EE161

Health care resource utilization and costs associated with transfusion burden in older US patients with relapsed *FLT3*-mutated acute myeloid leukemia who were prescribed gilteritinib: a Medicare claims–based cohort study

Priti Pednekar,[1] Alana Block,[1] Christopher Young,[1] Giridharan Gurumoorthy,[1] Peter Kardel,[2] Thomas W. LeBlanc[3]

[1]Astellas Pharma Global Development Inc., Northbrook, IL, USA; [2]ADVI Health LLC, Washington, DC, USA; [3]Duke University School of Medicine, Durham, NC, USA

INTRODUCTION

- Older patients with acute myeloid leukemia (AML) experience a poorer response to induction chemotherapy, with lower complete remission rates, higher relapse risk, and inferior survival compared with the broader AML population[1–4]
- Older patients with relapsed AML frequently require ongoing transfusion support because of persistent cytopenias from both targeted treatment and disease progression[5,6]
- Characterizing transfusion burden is important, as greater transfusion dependence (TD) has been linked to higher health care resource utilization (HRU), less favorable clinical outcomes, and worse quality of life[7–9]
- Gilteritinib is an *FMS*-like tyrosine kinase 3 (FLT3) inhibitor approved for adults with relapsed/refractory (R/R) *FLT3*-mutated (*FLT3*$^{mut+}$) AML,[10] but real-world evidence that describes HRU and costs associated with transfusion among patients who have been prescribed gilteritinib is limited

Objective

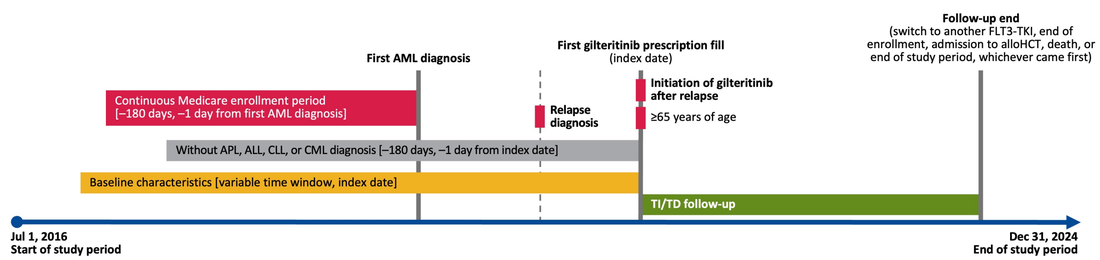
- **To describe HRU and costs associated with transfusion burden among Medicare beneficiaries with relapsed *FLT3*$^{mut+}$ AML who were prescribed gilteritinib**

METHODS

Study design

- This observational retrospective cohort study used Centers for Medicare & Medicaid Services claims data from 100% Research Identifiable Files (Medicare Fee-for-Service [Parts A, B], Part D Event Files, and Medicare Advantage Encounter data [Part C])
- The study period spanned July 1, 2016, through December 31, 2024 (Part C: January 1, 2017–December 31, 2022; **Figure 1**)
- The index date was defined as the date of first gilteritinib prescription fill that occurred on or after AML relapse

Figure 1. Study design



ALL, acute lymphocytic leukemia; alloHCT, allogeneic hematopoietic cell transplantation; AML, acute myeloid leukemia; APL, acute promyelocytic leukemia; CLL, chronic lymphocytic leukemia; CML, chronic myeloid leukemia; FLT3, *FMS*-like tyrosine kinase 3; TD, transfusion dependence; TI, transfusion independence; TKI, tyrosine kinase inhibitor.

Eligibility criteria

- Eligible patients:
  - Had ≥1 inpatient claim or any 2 outpatient claims ≥30 days apart with an AML diagnosis between the dates of July 1, 2016, and June 30, 2024 (Part C: January 1, 2017–June 30, 2022)
  - Had a relapse diagnosis on or after the first AML diagnosis date
  - Were prescribed gilteritinib on or after the first relapse and between the dates of January 1, 2019, and June 30, 2024 (Part C: January 1, 2019–December 31, 2022)
  - Were ≥65 years of age on the index date
  - Had ≥180 days of continuous enrollment before the AML diagnosis date
- Patients were excluded if, in the 180 days prior to the index date, they had a claims history of acute promyelocytic leukemia, acute lymphocytic leukemia, chronic lymphocytic leukemia, or chronic myeloid leukemia, or a history of allogeneic hematopoietic cell transplantation

Outcome measures

- Transfusion independence (TI) was defined as a continuous 56-day period without any red blood cell (RBC) or platelet (PLT) transfusions and was assessed on a rolling basis
- Primary outcome measures in this analysis were HRU (inpatient and outpatient services, and postacute care) and HRU-associated costs, which were evaluated for the TI and TD periods
  - HRU-associated costs were not adjusted for inflation over the study period and reflect the USD value at the time of the claim

Statistical analysis

- Baseline demographic and clinical characteristics were summarized descriptively
- Statistical comparison of mean HRU and HRU-associated costs between the TI and TD periods was assessed using Pearson's t-test

RESULTS

Patient demographic and clinical characteristics

- Of 169,642 Medicare beneficiaries with evidence of AML, 799 met the eligibility criteria and received gilteritinib for R/R AML during the study period
  - At baseline, 444 (55.6%) and 514 (64.3%) were RBC and PLT TI, while 355 (44.4%) and 285 (35.7%) were RBC and PLT TD, respectively
- Baseline demographic and clinical characteristics were broadly similar across the RBC and PLT TI/TD subgroups (**Table 1**)
- Median (interquartile range) treatment duration was 12.9 (8.3–25.7) weeks

Table 1. Baseline demographic and clinical characteristics of patients with relapsed AML who were prescribed gilteritinib (N=799)

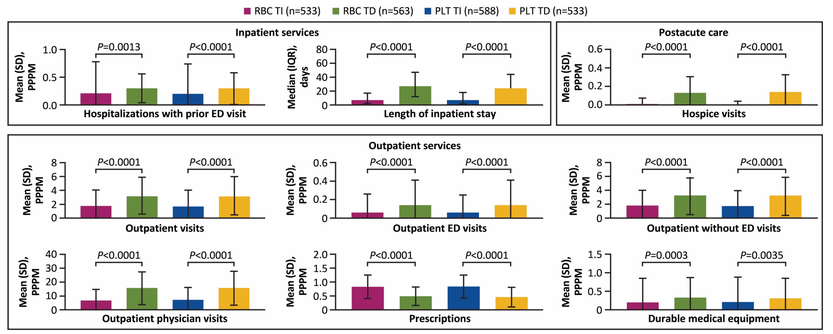
	RBC		PLT		
	TI (n=444 [55.6%])	TD (n=355 [44.4%])	TI (n=514 [64.3%])	TD (n=285 [35.7%])	Overall (N=799)
Median (IQR) length of follow-up, days	167 (83–360)	115 (59–259)	174 (80–361)	106 (55–218)	136 (71–320)
Mean (SD) age, years	74.1 (5.2)	75.2 (4.9)	74.4 (5.4)	75.0 (5.8)	74.6 (5.5)
Male, n (%)	234 (52.7)	189 (53.2)	260 (50.6)	163 (57.2)	423 (52.9)
White, n (%)	367 (82.7)	310 (87.3)	425 (82.7)	252 (88.4)	677 (84.7)
Payer plan type, n (%)					
Medicare FFS	172 (38.7)	296 (83.4)	228 (44.4)	240 (84.2)	468 (58.6)
Medicare Advantage	272 (61.3)	>55 (NR)	286 (55.6)	45 (15.8)	331 (41.4)
Mean (SD) CCI score	2.7 (1.4)	3.2 (1.5)	2.8 (1.4)	3.2 (1.5)	2.9 (1.5)
Common Charlson comorbidities (≥10% of all patients), n (%)					
Congestive heart failure	122 (27.5)	109 (30.7)	144 (28.0)	87 (30.5)	231 (28.9)
Chronic pulmonary disease	115 (25.9)	106 (29.9)	133 (25.9)	88 (30.9)	221 (27.7)
Renal disease	107 (24.1)	112 (31.5)	139 (27.0)	80 (28.1)	219 (27.4)
Peripheral vascular disease	90 (20.3)	110 (31.0)	115 (22.4)	85 (29.8)	200 (25.0)
Cerebrovascular disease	67 (15.1)	>70 (NR)	78 (15.2)	>60 (NR)	142 (17.8)
Diabetes with chronic complications	52 (11.7)	>70 (NR)	73 (14.2)	>45 (NR)	124 (15.5)
Diabetes with or without chronic complications	62 (14.0)	>50 (NR)	71 (13.8)	>40 (NR)	114 (14.3)
Mild liver disease	41 (9.2)	>55 (NR)	48 (9.3)	>50 (NR)	101 (12.6)
Other common comorbidities of interest (≥10% of all patients), n (%)					
Anemia	396 (89.2)	353 (99.4)	467 (90.9)	282 (98.9)	749 (93.7)
Thrombocytopenia	334 (75.2)	303 (85.4)	377 (73.3)	260 (91.2)	637 (79.7)
Kidney failure	189 (42.6)	187 (52.7)	230 (44.7)	146 (51.2)	376 (47.1)
Acute, requiring dialysis	152 (34.2)	157 (44.2)	183 (35.6)	126 (44.2)	309 (38.7)
Chronic, requiring dialysis	105 (23.6)	108 (30.4)	136 (26.5)	>70 (NR)	213 (26.7)
Elevated white blood cell count	156 (35.1)	138 (38.9)	175 (34.0)	119 (41.8)	294 (36.8)
Initial gilteritinib dose, mg, n (%)					
120	347 (78.2)	260 (73.2)	393 (76.5)	214 (75.1)	607 (76.0)
80	59 (13.3)	39 (11.0)	67 (13.0)	31 (10.9)	98 (12.3)
Other	38 (8.6)	56 (15.8)	54 (10.5)	40 (14.0)	94 (11.8)

TI was defined as a continuous 56-day period without any RBC or PLT transfusions and was assessed on a rolling basis. Following transfusion, patients were considered TD but could revert to TI status if 56 days had gone by without a transfusion event.
AML, acute myeloid leukemia; CCI, Charlson Comorbidity Index; FFS, Fee-for-Service; IQR, interquartile range; NR, not reported; PLT, platelet; RBC, red blood cell; SD, standard deviation; TD, transfusion dependence; TI, transfusion independence.

HRU and associated costs

- Median inpatient stay was significantly shorter (*P*<0.0001) during TI periods versus TD periods in both the RBC and PLT subgroups (**Figure 2**)
- Mean per-patient per-month visits were significantly lower (*P*≤0.0013) during TI periods versus TD periods for:
  - Inpatient hospitalizations with a prior emergency department (ED) visit
  - All outpatient visits
  - Outpatient ED visits
  - Outpatient without ED visits
  - Outpatient physician visits
  - Hospice visits
- No statistically significant differences were reported during TI periods versus TD periods for overall hospitalizations, hospitalizations without a prior ED visit, ambulatory surgery center visits, skilled nursing facility visits, or median length of hospice stay in either the RBC or PLT subgroups
  - Additionally, hospitalizations with intensive care unit (ICU) days and home health care visits were not significantly different in RBC and PLT subgroups, respectively
- Most HRU-associated inpatient and outpatient service (except for ambulatory surgery centers and durable medical equipment) and postacute care costs were significantly lower for TI periods versus TD periods (**Table 2**)
- Mean per-patient per-month prescriptions and associated costs were significantly higher (*P*<0.0001) during TI periods versus TD periods
- The highest contributor to inpatient service costs was hospitalizations, which was driven primarily by hospitalizations without a prior ED visit and hospitalizations with ICU days
- The highest contributors to outpatient service costs were prescriptions, followed by outpatient visits without ED visits
- Overall, the costs associated with postacute care were low relative to inpatient and outpatient service costs

Figure 2. HRU during TI periods versus TD periods among patients with relapsed AML who were prescribed gilteritinib



TI was defined as a continuous 56-day period without any RBC or PLT transfusions and was assessed on a rolling basis. Following transfusion, patients were considered TD but could revert to TI status if 56 days had gone by without a transfusion event. Results are reported at the TD/TI period level; patients may contribute multiple TI and/or TD periods during the study period.
AML, acute myeloid leukemia; ED, emergency department; HRU, health care resource utilization; IQR, interquartile range; PLT, platelet; PPPM, per-patient per-month; RBC, red blood cell; SD, standard deviation; TD, transfusion dependence; TI, transfusion independence.

Table 2. HRU-associated costs during TI periods versus TD periods among patients with relapsed AML who were prescribed gilteritinib

	RBC			PLT		
	TI (n=533)	TD (n=563)	*P* value	TI (n=588)	TD (n=533)	*P* value
Mean (SD) inpatient services, PPPM (USD)						
Hospitalizations	5872.59 (13,943.28)	15,671.03 (24,710.32)	<0.0001	6310.45 (14,218.02)	15,505.59 (17,435.53)	<0.0001
Hospitalizations with prior ED visit	1267.58 (5306.85)	4915.48 (7572.57)	<0.0001	1528.82 (5831.20)	5328.47 (8771.56)	<0.0001
Hospitalizations without prior ED visit	3353.23 (9680.50)	6238.41 (9964.07)	<0.0001	3605.40 (10,121.27)	6093.20 (10,594.98)	<0.0001
Hospitalizations with ICU days	2142.15 (8413.38)	4828.86 (9009.45)	<0.0001	2139.06 (7877.63)	5186.15 (10,407.29)	<0.0001
Mean (SD) outpatient services, PPPM (USD)						
Outpatient visits	657.41 (1411.30)	2578.10 (3107.60)	<0.0001	557.87 (1168.47)	2656.65 (3072.82)	<0.0001
Ambulatory surgery centers	1.00 (11.96)	4.18 (55.89)	0.1867	1.68 (23.68)	5.45 (84.29)	0.3184
Outpatient ED visits	36.17 (235.68)	169.83 (431.83)	<0.0001	35.50 (175.37)	176.80 (458.45)	<0.0001
Outpatient without ED visits	614.56 (1360.22)	2396.51 (3009.32)	<0.0001	514.75 (1094.31)	2476.68 (2956.66)	<0.0001
Outpatient physician visits	447.77 (1818.12)	1199.26 (1176.70)	<0.0001	498.49 (1553.52)	1180.45 (1237.18)	<0.0001
Prescriptions	17,908.91 (9172.86)	9770.07 (6407.55)	<0.0001	18,132.72 (8792.43)	9251.00 (7016.24)	<0.0001
Durable medical equipment	15.50 (146.15)	21.97 (114.99)	0.4173	23.78 (288.33)	17.51 (95.51)	0.6189
Mean (SD) postacute care, PPPM (USD)						
Skilled nursing facility visits	59.77 (505.15)	206.91 (908.75)	0.0009	47.34 (397.73)	212.49 (1039.28)	0.0006
Home health care visits	60.10 (208.68)	223.37 (402.02)	<0.0001	65.00 (228.53)	213.76 (399.08)	<0.0001
Hospice visits	13.75 (226.26)	288.10 (577.21)	<0.0001	2.28 (47.74)	319.78 (647.29)	<0.0001

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AML, acute myeloid leukemia; ED, emergency department; HRU, health care resource utilization; ICU, intensive care unit; PLT, platelet; PPPM, per-patient per-month; RBC, red blood cell; SD, standard deviation; TD, transfusion dependence; TI, transfusion independence; USD, United States dollar.

LIMITATIONS

- Several demographic and clinical variables (eg, race, socioeconomic status, laboratory measures, biometrics, physician intent, in-hospital treatments) were not captured, which limited clinical characterization
- Because claims data do not capture disease severity, prognostic factors, or medication adherence, treatment outcomes may be incompletely measured and are subject to bias
- Diagnosis codes for R/R status were unavailable in the claims database
- Clinical events derived from procedure codes may be misclassified (eg, R/R status)
- Generalizability may be limited by the exclusion of uninsured patients, military-insured patients, and patients <65 years of age

CONCLUSIONS

- **TI periods were associated with lower HRU and HRU-associated costs versus TD periods, except for prescriptions, among Medicare beneficiaries in the United States who had relapsed *FLT3*$^{mut+}$ AML and were prescribed gilteritinib**
- **These findings suggest that continued treatment with FLT3 inhibitors in older patients supports the maintenance of TI**
- **Key drivers of HRU-associated costs were prescriptions and hospitalizations**

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For more information, please contact:

Priti Pednekar, priti.pednekar@astellas.com

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