Healthcare Costs in Patients with Newly Diagnosed Advanced Ovarian Cancer Receiving Maintenance Treatment with Niraparib Monotherapy or Active Surveillance in the United States

Ramya Pratiwadi[1], John Hartman[2], Jinlin Song[3], Travis Wang[4], Xiaoyu Nie[3]

[1]At the time of study conduct: GSK, Philadelphia, PA, USA; [2]GSK, Philadelphia, PA, USA; [3]Analysis Group, Inc., Los Angeles, CA, USA; [4]Analysis Group, Inc., Boston, MA, USA

Introduction

- Ovarian cancer (OC) is a leading cause of cancer death among women.[1] Estimates for 2015–2019 include an incidence rate of 10.4 per 100,000 and a death rate of 6.3 per 100,000, age adjusted to the 2000 US standard population.[2]
- Platinum-based chemotherapy (PBT) is a standard of care for first-line (1L) treatment for advanced OC.[3] For patients who attain a partial or complete response to 1L chemotherapy (CT), monotherapy with niraparib, a poly (ADP-ribose) polymerase inhibitor (PARPi), is recommended as a potential maintenance strategy.
- Clinical studies have demonstrated the efficacy of maintenance niraparib in patients with newly diagnosed advanced OC who respond to 1L CT.[4–6] However, evidence is limited on the cost of maintenance treatment with niraparib in the real world.

Methods

- A retrospective cohort study evaluated the health resource utilization (HRU) and costs during 1L maintenance (1LM) therapy in eligible patients with newly diagnosed advanced epithelial OC treated with either niraparib or active surveillance (AS).
- Data were obtained from the Optum® Market Clarity and Enriched Oncology databases and comprised patient information from January 1, 2007, to March 31, 2021.

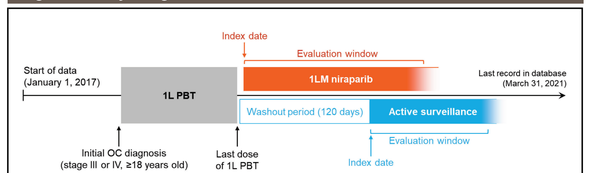
Table 1. Patient inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
Female age ≥18 years on the initial OC diagnosis date with any diagnosis code for ovarian, fallopian tube, retroperitoneum/peritoneum, or other unspecified female genital organ cancer from January 1, 2007, through March 31, 2021	Prior claim for advanced epithelial OC during 12 months before initial OC diagnosis
≥1 inpatient or ≥2 outpatient diagnoses from claims or electronic health record (EHR) (at least 30 days apart) for ovarian, fallopian tube, retroperitoneum/peritoneum, or other unspecified female genital organ cancer (ICD-9-CM: 183.0, 183.2, 158.x or ICD-10-CM: C56.x, C57.0x, C48.x) between January 1, 2015, and March 31, 2021 (the earliest occurrence of meeting the inpatient diagnosis or outpatient diagnosis criteria was defined as the first OC diagnosis)	Bleomycin use during January 1, 2014, through March 31, 2021
Evidence of advanced disease within 90 days after first OC diagnosis, defined as ≥1 of: • Stage III or IV OC • 'T3' extent of ovarian tumor spread (per AJCC TNM staging system) • 'M1' presence of metastasis from OC (per AJCC TNM staging system) • ≥1 diagnosis code (ICD-9-CM or ICD-10-CM) for secondary malignancy on or after the initial OC diagnosis	Pregnant any time during the data availability period
Epithelial tumor histology within 90 days after the first OC diagnosis	Started second-line treatment within 2 months (60 days) of the last dose of platinum-based 1L CT (to exclude patients with progressive disease)
Healthcare activity in the EHR database and/or continuous medical and pharmacy eligibility in the claims database for ≥12 months before and ≥3 months after the first OC diagnosis	Incurred zero cost in the claims data during the 1L or 1LM treatment period
Received platinum-based 1L chemotherapy (CT) (carboplatin, cisplatin, oxaliplatin) on or after the advanced OC diagnosis	
Received last dose of platinum-based 1L CT on or after January 1, 2017	
Continuous eligibility during the baseline period, i.e., from the initial OC diagnosis to the index date	
Continuous eligibility during the 120-day washout period for 1L maintenance therapy following the end of 1L CT, based on the line-of-therapy algorithm defined in the Optum data (to ensure every patient had the same evaluation period to avoid any selection bias)	

1L, first-line; 1LM, 1L maintenance; AJCC, American Joint Committee on Cancer; OC, ovarian cancer; TNM, tumor-node-metastasis.

- Key patient inclusion and exclusion criteria are shown in **Table 1**.
- Two cohorts were identified based on 1LM use: niraparib and AS. Niraparib must have been continued for ≥28 days after the end of PBT to have been considered maintenance therapy (**Figure 1**).
- Index date for the niraparib group was defined as the start of 1LM therapy. For the AS cohort, index date was defined as the end of a 120-day washout period following the final dose of 1L PBT, designed to screen out patients with progressive disease following 1L PBT who would be PARPi-ineligible.

Figure 1. Study design



1L, first-line; 1LM, first-line maintenance; OC, ovarian cancer ; PBT, platinum-based chemotherapy.

- Patient characteristics were assessed during the baseline period, and clinical characteristics on or before the index date. Follow-up time was defined as time from the index date (inclusive) to the earlier of death or end of continuous eligibility in claims.
- All-cause healthcare costs (2021 USD) were described on a per-patient-per-month (PPPM) basis for the two cohorts for the 1LM evaluation period, defined as extending from the index date (inclusive) to the earlier of the initiation of second-line therapy (exclusive) or the end of follow-up.
- All costs were indexed to 2021 USD using the medical consumer price index.

Results

Table 2. Patient demographic and clinical characteristics

	Niraparib (N=76)	Active surveillance (N=948)
Demographics		
Age at index date, years		
Mean ± SD	66.8 ± 11.5	64.7 ± 11.3
Median (IQR)	67.0 (60.8, 75.3)	65.0 (57.0, 73.0)
Age category at index date, n (%)		
18–44 years	3 (3.9)	35 (3.7)
45–74 years	52 (68.4)	708 (74.7)
75 years and above	21 (27.6)	205 (21.6)
Race/ethnicity, n (%)		
Non-Hispanic White	52 (68.4)	563 (59.4)
Non-Hispanic African American	1 (1.3)	60 (6.3)
Non-Hispanic Asian	2 (2.6)	17 (1.8)
Hispanic/Latino	2 (2.6)	36 (3.8)
Other/unknown	19 (25.0)	272 (28.7)
Clinical characteristics		
NCI comorbidity index		
Mean ± SD	0.6 ± 0.6	0.6 ± 0.6
Median (IQR)	0.5 (0.0, 1.0)	0.5 (0.0, 0.9)
Cancer stage at initial diagnosis, n (%)		
Stage III	5 (6.6)	79 (8.3)
Stage IV	71 (93.4)	863 (91.0)
Unknown	0 (0.0)	6 (0.6)
Duration of disease prior to index date, months*		
Mean ± SD	10.1 ± 7.6	11.0 ± 3.8
Median (IQR)	7.8 (6.5, 9.7)	10.3 (9.6, 11.4)
Debulking surgery, n (%)		
Primary debulking surgery only	36 (47.4)	532 (56.1)
Interval debulking surgery only	26 (34.2)	214 (22.6)
Both primary and interval debulking surgeries	4 (5.3)	36 (3.8)
No debulking surgery	10 (13.2)	166 (17.5)
Received bevacizumab in 1L therapy, n (%)	9 (11.8)	72 (7.6)

1L, first-line; IQR; interquartile range; NCI, National Cancer Institute; SD, standard deviation. *Difference between index date and initial diagnosis date.

- A total of 1,024 patients initiated 1LM therapy with either niraparib (N=76, 7.4%) or AS (N=948, 92.6%) (**Table 2**).
- The niraparib and AS cohorts were comparable with respect to demographic and clinical characteristics at baseline. Mean age at index date was 66.8 years and 64.7 years for the niraparib and AS cohorts, respectively.
- The mean National Cancer Institute comorbidity index was 0.6 in both cohorts; more than 90% of patients in each cohort had stage IV disease.

Table 3. Health resource utilization for 1LM

	Niraparib (N=76)	Active surveillance (N=948)
Duration of evaluation period (months)		
Mean ± SD	9.6 ± 5.9	12.8 ± 12.0
Median (IQR)	8.3 (5.4, 12.4)	9.0 (3.6, 18.6)
Year of index date, (%)		
2017	6 (7.9)	193 (20.4)
2018	13 (17.1)	274 (28.9)
2019	7 (9.2)	254 (26.8)
2020	43 (56.6)	196 (20.7)
2021	7 (9.2)	31 (3.3)
Number of IP admissions, PPPM		
Mean ± SD	0.0 ± 0.0	0.1 ± 0.3
Median (IQR)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)
Duration of IP stay (days)		
Mean ± SD	3.8 ± 1.9	8.4 ± 23.3
Median (IQR)	4.0 (3.0, 5.0)	4.0 (2.4, 7.0)
Number of ER visits, PPPM		
Mean ± SD	0.0 ± 0.1	0.1 ± 0.5
Median (IQR)	0.0 (0.0, 0.1)	0.0 (0.0, 0.0)
Number of OP visits, PPPM		
Mean ± SD	2.2 ± 2.6	1.7 ± 2.7
Median (IQR)	1.5 (1.0, 2.5)	1.1 (0.6, 1.8)

1LM, first-line maintenance; ER, emergency room; IP, inpatient; IQR; interquartile range; OP, outpatient; PPPM, per patient per month; SD, standard deviation.

- Mean duration of evaluation was 9.6 months for niraparib and 12.8 months for AS (**Table 3**); the distribution of index dates varied between cohorts, and follow-up ceased at death or end of claims eligibility.
- Mean duration of IP stay was lower for niraparib than for AS (**Table 3**). For niraparib and AS, 5 (6.6%) and 143 (15.1%) patients, respectively, recorded ≥1 IP visit, and 22 (28.9%) and 243 (25.6%) recorded ≥1 ER visit.
- Mean total healthcare cost (PPPM) was greater for niraparib ($11,302) than for AS ($6,406) (**Table 4**). Medical costs were lower for niraparib, driven by higher inpatient and outpatient costs for patients in the AS arm.

Table 4. Healthcare costs (PPPM) for 1LM (2021 USD)

	Niraparib (N=76)	Active surveillance (N=948)
Total medical (excluding pharmacy) cost		
Mean ± SD	3,001.9 ± 7,036.3	6,158.2 ± 32,511.8
Median (IQR)	1,529.8 (753.4, 2,496.5)	1,600.8 (563.3, 4,274.3)
IP cost		
Mean ± SD	829.2 ± 5,875.3	2,343.5 ± 18,298.2
Median (IQR)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)
ER cost		
Mean ± SD	190.2 ± 526.5	374.8 ± 2,739.1
Median (IQR)	0.0 (0.0, 118.8)	0.0 (0.0, 22.0)
OP cost		
Mean ± SD	1,487.5 ± 2,335.3	2,462.6 ± 26,224.8
Median (IQR)	774.7 (305.7, 1,640.5)	472.7 (164.7, 1,485.7)
Other cost		
Mean ± SD	495.0 ± 911.7	977.4 ± 2,450.1
Median (IQR)	169.6 (58.9, 607.3)	274.4 (68.7, 834.3)
Total pharmacy cost		
Mean ± SD	8,300.2 ± 6,849.7	247.9 ± 1,459.6
Median (IQR)	7,538.1 (2,675.4, 12,543.3)	33.4 (5.0, 173.1)
Total healthcare cost		
Mean ± SD	11,302.1 ± 10,385.0	6,406.1 ± 32,541.7
Median (IQR)	9,661.4 (4,185.9, 15,377.4)	1,815.9 (700.9, 4,639.5)

1LM, first-line maintenance; ER, emergency room; IP, inpatient; IQR, interquartile range; OP, outpatient; PPPM, per patient per month; SD, standard deviation.

Limitations

- The cancer stage distribution of the study cohorts was inconsistent with previous reports (higher proportion of patients with Stage IV disease at diagnosis)[4,7] and with the use of debulking surgery; this may reflect the inclusion/exclusion criteria used and/or deficiencies in stage reporting.
- Medical services obtained outside of a patient's plan were not captured and pharmacy dispensing may not have represented the actual drug utilization of the patient, a limitation common to claims database analyses.
- This study may not be generalizable to the entire advanced epithelial OC population in the US.
- This study does not include a comparison of the clinical effectiveness of the two cohorts, which should be weighed against the comparative costs.

Conclusions

- Monthly total healthcare cost (PPPM) and pharmacy cost were higher in the niraparib cohort than in the AS cohort.
- Monthly total medical cost (i.e., non-pharmacy costs), comprising inpatient, emergency room, outpatient, and other costs, was approximately $3,000 lower in the niraparib cohort than in the AS cohort.

References

1. Cortez AJ, et al. *Chemother Pharmacol* 2018;81:17–38.
2. American Cancer Society. https://cancerstatisticscenter.cancer.org/?_ga=2.144691061.1502763419.1676581491-713433359.1662659003#!/cancer-site/Ovary (accessed January 19, 2023).
3. National Comprehensive Cancer Network. https://www.nccn.org/professionals/physician_gls/pdf/ovarian.pdf (accessed January 19, 2023).
4. González-Martín A, et al. *N Engl J Med* 2019;381:2391–402.
5. Mirza MR, et al. *N Engl J Med* 2016;375:2154–64.
6. Moore KN, et al. *Lancet Oncol* 2019;20:636–48.
7. Moore K, et al. *Gynecol Oncol* 2022;166:S20–1.

Disclosures

JH: employee of GSK; **RP**: employee of GSK at the time of analysis; **JS**, **TW**, **XN**: employees of Analysis Group, Inc.

Study funding

GSK (Study 214308)

Acknowledgments

- Medical writing support was provided by Nick Rusbridge of Apollo, OPEN Health Communications, funded by GSK, in accordance with Good Publication Practice 3 (GPP) guidelines (www.ismpp.org/gpp-2022).

Author email address: john.d.hartman@gsk.com

Presented at the Academy of Managed Care Pharmacy (AMCP) 2023 , San Antonio, TX, USA, March 21–24, 2023