

Cost Sharing for Oral Lenvatinib Among Commercially Insured Patients

Margaret I. Liang, MD, MS; Ling Chen, MD, MPH; Emeline M. Aviki, MD, MBA; and Jason D. Wright, MD

Oral cancer therapies are increasingly common, with mean total monthly spending at the time a new drug is released of approximately \$9000 for agents launched after 2010.¹ Moreover, costs frequently continue to increase 10% to 20% in the years after product launch.¹ Depending on patients' pharmaceutical benefits, high patient cost sharing for oral cancer therapies can lead to financial strain.

Lenvatinib (Lenvima), an oral tyrosine kinase inhibitor, has received FDA approval for use in multiple cancer types, including differentiated thyroid cancer (February 2015), in combination with everolimus (Afinitor) for advanced renal cell carcinoma (May 2016), and unresectable hepatocellular carcinoma (August 2018).²⁻⁴ More recently, lenvatinib has been approved in combination with pembrolizumab (Keytruda) for certain types of advanced endometrial cancer (September 2019) and advanced renal cell carcinoma (August 2021).^{5,6} The price for a 30-day supply of lenvatinib is \$25,106, regardless of dosage, which differs depending on the indication.⁷ Our objective was to use nationally representative pharmaceutical claims data to estimate early trends in cost sharing for commercially insured patients with cancer who were prescribed lenvatinib.

METHODS

This study was classified as non-human subjects research by the Institutional Review Board of Columbia University. We utilized the IBM MarketScan Commercial Claims and Encounters and Medicare Supplemental and Coordination of Benefits databases. These databases capture prescription drug use and inpatient/outpatient claims and allow for longitudinal study of deidentified patient data. All patients within the databases have commercial insurance through their employer, and for patients 65 years and older, Medicare claims for fee-for-service plans are also captured in both databases. Patients were eligible for inclusion if they had an outpatient pharmaceutical claim for lenvatinib paid on a noncapitated basis between 2015 and 2019. Cancer type was identified using *International Classification of Diseases, Ninth Revision* and *International Statistical Classification of Diseases, Tenth Revision* codes.

ABSTRACT

OBJECTIVE: To use a nationwide pharmaceutical claims database to evaluate cost-sharing trends for commercially insured patients with cancer who were prescribed lenvatinib (Lenvima).

STUDY DESIGN: IBM MarketScan databases were used to evaluate lenvatinib costs for patients with employer-based commercial insurance, and for patients 65 years and older, Medicare claims for fee-for-service plans.

METHODS: Patients were included if they had least 1 outpatient pharmaceutical claim for lenvatinib paid on a noncapitated basis from 2015 to 2019. Median and IQR costs were estimated and inflation adjusted to 2019 US\$ for 30-day supplies and reported as total, insurance liability, coordination of benefits, and out-of-pocket costs.

RESULTS: A total of 685 patients had at least 1 pharmaceutical claim for lenvatinib, which included patients with thyroid (n = 251; 36.6%), renal cell (n = 202; 29.5%), hepatocellular (n = 160; 23.4%), and endometrial (n = 48; 7.0%) cancer. The median (IQR) number of prescriptions per patient was 3 (2-7), and the median (IQR) total days of supply was 90 (45-210) days. The median (IQR) 30-day cost of lenvatinib was \$17,253 (\$15,597-\$18,120). Median (IQR) 30-day insurance liability was \$16,847 (\$15,000-\$17,981). Median (IQR) 30-day coordination of benefits was \$0 (\$0-\$0). Median (IQR) 30-day patient out-of-pocket cost was \$32 (\$0-\$100). However, the maximum 30-day out-of-pocket cost in our patient cohort was \$12,538.

CONCLUSIONS: In this cohort, insurance was liable for the majority of total lenvatinib drug costs, and 75% of patients paid \$100 or less per month out of pocket. This information can be used by care teams to counsel insured patients. Health systems and drug manufacturers must identify patients with high out-of-pocket costs and provide convenient access to financial assistance programs so that patients are not forced to forgo the benefits of these drugs due to financial barriers. Value-based payment models and drug pricing reform are also needed to address underlying drivers of high drug costs.

Am J Manag Care. 2024;30(3):114-117. doi:10.37765/ajmc.2024.89512

Patient characteristics were reported descriptively. Lenvatinib costs were reported as 30-day supply costs per patient by taking the sum of all the costs from the first to the last prescription, dividing by the total days of supply, and then multiplying by 30 to account for prescriptions dispensed for different durations. Total costs were divided into insurance liability, coordination of benefits and other savings (ie, costs paid by second insurance carriers such as Medicare or other third-party payers), and out of pocket. Costs were inflation adjusted to 2019 US\$ using the Consumer Price Index from the US Bureau of Labor Statistics and reported as medians with IQRs.

TAKEAWAY POINTS

- ▶ Although most insured patients with cancer paid \$100 or less out of pocket for a 30-day supply of oral lenvatinib (Lenvima), there can also be extreme costs, with a 30-day out-of-pocket cost of \$12,538 in one case.
- ▶ Managed care pharmacies play a critical role identifying patients who may have difficulty affording oral cancer therapies and linking them to financial assistance programs so that these patients do not forgo the benefits of these drugs due to cost barriers.
- ▶ Value-based payment models and drug pricing reform are also needed to address underlying drivers of high drug costs.

RESULTS

There were 685 patients with at least 1 pharmaceutical claim for lenvatinib (Table). This included patients with thyroid (n=251; 36.6%), renal cell (n=202; 29.5%), hepatocellular (n=160; 23.4%), endometrial (n=48; 7.0%), and other (n=24; 3.5%) cancers. The median (IQR) age was 59 (53-64) years, and 274 (40.0%) of the patients were female. Most of the first lenvatinib prescriptions were dispensed between 2018 and 2019 (n=426; 62.2%), which was consistent with the increasing number of FDA approvals for the drug. The median (IQR) number of prescriptions per patient was 3 (2-7), and the median (IQR) total number of days of supply was 90 (45-210).

The median (IQR) 30-day cost of lenvatinib per patient was \$17,253 (\$15,597-\$18,120) (Figure 1); by type of cancer, this was \$15,696 (\$15,078-\$17,453) for thyroid, \$17,016 (\$15,705-\$17,906) for renal cell, \$17,915 (\$17,419-\$18,521) for hepatocellular, and \$18,423 (\$17,918-\$19,173) for endometrial cancer. Median (IQR) 30-day insurance liability per patient was \$16,847 (\$15,000-\$17,981); by cancer type, this was \$15,433 (\$14,443-\$17,192) for thyroid, \$16,806 (\$15,395-\$17,828) for renal cell, \$17,810 (\$17,018-\$18,423) for hepatocellular, and \$18,334 (\$17,518-\$19,170) for endometrial cancer. Median (IQR) 30-day coordination of benefits per patient was \$0 (\$0-\$0) for the entire cohort and all 4 cancer types. Finally, median (IQR) 30-day patient out-of-pocket costs were \$32 (\$0-\$100), with a maximum of \$12,538; by cancer type, this was \$48 (\$0-\$129) for thyroid, \$21 (\$0-\$75) for renal cell, \$30 (\$0-\$80) for hepatocellular, and \$0 (\$0-\$58) for endometrial cancer. Overall, 30-day patient out-of-pocket costs were \$0 for 36.9% of the patients and greater than \$500 for 6.7% of the patients (Figure 2).

DISCUSSION

Among commercially insured patients, insurance coverage results in monthly out-of-pocket costs of \$100 or less for lenvatinib among most patients with cancer. However, the maximum 30-day out-of-pocket cost in our patient cohort was \$12,538 (Figure 1), which

TABLE. Patient Characteristics Among Commercially Insured Patients With Cancer Who Received Lenvatinib From the MarketScan Databases (N = 685)

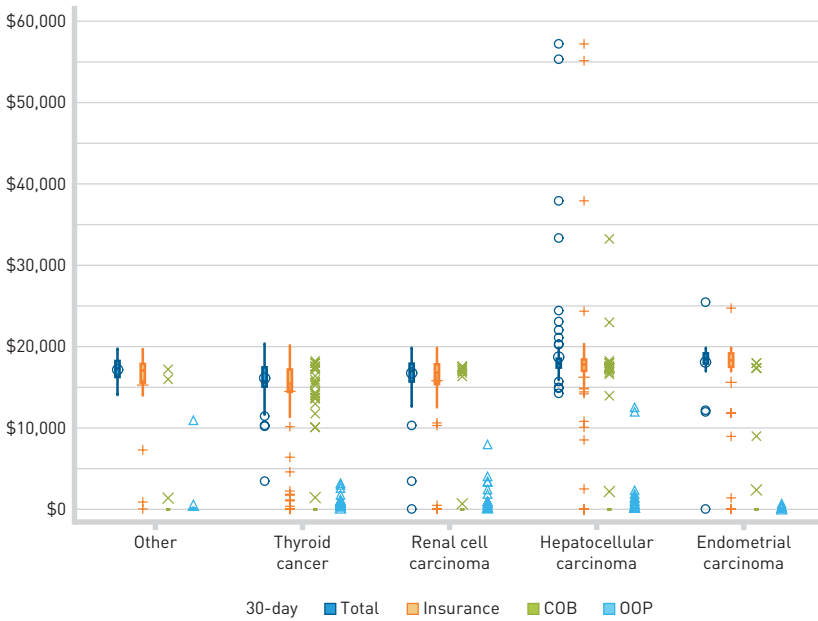
| Patient characteristics | Median (IQR) or n (%) |
|--|-----------------------|
| Age in years, median (IQR) | 59 (53-64) |
| Sex, n (%) | |
| Female | 274 (40.0) |
| Male | 411 (60.0) |
| Cancer type, n (%) | |
| Thyroid | 251 (36.6) |
| Renal cell | 202 (29.5) |
| Hepatocellular | 160 (23.4) |
| Endometrial | 48 (7.0) |
| Other | 24 (3.5) |
| Region, n (%) | |
| Northeast | 165 (24.1) |
| North central | 113 (16.5) |
| South | 315 (46.0) |
| West | 87 (12.7) |
| Unknown | 5 (0.7) |
| MSA, n (%) | |
| MSA | 500 (73.0) |
| Non-MSA | 87 (12.7) |
| Unknown | 98 (14.3) |
| Year of first lenvatinib prescription, n (%) | |
| 2015 | 74 (10.8) |
| 2016 | 91 (13.3) |
| 2017 | 94 (13.7) |
| 2018 | 144 (21.0) |
| 2019 | 282 (41.2) |
| Number of lenvatinib pharmaceutical claims, median (IQR) | 3 (2-7) |

MSA, metropolitan statistical area.

demonstrates that certain patients may face high out-of-pocket costs. Overall, the cost-sharing trends were similar for different cancer types.

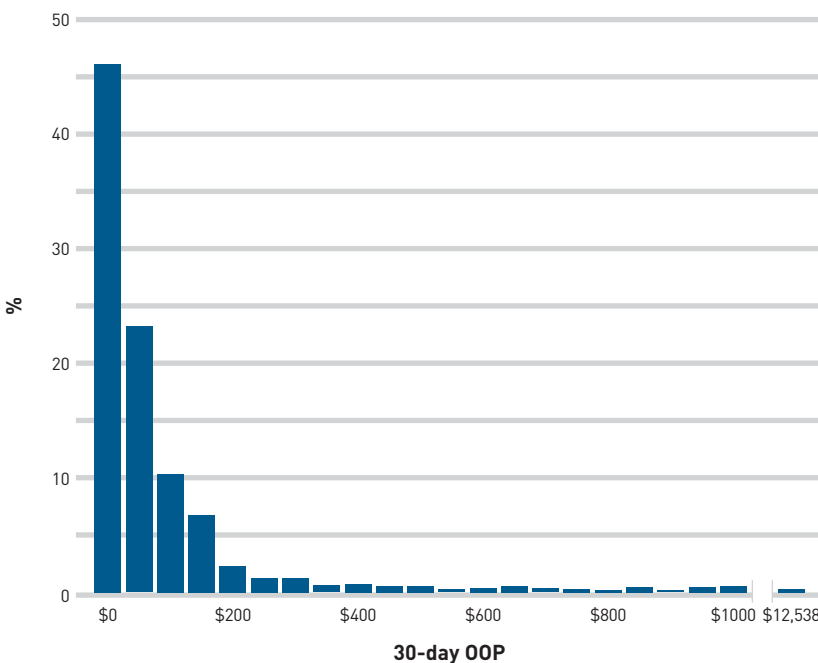
Out-of-pocket cost information is important because higher out-of-pocket costs for oral cancer therapies have been associated with

FIGURE 1. Box and Whisker Plot of 30-Day Costs (Total, Insurance, COB, OOP) for Lenvatinib Among Commercially Insured Patients Stratified by Cancer Type



COB, coordination of benefits; OOP, out of pocket.

FIGURE 2. 30-Day OOP Costs (\$) for Lenvatinib Among a Cohort of Commercially Insured Patients With Cancer



OOP, out of pocket.

lower initiation of and adherence to therapy. A recent study found a 30% noninitiation rate among Medicare beneficiaries without low-income subsidies for Part D high-priced specialty cancer drugs compared with 14% for beneficiaries with partial or full low-income subsidies to offset patient cost-sharing requirements.⁸ Several studies have found higher rates of prescription abandonment for oral cancer therapies with high out-of-pocket costs.^{9,10} In addition, dose reductions are an important consideration when examining cost-sharing patterns for lenvatinib. In the KEYNOTE-775 clinical trial (NCT03517449), which led to FDA approval of lenvatinib and pembrolizumab in certain types of endometrial cancer, 70% of study participants required 1 dose reduction, and 45% required 2 or more dose reductions⁵; a dose reduction often requires that payers and patients pay for a completely new dose pack. The most frequent adverse events ($\geq 10\%$) leading to dose reductions in the lenvatinib and pembrolizumab arm were for hypertension (17.7%) and diarrhea (11.1%).⁵

Limitations

This study has several limitations. Given the timing of FDA approvals, the current study only depicts the cost-sharing experience of commercially insured patients using the most recent available data; however, these data are informational to both health care providers and patients given the increasing usage of this drug in multiple cancer types. Due to the nature of the claims data, we are unable to identify patients for whom lenvatinib may have been indicated but was not prescribed due to costs. For context, in a claims-based study of oral cancer therapies (not including lenvatinib), there was an 18% abandonment rate, defined as reversal of an oral anticancer prescription with no fill of the same agent within 90 days after adjudication.⁹ Importantly, the risk-adjusted abandonment rate was higher as the category of out-of-pocket costs increased.⁹ We were also unable to measure the contribution of financial assistance programs or meaningfully examine differences in cost sharing based on drug dosing or insurance characteristics (ie, high-deductible health plans) given the sample size. Although we estimated 30-day supply costs, we were unable to account for patients

who were not taking the medication continuously (ie, holding the medication due to toxicity), which could overestimate patients' out-of-pocket costs.

CONCLUSIONS

Oral cancer therapies such as lenvatinib are becoming increasingly common in oncology. In this cohort of commercially insured patients with cancer, the median 30-day total drug cost was \$17,253, with insurance covering most of the costs and 75% of patients paying \$100 or less per month. These cost estimates do not fully capture the burden of cost sharing per patient, which would also include the costs of managing preexisting comorbidities, symptoms of cancer, and treatment-related toxicities. Nonetheless, it is important for providers and specialty pharmacists to have this information on cost-sharing patterns for lenvatinib as they counsel patients on this novel drug class. Moreover, it is imperative that health systems, pharmacies, and drug manufacturers provide convenient access to financial assistance programs so that patients are not forced to forgo the benefits of these drugs due to financial barriers. Although financial assistance programs can help mitigate short-term concerns of treatment nonadherence due to costs, they do not address the underlying issues of overall high health care costs and rising drug costs that contribute to increasing out-of-pocket costs for patients with cancer.¹¹ Value-based payment arrangements that link clinical outcomes to reimbursement and legislative policies focused on drug pricing reform can have a broader impact on decreasing overall cancer costs, which could ultimately decrease the downstream cost to patients.^{12,13} Future studies are needed on how out-of-pocket costs of oral cancer therapies are impacted by different pharmaceutical benefit designs and national policies such as the Inflation Reduction Act, which will affect the structure of Medicare Part D pharmaceutical benefits.¹⁴ ■

Author Affiliations: Division of Gynecologic Oncology, Department of Obstetrics and Gynecology, Cedars-Sinai Medical Center (MIL), Los Angeles, CA; Columbia University Vagelos College of Physicians and Surgeons (LC, JDW), New York, NY;

Memorial Sloan Kettering Cancer Center (EMA), New York, NY; Herbert Irving Comprehensive Cancer Center, Columbia University (JDW), New York, NY.

Source of Funding: None.

Author Disclosures: Dr Wright has received grants from the National Institutes of Health and Merck, honoraria from the American College of Obstetricians and Gynecologists, and royalties from UpToDate, Inc. The remaining authors report no relationship or financial interest with any entity that would pose a conflict of interest with the subject matter of this article.

Authorship Information: Concept and design (MIL, LC, JDW); acquisition of data (LC, JDW); analysis and interpretation of data (MIL, LC, EMA, JDW); drafting of the manuscript (MIL, LC, EMA, JDW); critical revision of the manuscript for important intellectual content (MIL, LC, EMA, JDW); statistical analysis (LC); and supervision (MIL, JDW).

Address Correspondence to: Margaret I. Liang, MD, MS, Division of Gynecologic Oncology, Department of Obstetrics and Gynecology, Cedars-Sinai Medical Center, 8635 W 3rd St, Ste 160W, Los Angeles, CA 90048. Email: margaret.liang@cshs.org.

REFERENCES

- Dusetzina SB. Drug pricing trends for orally administered anticancer medications reimbursed by commercial health plans, 2000-2014. *JAMA Oncol*. 2016;2(7):960-961. doi:10.1001/jamaoncol.2016.0648
- Schlumberger M, Tahara M, Wirth LJ, et al. Lenvatinib versus placebo in radioiodine-refractory thyroid cancer. *N Engl J Med*. 2015;372(7):621-630. doi:10.1056/NEJMoa1406470
- Motzer RJ, Hutson TE, Glen H, et al. Lenvatinib, everolimus, and the combination in patients with metastatic renal cell carcinoma: a randomized, phase 2, open-label, multicentre trial. *Lancet Oncol*. 2015;16(15):1473-1482. doi:10.1016/S1470-2045(15)00290-9
- Kudo M, Fin RS, Qin S, et al. Lenvatinib versus sorafenib in first-line treatment of patients with unresectable hepatocellular carcinoma: a randomized phase 3 non-inferiority trial. *Lancet*. 2018;391(10126):1163-1173. doi:10.1016/S0140-6736(18)30207-1
- Makker V, Colombo N, Herráez AC, et al; Study 309-KEYNOTE-775 Investigators. Lenvatinib plus pembrolizumab for advanced endometrial cancer. *N Engl J Med*. 2022;386(5):437-448. doi:10.1056/NEJMoa2108330
- Motzer R, Alekseev B, Rha SY, et al; CLEAR Trial Investigators. Lenvatinib plus pembrolizumab or everolimus for advanced renal cell carcinoma. *N Engl J Med*. 2021;384(14):1289-1300. doi:10.1056/NEJMoa2035716
- Lenvatinib. Lexi-Drugs Online. UpToDate Inc; 2022. Accessed April 4, 2022. <http://online.lexi.com>
- Dusetzina SB, Huskamp HA, Rothman RL, et al. Many Medicare beneficiaries do not fill high-price specialty drug prescriptions. *Health Aff (Millwood)*. 2022;41(4):487-496. doi:10.1377/hlthaff.2021.01742
- Doshi JA, Li P, Huo H, Pettit AR, Armstrong KA. Association of patient out-of-pocket costs with prescription abandonment and delay in fills of novel oral anticancer agents. *J Clin Oncol*. 2018;36(5):476-482. doi:10.1200/JCO.2017.74.5091
- Streeter SB, Schwartzberg L, Husain N, Johnsrud M. Patient and plan characteristics affecting abandonment of oral oncolytic prescriptions. *J Oncol Pract*. 2011;17(suppl 3):46S-51S. doi:10.1200/JOP.2011.000316
- Yabroff KR, Mariotto A, Tangka F, et al. Annual report to the nation on the status of cancer, part 2: patient economic burden associated with cancer care. *J Natl Cancer Inst*. 2021;113(12):1670-1682. doi:10.1093/jnci/djab192
- Seymour EK, de Souza JA, Fendrick AM. Incorporating value-based care into oncology. *Cancer J*. 2020;26(4):311-322. doi:10.1097/PP0.0000000000000459
- Kesselheim AS, Avorn J, Sarpatwari A. The high cost of prescription drugs in the United States: origins and prospects for reform. *JAMA*. 2016;316(8):858-871. doi:10.1001/jama.2016.11237
- Dusetzina SB, Huskamp HA. Impending relief for Medicare beneficiaries – the Inflation Reduction Act. *N Engl J Med*. 2022;387(16):1437-1439. doi:10.1056/NEJMp2211223

Visit ajmc.com/link/89512 to download PDF