The financial toxicity of FDA-Drugs approved for malignant hematology.

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Abstract

CONTEXT: The high prices of cancer drugs affect the care of cancer patients and our health care system.

OBJECTIVE: Many Food and Drug Administration (FDA) drugs (FDADs) are available now for patients with malignant hematology (MH).

DESIGN: We reviewed one monthly supply price (OMSP) for FDADs for MH approved between 2011 and 2021.

SETTING: We performed a retrospective review of randomized clinical trials that led to FDAs approval for MH. Sixty-three FDADs were identified.

PATIENTS OR OTHER PARTICIPANTS: FDADs were divided into disease groups: acute myeloid leukemia (AML), chronic myeloid leukemia (CML), acute lymphoblastic leukemia (ALL), chronic lymphocytic leukemia (CLL), multiple myeloma (MM), myelodysplastic syndrome + myeloproliferative neoplasms (MDS+MPN), and lymphoma.

INTERVENTIONS: We compared prices between drug.com and UpTo Date. The percentage change was low (0.18).

MAIN OUTCOMES MEASURES: We calculated the median of OMSP for FDADs for each group. We compared the median of OMSP between oral (PO), subcutaneous (SQ), and intravenous (IV) FDADs.

RESULTS: The median of OMSP for AML, CML, ALL, CLL, and MDS+MPN were $30923 [range, 5989 to 36099], $19343 [range, 20834 to 22570], $84749 [range, 75839 to 373000], $15263 [range, 3532 to 23091], and $15284 [range, 8060 to 24157], respectively. All FDADs for ALL patients were IV. The median of OMSP for MM and lymphoma were $20982 [range, 12054 to 441,743] and $23091 [range, 6834 to 475000], respectively. The median of OMSP for PO, SQ, and IV FDADs were $18291 [range, 2628 to 31,686], $18370 [range, 6934 to 22583] and $24691 [range, 2090 to 93660] (discounting CAR-T cell therapy), respectively. The median of OMSP for FDADs approved from (2011 to 2016) and (2016 to 2021) were $22233 (range, 8300 to 23091) and $24517 (range, 2352 to 475000), respectively. The median household monthly income was $6,558 in 2020 in the United States (US). There are currently no generic drug products of FDADs available in the US.

CONCLUSIONS: MH patients are affected by treatment-related financial harm. The need for generic versions to lower the price is urgent. IV FDADs are more expensive than PO or SQ. The value of drugs should be considered in formulating treatment guidelines.

Background

- The high prices of Food and Drug Administration-approved (FDA) drugs (FDADs) for malignant hematology (MH) affect the care of these patients and our health care system.
- Here, we estimated one monthly supply price (OMSP) for FDADs for MH approved between 2011 and 2021. We compared prices between drug.com and UpToDate.
- We reported the total cost (TC) of FDADs by multiplying OMSP times the assumed duration of therapy based on the available overall survival (OS) (OMSP x OS (months)).

Objective

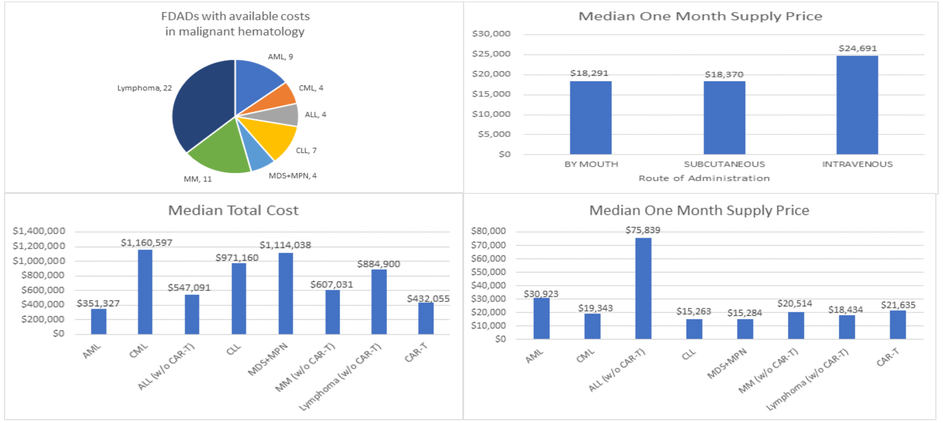
- We performed a retrospective review of clinical trials (CTs) published from January 2011 to May 2021 that led to FDA approval of hematological malignancy drugs (Leukemias, lymphomas, Multiple Myeloma (MM), Myelodysplastic Syndrome (MDS), and Myeloproliferative Neoplasm (MPN)).
- CTs were also reviewed on ClinicalTrials.gov (CT.gov) and Primary Literature on drug approval.
- FDADs were divided into disease groups: acute myeloid leukemia (AML), chronic myeloid leukemia (CML), acute lymphoblastic leukemia (ALL), chronic lymphocytic leukemia (CLL), MDS+MPN, MM, and lymphoma.
- We used the lowest price for each drug when compared between drug.com and UpToDate (the percentage change was low 0.18).
- We calculated the median of OMSP for each group, compared the median of OMSP between oral (PO), subcutaneous (SQ), and intravenous (IV) FDADs, and calculated TC for each group. For non-reached OS, we used 60 months to calculate TC.

Results

- Sixty-one FDADs were identified: 9,4,4,7 and 4 for AML, CML, ALL, CLL, and MDS+MPN, respectively. For MM and lymphoma, we identified 11 and 22, FDADs, respectively.
- The number of PO, SQ, and IV FDADs were 29, 4, and 30, respectively (some drugs were approved for more than one disease).
- All FDADs for ALL patients were IV. The highest OMSP was for ALL but not the TC due to the short median OS (10 months) for these patients.
- There are currently no generic drug products of these FDADs (approved between 2011 and 2021) available in the US.

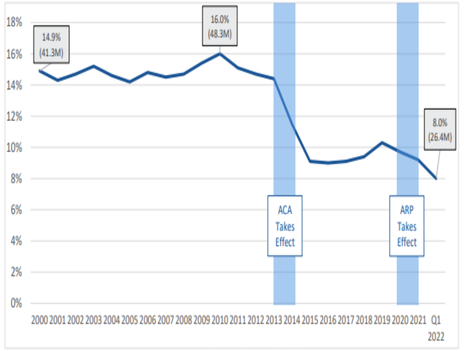
Results

Figure (1). The number of FDA drugs in each group, the median one-month supply price, and the median total cost.



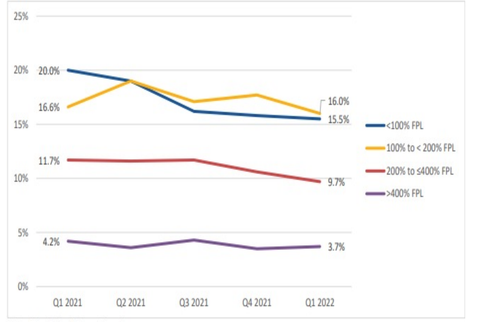
FDADs: Food and Drug Administration drugs; AML: acute myeloid leukemia; CML; chronic myeloid leukemia; ALL: acute lymphoblastic leukemia; CLL: chronic lymphocytic leukemia, MDS: Myelodysplastic Syndrome, MPN: Myeloproliferative Neoplasm; MM: Multiple Myeloma; W/O: without; CAR-T: chimeric antigen receptor-T cell.

Figure (2). National uninsured rate, all ages (2000-Q12022).



Source: National Health Interview Survey's Health Insurance Coverage Reports, 2000-2021.

Figure (3). Uninsured rate among US residents under age 65, by income (2000-Q12022).



Note: FPL = Federal Poverty Level.

Source: Health Insurance Coverage: Early Release of Quarterly Estimates From the National Health Interview Survey, January 2021–March 2022. https://www.cdc.gov/nchs/data/nhis/earlyrelease/Quarterly_Estimates_2022_Q11.pdf

Summary

- The cost-effectiveness of CAR-T products is somewhat similar (if not somewhat lower) to other FDA drugs.
- Patients with malignant hematologic disorders are affected by treatment-related financial harm.
- The value of drugs should be considered in formulating treatment guidelines.

Discussion

- In 2015, 115 American scientists published a manuscript emphasizing the impact of high prices of cancer drugs on the clinical and health system.
- In 2017, the American Society of Clinical Oncology (ASCO) released a statement regarding the affordability of cancer drugs due to the high pricing of cancer drugs.
- Still, more efforts should be spent to lower the price of cancer drugs, including not limited to making generic drug products and considering drug prices in formulating treatment guidelines.
- Although the costs used for this analysis may be modulated by many factors where the actual cost may not be what is reported in the sources, the financial impact is still significant for many patients.

References

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Disclosures

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