
ADVANCED PRACTICE PROVIDER
Strategies for Managing Toxicities of Oral Oncolytics
July 17
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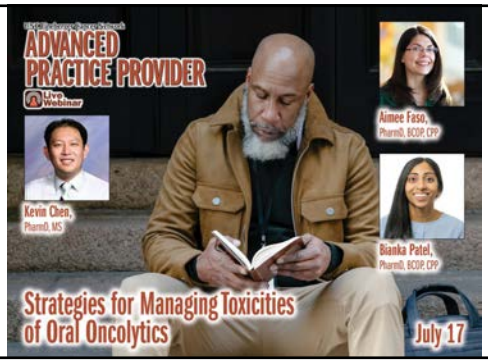

7

Our Presenter

Aimee Faso, PharmD, CPP BCOP

Aimee Faso, PharmD, CPP BCOP, is a clinical pharmacist practitioner in breast oncology at the North Carolina Cancer Hospital in Chapel Hill, NC. She received her PharmD degree from the University of Florida in 2003 and completed residency at the Dartmouth Hitchcock Medical Center in 2004. She joined UNC as an oncology pharmacist in 2008 and has now been working with the UNC breast team since 2014. She provides drug and chemotherapy education to patients as well as direct care to patients, such as management of drug-related adverse effects.

8

Our Presenter

9

Our Presenter

3. Aimee Faso, PharmD, CPP, BCOP, is a clinical pharmacist practitioner in breast oncology at the North Carolina Cancer Hospital in Chapel Hill, NC.

10

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11

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3. Aimee Faso, PharmD, CPP, BCOP, is a clinical pharmacist practitioner in breast oncology at the North Carolina Cancer Hospital in Chapel Hill, NC.
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1. She joined UNC as an oncology pharmacist in 2008 and has now been working with the UNC breast team since 2014.

12

Our Presenter

Bianka Patel,
PharmD, BCOP

Bianka Patel, PharmD, BCOP, is a clinical pharmacist practitioner at UNC Medical Center. She went to pharmacy school at UNC Eshelman School of Pharmacy. She completed her first year of residency training at VCU Medical Center and hematology/oncology training at UNC Medical Center. She is currently practicing as a hematology clinical pharmacist at UNC Medical Center in outpatient leukemia services and works on a multidisciplinary team to care for patients with acute and chronic leukemias.

13

Our Presenter

14

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15

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16

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17

Our Presenter

Kevin Chen,
PharmD, MS

Kevin Chen, PharmD, MS, is a clinical pharmacist practitioner at the University of North Carolina (UNC) Medical Center specializing in the care of patients with thoracic malignancies and sarcoma. He completed his graduate and pharmacy education at the University of Kentucky College of Pharmacy and subsequently went on to complete his oncology pharmacy residency at UNC Medical Center in 2020. His clinical interests center around precision medicine and dose-optimization of targeted therapies. In his free time, Kevin enjoys traveling, trying new breweries and restaurants, and cycling.

18

Our Presenter

19

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20

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21

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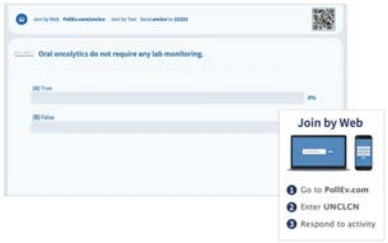
22

Sample Poll Everywhere Question



23

ACCME Disclosure

This activity has been planned and implemented under the sole supervision of the Course Director, Stephanie Wheeler, PhD, MPH, in association with the UNC Office of Continuing Professional Development (CPD). The course director received research support from AstraZeneca (ended June 2023) and Pfizer Medical Foundation (ended December 2023). These financial relationships have been mitigated. CPD staff have no relevant financial relationships with ineligible companies as defined by the ACCME.

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25

Oral oncolytics do not require any lab monitoring.

True 0%

False 0%

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26

Strategies for Managing Toxicities of Oral Oncolytics

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07/17/2024

27

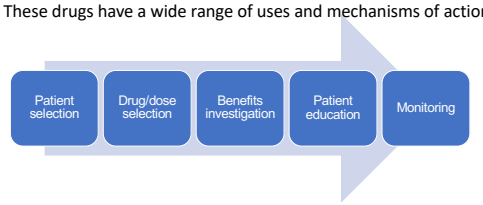
Objectives

- Describe various oral oncolytics utilized in the treatment of hematologic and solid tumor malignancies
- Explain key considerations in the prescribing of oral oncolytics
- Develop a plan for toxicity management and monitoring for patients on oral oncolytics

28

Introduction to Oral Oncolytics

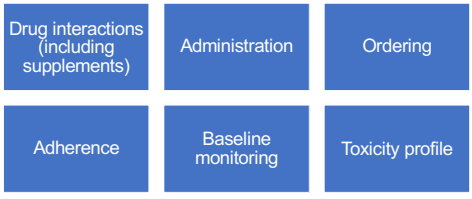
- Oral oncolytics are medications taken by mouth to treat cancer
- Many oral oncolytics are currently available for use
- These drugs have a wide range of uses and mechanisms of action



Neuss et al. ONF 2016; 44:31-43.

29

Drug/dose Selection



Neuss et al. ONF 2016; 44:31-43.

30

Safe Prescribing

Neuss et al. ONF 2016; 44:31-43.

31

Breast Cancer

Aimee Faso

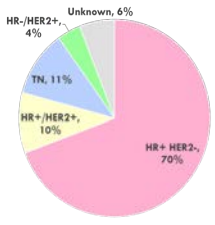
UNC HEALTH

32

Breast Cancer

- Most common non-skin related cancer in women in the US
- Overall risk for a woman to develop breast cancer is 1 in 8
- Second leading cause of cancer-related deaths in women
- Incidence rates have been increasing by 0.6% per year while death rates have been declining
- Treatments for breast cancer include:
  - Chemotherapy
  - Hormone therapy
  - Targeted therapy
  - Immunotherapy

- Prevalence of breast cancer subtypes, US



7/16/24 National Cancer Institute; 2024 Apr 17. SEER Incidence Data, November 2023 Submission (1975-2021), SEER 22 registries. 33

33

Breast Cancer Oral Oncolytics

CDK 4/6 Inhibitors
- Palbociclib
- Ribociclib
- Abemaciclib

PIK3CA Inhibitors
- Alpelisib
- Capivasertib

HER2
- Lapatinib
- Neratinib
- Tucatinib

Antimetabolite
- Capecitabine

PARP Inhibitors
- Olaparib
- Talazoparib

34

Selected Adverse Effects

CDK 4/6	PIK3CA	HER2	Antimetabolite	PARP
• Neutropenia • Diarrhea • Hepatotoxicity • Pneumonitis	• Hyperglycemia • Rash • Diarrhea	• Diarrhea • Hepatotoxicity • Cardiomyopathy	• Hand/foot syndrome • Diarrhea • Mucositis	• Anemia • Nausea

Understanding adverse effects can help determine drug selection and adverse reaction prophylaxis

- Ribociclib (CDK 4/6) – Neutropenia, hepatotoxicity and QTc prolongation
- Alpelisib (PIK3CA) – Hyperglycemia and rash
- Tucatinib (HER2) – Diarrhea and hepatotoxicity
- Capecitabine (Antimetabolite) – Diarrhea and hand/foot syndrome
- Olaparib (PARP) – Anemia and N/V

35

Case Presentation

- SL is a 65 yo woman, with a h/o of basal cell carcinoma, was initially diagnosed with L breast cancer in 2013, ER-positive, PR-positive, HER2-negative. She had breast conserving surgery and radiation. She had a low-risk Oncotype score so chemotherapy was not recommended. She initiated tamoxifen for adjuvant endocrine therapy with the plan to treat for 10 years. In 2020, 7 years after initiation of tamoxifen, she presented to her oncologist with severe back pain. Work-up revealed a vertebral facture. CT also identified multiple pulmonary lesions. Biopsy confirmed ER-positive, PR-positive, HER2-negative metastatic breast cancer.
- Per NCCN guidelines, her oncologist would like to start standard of care, first line treatment for HR-positive, HER2-negative metastatic breast cancer. The recommendation is an aromatase inhibitor (AI) and a CDK 4/6 inhibitor.
- There are 3 CDK 4/6 inhibitors. How does the oncologist choose?

• National Comprehensive Care Network. NCCN Clinical Practice Guidelines in Oncology – Breast Cancer. (Version 3.2024).

36

Comparison of CDK 4/6 Inhibitors

Adverse Effects	Palbociclib (Ibrance®)	Ribociclib (Kisqali®)	Abemaciclib (Verzenio®)
Neutropenia	++	++	+
Diarrhea	+	+	+++
Fatigue	+	+	+
Nausea	+	+	++
Monitor for Hepatotoxicity		✓	✓
Monitor for QTc prolongation		✓	

37

Comparison of CDK 4/6 Inhibitors

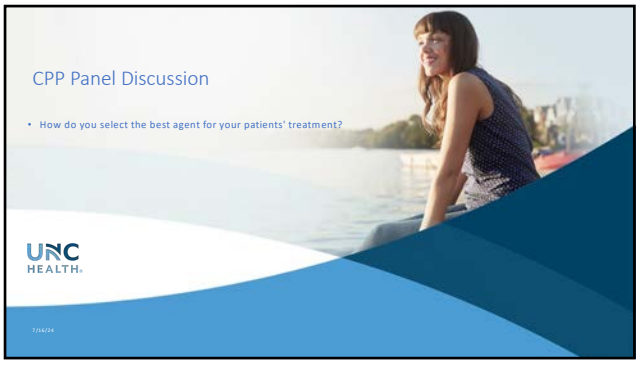
Trial Data	Palbociclib	Ribociclib	Abemaciclib
Significant OS found in clinical trial when given as 1st line with an AI in mBCa	PFS only	✓	PFS only
Significant OS found in clinical trial when given as 2nd line with fulvestrant in mBCa	PFS only	✓	✓

Based on potential adverse effects and efficacy, SL was started on an AI (letrozole) with ribociclib. Denosumab was also initiated for bone metastases.

OS – Overall Survival
PFS - Progression Free Survival

N Engl J Med 2016; 375:1925-193, N Engl J Med 2018;379:1926-1936, N Engl J Med 2022;386:942-950, N Engl J Med 2019;381:307-316, N Engl J Med 2020;382:514-524, JCO 2017;35:3638-3646, JAMA Oncol. 2020;6:116-124

38



39

Case Presentation

SL subsequently tolerated first line treatment with ribociclib, letrozole, and denosumab with mild neutropenia and manageable fatigue. In March 2023, staging CT scans showed increased pulmonary lesions and new osseous mets. Liquid biopsy demonstrated a PIK3CA mutation. Her treatment was changed to fulvestrant with alpelisib. Denosumab was continued for bone metastases.

Is SL a good candidate for alpelisib?

40

Case Presentation

Alpelisib indication: Post-menopausal women with HR-positive/HER2-negative with advanced breast cancer and a PIK3CA mutation following progression on previous endocrine therapy.

Risk factors for hyperglycemia with alpelisib:

1. Age ≥ 75 yo
2. FBG > 140
3. Hba1c > 6.4
4. BMI > 25
5. Diabetes history (family history, prediabetes or gestational)
6. CV disease/HTN
7. Polycystic ovarian syndrome
8. Low HDL (< 35) or elevated TG (> 250)
9. Ethnicity: AA, Latino, Native American, Asian American, Pacific Islander

Our patient

65 yo Caucasian woman with PIK3CA mutation and progressed on endocrine therapy with ribociclib and letrozole

Baseline labs

FBG = 93
Hba1c = 5.8

BMI = 20

Cholesterol WNL

No other contributing history

41

Case Presentation

Alpelisib adverse effect prophylaxis

Hyperglycemia

- Metformin 500 mg BID x 3 days then increase to 1000 mg BID started one week prior to the initiation of alpelisib
- Counsel on low carbohydrate, diabetic diet
- Alpelisib dose is best taken in the morning after fasting with a low carbohydrate breakfast
- Encourage exercise
- Counsel on symptoms of hyperglycemia

Rash

Cetirizine 10 mg daily started with the initiation of alpelisib for rash prophylaxis

Rugo, HS et al. A multidisciplinary approach to optimizing care of patients treated with alpelisib. The Breast 2022;61:156-67
Llombart-Cussac A et al. METALLICA. EClinicalMed 2024;71: 102520

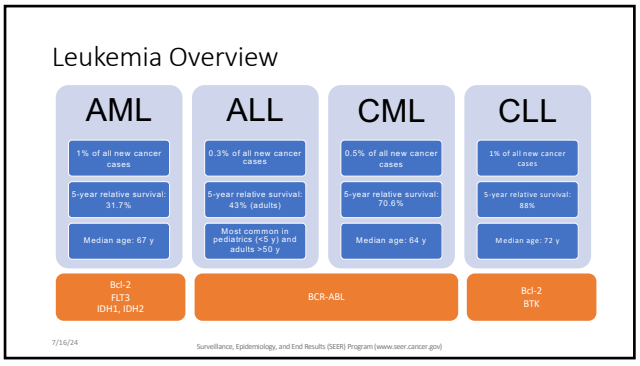
42


Which of the following factors can determine prescribing of an oral oncolytic?
Patient comorbidities
0%
Patient's baseline organ function
0%
Genetic mutations of the cancer
0%
All of the above
0%

43


Leukemia
Bianka Patel
UNC HEALTH

44


Leukemia Overview
AML
1% of all new cancer cases
5-year relative survival: 31.7%
Median age: 67 y
ALL
0.3% of all new cancer cases
5-year relative survival: 43% (adults)
Most common in pediatrics (<5 y) and adults >50 y
CML
0.5% of all new cancer cases
5-year relative survival: 70.6%
Median age: 64 y
CLL
1% of all new cancer cases
5-year relative survival: 88%
Median age: 72 y
Bcl-2
FLT3
IDH1, IDH2
BCR-ABL
Bcl-2
BTK
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Surveillance, Epidemiology, and End Results (SEER) Program (www.seer.cancer.gov)

45

Leukemia Overview

AML
- May use oral targeted therapy up-front in combination with induction therapy depending on mutation profile
- May use Bcl-2 inhibitor venetoclax in combination with azacitidine up front for poor PS
- Can use venetoclax and targeted therapies in relapsed/refractory setting as well

ALL
- For patients with B-ALL who have Ph+ chromosome positive disease, a BCR-ABL targeted TKI is standard therapy (often in combination with multi-agent chemotherapy)

CML
- BCR-ABL targeted TKI is used up front and after relapse

CLL
- Either Bcl-2 inhibitor venetoclax with an anti-CD20 mAb or a BTK inhibitor for up-front or relapsed setting

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46

Drug Specific Monitoring

Bcl-2 inhibitor
- Myelosuppression
- TLS

FLT3/IDH1/IDH2 inhibitors
- Differentiation syndrome
- QTc prolongation

BCR-ABL tyrosine kinase inhibitor
- Myelosuppression
- Cardiovascular toxicity
- Pancreatitis

Bruton's tyrosine kinase inhibitor
- Atrial fibrillation
- Bleeding

Venetoclax	Quizartinib	Ponatinib
• TLS labs • Renal function	• QTC • Electrolytes	• Lipid panel • Amylase, lipase

CMP
Mg
Phos
Uric acid
LDH

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47

Case

- JS is a 73 yo M with PMH of COPD, GERD, and T2DM found to have new diagnosis of AML. He presents today to start standard of care therapy with azacitidine and venetoclax.
- Medication list: allopurinol, Breo Ellipta (fluticasone/vilanterol), metformin, pantoprazole
- What kind of lab monitoring does he need?

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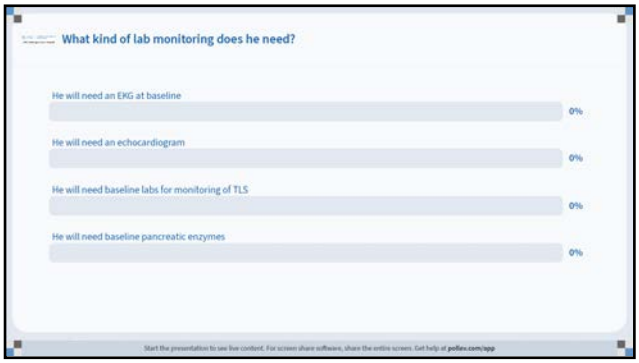
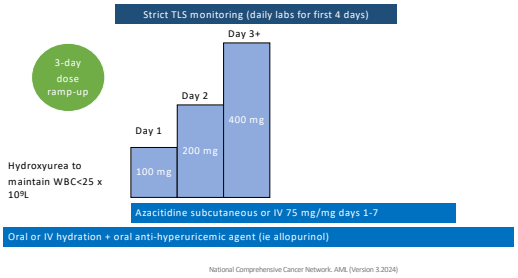
48



49

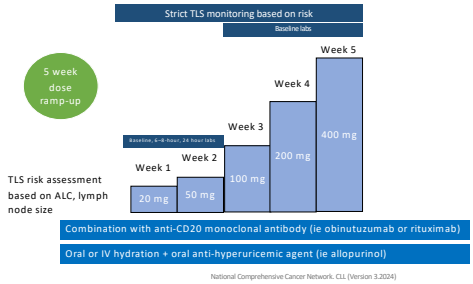
Venetoclax monitoring in AML



National Comprehensive Cancer Network. AML (Version 3.2024)

50

Venetoclax monitoring in CLL



National Comprehensive Cancer Network. CLL (Version 3.2024)

51

Case

- JD is a 52 yo M who was diagnosed with chronic phase CML in 2017. He has a PMH of asthma and depression. He began therapy with imatinib 400 mg daily, which was dose reduced, and then eventually stopped due to fatigue, fluid retention, and GI upset. He was then transitioned to dasatinib 100 mg daily which he has responded well to but unfortunately developed recurrent pleural effusions despite dose reductions in dasatinib. He is now planning to switch to nilotinib.
- What baseline labs does he need?

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52

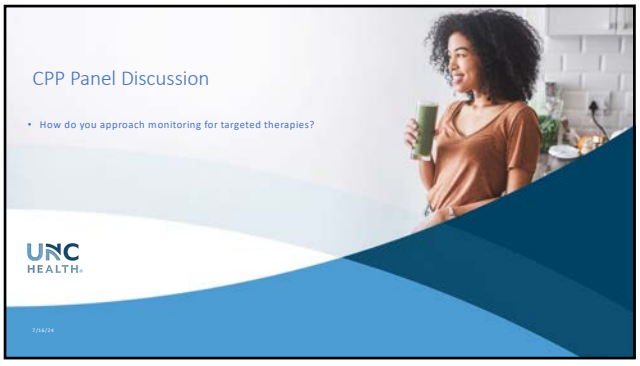
CML TKIs

	Imatinib (1st generation)	Dasatinib (2nd generation)	Nilotinib (2nd generation)	Bosutinib (2nd generation)	Ponatinib (3rd generation)	Asciminib (STAMP inhibitor)
Dosing/ Administration	400 mg once daily with food	100 mg once daily	300 mg twice daily on empty stomach	400 mg once daily with food	45 mg once daily	80 mg once daily on empty stomach
Notable toxicities	Edema, CHF, GI upset, rash, myalgias	Pleural effusion, superficial edema	Hyperglycemia, QTc prolongation, pancreatitis	Diarrhea	Arterial occlusive events, VTE, pancreatitis, hypertension	Hypertension, pancreatitis
Baseline monitoring, other comments	Monitor renal function	Avoid acid suppression	Lipid panel, HgbA1c, amylase, lipase, EKG Avoid acid suppression	Avoid acid suppression Renal dose adjustment	Lipid panel, amylase, lipase, EKG	Amylase, lipase

Class toxicities:
Myelosuppression
Fatigue
Headaches
Rash
Myalgias
Hepatotoxicity
Cardiovascular
Fluid retention

National Comprehensive Cancer Network. CML (Version 1.2024)

53



54

Case

- JD has returned for follow up one month after nilotinib. He feels well. He has had one medication change - he began quetiapine as an adjunct agent for mood.

CBC: WBC 8.5, ANC 3.7, Hgb 12.5, PLT 231

CMP: creatinine 0.9 (stable/baseline), electrolytes, glucose 113, **AST 85** (up from 20), **ALT 130** (up from 41), Tbili wnl, **lipase 212**

EKG (at baseline): QTc Fridericia 444 msec

- Do we need another EKG today?
- Is any other action required?

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55

Lung Cancer

Kevin Chen

UNC HEALTH

56

Lung Cancer

Third most common cancer in the US

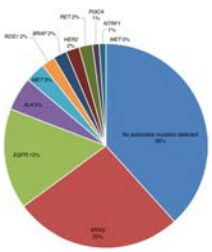
- Leading cause of cancer-related mortality (135,360 deaths/year)
- 15% of lung cancer deaths are in non-smokers

Driver mutations enriched in non-smokers

- Other factors include histology, age, gender, and ethnicity

Targeted therapy is better than chemotherapy

- More efficacious
- Less toxic (mostly)
- More convenient (if oral)



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Pakkala S & Ramalingam SS. JCI Insight. 2018; 3(15):e120858; Siegel RL. et al., CA Cancer J Clin. 2022;72(1):7-33.

57

Targeted Therapies in NSCLC

EGFR	ALK	RET	BRAF V600E	EGFR (exon20ins)
Erlotinib	Crizotinib	Selpercaptinib	Dabrafenib	Amivantamab*
Gefitinib	Ceritinib	Pralsetinib	Trametinib	
Afatinib	Alectinib	Cabozantinib	Encorafenib	
Dacomitninb	Brigatinib		Binimetinib	
Osimertinib	Lorlatinib	MET	Vemurafenib	HER2
		Capmatinib		Trastuzumab-* deruxtecan
KRAS G12C	ROS1	Tepotinib	NTRK	Trastuzumab-emtansine*
Adagrasib	Crizotinib	Crizotinib	Larotrectinib	
Sotorasib	Ceritinib		Entrectinib	
	Entrectinib			
	Lorlatinib			
	Repotrectinib			

*IV therapy

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58

Adverse Effects of Specific Classes

EGFR	HER2	MET	TRK
• Rash • Diarrhea • Mucositis • Paronychia	• Diarrhea • Cardiomyopathy	• Peripheral edema • Hypoalbuminemia	• Dizziness • Ataxia • Paresthesia • Cognitive changes

Knowing the spectrum of activity helps to understand side effect profile

- Osimertinib → cardiomyopathy (HER2)
- Brigatinib → rash (EGFR)
- Crizotinib → edema (MET)
- Selpercaptinib & pralsetinib side effects comes from their off-target VEGF activity

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59

Management of Adverse Effects

Grade 1	• Continue targeted therapy • Provide supportive care (e.g. topical steroids for EGFR rash)
Grade 2	• Consider holding targeted therapy • Increase supportive care (e.g. doxycycline for EGFR rash)
Grade 3/4	• Hold targeted therapy, restart at a reduced dose • Maximize supportive care (e.g. systemic steroids for EGFR rash)

60

Case Presentation

DM is a 49 y/o F never-smoker w/ metastatic adenocarcinoma of the lung. Known sites of disease are her lungs, bone, and brain. Initial NGS testing revealed EML4-ALK fusion and patient was started on first-line alectinib. After 4 years of disease control, patient presented with worsening abdominal pain. Restaging scans show development of new liver metastasis. Repeat biopsy was performed on liver met which showed adenocarcinoma histology with EML4-ALK fusion and new ALK G1202R mutation. Your medical oncologist wants to start DM on second-line lorlatinib.

What are appropriate side effects to counsel this patient on?

Most common lorlatinib ADRs include:

- Hyperlipidemia, edema, weight gain, peripheral neuropathy, cognitive dysfunction, and mood disorders

Serious lorlatinib ADRs include:

- AV node block, hypertension, hyperglycemia, and pneumonitis

61

Lorlatinib Adverse Effects

7/16/24 Liu G. et al. Lung Cancer. 2024;191:107535.

62

Lorlatinib Adverse Effects

Hyperlipidemia (~75-95%)

- Management similar primary hyperlipidemia (statins, ezetemibe, fibrates, fish oil, PCSK9 inhibitors)
- Rosuvastatin, pitivastatin, pravastatin preferred given drug-drug interactions
- HOLD lorlatinib if cholesterol >500mg/dL or triglycerides >1000mg/dL

Edema (~50-60%)

- Evaluate for other contributing etiologies
- Lifestyle modifications & diuretic trial, can dose reduce if significant

Weight Gain (~40-50%)

- May be related to or independent of edema
- No robust treatments – general guidance on diet & exercise

Peripheral Neuropathy (~30-40%)

- Managed similarly to other forms of peripheral neuropathy (gabapentinoids, duloxetine, TCAs)
- Dose holds & dose reductions may be helpful

Cognitive Effects (~20-30%)

7/16/24 Liu G. et al. Lung Cancer. 2024;191:107535.

63

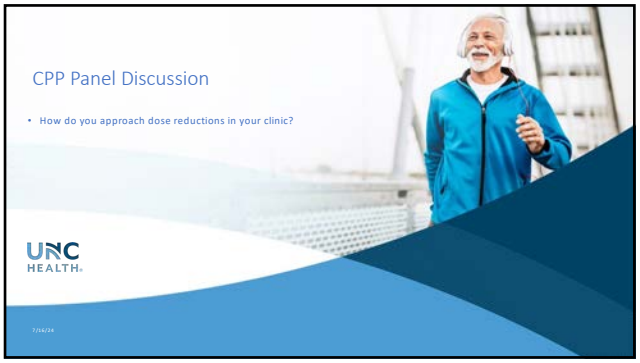
Case Presentation

DM has been on second-line lorlatinib treatment (100mg/d) for 2 months now. She has since been started on rosuvastatin for hyperlipidemia and duloxetine for peripheral neuropathy. Today she comes to clinic with her husband for routine check-in and tells you that she's been having difficulty remembering things, and now forgets to feed her newborn baby once or twice a week. Additionally, her husband states that she has become very irritable and impatient, which is not like her at all. She now yells at everyone for any minor inconvenience such as while shopping or driving.

What grade cognitive & mood effects is your patient experiencing from lorlatinib?

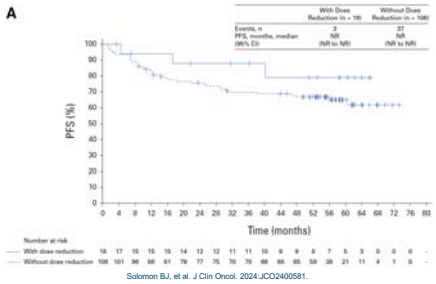
What is your recommendation for managing this adverse effect?

64



65

Impact of Dose Reductions



7/16/24

Solomon BJ, et al. J Clin Oncol. 2024:JCO2400581.

66

67

Conclusions

- It is important to consider several patient- and disease-specific factors when prescribing oral oncolytics
- Choosing an agent within a class of agents includes efficacy, dosing/administration, adverse effects, and comorbidities
- Baseline and subsequent monitoring is critical to maintain patient safety on an oral oncolytic
- There are several strategies for managing dose reductions for oral oncolytics

68

Strategies for Managing Toxicities of Oral Oncolytics

- Aimee Faso, PharmD, BCOP, CPP
- Bianka Patel, PharmD, BCOP, CPP
- Kevin Chen, PharmD, MS, BCOP, CPP

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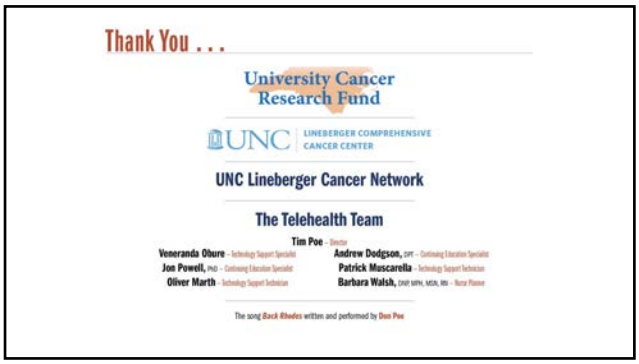
69


Questions/Comments?
Nobody has responded yet.
Hang tight! Responses are coming in.

70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Oliver Marth
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Barbara Walsh, DNP MPH, MSN, RN
The song Back Rhodes written and performed by Don Poe

71


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Veronica Carlisle, MPH, CHES
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Samuel M Rubinstein, MD
PATIENT-CENTERED CARE
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12:00 PM
Bereavement Care in Oncology
Rev. Bailey Brislin, MDiv

72


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Melissa Holt, DNP, PMHNP-BC
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73


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74