# PQIIN ACTION





TAZEMETOSTAT (TAZVERIK®)

MANAGEMENT IN RELAPSED/
REFRACTORY FOLLICULAR LYMPHOMA



NCODA'S POSITIVE QUALITY INTERVENTION IN ACTION

#### INTRODUCTION

The continuous change and evolution of treating and managing oncology patients has led to a significant need to promote higher quality patient care. This need motivated NCODA to develop the Positive Quality Intervention (PQI) as a peer-reviewed clinical guidance resource for healthcare providers. By providing Quality Standards and effective practices around a specific aspect of cancer care, PQIs equip the entire multidisciplinary care team with a sophisticated yet concise resource for managing patients receiving oral or IV oncolytics. This PQI in Action is a follow up to the Tazemetostat (TAZVERIK®) Management in Relapsed/Refractory Follicular Lymphoma PQI and explores how the medically integrated teams at Utah Cancer Specialists (UCS) and Tennessee Cancer Specialists incorporate PQIs as part of their daily workflow. This article will discuss how utilizing the Tazemetostat (TAZVERIK®) Management in Relapsed/Refractory Follicular Lymphoma PQI elevates patient care.

Tennessee Cancer Specialists provides innovative, comprehensive cancer care with a personal touch. They are a full-service, Quality Oncology Practice Initiative (QOPI) certified, medical oncology and hematology practice with a team of highly trained and experienced board-certified physicians, nurse practitioners and oncology-certified nurses. With 13 physicians and over 25 nurse practitioners providing services in 14 locations within the East Tennessee area, they are providing convenient access to comprehensive care for cancer patients

Utah Cancer Specialists is the largest community-based oncology and hematology practice in Utah made up of 18 medical oncologists, 17 advanced practice providers, and 3 radiation oncologists. They are dedicated to the diagnosis, treatment and management of all forms of cancer and blood-related diseases. UCS providers have expertise in every type of cancer, including rare malignancies. They also actively participate in clinical research. Their pharmacy staff handles inventory management, prior authorizations, and financial assistance through their Medically Integrated Dispensing (MID) pharmacy.

#### THE PARTICIPANTS

### Utah Cancer Specialists Salt Lake City, Utah



Richard Frame, MD

Medical Oncologist



Colby Hancock, PharmD

Clinical Pharmacist



Jamie LeVieux, CPhT
Pharmacy Technician

#### Tennessee Cancer Specialists Knoxville, Tennessee



**Tracy W. Dobbs, MD** *Medical Oncologist* 



**Joy Pratt, PharmD** *Pharmacy Manager* 



Cassy Moses, RN Registered Nurse



**Ashley Botts, CPhT** *Pharmacy Technician* 



**Leah Wilson, CPhT** *Pharmacy Technician* 

#### **TAZEMETOSTAT AND Medically Integrated Dispensing**

ollicular lymphoma (FL) is the second most common type of non-Hodgkin lymphoma (NHL) and is the most common type of the clinically indolent, or slower growing, NHLs.<sup>1</sup> Around 1 out of 5 lymphomas in the U.S. is a FL with an estimated incidence of 6 new cases out of 100,000 persons per year.<sup>2</sup> The methyltransferase, EZH2, plays a role in the normal physiology of many cell types and, in healthy cells, its activity is down-regulated to allow for differentiation of B-cells and apoptosis. However, dysregulation of EZH2 has been observed in different types of cancers and is associated with poor outcomes and prognosis.<sup>3</sup>

More specifically in FL, tumors are dependent on EZH2 for growth and survival. Whether patients have the wild-type EZH2 or a gain of function mutation of EZH2, multiple oncogenic hits drive increased activity of EZH2, causing aberrant B-cell proliferation leading to the development of FL.<sup>3</sup> Most patients treated with FL will have an initial response to therapy with 40-80% demonstrating a complete response, depending on the initial regimen used. However, conventional therapy for FL is not curative. Most of these patients may develop progressive disease while some, who were treated with chemoimmunotherapy, may not respond to their treatment (i.e., refractory disease).<sup>4</sup>

Tazemetostat is the first and only FDA-approved EZH2 inhibitor for patients with relapsed or refractory (R/R) FL. Within the FL space, it is indicated for the treatment of:

- Adult patients who have R/R FL with tumors that are positive for an EZH2 mutation (as detected by an FDA-approved test, such as via the cobas® EZH2 Mutation Test) and have received at least 2 prior systemic therapies.
- Adult patients with R/R FL who have no satisfactory alternative treatment options.<sup>5</sup>

In June 2020, the FDA approved tazemetostat for these two distinct FL indications, based on evaluating its efficacy in an open-label, single-arm, multicentered, phase 2 trial. A total of 99 patients (45 in the EZH2 mutant cohort and 54 in the EZH2 wildtype cohort) were enrolled in the study and received 800 mg of tazemetostat orally twice daily until disease progression or unacceptable toxicity with tumor assessments every 8 weeks. Trial results demonstrated an objective response rate of 69% (95% CI 53–82; 31 of 45 patients) in the EZH2 mutant cohort and 35% (23–49; 19 of 54 patients) in the EZH2 wildtype cohort. Median progression-free survival was 13.8 months (95% CI 10.7–22.0) for the EZH2 mutant cohort and 11.1 months (95% CI 3.7–14.6) for the EZH2 wildtype cohort. <sup>5</sup>



Richard Frame, MD, of Utah Cancer Specialists, engaging in effective interprofessional collaboration.

Also, the median time to response was 3.7 months in the EZH2 mutant cohort and 3.9 months in the EZH2 wildtype cohort. Regarding side effects in the trial, the treatment was fairly well tolerated. The most common adverse reactions (≥20%) in patients with R/R FL were fatigue, upper respiratory tract infection, musculoskeletal pain, nausea, and abdominal pain. Only 8% of patients permanently discontinued therapy due to adverse events, and 9% of patients required dose reductions.<sup>5</sup>

Tazemetostat can be dispensed by the Medically Integrated Team, which ultimately offers patients more comprehensive care. NCODA defines Medically Integrated Dispensing (MID) as a dispensing pharmacy within an oncology center of excellence that promotes a patient-centered, multidisciplinary team approach. The MID is an outcome-based collaborative and comprehensive model that involves oncology healthcare professionals and other stakeholders who focus on the continuity of coordinated, quality care and therapies for cancer patients.<sup>6</sup>

The MID model can improve management of patients on therapies like tazemetostat in several ways including enhanced communications, measuring adherence, managing regimen changes, quicker therapy initiation, improved patient satisfaction, financial assistance, cost avoidance and producing less waste. NCODA offers multiple tools to aid the MID practice in managing oncolytics. This toolbox contains a patient survey, Financial Assistance Database, Treatment Support Kits, Oral Chemotherapy Education sheets, and PQI clinical resource documents.<sup>7</sup>

# THE POSITIVE QUALITY INTERVENTION: A VALUABLE CLINICAL RESOURCE

he PQI is a peer-reviewed clinical guidance document that provides quality standards and effective practices around a specific aspect of cancer care. The Medically Integrated Pharmacy team is in a unique position to ensure appropriate treatment, increase compliance and maximize clinical outcomes. Each PQI, an NCODA Quality Standard, is designed to operationalize and standardize these practices to achieve positive clinical outcomes.

Tennessee Cancer Specialists Pharmacy Manager Joy Pratt, PharmD discusses the value PQIs bring to the care team. Pratt mentions, "PQIs are utilized in Tennessee Cancer Specialists often, especially for new drugs that have not been dispensed before. This gives pharmacists the opportunity to review the PQI so that they are comfortable with counseling

CLICK HERE TO VIEW PQI the patient. Unlike the prescribing information, PQIs are concise. I can be very comfortable with the PQI right in front of me, allowing me to make dosing modifications and take other recommendations to the physician." One of the Medical Oncologists also at Tennessee Cancer

Specialists, Tracy Dobb, MD shares a similar perspective on PQIs. He mentions that the PQI for tazemetostat is, "a valua-

ble tool when prescribing or following a patient currently on tazemetostat."

This article will explore the benefits of PQI utilization as a core standard of the MID and how adoption can benefit any practice. Both Utah Cancer Specialists and Tennessee Cancer Specialists position their Medically Integrated Teams in a way to ensure appropriate treatment, increase compliance, and maximize clinical outcomes. We will explore their practice settings, how implementing the steps found in the Tazemetostat (TAZVERIK®) Management in Relapsed/Refractory Follicular Lymphoma PQI benefits their staff and patients, and how they advance patient care on a daily basis.

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Joy Pratt, PharmD

### MEDICALLY INTEGRATED DISPENSING: TRANSFORMING THE QUALITY OF CARE

ith the continuous innovation of cancer treatment, including the rise of new oral oncolytics and intricacies of IV, oral, and combination regimens, incorporation of MID within a multidisciplinary team is the framework for transforming the quality of care cancer patients receive. The MID and multidisciplinary staff has unparalleled access to patient information and methods to engage in enhanced communication with other members of the team. The pharmacy team also has direct access to communication with patients and can easily report information back to the

providers. This model greatly reduces fragmentation of care.

Tennessee Cancer Specialists Registered Nurse Cassy Moses sees the value in MID and shares, "the most beneficial aspect of an MID is less delays in fulfillment times for patients. They are able to start treatment sooner." From the same practice, Leah Wilson, CPhT shares her insight on MID and mentions, "having pharmacy onsite makes communication easier. We can always just walk down the hall to the physicians' offices to ask them any questions. This is much faster than trying to get in contact with offices outside of the facility or even across the country."

Utah Cancer Specialists Clinical Pharmacist, Colby Hancock, PharmD, has similar words to share regarding MID. He mentions that the pharmacy team has the, "ability and expertise to help patients on a local level to navigate their medication needs." He also states that, "providers benefit with the confidence knowing that patients' medications will be dispensed quickly and on time. We have a direct communication link that an outside pharmacy would not have." From the same practice, Jaime LeVieux, CPhT, shares positive words regarding MID and states, "pharmacy and providers are all within the same vicinity, so we are really able to help patients. If there are treatment changes, it's easier to take care of these changes since we are all in the same clinic."



prescription for a patient with excellence.

### **PUTTING THE TAZEMETOSTAT (TAZVERIK®) MANAGEMENT IN RELAPSED/REFRACTORY** FOLLICULAR LYMPHOMA PQI INTO ACTION

he first two sections of Tazemetostat (TAZVERIK®) Management in Relapsed/Refractory Follicular Lymphoma PQI are the Description and Background. The Description provides an overview of this PQI, which is to discuss the initiation and management of tazemetostat in the treatment of R/R FL. The Background focuses on the mechanism of action for tazemetostat, clinical trial data, and genetic testing information. The tazemetostat clinical trial data showed that the majority of patients treated with tazemetostat tolerated the medication well. Hancock shares similar experiences with patients on tazemetostat at his practice. He mentions, "for one of our relapsed FL patients, the tazemetostat experience has been positive. There weren't many adverse events which prevented the patient from continuing to take tazemetostat. The pharmacy team was able to get tazemetostat covered and had a payment in place easily. It's a routine process for this patient and the patient has done really well on this medication."

Pratt shares her knowledge of the clinical trial data and mentions, "98% of patients with the EZH2 mutation had tumor reduction. 65% of patients with wild-type EZH2 also demonstrated a reduction. This is huge. Whether or not they had the mutation, tazemetostat was beneficial for the patient. In a

space where there have been some drugs for which the FDA has taken their indication away, it's very exciting to see tazemetostat's benefits." Regarding genetic testing, the PQI mentions that for R/R FL, mutation status was determined in the clinical trial using an FDA-approved test, cobas® EZH2 mutation test, to detect: Y646X [S,H,C], y646F, Y646N, A682G, and A692V.

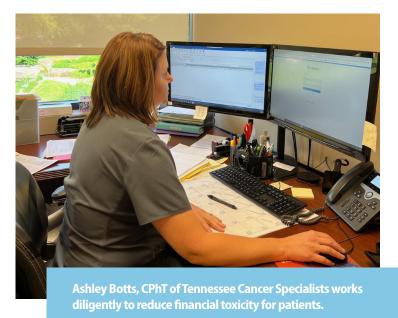
"FOR ONE OF OUR RELAPSED FL PATIENTS, THE TAZEMETOSTAT EXPERIENCE HAS BEEN **POSITIVE. THERE WEREN'T MANY ADVERSE EVENTS WHICH PREVENTED THE PATIENT** FROM CONTINUING TO TAKE TAZEMETO-STAT. THE PHARMACY TEAM WAS ABLE TO **GET TAZEMETOSTAT COVERED AND HAD A PAYMENT IN PLACE EASILY."** 

Colby Hancock, PharmD

#### THE PQI PROCESS

ollowing the background, the next section of the Tazemetostat (TAZVERIK®) Management in Relapsed/Refractory Follicular Lymphoma PQI is the PQI Process. The first step in the PQI Process involves confirming acceptable diagnosis and associated indication. More specifically, it states that EZH2 testing is not required by most payers when tazemetostat is the most satisfactory option and provides hyperlinks to FDA approved testing available as well as the EZH2NOW Testing Program (offers national single gene testing for EZH2). For patients who have received two systemic therapies, the PQI recommends to consider EZH2 testing and if they are positive, the patient would be eligible for tazemetostat. This recommendation is well observed with what Utah Cancer Specialists Medical Oncologist, Richard Frame, MD, did for one of his patients who had a recurrence of FL. Dr. Frame mentions, "at the time of this patient's recurrence, I had decided to do EZH2 testing, for which the patient was positive." He emphasized, "the positive EZH2 status influenced my decision to start tazemetostat. This was one of those aha moments. I decided to give it a try and so far, we have had very favorable outcomes."

The next steps in the PQI Process mention the starting dose for tazemetostat and then dose modifications for adverse reactions. Pratt discusses, "at our practice, all patients on TAZVERIK® were started on 800 mg twice daily by mouth with or without food. There is a two-part follow up process we abide by. The nurse practitioners and pharmacists follow up on bloodwork. Then the pharmacy team reviews side effects during treatment and maintains communication with the physician." More specifically regarding adverse reactions and dose modifications, Pratt shares, "none of our patients have had to be dose reduced. I can say that from a safety and side effect profile, tazemetostat has been very good for our patients." She comments that there has been experiences with diarrhea, nausea, and increases in serum glucose, however, none of these have led to discontinuation of tazemetostat. Furthermore, Pratt emphasizes that the Tazemetostat (TAZVERIK®) Management in Relapsed/Refractory Follicular Lymphoma PQI is a very useful tool when it involves dosing considerations and mentions, "thanks to the PQI, we know when we have to hold tazemetostat. As we review each patient, I pull the PQI and have it by my deskside so that, if there is something I need to address with the physician, it's right there."



Dr. Dobbs more specifically discusses dose reduction protocols he follows. For various cytopenias he mentions, "We will hold treatment until the patient returns to baseline and resume at the same or reduced dose. Cytopenias are dose reduced differently and for most, there will be reduced doses or the patient will be discontinued on tazemetostat after the 3rd occurrence." Similar to what is stated in the POI Process section, Dr. Dobbs mentions that, "for grade 3 and 4 side effects, we withhold tazemetostat until the patient returns to baseline and resume with a dose reduction." From Utah Cancer Specialists, Dr. Frame shares, "when we have toxicities from cytopenias, we know to reduce the dose of tazemetostat. However, we had no issues with cytopenias or side effects so far and have been pleasantly surprised with tazemetostat. Currently, there are no plans to stop this medication for our patient and we plan to continue it until the patient develops toxicity or disease progression."

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Dr. Richard Frame, MD

# PATIENT-CENTERED ACTIVITIES: KEEPING THE FOCUS ON PATIENTS

he Patient-Centered Activities section follows the PQI Process and gives patient-centered guidance for the team. Within this section of the PQI, there is an

emphasis in providing patients with the NCODA Oral Chemotherapy Education (OCE) sheet for tazemetostat and counseling on potential drug interactions. Following this, the PQI directs clinicians to counsel patients on common side



effects and utilize the NCODA Financial Assistance Tool to seek patient assistance if necessary.

Both Tennessee Cancer Specialists and Utah Cancer Specialists play a significant role in maintaining care that is patient-focused. Hancock from Utah Cancer Specialists finds great value in OCE sheets and emphasizes, "the OCE sheets give me a good framework and flow to go through. Patients are so anxious to hear about side effects and these sheets help me start with administration and storage and then move into side effects at the end. They help me frame a path to speak to a patient about a new start medication." Moses from Tennessee Cancer Specialists is heavily involved with patient education. She typically begins educating patients about the disease state followed by the specific drugs they are on. For tazemetostat and other drugs, she mentions, "I try to educate patients on things they may not be aware of. For example, whether their treatment is for a curative response, a palliative treatment, and how long the patient is going to be on the drug. Then I mention when they may have to stop taking the drug, such as in the case that they are not tolerating it well or they have disease progression. After that, we talk about the drug, how to take it, things to avoid, such as St. John's wort and grapefruit juice with tazemetostat." More specific to the way Moses provides this education, she explains, "personally, I like the 'teach-back' method because I want to make sure patients understand the disease state and the drug. I want them to teach me what the physician explained to them, what issues to watch out for with the drug, and when or how they will report issues to our office."

In regards to patient monitoring, Pratt mentions, "with each visit for patients on tazemetostat, we do a CBC, CMP, and review ANC, RBC, WBC, and platelets to assess for any cytopenias the patients may be experiencing. The nurse prac-

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titioner monitors this during their follow up with the patient and, as pharmacists, we follow up on this as well." Furthermore, both Dr. Frame from Utah Cancer Specialists and Dr. Dobbs from Tennessee Cancer Specialists share similar monitoring patterns. They both mention once a month check on CBC and CMP for patients on tazemetostat to assess blood counts and cytopenias. LeVieux from Utah Cancer Specialists mentions, "I am actively involved with following up with patients and checking for their refills, including patients on tazemetostat. From pharmacy, we hand out the OCEs to all new patients or if they ask for it when they are getting a refill. We also provide the NCODA treatment support kits for the medications they are available for."

#### **TAZEMETOSTAT PQI PATIENT EDUCATION ACTIVITIES**

- Provide <u>Oral Chemotherapy Education (OCE) sheet</u> and counsel patient on potential drug interactions
- Counsel patient on common side effects including pain, fatigue, nausea, decreased appetite, vomiting, and constipation
- Patient Assistance: NCODA Financial Assistance Tool

## FINANCIAL ASSISTANCE - ADDITIONAL PATIENT-CENTERED CARE

hanks to the advancement of treatment and maintenance for cancer patients, aging and growing U.S. population, and progression in effective screening/early detection, the prevalence of cancer survivorship is increasing. However, this also means that the medical costs associated with cancer is increasing. Moreover, the cost of cancer care continues to rise and is expected to reach almost \$240 billion by 2030. Specifically for NHL, costs associated with medical services are expected to increase by 45% by the year 2030 and the costs associated with oral prescriptions are expected to increase by 49% by the year 2030.8 Practitioners from Utah Cancer Specialists and Tennessee Cancer Specialists share insight on how patients are able to obtain financial assistance and guidance for their care.

Tennessee Cancer Specialists Pharmacy Technician Ashley Botts, CPhT shares her leadership in helping patients on tazemetostat avoid financial toxicities. She shares, "for one patient, I went through the manufacturer and obtained free drug assistance. For another patient, I was able to obtain a foundation grant to help pay their copay. Both patients obtained tazemetostat and were able to begin therapy quickly." Even during her educational sessions, Moses has financial considerations for the patient in mind. She shares, "you discover a lot of things during educational sessions, such as barriers to adherence. These barriers are always brought up in the sessions and we take the necessary steps to involve financial assistance or someone who assists with transportation when

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needed." Hancock from Utah Cancer Specialists speaks about their dedication to making sure patients are able to get their hands on their needed medications. He shares, "we have four pharmacy technicians who work at a patient advocate level, assisting with financial aid. There are technicians who work specifically on formulary changes and health insurance to obtain medication coverage. We also have a technician who oversees all prior authorizations and helps patients apply for grants."

"Providing patients with resources to help them acheive increased access to care can make a significant impact in their cancer journey and outcomes. NCODA provides valuable resources to ease financial burdens and help

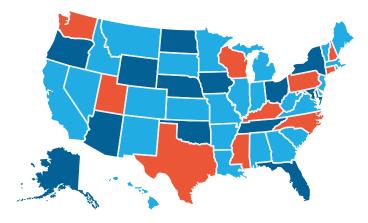
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NCODA'S ONCOLOGY

STATE LEGISLATION

TRACKER

avoid financial toxicities. Through NCODA's Financial Assistance Tool, upon searching for tazemetostat, patients will have access to links to the commercial co-pay card and patient assistance program websites. Regarding co-pay assistance, different states may have different laws which impact access and costs associated with medications. NCODA's Oncology State Legislation Tracker provides state specific summaries on laws and legislation relating to insurer application of co-pay assistance towards patients' cost-sharing requirements as well as pharmacy benefit manager reform. Both tools help health-care professionals and patients become more knowledgeable on potential barriers to care, which can then increase access to care.



CLICK LINK HERE TO VIEW NCODA'S
ONCOLOGY STATE LEGISLATION TRACKER

Cassy Moses, RN

# CONCLUSION: ALWAYS COLLABORATIVE - NCODA, THE MID, AND PQI

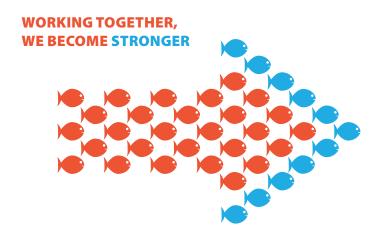
eam members from Utah Cancer Specialists and Tennessee Cancer Specialists agree that the MID model and the PQI Clinical Resource are valuable to their team as well as the patients they provide care to. Multidisciplinary teams, through collaboration within a MID model, are transforming the lives of patients and elevating quality care.

LeVieux from Utah Cancer Specialists speaks about her dedication to making sure patients are able to obtain their medication. She shares, "when patients need copay assistance for their medications, we initiate the conversation with them to obtain all of the necessary information." From the same practice, Hancock emphasizes collaboration with pharmacy and providers. He mentions, "having an integrated pharmacy onsite lifts the level of care patients receive. We help to monitor medication adherence and serve as a direct link to the doctor if there are issues with adherence or adverse events." Similarly, from Tennessee Cancer Specialists, Pratt highlights her collaboration with providers and shares, "several older drugs lost their indication for R/R FL, so as part of our

clinical pharmacy process, we are reviewing patients who were on those drugs and assessing their current status. If I see the need, I will send a recommendation to the provider to change them to tazemetostat. Currently, tazemetostat is our drug of choice for R/R FL."

By utilizing the PQI, MID teams can continually innovate and deliver quality care to their patients. The PQI fosters this through appropriate patient identification, selection, up-to-date dosing recommendations and adjustments, increased speed to therapy, reduced cost and hospitalizations, and by improving adherence techniques for the patient and Medically Integrated Teams. Pairing Medically Integrated Dispensing with the Tazemetostat (TAZVERIK®) Management in Relapsed/Refractory Follicular Lymphoma PQI meets NCODA's Guiding Values of being Patient-Centered and Always Collaborative.

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ADHERENCE OR ADVERSE EVENTS."



#### ON THE COVER:

• Pharmacy is integral to promote continuity of care within medically integrated dispensing practices. Photo courtsey of Tennessee Cancer Specialists.

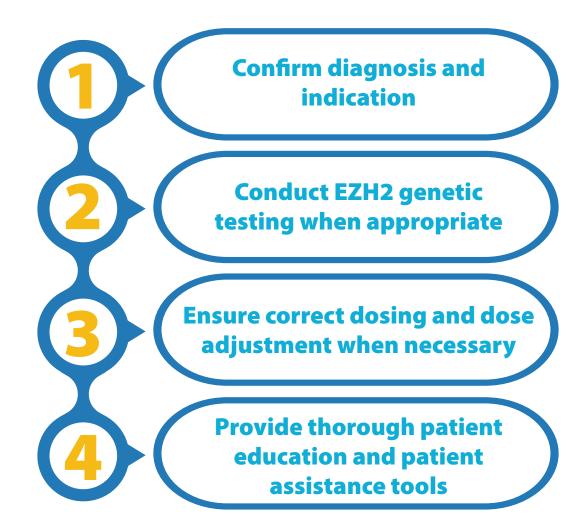
Colby Hancock, PharmD

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### **PQI PRINCIPLES:**





#### **Helpful Online Resources**

- Tazemetostat (TAZVERIK®) Management in Relapsed/Refractory Follicular Lymphoma PQI
- Positive Quality Interventions
- Tazemetostat Oral Chemotherapy
  Education Sheet
- Oral Chemotherapy Education Sheets
- NCODA Website
- NCODA Financial Assistance Tool
- NCODA Oncology State Legislation Tracker

Practice panelist's comments reflect their experiences and opinions and should not be used as a substitute for medical judgement.

Important notice: NCODA has developed this Positive Quality Intervention in Action platform. This platform represents a brief summary of medication uses and therapy options derived from information provided by the drug manufacturer and other resources. This platform is intended as an educational aid and does not provide individual medical advice and does not substitute for the advice of a qualified healthcare professional. This platform does not cover all existing information related to the possible uses, directions, doses, precautions, warning, interactions, adverse effects, or risks associated with the medication discussed in the platform and is not intended as a substitute for the advice of a qualified healthcare professional. The materials contained in this platform are for informational purposes only and do not constitute or imply endorsement, recommendation, or favoring of this medication by NCODA, which assumes no liability for and does not ensure the accuracy of the information presented. NCODA does not make any representations with respect to the medications whatsoever, and any and all decisions, with respect to such medications, are at the sole risk of the individual consuming the medication. All decisions related to taking this medication should be made with the guidance and under the direction of a qualified healthcare professional.



