

Positive Quality Intervention: Umbralisib (Ukoniq®) Patient Management

Description: This PQI will provide background information on umbralisib's novel mechanism of action and discuss effective practices to maximize the use of umbralisib therapy in the management of relapsed refractory follicular lymphoma.

Background: Phosphatidylinositol-3-kinase (PI3K) dysregulation is thought to be a driver of B cell malignancies. Multiple PI3K inhibitors (idelalisib, duvelisib, copanlisib) have shown efficacy in non-Hodgkin lymphoma (NHL) however, toxicities have limited their use. Umbralisib (Ukoniq®) is an oral medication indicated for patients with relapsed or refractory marginal zone lymphoma (MZL) who have received at least one prior anti-CD20-based regimen and relapsed or refractory follicular lymphoma (FL) who have received at least three prior lines of systemic therapy. Umbralisib is a novel dual inhibitor of (PI3K) δ -isoform and casein kinase-1 ϵ (CK1 ϵ) with an improved side effect profile. In the phase IIb UNITY-NHL trial involving patients with marginal zone and follicular lymphoma, umbralisib showed a favorable response rate with a manageable side effect profile.¹⁻³

PQI Process:

Upon receiving a new prescription for umbralisib:

- Confirm appropriate dose of umbralisib 800 mg (4 x 200 mg tablet) by mouth once daily with food
- Confirm that patient does not have a history of allergic reactions due to FD&C Yellow No. 5. If the patient does have a history of allergic reactions to FD&C Yellow No. 5 contact prescribers office before dispensing
- Verify that the patient has prophylaxis for *Pneumocystis jirovecii* (PJP) during treatment with umbralisib. Interrupt umbralisib therapy in patients with suspected PJP and discontinue in patients with confirmed PJP³
- Consider prophylactic antivirals during treatment to prevent cytomegalovirus (CMV) infection, including CMV reactivation. Hold umbralisib therapy until CMV infection or viremia resolves, then resume at same or reduced dose. If umbralisib is resumed, monitor CMV reactivation by PCR or antigen test at least monthly³
- Verify monitoring parameters:
 - CBC with differential – at least every 2 weeks for the first 2 months and at least weekly in patients with neutrophil counts $<1 \times 10^9/L$
 - CMP at baseline and as clinically necessary
 - Consider monitoring CMV PCR or antigen test monthly

Patient Centered Activities:

- Provide [Oncology Chemotherapy Education \(OCE\)](#) sheet
- Provide patient with the umbralisib (Ukoniq®) medication guide
- Ensure patients understand how to take their umbralisib dose
 - Administer once daily with food and a glass of water

Important notice: NCODA has developed this Positive Quality Intervention 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.

Patient Centered Activities Continued:

- Medication should not be crushed, broken or chewed, but should be swallowed whole
- If a dose of umbralisib is missed, take a missed dose unless it is less than 12 hours until the next scheduled dose
- Verify PJP prophylaxis and review importance with patient
- Ensure patients understand how to monitor for signs and symptoms of side effects of umbralisib, including: Infections, diarrhea or non-infectious colitis, hepatotoxicity, and skin rash and when to call their provider
- Monitor for adherence and adverse effects throughout treatment

Supplemental Information:[TG Co-Pay Assistance Program and Patient Support:](#)

- Patients with commercial or private insurance may be eligible to receive umbralisib for \$5 per prescription
- Quick start/bridge program
 - Provides free umbralisib to eligible patients who experience delays of at least 5 business days
- No insurance or underinsured
 - Provides free umbralisib to eligible patients

References:

1. Fowler NH, Samaniego F, Jurczak W, et al. Umbralisib, a dual PI3K δ /CK1 ϵ inhibitor in patients with relapsed or refractory indolent lymphoma. *Journal of Clinical Oncology*. 2021; 39:1609-1618.
2. Hanlon A and Brander DM. Managing toxicities of phosphatidylinositol-3-kinase (PI3K) inhibitors. *Hematology*. 2020; 346-56.
3. Ukoniq (umbralisib) [package insert]. Edison, NJ: TG Therapeutics, Inc; 2021.

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