# Impact of Integrated Health System Specialty Pharmacy Services on Venetoclax Access and Safety in Acute Myeloid Leukemia

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## Background

- According to National Comprehensive Cancer Network (NCCN) Guidelines, venetoclax in combination with azacitidine is a Category 1 preferred regimen for patients with AML, who are not candidates for intensive induction chemotherapy.[1]
- Successful initiation with venetoclax therapy requires genetic evaluation, close laboratory monitoring, dose escalation to mitigate tumor lysis syndrome (TLS), and careful management of drug–drug interactions.[1]
- In the outpatient setting, timely medication access may be hindered by prior authorization and financial assistance requirements, creating additional barriers to treatment initiation.[2]
- Previous studies have demonstrated that prescriptions processed through the integrated health system specialty pharmacy (HSSP) are associated with faster treatment access compared to external specialty pharmacies.[2]

## Objective

- To evaluate the impact of an integrated health system specialty pharmacy on the time to venetoclax initiation and early treatment outcomes in patients with AML.

## Methods

This retrospective chart review included patients who initiated venetoclax between Jan 1, 2025, to December 31, 2025, from a HSSP

The primary outcome included evaluating the Time to Treatment Initiation (TTI); defined as mean time from provider signature to treatment initiation

Time to prior authorization (PA) approval and rates of known adverse events, TLS, Febrile Neutropenia (FN), were evaluated for secondary outcomes.

Demographic data, mutations, and drug interactions addressed at time of prescribing were also evaluated.

Figure 1: Patient Characteristics

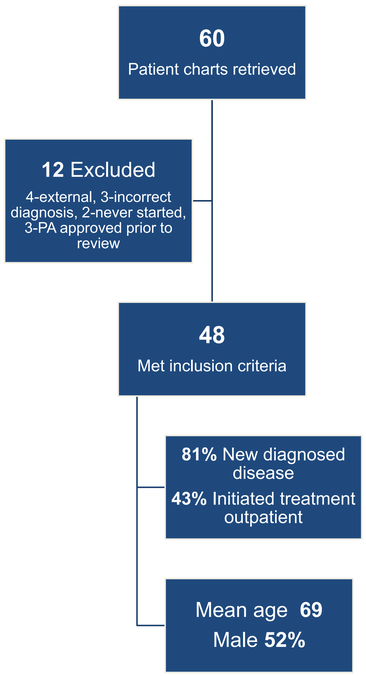
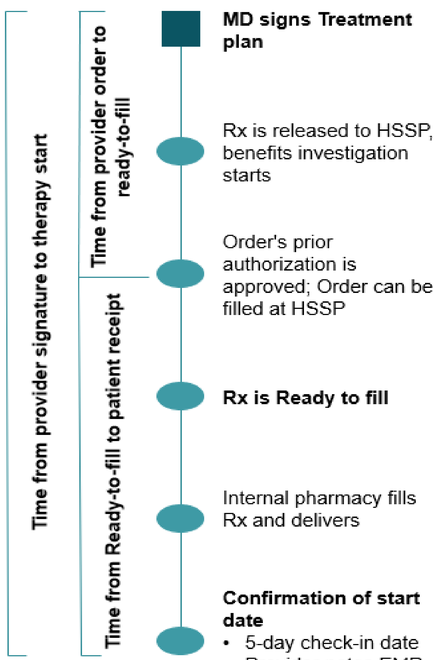



Figure 2: HSSP Timeline for a Prescription Fill




## Results

Table 1: Treatment Regimen at Initiation of Therapy

| Regimen | Number of patients |
|---|---|
| Ven + Azacitidine | 24 |
| Ven + Decitabine | 9 |
| Ven + Azacitidine + Gilteritinib | 3 |
| Ven + Azacitidine + Tuspetinib (Clinical Trial) | 3 |
| Ven + Azacitidine + Ivosedinib | 2 |
| Ven + Azacitidine + Cusatazumab (Clinical Trial) | 2 |
| mini-HyperCVD* + Venetoclax + Blinatumomab | 1 |
| Ven + Azacitidine + Bortezomib | 1 |
| mini-HyperCVD + Venetoclax | 1 |
| Ven + Azacitidine + Ziftomenib | 1 |
| Ven + Azacitidine + Avapritinib | 1 |

*mini-HyperCVAD included: cyclophosphamide, vincristine, dexamethasone, methotrexate, and cytarabine

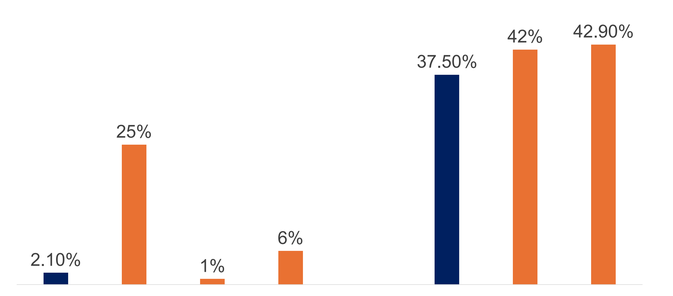
Table 2: Number of Mutations in the Cohort

| Number of major mutations | Percentage |
|---|---|
| 0 | 9% |
| 1 | 32% |
| 2 | 38% |
| 3 | 15% |
| 4+ | 6% |

Figure 3: Approval Times

| Mean PA Approval time 1.8 days | Mean Medication Access 3 days | Mean time to treatment initiation **8 days** |
|---|---|---|
| • Order signature to PA approval | • PA approval + medication assistance time=Ready to fill | • Order signature to therapy initiation |

Figure 4: Adverse Outcomes in First Month of Treatment




*RW real world published studies

## Discussion

- Mean TTI of 8 days, is consistent with published literature. A key distinction of this review is the method used to capture TTI, other RW (Real World) studies utilized prescription delivery as a surrogate marker for therapy start.[2]
- Patient reported data and provider consult notes in the electronic medical record were used in this review.
- Mean medication access time of 3 days also compares favorably to published benchmarks suggesting proactive benefits investigation, and dedicated PA support can reduce provider administrative burden.[7]
- Rates of febrile neutropenia (37.5%) and tumor lysis syndrome (2.10%) in the cohort were comparable to those reported in the VIALE-A landmark study 42.90% and 1.1%, respectively.[3]
- Febrile neutropenia rate (37.5%) likely reflects the disease and treatment related myelosuppression rather than a gap in access or care coordination.[1]
- The most common drug interactions requiring dose interactions involved voriconazole and isavuconazole. Specialty pharmacist led medication reconciliation and interaction management is vital is this population since patients with AML frequently receive concomitant antifungal prophylaxis for neutropenia.
- This retrospective review demonstrates that integrated HSSP can streamline venetoclax access for patients with AML.

## Limitations

- Retrospective, single health system chart review may not be generalizable to other institutions.
- Mixed inpatient and outpatient initiation settings may introduce variability in TTIs.

## Conclusions

- Integrated health system specialty pharmacy services can facilitate timely access to venetoclax and support safe treatment delivery in real-world AML populations.

## References

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