



## **Nirogacestat (OGSIVEO®) Medically Integrated Oncology Treatment Discussion Guide**

This guide equips providers with the knowledge and confidence to lead meaningful treatment conversations—ensuring every patient feels supported, empowered, and prepared for their journey with nirogacestat.

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## PHARMACIST QUESTIONS



### Medication Adherence and Tools



#### Question(s)

- ☐ How did your doctor instruct you to take nirogacestat?
- ☐ How confident do you feel in remembering to take nirogacestat? What tools or strategies have you used to remember to take your medications on time?
- ☐ Have you looked through your nirogacestat Treatment Support Kit (TSK)?

#### Actionable Recommendations

##### If the patient is unsure on how to take nirogacetstat

- > Reinforce instructions and prescribed dosage. Per package insert, nirogacestat is taken 150 mg by mouth twice daily, with or without food, at consistent times each day.

##### If the patient has difficulty or anticipates issues remembering to take nirogacestat

- > Recommend using digital adherence tools such as phone alarms or mobile applications such as Medisafe® to support dose reminders.

##### If the patient has questions about the nirogacestat TSK

- > Review the contents of the TSK and how each item supports early side effect management:
- > Educational Booklet for disease/treatment insights
- > Treatment Calendar to track doses
- > Loperamide Hydrochloride Caplets (2mg X 12 caplets) to manage diarrhea
- > Queasy Drops for managing nausea/vomiting
- > Water Bottle to maintain hydration
- > Hydrocortisone 1% Cream for rash relief



## PHARMACIST QUESTIONS



### Managing Common Side Effects and Dose Adjustments



#### Question(s)

- ☐ Did your care team explain what side effects are most likely to occur in the first few weeks?
- ☐ Do you feel prepared to manage mild side effects like diarrhea or rash at home?
- ☐ Has your care team mentioned that your dose might be adjusted if side effects occur?

#### Actionable Recommendations

##### If the patient is unsure about side effects and side effect management

- > Educate that most side effects occur in the first treatment cycle but typically improve over time
- > If appropriate, share that in the DeFi Trial, the first onset of most adverse events occurred within the first cycle; 95% were grade 1 or 2 with no grade 4-5 events reported.

##### For diarrhea (84% incidence in the DeFi trial)

- > Instruct patients to start loperamide at the first sign of loose stools (provided in TSK). Also emphasize hydration and electrolyte intake and advise patients to call the care team if diarrhea lasts longer than a few days and does not improve after taking antidiarrheal medicines.

##### For rash (68% incidence in the DeFi trial)

- > Recommend use of hydrocortisone cream from TSK for mild cases. Encourage reporting of rash that spreads or disrupts daily life.

##### If patient has questions or concerns regarding dose modifications

- > Reinforce that dose modifications may be needed if certain side effects occur, that this is common, and does not affect treatment success.
- > For recommended dose modifications for adverse reactions, please see table 1 in this [Positive Quality Intervention \(PQI\)](#)
- > Share that data from the DeFi trial showed no difference in progression free survival (PFS) or objective response rate (ORR) between patients who reduced to 100 mg twice daily and those who stayed on 150 mg twice daily—this can help reduce anxiety around dose adjustments.
- > If a dose is missed or vomited after taking it, do not take an extra dose. Instruct patient to wait and take next dose at the regular scheduled time.



## PHARMACIST QUESTIONS



### Drug Interactions and Safe Administration



#### Question(s)

- ☐ Are you currently taking anything for heartburn, reflux, or indigestion?
- ☐ Did your provider talk about any foods or drinks to avoid while on nirogacestat?
- ☐ Do you use any supplements, herbal products, or over-the-counter medications regularly?

#### Actionable Recommendations

##### **If patient has a history of acid reflux/GERD or is currently using any medications for heartburn, reflux, or indigestion**

- > Inform patient to avoid use of proton pump inhibitors (PPIs) such as omeprazole and esomeprazole. Avoid H2 receptor antagonists (H2RAs) such as famotidine and ranitidine. If antacid use is needed, calcium carbonate or aluminum hydroxide and magnesium hydroxide, may be taken, but patients must separate these by at least 2 hours before or after taking nirogacestat.

##### **If patient is unsure on foods and drinks to avoid**

- > Counsel patients to avoid grapefruit, Seville oranges, and starfruit, as these can interfere with drug metabolism.

##### **If the patient is currently taking any supplements, herbal products or OTCs**

- > Recommend a review of all prescriptions, over the counter (OTC), and herbal supplements to assess for strong or moderate CYP3A4 inhibitors or inducers. Refer concerns to the provider for follow-up if interactions are possible.



## NURSING QUESTIONS



### Symptom Management



#### Question(s)

##### Since starting nirogacestat:

- ☐ Have you experienced any diarrhea? If so, how many times per day and for how long has it lasted?
- ☐ Have you experienced any skin changes such as rashes, new or changing moles, or lesions?
- ☐ Have you experienced any mouth sores?
- ☐ Have you experienced any muscle cramps?
- ☐ Have you experienced any fatigue, headache, or weakness?
- ☐ Have you experienced any pain just below your diaphragm or noticed any yellowing of the skin? Has your urine been dark or burnt orange in color?

#### Actionable Recommendations

##### If patient reports frequent or worsening diarrhea

- > Reinforce that diarrhea is a common side effect of nirogacestat. Encourage the use of loperamide as provided in the TSK and maintain fluid intake. Advise them to contact the care team if diarrhea persists for  $\geq 3$  days or worsens, as a dose hold or reduction may be needed.

##### If the patient reports skin changes such as rashes, new or changing moles, or lesions

- > Reinforce the importance of routine dermatologic evaluations.
- > For new rashes, or if an existing rash worsens, have the patient contact the healthcare team immediately.
- > Inform patient they may be instructed to use OTC creams to help rash
- > A less common side effect, nirogacestat has been associated with non-melanoma skin cancers.
- > Instruct patient to report any skin changes promptly.

##### If the patient experiences mouth sores

- > Encourage symptom tracking and support use of hydration and basic oral care.

##### If the patient reports muscle cramps

- > Explain that nirogacestat may cause electrolyte abnormalities such as low phosphate or potassium. Inform the patient they will receive timely lab work for monitoring
- > Advise the patient to notify the care team if symptoms persist or worsen, as supplementation or dose modification may be needed.

##### If patient experiences fatigue, headache, or weakness

- > Reassure patient that these are common side effects, particularly in the first treatment cycle. Notify the care team if symptoms impair daily functioning or persist into later cycles.

##### If the patient complains of right upper quadrant pain, jaundice, or dark urine

- > Assess for possible hepatotoxicity. Reinforce the need for routine liver function testing and escalate to the provider for further evaluation if liver-related symptoms are reported



## PHYSICIAN AND APP QUESTIONS



### Treatment Oversight & Education



#### Question(s)

- ☐ Do you have any questions on the goals of therapy with nirogacestat?
- ☐ Do you have any questions on how we will monitor treatment response to nirogacestat?
- ☐ Do you have any questions on when we would stop or hold treatment due to toxicity or loss of effectiveness?
- ☐ Are you aware of the symptoms or side effects that should prompt you to contact the care team?

#### Actionable Recommendations

##### If patient unsure of goals of therapy

- > Educate patient on goals of treatment, such as tumor shrinkage, disease stabilization and/or symptom relief.

##### If patient unsure how treatment response will be monitored

- > Advise the patient that treatment response may be monitored via imaging (e.g., magnetic resonance imaging (MRI) or computed tomography (CT)), symptom improvement, and functional status.
- > Help set realistic expectations for the patient, with the goal of treatment typically being disease stabilization.

##### If patient unsure on when nirogacestat treatment could temporarily be put on hold or discontinued

- > Discuss with patient that treatment may be interrupted, dose-reduced, or discontinued if side effects become difficult to manage or if the benefit of therapy decreases over time.

##### If patient unsure when to report symptoms or side effects to the care team

- > Reinforce patients should report persistent diarrhea (>3 days), new or unusual menstrual changes, jaundice, dark urine, or skin changes.



### Reproductive Health



#### Question(s)

- ☐ If sexually active, what contraception do you use, if any?

##### For Females:

- ☐ Have you noticed any changes to your menstrual cycle, such as irregularity, spotting, or lack of menstruation?

#### Actionable Recommendations

##### If patient is sexually active

- > Confirm that effective contraception is used during treatment and for 1 week after the last dose. Refer for pregnancy testing if indicated.

##### If the patient experiences hot flashes, menstrual irregularities, or missed periods

- > Educate the patient on the risk of ovarian toxicity with nirogacestat. Inform them that these effects often resolve and have them notify the provider and/or care team to assess hormone-related symptoms.
- > Confirm fertility preservation, if desired, has already been addressed.



## PHARMACY TECHNICIAN QUESTIONS



### Prescription and Medication Pickup



#### Question(s)

- ☐ Do you know the best way to store nirogacestat at home to keep it safe and effective?
- ☐ Do you have any questions on how you'll receive your nirogacestat and when you can expect it to be ready?
- ☐ Would it be helpful if we set up a reminder for when it's time to request your next refill?

#### Actionable Recommendations

##### If the patient is unsure on how to store nirogacestat

- > Reinforce that nirogacestat should be stored at room temperature, in the original blister packaging, and away from heat, moisture, and direct sunlight.

##### If patients are unsure how they'll receive nirogacestat

- > Offer to track the shipment and confirm delivery details with the specialty pharmacy if not being filled at the medically integrated pharmacy.
- > Educate patients on the [SpringWorks Quick Start Program](#) if there are delays due to prior authorization approval.

##### If patient requests refill reminders

- > Offer to set up refill reminders through automated text alerts, phone calls, or mobile apps to prevent missed doses or treatment delays.



### Refills and Medication Instructions



#### Question(s)

- ☐ About how many nirogacestat tablets do you have on hand right now?
- ☐ Would you like assistance in making sure there's no gap in your supply before your next shipment?
- ☐ Do you feel confident that you have enough medication to stay on track with your treatment schedule?
- ☐ Have you had any issues opening the nirogacestat blister packaging or understanding how to remove the tablets properly?

#### Actionable Recommendations

##### If the patient has more medication supply than expected

- > Offer calendar tracking tools to simplify medication management.
- > Remind patient about the importance of adherence.
- > Educate patients on the importance of maintaining consistent therapy and avoiding treatment gaps.

##### If patient expresses concern about running out of nirogacestat

- > Inform patient the provider will be proactively contacted to initiate the refill process to prevent interruptions.
- > Educate patients on the [SpringWorks Bridge Program](#) to avoid gaps in treatment due to insurance changes.

##### If patient reports difficulty opening the nirogacestat blister pack

- > Provide a demonstration on how to open the blister pack



## PHARMACY TECHNICIAN QUESTIONS



### Patient Assistance / Co-Pay Support



#### Question(s)

- ☐ Have you been informed about your potential copay responsibility or financial assistance options?
- ☐ Would you like help applying for financial support?

#### Actionable Recommendations

##### **If the patient is unsure of financial responsibility or needs financial assistance**

- > Inform the patient that you are working on your insurance approval for nirogacestat.
- > Verify the patient has been informed about insurance approval and copay responsibilities.

##### **If patient needs help applying for financial support**

- > Inform patients that they may be eligible for financial assistance through the [OGSIVEO Patient Support Program](#).



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