National Community Oncology Dispensing Association, Inc.
PASSION FOR PATIENTS

Written By: Todd Murphree, PharmD

Positive Quality Intervention: Venetoclax Dispensing Procedure

Description of PQI: Venetoclax (Brand name: VENCLEXTA) is an oral BCL-2 inhibitor that is indicated for the treatment of CLL in patients with 17p deletion who have received at least one prior line of therapy. Venetoclax has a specific dose titration schedule and recommendations for patients in different risk categories for Tumor Lysis Syndrome (TLS). This poses potential challenges in the workflow of dispensing the drug.

Background: Below, you will find an overall dispensing process with additional ramp-up phase dosing schedule and TLS risk assessment and prophylaxis information. Patient Centered Activities **(PCA)** are placed within process to highlight areas of additional intervention.

PQI Process: Upon receipt of a new prescription for Venetoclax:

1) Ensure that the prescriber has assigned a TLS risk category to the patient and the dose is appropriate for assigned risk category*
2) Confirm based on recent labs that TLS risk category is still appropriate*
3) Ensure a prescription for allopurinol is sent (unless patient receiving Elitek).
    a. Allopurinol should be started 2-3 days prior to Venetoclax if possible.
4) Once Venetoclax is ready to be dispensed
    a. Alert them that their prescription is ready for pick up/shipment.
    b. **(PCA)** Educate patient on lab/hydration schedule.

If the patient is picking up the prescription and starting **outpatient**:

1) Pharmacy should ask patient when they are coming to pick up and start.
    a. Example method:
        i. Patient starting on cycle 1, with day 1 between Tuesday and Thursday
        ii. Patient must take each dose at 9:00 a.m.
        iii. These two requirements allow time for pre-dose and post-dose labs as recommended.
2) Pharmacy should notify healthcare team that patient is ready start treatment so appropriate follow up labs can be scheduled.
3) Patient should be counseled by pharmacy on dosing and lab schedule at time of dispense
    a. Example method:
        i. Labs drawn prior to first dose (day before).
        ii. Take first dose at 9:00a.m. the following day.
        iii. Patient returns to receive labs 6 hours after dose (3:00 p.m.).
        iv. Patient should return the next day at 9:00 a.m. for labs
4) **(PCA)** Consider providing a calendar with dosing and lab appointments populated by the pharmacist.

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If the prescription is **shipped to patient**:

1) Pharmacy should contact patient by phone and ask what date they are starting.
    a. Example Method:
        i. Patient to start cycle 1, day 1 between Tuesday and Thursday
        ii. Patient should take each dose at 9:00 a.m.
2) Pharmacy will coordinate with shipping carrier for delivery date.
3) Pharmacy will coordinate with healthcare team to schedule labs
4) **(PCA)** Patient can receive schedule/calendar with dosing and lab appointments populated by the pharmacist with their prescription.
5) Patient will be counseled on dosing and lab schedule.

If the patient is starting **inpatient:**

1) Pharmacy should ensure that the physician has added the proper inpatient regimen into the patient's chart so that the patient's labs will be scheduled correctly while inpatient.
2) Pharmacy should provide calendar of patient's schedule with prescription.
    a. Allopurinol start date
    b. Admittance date
    c. Start date
    d. Lab schedule
    e. Ramp-up dates
3) **(PCA)** Patient will receive all other counseling as detailed in previous paths.

References:

1. VENCLEXTA® (Venetoclax) [Prescribing Information]. Chicago, IL: AbbVie, Inc., February 2018.

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Supplemental Information

Venetoclax Dosing schedule for ramp-up phase:

Week	Venetoclax Daily Dose*
1	20mg
2	50mg
3	100mg
4	200mg
5 and beyond	400mg (continued until disease progression or unacceptable toxicity)

*(VENCLEXTA Starting Pack provides the ramp-up dosing for the first four weeks of therapy)

Adverse Effects and Noted Drug Interactions

The common side effects that have been known to happen in more than 30% of patients taking venetoclax are listed below. You MAY NOT experience these side effects. These should be discussed with the proper care provider. If you experience any side effect you cannot manage or that is not listed here, contact your care provider.

- Decreased white blood cells (WBCs) and increased risk for infection
- Diarrhea (loose and/or urgent bowel movements)
- Nausea or vomiting.

Below are a few commonly seen, but not a complete list of Drug-Drug Interactions involved with venetoclax. Please use clinical discretion when utilizing these drugs together with venetoclax

- Carvedilol (commonly referred to as COREG)
- Amiodarone
- Azithromycin

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Supplemental Information

Tumor Burden Assessment:

Tumor Burden Assessment	Prophylaxis (Hydration/Anti-hyperuricemics)	Blood chemistry Monitoring
Low Risk: **All LN <5cm** **And** **ALC <25 x 10(9)/L**	Oral Hydration (1.5-2L per day) + Allopurinol	**Outpatient:** - Pre-dose at initial and all ramp-up doses - Post-dose: 6-8 and 24 hours after initial dose of 20 and 50mg
Medium Risk: **Any LN 5cm to <10cm** **OR** **ALC >/= 25 x 10(9)/L**	Oral Hydration (1.5-2L per day) Consider additional IV + Allopurinol	**Outpatient:** - Pre-dose at initial and all ramp-up doses - Post-dose: 6-8 and 24 hours after initial dose of 20 and 50mg **Consider inpatient:** If CrCl <80mL/min at initial dose of 20mg and 50mg. (hospital monitoring as detailed below would apply)
High Risk: **Any LN >/=10cm** **Or** **Any LN >/=5cm and ALC >/=25 x 10(9)/L**	Oral Hydration (1.5-2L per day) + 150-200mL/hr IV Hydration + Allopurinol (consider Elitek if baseline uric acid is elevated)	**Inpatient: 20mg and 50mg** - Pre-dose and at initial dose of 20mg and 50mg - Post dose: 4,8,12, and 24 hours after initial dose of 20mg and 50mg **Outpatient: subsequent doses** - Pre-dose and before all ramp-up doses - Post-dose after subsequent ramp up doses 6-8 and 24 hours