From Framework to Practice:
PQIs in Action and NCODA Resources

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Medically Integrated Pharmacy (MIP): Enhancing Cancer Care Delivery

A patient-centered, multidisciplinary approach within oncology centers of excellence.

Definition
A dispensing pharmacy situated within an oncology center of excellence, fostering a patient-centered, multidisciplinary team approach.

Key Benefits
Provides seamless coordination, personalized patient support, improved treatment outcomes (adherence, and affordability), and timely access to oral anti-cancer medications.

NCODA's Pillars of MIP
Includes abandonment, adherence, access & affordability, time to fill, education, satisfaction, and cost avoidance.

MIPs streamline processes and provide proactive interventions, ensuring patients stay on track with treatment, minimizing financial burdens, and achieving better overall care.

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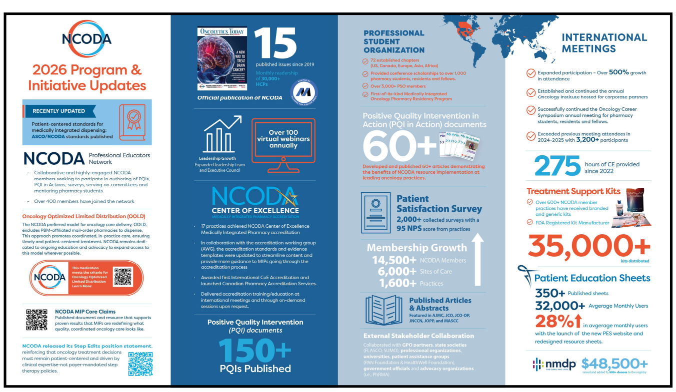

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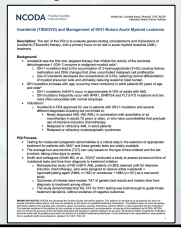
What is a PQI?

- Positive Quality Intervention (PQI): a peer-reviewed clinical guidance resource



Content

- Clinical guidance document which provides concise, precise, and step by step guidance on:
  - Oral and IV oncolytic therapies
  - Supportive care
  - Disease state management

Sections

- Description
- Background
- PQI Process
- Patient-Centered Activities

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PQI Description and Background

NCODA Positive Quality Interventions

Written By: Laonetta Kemp, PharmD, CPE, BCOP
Institution: Miami Cancer Institute

Ivosidenib (TIBSOVO) and Management of IDH1 Mutant Acute Myeloid Leukemia

Description: The aim of this PQI is to evaluate genetic testing considerations and implications of Ivosidenib (Tibsovo®) therapy, with a primary focus on its role in acute myeloid leukemia (AML) treatment.

Background:

- Ivosidenib was the first oral, targeted therapy that inhibits the activity of the isocitrate dehydrogenase-1 (IDH-1) enzyme in malignant myeloid cells[1]
  - IDH-1 mutations lead to the accumulation of 2 hydroxyglutarate (2-HG) causing histone methylation and DNA changes that drive uncontrolled malignant cell proliferation
  - Use of ivosidenib decreases the concentration of 2-HG, restoring normal differentiation of myeloid precursor cells and ultimately reducing leukemic blast burden
- IDH mutations increase with age, occurring more commonly in adult patients 60 years of age and older[2]
  - IDH-1 mutations (mIDH1) occur in approximately 6-16% of adults with AML
  - IDH mutations frequently occur with NPM1, DNMT3A and FLT3-ITD mutations and are more often associated with normal karyotype
- Indications[1]
  - Ivosidenib is FDA approved for use in patients with IDH-1 mutations and several different diagnoses including but not limited to:
    - Newly diagnosed AML (ND AML) in combination with azacitidine or as monotherapy in adults 75 years or older, or who have comorbidities that preclude use of intensive induction chemotherapy
    - Relapsed or refractory AML in adult patients
    - Relapsed or refractory myelodysplastic syndromes

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PQI Process

PQI Process:

- Testing for molecular/cytogenetic abnormalities is a critical step in the selection of appropriate treatment for patients with AML[5] and these genetic tests are widely available
- The average turn-around-time (TAT) can vary based on the type of test ordered and the lab involved, taking a few days to weeks
- Smith and colleagues (Smith BD, et al., 2024)[3] conducted a study to assess turnaround time of mutational tests and time from diagnosis to treatment initiation
  - Retrospective study of ND mIDH1 AML patients (n=283) deemed unfit for intensive induction chemotherapy, who were assigned to receive either ivosidenib + hypomethylating agent (HMA; n=182) or venetoclax + HMA (n=101) as a real-world study
  - Outcomes of interest were median TAT of genetic test results and median time from diagnosis to treatment among others
  - The study demonstrated that the TAT for IDH1 testing was brief enough to guide timely treatment decisions, without evidence of negative outcomes

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- Median TAT from IDH1 test to results was 7 days in both cohorts, with an interquartile range of 6 – 14 days in the entire patient population
- Median time from IDH1 test result to treatment initiation was 1 day for ivosidenib and 4 days for venetoclax
- Median time from diagnosis to treatment was 14 days for ivosidenib and 20 days for venetoclax (P=0.032)
- 66% of patients received test results within less than 11 days, allowing for earlier start of appropriate treatment

  - Over two-thirds (66%) of patients with ND AML (unfit for intensive therapy) received mutational test results well within the common timeframe from diagnosis to treatment initiation.

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PQI Process

- Improved efficacy and disease response have been demonstrated when patients with mIDH1 AML are treated with IDH1 targeted therapy
  - AGILE was the pivotal phase 3 study that lead to the approval of ivosidenib in combination with azacitidine (AZA) for ND AML with mIDH1 – long-term data now available (median follow-up of 28.6 months)[4]
    - Ivosidenib + AZA (n = 73) vs placebo + AZA (n = 75)
    - Median OS was significantly longer with ivosidenib (29.3 months; 95% CI 13.2, not reached) than with placebo (7.9 months; 95% CI 4.1, 11.3; hazard ratio 0.42 [0.27, 0.65]; p<.0001)
    - Median time to complete remission was 4.3 months with ivosidenib + azacitidine versus 3.8 months with placebo + azacitidine
    - 53.4% of patients were red blood cell and/or platelet transfusion dependent in the ivosidenib + AZA arm and 54.7% in the placebo + AZA arm. A greater proportion of these patients became transfusion independent during treatment with ivosidenib-AZA (21/39, 53.8%) vs placebo-AZA (7/41, 17.1%; one-sided p=.0004)
  - Data for triplet therapy with IDH-targeted agent + venetoclax (VEN) + AZA has also demonstrated efficacy but has not yet been verified in a randomized control trial [5]
    - DiNardo and colleagues studied triplet regimens for ND mIDH1 AML
    - 60 patients received either ivosidenib + AZA + VEN (IDH1-mutated patients only) or oral decitabine + VEN + ivosidenib/enasidenib (arms for IDH1- and IDH2-mutant disease, respectively)
    - The composite complete remission rate (CRc) was 92% (55/60), with an overall response rate of 95% (57/60)
    - Median overall survival (OS) has not yet been reached with a median follow-up of 27.4 months
    - 2-year OS was 69% with a 2-year cumulative incidence of relapse of 24%

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Patient-Centered Activities

Patient-Centered Activities:

- Communicate with patient regarding need for testing to identify any possible genetic mutations and what implications that could have for treatment
- Advise patient that it can take several days for genetic tests to result, but this has not been shown to negatively impact treatment efficacy or outcomes
- If patient is a candidate for ivosidenib therapy:
  - Provide them with ivosidenib Patient Education Sheet
  - Review symptoms of differentiation syndrome and when they should contact the care team and/or report for evaluation
  - Patient support materials available via ServierONE Patient Support Services

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The PQI in Action

- Explores how medically integrated oncology teams at practice sites incorporate PQI in their clinics
- Emphasizes the significance of a collaborative, team-based approach to cancer care
- Walks through the PQI and demonstrates best practices

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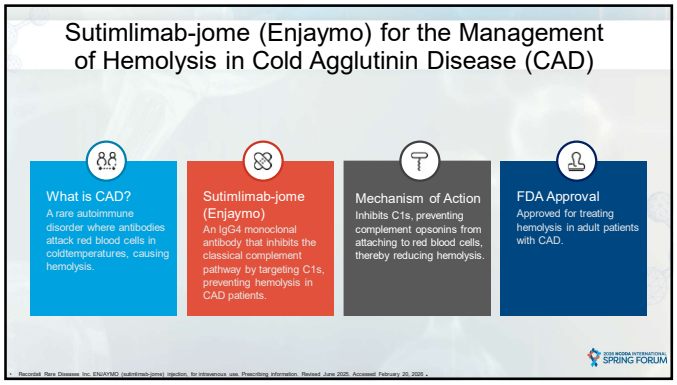
Sutimlimab-jome (Enjaymo) for the Management of Hemolysis in Cold Agglutinin Disease (CAD)
What is CAD?
A rare autoimmune disorder where antibodies attack red blood cells in coldtemperatures, causing hemolysis.
Sutimlimab-jome (Enjaymo)
An IgG4 monoclonal antibody that inhibits the classical complement pathway by targeting C1s, preventing hemolysis in CAD patients.
Mechanism of Action
Inhibits C1s, preventing complement opsonins from attaching to red blood cells, thereby reducing hemolysis.
FDA Approval
Approved for treating hemolysis in adult patients with CAD.
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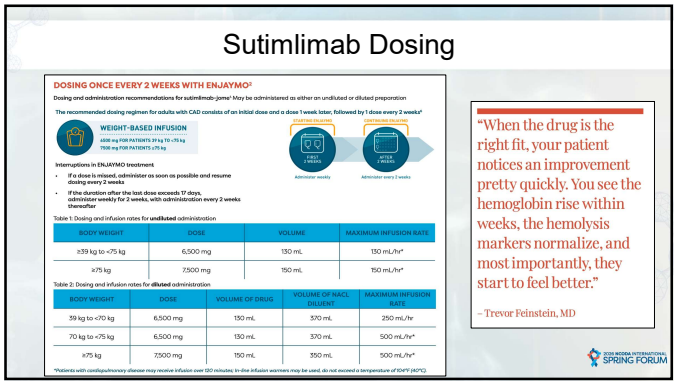
Sutimlimab Dosing
DOSING ONCE EVERY 2 WEEKS WITH ENJAYMO®
Dosing and administration recommendations for sutimlimab-jome1 May be administered as either an undiluted or diluted preparation
The recommended dosing regimen for adults with CAD consists of an initial dose and a dose 1 week later, followed by 1 dose every 2 weeks*
WEIGHT-BASED INFUSION
6500 mg FOR PATIENTS 39 kg TO <75 kg
7500 mg FOR PATIENTS ≥75 kg
STARTING DOSING
CONTINUING DOSING
FIRST 2 WEEKS
AFTER 2 WEEKS
Administer weekly
Administer every 2 weeks
Interruptions in ENJAYMO treatment
If a dose is missed, administer as soon as possible and resume dosing every 2 weeks
If the duration after the last dose exceeds 17 days, administer weekly for 2 weeks, with administration every 2 weeks thereafter
Table 1: Dosing and infusion rates for undiluted administration
BODY WEIGHT
DOSE
VOLUME
MAXIMUM INFUSION RATE
≥39 kg to <75 kg
6,500 mg
130 mL
150 mL/hr*
≥75 kg
7,500 mg
150 mL
150 mL/hr*
Table 2: Dosing and infusion rates for diluted administration
BODY WEIGHT
DOSE
VOLUME OF DRUG
VOLUME OF NACL DILUENT
MAXIMUM INFUSION RATE
39 kg to <70 kg
6,500 mg
130 mL
370 mL
250 mL/hr
70 kg to <75 kg
6,500 mg
130 mL
370 mL
500 mL/hr*
≥75 kg
7,500 mg
150 mL
350 mL
500 mL/hr*
*Patients with cardiopulmonary disease may receive infusion over 120 minutes; in-line infusion warmers may be used; do not exceed a temperature of 104°F (40°C)
"When the drug is the right fit, your patient notices an improvement pretty quickly. You see the hemoglobin rise within weeks, the hemolysis markers normalize, and most importantly, they start to feel better."
– Trevor Feinstein, MD
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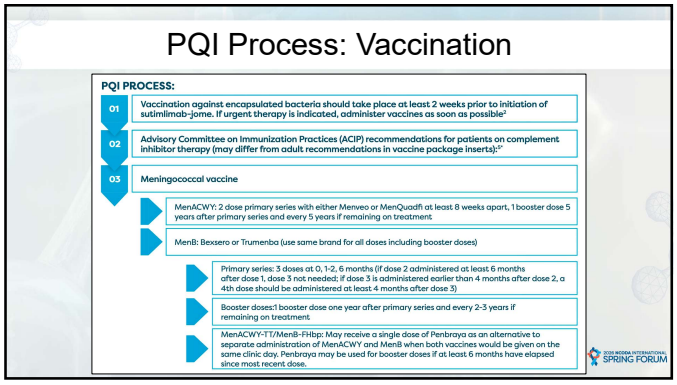
PQI Process: Vaccination
PQI PROCESS:
01
Vaccination against encapsulated bacteria should take place at least 2 weeks prior to initiation of sutimlimab-jome. If urgent therapy is indicated, administer vaccines as soon as possible2
02
Advisory Committee on Immunization Practices (ACIP) recommendations for patients on complement inhibitor therapy (may differ from adult recommendations in vaccine package inserts):2*
03
Meningococcal vaccine
MenACWY: 2 dose primary series with either Menveo or MenQuadfi at least 8 weeks apart, 1 booster dose 5 years after primary series and every 5 years if remaining on treatment
MenB: Bexsero or Trumenba (use same brand for all doses including booster doses)
Primary series: 3 doses at 0, 1-2, 6 months (if dose 2 administered at least 6 months after dose 1, dose 3 not needed; if dose 3 is administered earlier than 4 months after dose 2, a 4th dose should be administered at least 4 months after dose 3)
Booster doses:1 booster dose one year after primary series and every 2-3 years if remaining on treatment
MenACWY-TT/MenB-FHbp: May receive a single dose of Penbraya as an alternative to separate administration of MenACWY and MenB when both vaccines would be given on the same clinic day. Penbraya may be used for booster doses if at least 6 months have elapsed since most recent dose.
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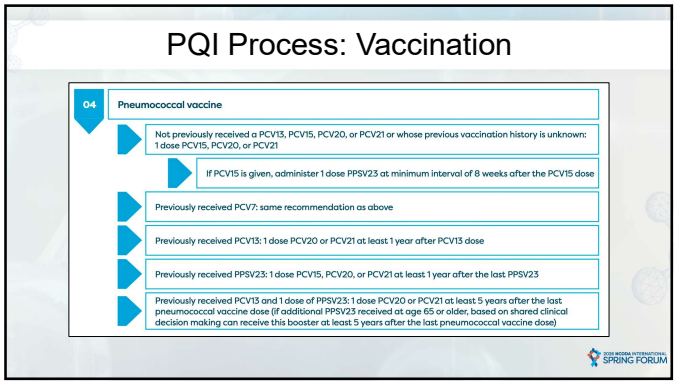
PQI Process: Vaccination
04
Pneumococcal vaccine
Not previously received a PCV13, PCV15, PCV20, or PCV21 or whose previous vaccination history is unknown: 1 dose PCV15, PCV20, or PCV21
If PCV15 is given, administer 1 dose PPSV23 at minimum interval of 8 weeks after the PCV15 dose
Previously received PCV7: same recommendation as above
Previously received PCV13: 1 dose PCV20 or PCV21 at least 1 year after PCV13 dose
Previously received PPSV23: 1 dose PCV15, PCV20, or PCV21 at least 1 year after the last PPSV23
Previously received PCV13 and 1 dose of PPSV23: 1 dose PCV20 or PCV21 at least 5 years after the last pneumococcal vaccine dose (if additional PPSV23 received at age 65 or older, based on shared clinical decision making can receive this booster at least 5 years after the last pneumococcal vaccine dose)
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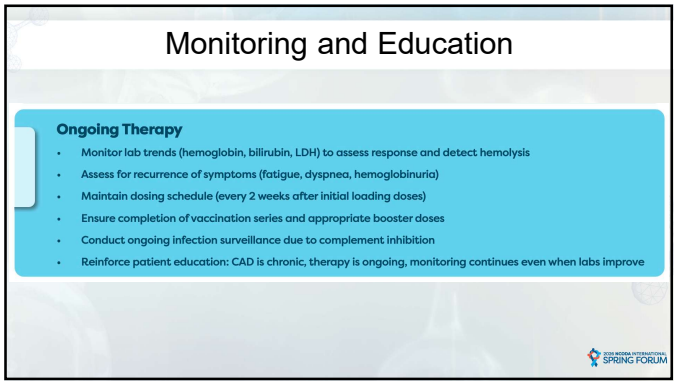
Monitoring and Education
Ongoing Therapy
Monitor lab trends (hemoglobin, bilirubin, LDH) to assess response and detect hemolysis
Assess for recurrence of symptoms (fatigue, dyspnea, hemoglobinuria)
Maintain dosing schedule (every 2 weeks after initial loading doses)
Ensure completion of vaccination series and appropriate booster doses
Conduct ongoing infection surveillance due to complement inhibition
Reinforce patient education: CAD is chronic, therapy is ongoing, monitoring continues even when labs improve
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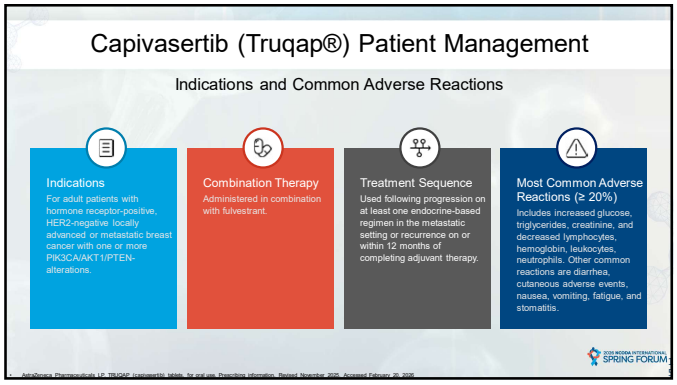
Capivasertib (Truqap®) Patient Management
Indications and Common Adverse Reactions
Indications
For adult patients with hormone receptor-positive, HER2-negative locally advanced or metastatic breast cancer with one or more PIK3CA/AKT1/PTEN-alterations.
Combination Therapy
Administered in combination with fulvestrant.
Treatment Sequence
Used following progression on at least one endocrine-based regimen in the metastatic setting or recurrence on or within 12 months of completing adjuvant therapy.
Most Common Adverse Reactions (≥ 20%)
Includes increased glucose, triglycerides, creatinine, and decreased lymphocytes, hemoglobin, leukocytes, neutrophils. Other common reactions are diarrhea, cutaneous adverse events, nausea, vomiting, fatigue, and stomatitis.
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Capivasertib Dosing

DOSING CONSIDERATIONS FOR CAPIVASERTIB[1]

Dosage form	Tablet, Oral – 160 mg, 200 mg Blister pack – 160 mg, 200 mg (each carton has 4 blister packs (64 tabs total) - each blister pack contains 16 tabs)
Usual starting dose	400 mg twice daily (~12 hours apart) for 4 consecutive days, followed by 3 days off (administer capivasertib on days 1 to 4 of each week); in combination with fulvestrant; continue until disease progression or unacceptable toxicity
Dose adjustments (renal/hepatic)	Capivasertib has not been studied in patients with severe hepatic or renal impairment
Dose reductions for toxicity	400 mg BID ❍ 320 mg BID ❍ 200 mg BID ❍ permanently discontinue if unable to tolerate the final dose reduction

1. AstraZeneca Pharmaceuticals LP. TRUQAP (capivasertib) tablets, for oral use. Prescribing information. Revised: November 2025. Accessed February 20, 2026.

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Hyperglycemia

"I have patients monitor their blood glucose early, particularly in the first cycle, and focus on a low carbohydrate, low sugar diet because hyperglycemia can emerge quickly."

— Joyce O'Shaughnessy, MD

HYPERGLYCEMIA MANAGEMENT WITH CAPIVASERTIB[1]

01 Baseline Risk Assessment
- Evaluate fasting blood glucose and HbA1C prior to initiation
- Identify high risk patients (prediabetes, elevated A1C, higher BMI)
- Optimize glycemic control before starting therapy
- Consider early involvement of endocrinology for higher risk patients

02 Early Monitoring (First Cycles = Highest Risk)
- Monitor FBG prior to treatment and frequently during weeks 1-8
- Encourage home glucose monitoring, especially early in therapy
- Focus on early onset, often within the first cycle
- Increase monitoring frequency if elevations occur

1. Iyengar NM, O'Shaughnessy JA, Moore HN, et al. Optimizing clinical monitoring and management guidelines for capivasertib in HR-positive/HER2-negative advanced breast cancer: expert opinion. *npj Breast Cancer*. 2025;11:25. doi:10.1038/s41523-025-00728-2.

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Hyperglycemia

03 Prevention and Patient Education
- Set expectations that hyperglycemia is an early and common toxicity
- Counsel on low carbohydrate, low sugar diet
- Reinforce when and how to check blood glucose at home
- Encourage early reporting of symptoms

04 Intervention and Management
- Initiate or escalate anti diabetic therapy (for example, metformin)
- Coordinate care with endocrinology when appropriate
- Adjust monitoring based on response
- Use a patient specific approach based on baseline risk and trends

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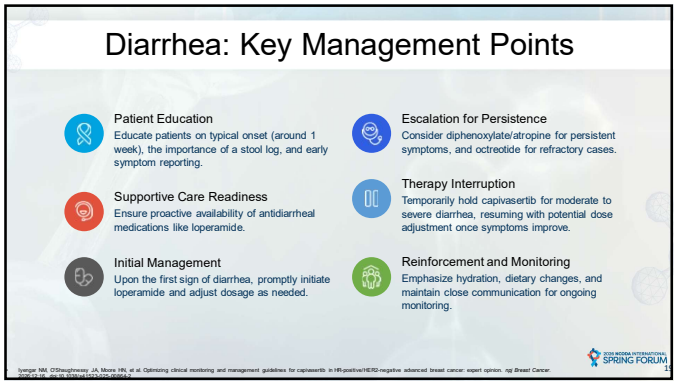
Diarrhea: Key Management Points
Patient Education
Educate patients on typical onset (around 1 week), the importance of a stool log, and early symptom reporting.
Supportive Care Readiness
Ensure proactive availability of antidiarrheal medications like loperamide.
Initial Management
Upon the first sign of diarrhea, promptly initiate loperamide and adjust dosage as needed.
Escalation for Persistence
Consider diphenoxylate/atropine for persistent symptoms, and octreotide for refractory cases.
Therapy Interruption
Temporarily hold capivasertib for moderate to severe diarrhea, resuming with potential dose adjustment once symptoms improve.
Reinforcement and Monitoring
Emphasize hydration, dietary changes, and maintain close communication for ongoing monitoring.
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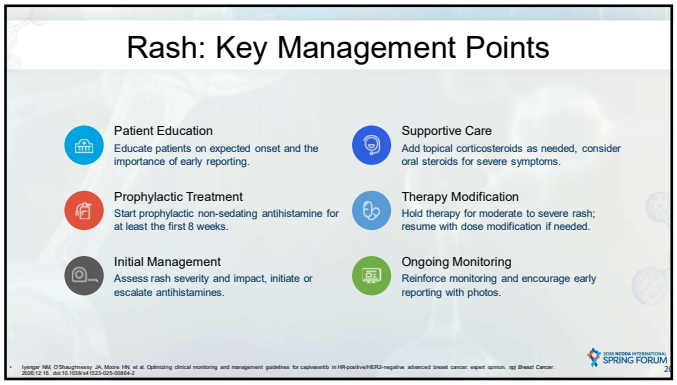
Rash: Key Management Points
Patient Education
Educate patients on expected onset and the importance of early reporting.
Prophylactic Treatment
Start prophylactic non-sedating antihistamine for at least the first 8 weeks.
Initial Management
Assess rash severity and impact, initiate or escalate antihistamines.
Supportive Care
Add topical corticosteroids as needed, consider oral steroids for severe symptoms.
Therapy Modification
Hold therapy for moderate to severe rash; resume with dose modification if needed.
Ongoing Monitoring
Reinforce monitoring and encourage early reporting with photos.
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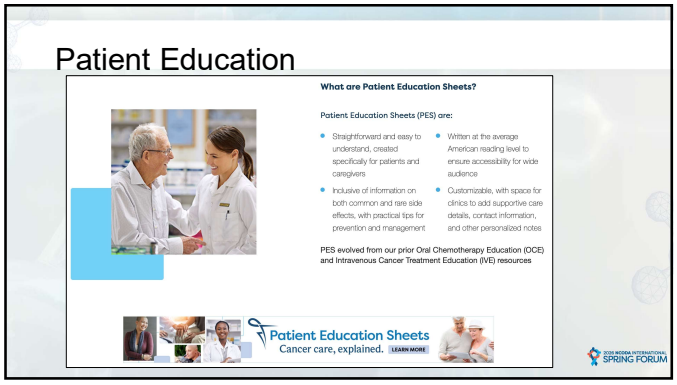
Patient Education
What are Patient Education Sheets?
Patient Education Sheets (PES) are:
Straightforward and easy to understand, created specifically for patients and caregivers
Written at the average American reading level to ensure accessibility for wide audience
Inclusive of information on both common and rare side effects, with practical tips for prevention and management
Customizable, with space for clinics to add supportive care details, contact information, and other personalized notes
PES evolved from our prior Oral Chemotherapy Education (OCE) and Intravenous Cancer Treatment Education (IVE) resources
Patient Education Sheets
Cancer care, explained.
LEARN MORE
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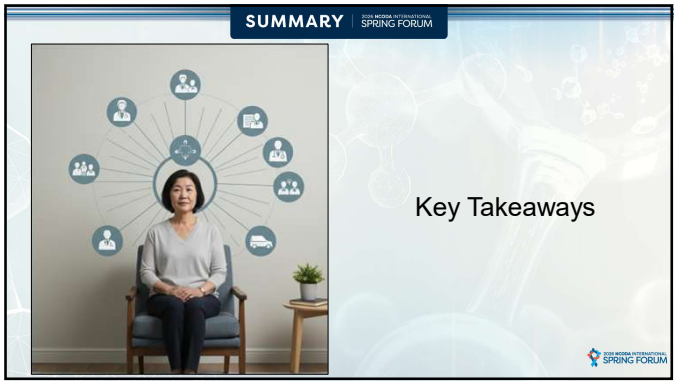
SUMMARY
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Key Takeaways

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PQI and PQIiA in Action Resources
Ivosidenib PQI
Sutimlimab PQIiA
Capivasertib PQI

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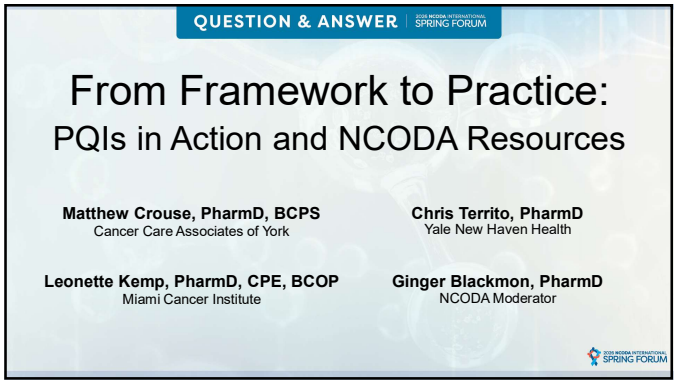
QUESTION & ANSWER
SPRING FORUM
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