ASHP BEST PRACTICES AWARD

Pharmacist-Led Program Leads to Safe and Efficient Outpatient Initiation of AML Venetoclax-Based Regimen

Kaitlyn Buhlinger, PharmD, BCOP, CPP John Valgus, PharmD, MHA, BCOP Maurice Alexander, PharmD, BCOP, CPP Suzanne Francart, PharmD, BCPS Stephanie Jean, PharmD, MS, BCPS Jeffrey Reichard, PharmD, MS, BCOP Udobi Campbell, PharmD, MBA Benyam Muluneh, PharmD, BCOP, CPP

UNC Medical Center Chapel Hill, NC

Authors of this presentation have the following to disclose concerning possible financial or personal relationships with commercial entities that may have direct or indirect interest in the subject matter of this presentation:

Authors have nothing relevant to disclose.



Introduction

Health-Care Facility

- 803 bed facility, serving more than 37,000 patients per year; not-for profit medical system
 - North Carolina Memorial Hospital
 - North Carolina Children's Hospital
 - > North Carolina Neurosciences Hospital
 - North Carolina Woman's Hospital
 - North Carolina Cancer Hospital
- Pharmacist involvement in patient care:
 - Inpatient medicine, oncology, surgical, and pediatric services
 - Outpatient clinics as Clinical Pharmacist Practitioners (CPPs)
 - Emergency Medicine
 - Retail/Outpatient Pharmacies
 - URAC-accredited Specialty Pharmacy

Background

- Venetoclax, an oral BCL2 inhibitor, is approved in combination with a hypomethylating agent for elderly/unfit acute myeloid leukemia (AML) patients
- This regimen is often given inpatient due to risk of tumor lysis syndrome (TLS) requiring:
- Cytoreduction with hydroxyurea
- > Uric acid lowering therapies (ie allopurinol)
- > Intravenous hydration
- Dosing ramp-up
- Drug interaction assessment/modifications
- Close lab monitoring
- Therapy should be initiated rapidly due to acute nature of disease, and medication access to venetoclax poses a barrier to outpatient initiation

Purpose

- Describe and assess a pharmacist-led program used to initiate venetoclax-based AML regimen in the outpatient setting:
- Prevent, monitor, and manage TLS outpatient
- Provide rapid turnaround of venetoclax access to prevent treatment delays
- Reduce hospitalizations and associated costs to the health system
- Maintain response rates as reported in real world data

Description of the Program

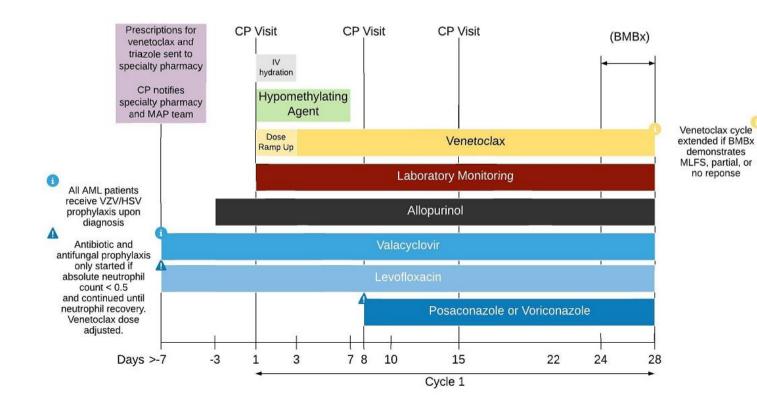
Program Team Members

- Leukemia Clinical Pharmacist
- Medication Assistance Program (MAP) specialist
- Integrated specialty pharmacy
- Interdisciplinary team



Workflow

- Upon treatment decision, the clinical pharmacist assists in chemotherapy and supportive care orders
- The MAP specialist and the integrated specialty pharmacy support prior authorization and copay assistance needs prior to dispensing/delivering to patient
- The clinical pharmacist sees the patient at structured time points during Cycle 1 to provide education, monitoring, and management of symptoms and infection prevention



Experience with the Program

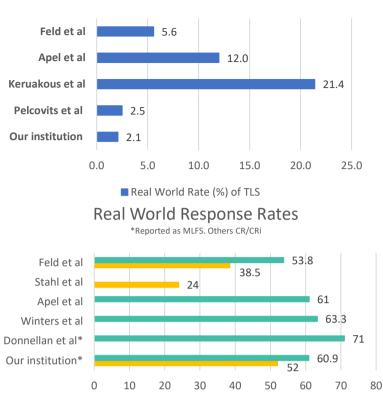
- Data collected April 1, 2019 to June 30, 2020 (15 months)
- Total 82 AML-venetoclax patients included in the study, with 47 (57%) started outpatient

Endpoint	Outpatients (n = 47)
No TLS hospitalizations within 7 days, n (%)	46 (97.9)
Time to drug access, median (range), days	3 (0-37)
Hospitalization within 7 days for any reason, n (%)	8 (17)
Achieved < 5% blasts by end of cycle 1 or 2	
First line treatment	14/23 (60.9%)
Relapsed/refractory	12/23 (52%)

Estimated daily AML inpatient cost	\$3,300/day
Estimated hospital days saved (no hospitalizations in first week, n = 39)	273 days
Estimated hospitalization cost avoidance over study period	\$900,900
Estimated cost of week 1 of venetoclax (AWP)	\$2,969
Estimated drug cost avoidance (n=39) over study period	\$115,791
Total estimated cost avoidance over study period	\$1,016,691
Approximate medication access obtained for patients (n=47)	\$2,130,645

Experience with the Program (continued)

Real World Rate of TLS



Newly Diagnosed % Responders Relapsed/Refractory % Responders

Discussion/Conclusion

- A pharmacy-led venetoclax outpatient initiation protocol has proven successful in prevention of TLS and associated hospitalizations
- With the support from the MAP specialist and integrated specialty pharmacy, treatment was able to be initiated outpatient while minimizing delays.
- The program avoided over a million dollars in cost to the health system over a 15 month time period.

References

- DiNardo CD, Jonas BA, Pullarkat V, et al. Azacitidine and Venetoclax in Previously Untreated Acute Myeloid Leukemia. N Engl J Med. 2020;383(7):617-629. doi:10.1056/NEJMoa2012971
- 2. Venclexta (Venetoclax) [Package insert]. North Chicago, IL. AbbVie Inc.; 2020.
- Jonas BA, Pollyea DA. How we use venetoclax with hypomethylating agents for the treatment of newly diagnosed patients with acute myeloid leukemia. *Leukemia*. 2019:33(12):2795-2804.
- Pelcovits, A., Moore, J., Bakow, B. et al. Tumor lysis syndrome risk in outpatient versus inpatient administration of venetoclax and hypomethlators for acute myeloid leukemia. Support Care Cancer (2021). https://doi.org/10.1007/s00520-021-06119-7
- Keruakous A, Saleem R, Asch A. <u>Venetoclax-induced tumor lysis syndrome in acute myeloid leukemia: Real world</u> <u>experience</u>. Journal of Clinical Oncology 2020 38:15_suppl, e19542-e19542
- Apel A, Moshe Y, Ofran Y, et al. Venetoclax combinations induce high response rates in newly diagnosed acute myeloid leukemia patients ineligible for intensive chemotherapy in routine practice. Am J Hematol. 2021;96(7):790-795
- Feld J, Tremblay D, Dougherty M, et al. Safety and efficacy: clinical experience of venetoclax in combination with hypomethylating agents in both newly diagnosed and relapsed/refractory advanced myeloid malignancies. *HemoSphere*. 2021;5(4):e549
- Winders AC, Gutman JA, Purev E, et al. Real-world experience of venetoclax with azacitidine for untreated patients with acute myeloid leukemia. *Blood Adv.* 2019;3(20):2911-2919
- Donnellan W, Xu T, Ma E, et al. Use of venetoclax and hypomethylating agents in newly diagnosed AML in the US
 – Real world response, treatment duration, dose, and schedule modifications. Abstract 1906. Presented at the
 American Society of Hematology (ASH) Annual Meeting, December 2020.
- Stahl M, Menghrajani K, Derkach A, et al. Clinical and molecular predictors of response and survival following venetoclax therapy in relapsed/refractory AML. Blood Adv. 2021;5(5):1552-1564. doi:10.1182/bloodadvances.2020003734
- Roemer, M. Cancer-Related Hospitalizations for Adults 2017. Statistical Brief #270. Agency for Healthcare Research and Quality. https://www.hcup-us.ahrq.gov/reports/statbriefs/sb270-Cancer-Hospitalizations-Adults-2017.pdf

Acknowledgements

Bianka Patel, PharmD, BCOP; Shannon Palmer, PharmD; Anand Patel, PharmD; Christopher Wang, PharmD; Davon Townsend Howell, PharmD; Sonali Acharya, PharmD; Paige Roop, CPhT; Delores Dykeman, CPhT; Shanybel Santer Torres, CPhT