type management strategies to a large group of patients with similar treatment plans with the needs of a few patients and the personalized, precision medicines available to best treat their disease or condition. Going forward, we must ask ourselves: How [will] we ensure that the right patient truly gets the right drug at the right time? I believe we no longer will be routinely stepping patients through prerequisite therapies with the hope that they may respond when we know they will not. Up until this point, the variability in predicting patient response and contractual arrangements supported this one-size-fits-all approach. When I look back and think about the immunology class, patients across the country were subjected to double and triple step therapy with preferred agents unless a true contraindication existed because we didn't know then what we are discovering today. Now we are better able to understand why a trial of a particular agent does not make sense clinically or economically based on the patient's genetic profile. Today, when we look at some of the oncology agents and at some of the rare types of cancers, we don't have to subject patients to the gamut of available drugs hoping for a positive response. Because of personalized treatments, we know what the patient is going to respond to and can limit the patient's exposure to toxic medications that will not produce the desired response.

We need to appreciate that the population health based approach is no longer going to be sufficient to manage all patients and diseases. Plans will begin to move away from requiring a trial of drug [X] for all patients as we are able to better identify up front those who will not respond. Managed care pharmacists will have the opportunity to partner with prescribers to select the most appropriate drug for the specific patient and demonstrate their value as a member of the healthcare delivery team. We need to focus on achieving the outcome that we expect based on the available literature and to be better at having critical conversations with patients when the drug isn't working, and we have to discontinue or switch to a different agent. The entire thought process regarding contracting and rebate strategy is going to change and will be influenced not only by how CMS and HHS [the Department of Health & Human Services] decide to move forward but as the shift from volume to value continues. The innovation and developments we are now seeing lend themselves to more outcomes-based contracting because we will no longer be treating the same volume of patients with the same medications. I believe it is going to be 2 different schools of thought and approaches at least in the short term as we work to keep pace and adjust to the changes happening across our industry. We must be ready, nimble, and flexible enough to react so that patients do not get caught in the middle.

***AJMC®*: Can you discuss managed care strategies from the perspective of staging?**

ARQUETTE: Some payers and health plans are looking at staging. When, in the treatment course, have we gone past the point of clinical appropriateness and utility for this drug based on disease progression and clinical presentation? These are really difficult questions and discussions [based on] ethics and morals. At what point do you tell a patient there really is no hope? You hear all the time [about] patients [being] told they have 3 months to live, yet they are alive 5 years later. The conversation between physician and patient must be [difficult] when the decision is made that continued treatment is not expected to provide any additional value. Staging is being incorporated where there is evidence and outcomes data to support the inclusion of stage in treatment decisions. Widespread use of staging when developing prostate cancer treatment plans in addition to the patient's functional score, presence of disease progression, tumor type, propensity of the cancer to advance and spread, and the presence of metastases is commonplace. So I think we're now thinking differently about what's truly best for patients and considering them as individuals. It's important to note that many people fail to realize that just because many oncology drugs are orally administered, [chemotherapy is still toxic]. With limiting patient exposure to potentially toxic medications in mind, you don't want to take a shotgun approach to treating the patient if there is a more personalized, precision treatment regimen to consider. There are over 700 oral cancer drugs in the pipeline that are being developed and will go through the FDA approval process. Staging will definitely continue to be evaluated and utilized to ensure the right patient receives the right drug at the right time. ◆