CHAMPIONING MEDICALLY INTEGRATED ONCOLOGY:

Celebrating a Decade of Impact

2025 NCODA INTERNATIONAL FALL SUMMIT

NCODA PQI in Actions:
Practical Strategies to Transform Oncology Care

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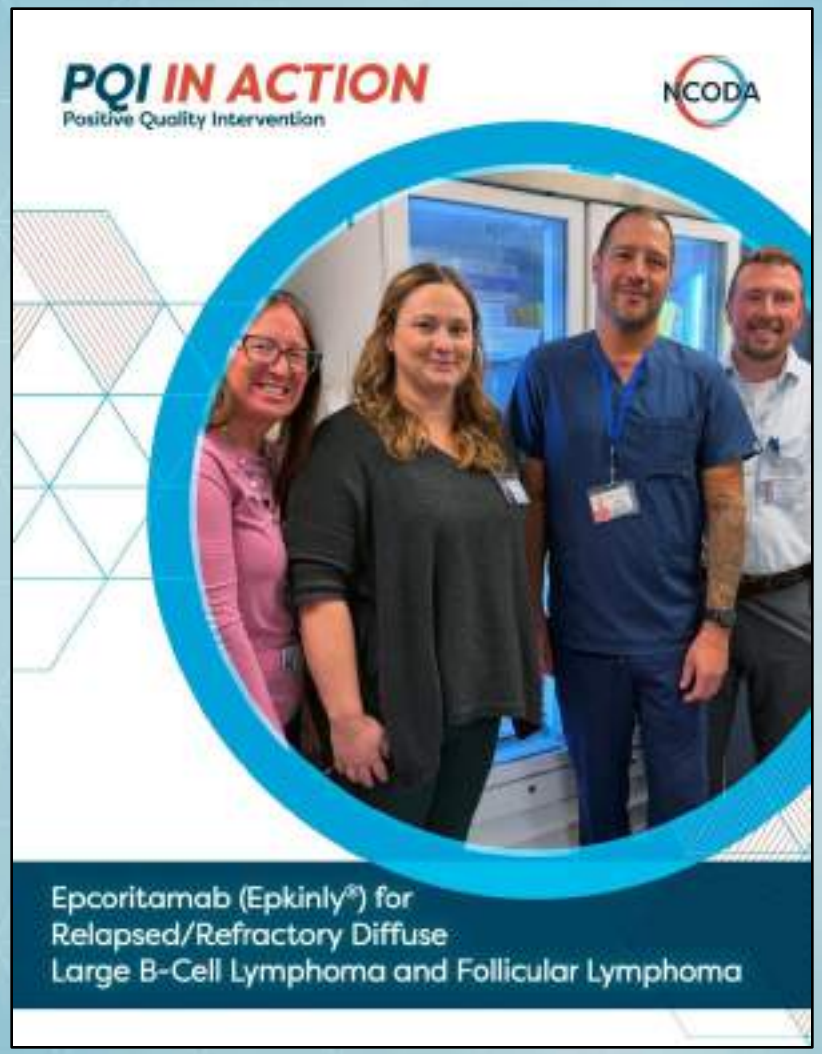
PQI in Action



What is a Positive Quality Intervention?

Written By: Tony Philip, MD
Northwell Health

Positive Quality Intervention: Nirogacestat (OGSIVEO®) use in Management of Adults with Progressing Desmoid Tumors (or fibromatosis or aggressive fibromatosis)

Description: This PQI will discuss the initiation and management of adult patients with desmoid tumors (DT) with nirogacestat (OGSIVEO®).

Background: Nirogacestat (OGSIVEO®) is an oral targeted gamma secretase inhibitor indicated for adult patients with progressing desmoid tumors who require systemic treatment.[1] Desmoid tumors are rare, non-cancerous, locally aggressive tumors. They may occur in any anatomical location, and, while affecting all ages, often occur in people 20-39 years old.[2,3] Inhibition of gamma secretase prevents activation of the notch receptor and downstream effects that may contribute to desmoid tumor growth. Nirogacestat is recommended by the National Comprehensive Cancer Network® (NCCN®) as a category 1, preferred systemic therapy option for patients with desmoid tumors (aggressive fibromatosis).[2]
The efficacy and safety of nirogacestat were demonstrated through enrollment in the DeFi study. DeFi was a phase 3 international, multicenter, double-blind, randomized (1:1), placebo-controlled trial of nirogacestat in 142 adults with progressing (≥20%) desmoid tumors (DT) per RECIST version 1.1 criteria within 12 months prior to treatment initiation. Patients were randomized to oral nirogacestat (150 mg) or placebo twice daily, taken continuously in 28-day cycles until disease progression or unacceptable toxicity. Nirogacestat demonstrated a statistically significant improvement in the primary endpoint, progression-free survival (PFS), with 71% reduction in the risk of disease progression compared to placebo (hazard ratio = 0.29 [95% CI: 0.15, 0.55]; P<0.001). The PFS benefit was shown across patients who received prior therapy with tyrosine kinase inhibitors or chemotherapy. In addition, nirogacestat resulted in a statistically significant improvement in the secondary endpoint of objective response rate (ORR; 41%, n=24 [95% CI, 29.8, 53.8] vs 8%, n=6, [95% CI, 3.1, 17.3], respectively; P<0.001). At Cycle 10, nirogacestat demonstrated statistically significant and clinically meaningful improvement in all prespecified assessments of patient-reported outcomes of pain, DT-specific symptom burden, physical functioning, role functioning (P<0.001), and overall quality of life (P<0.01).[4]
The most common (≥ 15%) adverse reactions experienced by patients who received nirogacestat were diarrhea, ovarian toxicity, rash, nausea, fatigue, stomatitis, headache, abdominal pain, cough, alopecia, upper respiratory tract infection, and dyspnea. Most (95%) adverse events were Grade 1 or 2 in patients treated with nirogacestat. Laboratory abnormalities (≥15%) that worsened from baseline in patients who received nirogacestat in DeFi were decreased phosphate, increased urine glucose, increased urine protein, increased AST, increased ALT, and decreased potassium. Overall, investigators identified ovarian toxicity events in 27 of 36 (75%) females of reproductive potential on nirogacestat, based on abnormal reproductive hormone levels and/or presence of peri-menopausal symptoms (e.g., changes in menstrual cycle regularity). However, investigators reported that ovarian toxicity resolved in 71% (10/14) while receiving nirogacestat and in 100% (11/11) after stopping nirogacestat for any reason (excluding 2 patients for whom follow-up data were not available).[1]

PQI Process: Upon receiving prescription for nirogacestat (OGSIVEO®)[1]

- Confirm diagnosis of a patient with progressing DT who requires systemic treatment
- Verify dose – the recommended dosage is 150 mg by mouth BID administered orally until disease progression or unacceptable toxicity
  - Available tablet strengths:
    - 100 mg (14-count blister pack)
    - 150 mg (14-count blister pack)
- Dose modifications for adverse reactions

IMPORTANT NOTICE: [illegible]

- Positive Quality Intervention (PQI): A precise and concise peer-reviewed clinical guidance resource
- Created by practitioners, for practitioners
- Standardize best practices in oral and IV oncology therapies
- Support consistent, patient-centered care across the team

Treatment Support Kits

What are Treatment Support Kits (TSKs)?

- Drug specific kits designed to support patients through their cancer therapy and help with common adverse events

Available TSKs

- Abemaciclib
  - (Loperamide and Non-Loperamide)
- Abiraterone Acetate
- Cabozantinib
- Capecitabine
- Fruquintinib
- Inavolisib
- Mirdametinib
- Neratinib
- Nirogacestat
- Pacritinib
- Tivozanib
- Temozolomide

Newly Released
Elranatamab-bcmm

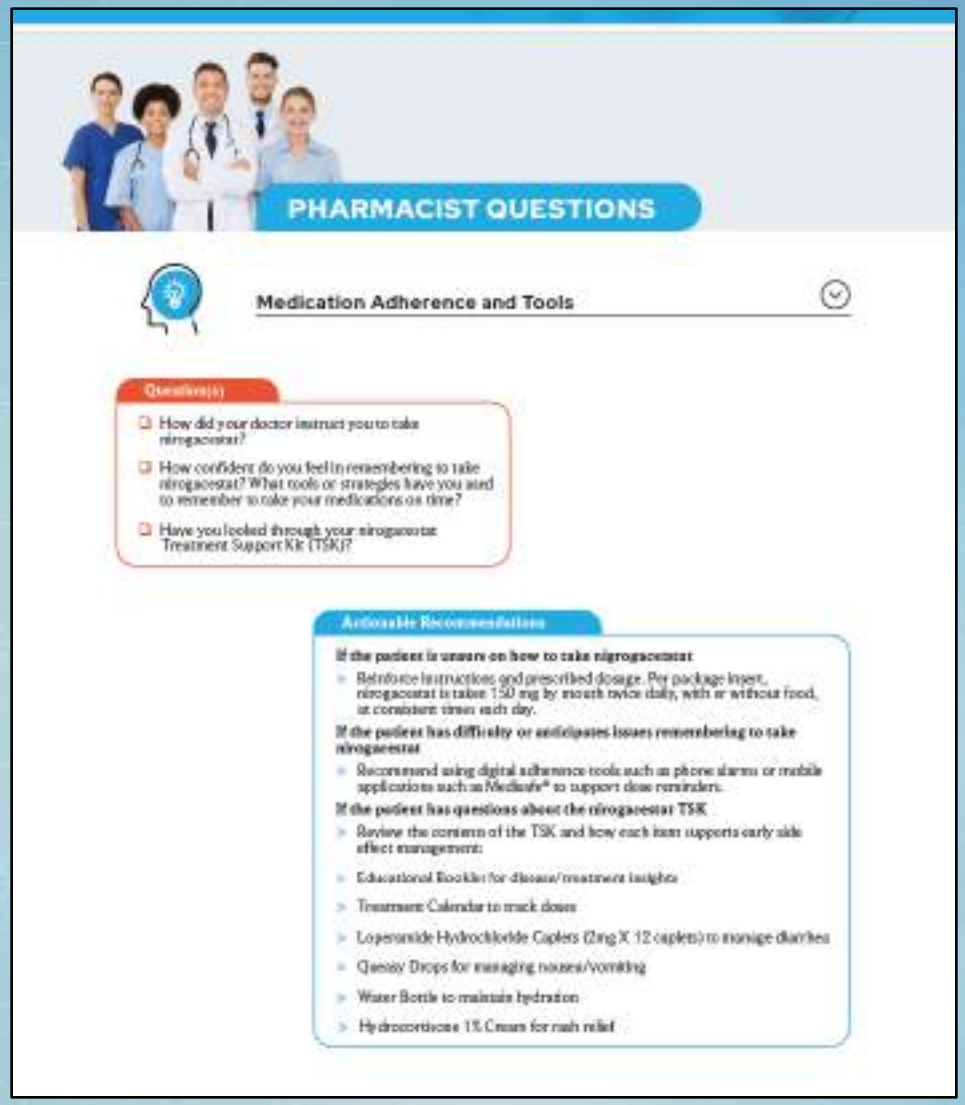
NCODA

Medically Integrated. Patient-Centered.

Treatment Discussion Guide

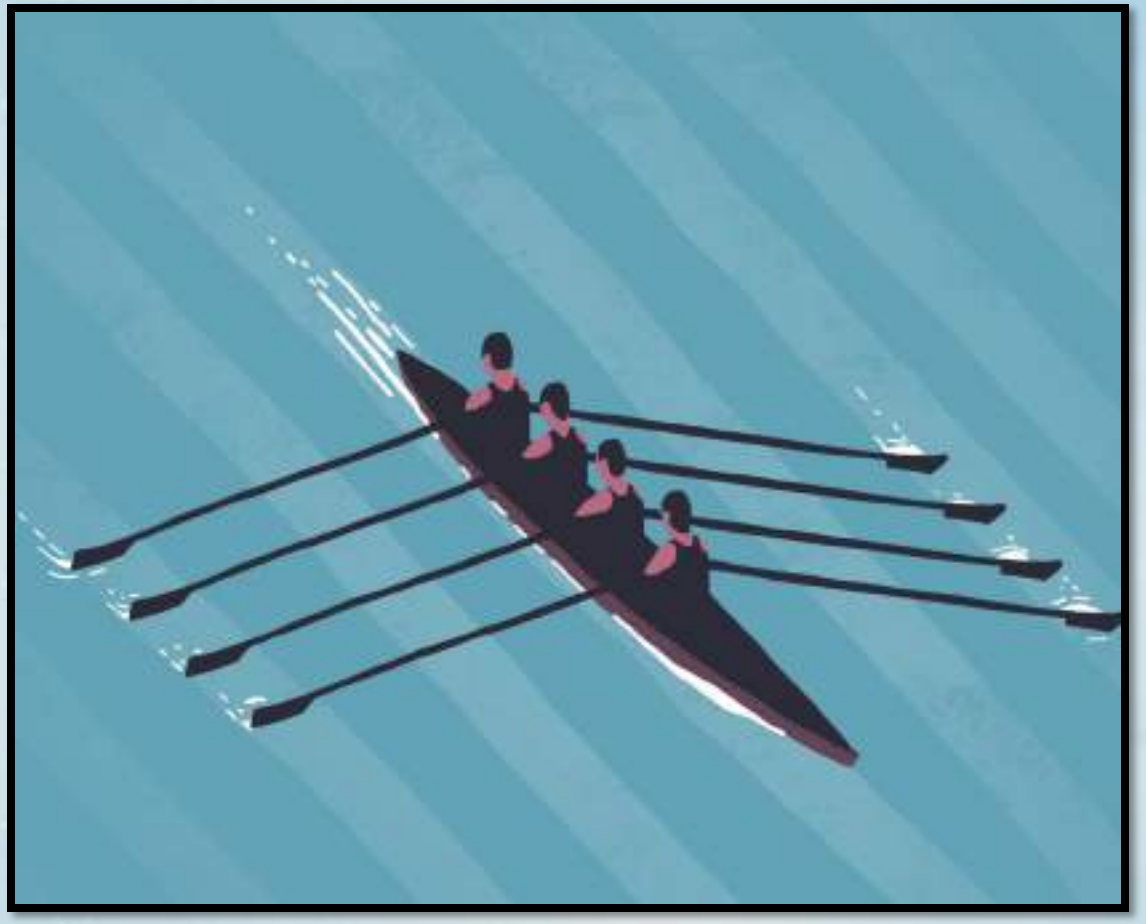
Key Features of the Guide Include:

- **Role-Specific Questions & Recommendations**
  Practical, thoughtful prompts that encourage open dialogue with patients—customized for each team role.
- **Actionable Patient Education Pearls**
  Guidance on topics like adherence, drug interactions, monitoring, financial support, and more.
- **Patient-Centered Approach**
  Every section is designed to support better understanding, emotional reassurance, and proactive care.



One Team, One Mission

- PQIs align physicians, APPs, pharmacists, nurses, and pharmacy technicians
- Improve communication and streamline workflows
- Support education and timely interventions



Ogsiveo® (Nirogacestat) in Action

- Oral targeted gamma secretase inhibitor indicated for adult patients with progressing desmoid tumors who require systemic treatment
- Desmoid tumors are rare, noncancerous, locally aggressive tumors
- First and only FDA-approved targeted therapy developed specifically for adult patients with progressing desmoid tumors requiring systemic therapy

> "With Nirogacestat, we are seeing more effective options for these patients."
>
> — Sean Warsch, MD

- SpringWorks Therapeutics, Inc. OGSIVEO (nirogacestat) US Prescribing Information. Published April 4, 2024. https://springworkstx.com/wp-content/uploads/2024/04/OGSIVEO-US-Prescribing-Information-04.04.24.pdf. Accessed October 7, 2025.
- Alman B, Attia S, Baumgarten C, et al. The management of desmoid tumours: A joint global consensus-based guideline approach for adult and paediatric patients. European Journal of Cancer. 2020. 127: 96-107.

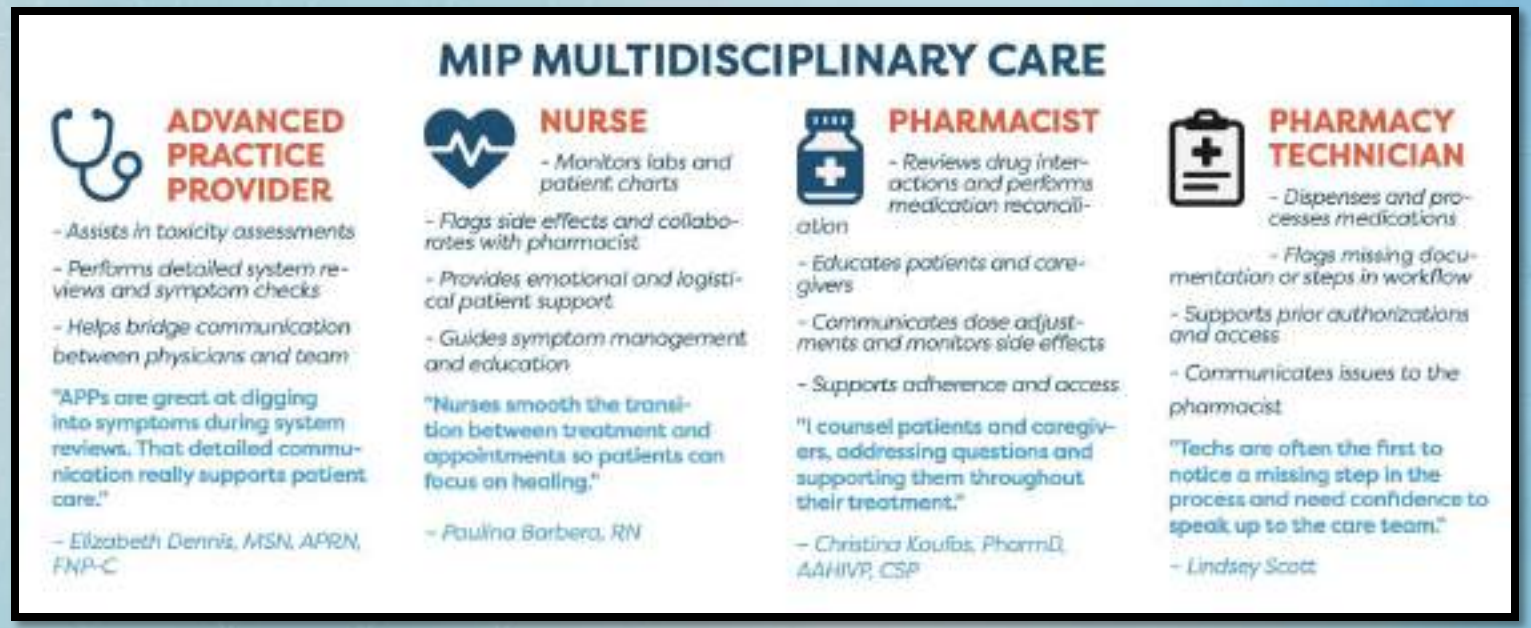
Ogsiveo Overview: Packaging & Patient Education

Packaging:

Unique blister design supports adherence and dosing accuracy

Patient Counseling Focus:

- Dosing schedule and missed doses
- Adverse event discussions
- Adherence tracking



Access and Support Pathways

Financial Navigation:

- Benefits investigation & co-pay support
- Coordination with manufacturer programs and assistance foundations

NCODA Resources

PQI

PQI in Action

Treatment Support Kit

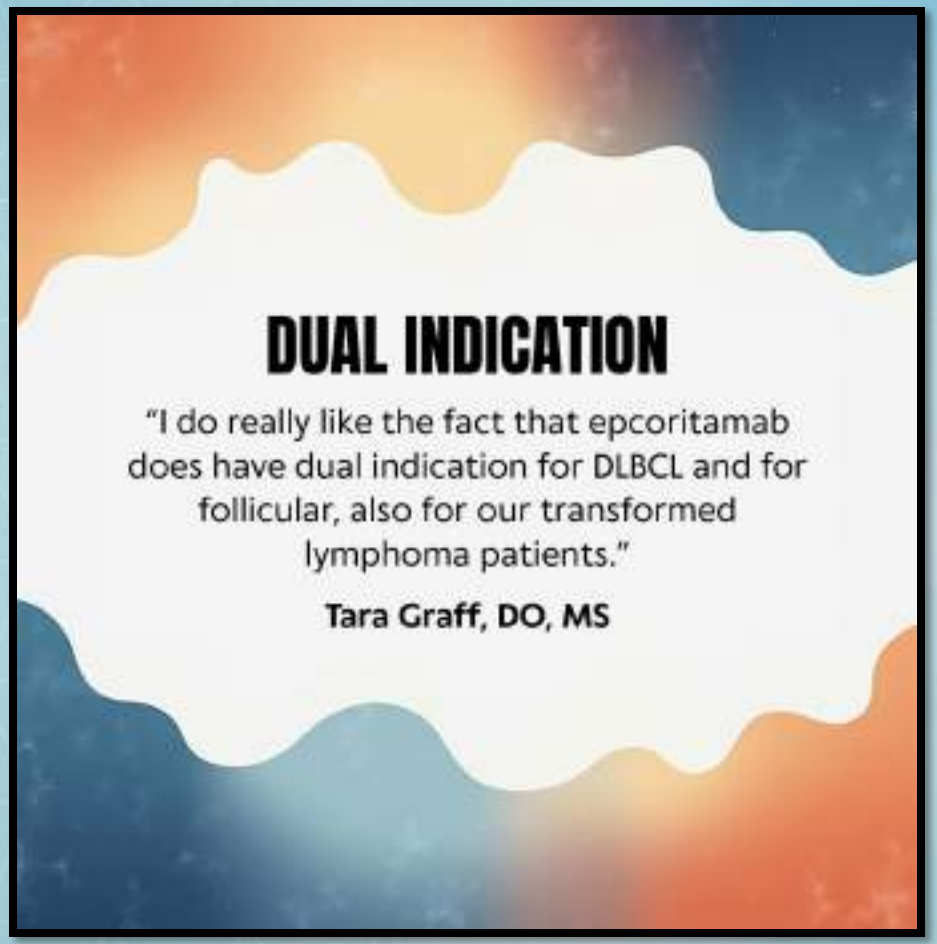
Patient Education Sheet

Treatment Discussion Guide

Epkinly® (Epcoritamab-bysp) in Action

- A subcutaneous bispecific antibody that targets CD20 on B-cells and CD3 on T-cells activating T-cell-mediated destruction of malignant B-cells

- FDA Accelerated Approval:
  - R/R DLBCL, not otherwise specified, including DLBCL arising from indolent lymphoma, and highgrade B-cell lymphoma after ≥ 2 lines of systemic therapy
  - R/R FL after ≥ 2 lines of systemic therapy



- Genmab US, Inc. *EPKINLY (epcoritamab-bysp) US Prescribing Information*. From: *Prescribing Information*. Revised September 2025. https://www.genmab-pi.com/prescribing-information/epkinly-pi.pdf. Accessed October 7, 2025.

Establishing a Bispecific Program

- **Why It Matters:**
  - Expanding access to advanced immunotherapy in community settings
- **Program Infrastructure**:
  - EMR alerts & standardized orders
  - CRS/ICANS protocols & emergency readiness
  - Tocilizumab and supportive meds on hand
- **Team Collaboration:**
  - Align on start criteria and monitoring
  - Weekly case reviews for appropriateness

Education and NCODA Resources

Continuous Education:

- Staff training on bispecific mechanisms & AE management
- Patient teaching on safety and follow-up expectations

PQI

PQI in Action

Patient Education Sheet

Immunotherapy Hub

Closing Thoughts

What advice would you give to other practices looking to implement these therapies using NCODA resources?

QUESTION & ANSWER

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