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Prior authorization for FDA-approved PARP inhibitors in ovarian cancer

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ABSTRACT

Objectives: PARP inhibitors (PARP-I) improve survival in ovarian cancer, especially in patients with germline or somatic BRCA mutations or other homologous recombination deficiency (HRD). With high efficacy and costs, insurers may enact barriers or facilitators to PARP-I. Our objective was to examine the prevalence of prior authorization for PARP-I in ovarian cancer.

Methods: We performed a retrospective cross-sectional study of patients with ovarian cancer prescribed a PARP-I within the University of Pennsylvania practices from December 2018 through May 2021. We assessed prevalence of prior authorization for PARP-I overall, by frontline or recurrent maintenance, and by genetic status. We then assessed approval and appeal rates and time to PARP-I start.

Results: Of 180 patients with a PARP-I prescription and information regarding prior authorization, 116 (64 %, 95 % CI 57–71) experienced prior authorization. Of patients in the frontline setting, 60 of 90 (67 %, 95 % CI 56–76) experienced prior authorization. Of patients prescribed PARP-I in recurrence, 55 of 85 (65 %, 95 % CI 54–74) experienced prior authorization. Having a germline or somatic genetic mutation was associated with higher risk of prior authorization (adjusted risk ratio 1.35, 95 %CI 1.09–1.67). 102 patients (89 %, 95 % CI 83–94) required one appeal, 8 required two appeals and 5 cases required 3 appeals. Five patients were denied. Mean time from PARP-I prescription to PARP-I start was 10 days longer for patients who experienced prior authorization.

Conclusions: 64% of patients experienced prior authorization for PARP-I. Risk of prior authorization was increased for patients with BRCA, despite greater clinical benefit. Prior authorization contributes to delays in care, and reform is needed.

1. Introduction

Ovarian cancer is the most lethal gynecologic malignancy in the United States, and treatment to reduce morbidity and mortality remains a challenge (Siegel et al., 2021). Most patients with ovarian cancer present with advanced-stage disease and require multimodal treatment, including chemotherapy, cytoreductive surgery, and additional lines of therapy for maintenance and recurrence. Within the past decade, significant advancements have been made to develop targeted therapies, specifically through inhibition of DNA Poly(ADP-ribose) polymerase (PARP). PARP inhibitors are a targeted biologic approach for patients with defects in DNA repair pathways, specifically germline and somatic homologous recombination deficiency (HRD) like BRCA (Xie et al., 2020). Three PARP inhibitors are approved by the U.S. Food and Drug Administration (FDA) and have been shown to improve survival in ovarian cancer, especially in patients with BRCA 1/2 mutations or somatic HRD, when used as maintenance therapy (González-Martín et al., 2019; Monk et al., 2022; Cadoo et al., 2022; Disilvestro et al., 2023). Prescribing PARP inhibitor maintenance therapy is now considered standard of care in the front-line and recurrent platinum-sensitive setting (Pothuri et al., 2020); (Armstrong et al., 2022).

As use of PARP inhibitors is expanding, their high cost may

Abbreviations: HER, Electronic health record; FDA, U.S. Food and Drug Administration; HRD, Homologous repair deficiency; PARP, DNA Poly(ADP-ribose) polymerase; PARP-I, PARP inhibitor.

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contribute to financial toxicity during treatment (Liang and Huh, 2018). For PARP inhibitors alone, the average total monthly drug cost may be greater than $12,000 (Goldsberry et al., 2021; Liang et al., 2021; Harrison et al., 2021). Because of these high costs, insurance companies may use policies, such as prior authorizations, to target PARP inhibitor usage for on-label (i.e., FDA-approved) indications or to those patients most likely to benefit (i.e., HRD-positive patients).. The prior authorization is the process when an insurer requires additional submission of information about the ordered service, treatment plan, prescription, or test to the insurance company after a clinician has ordered or prescribed a plan of care. The insurance company reviews the information to determine if the prescribed service or medication will be covered. The prior authorization process is typically completed by prescribing clinicians and/or supporting staff electronically or over the phone, and the insurance company then approves or denies coverage. While prior authorizations are designed to reduce medically unnecessary tests and promote high value care, our prior work has shown that prior authorization is not consistently evidence-based, and its occurrence is associated with cancer treatment delays of 2 or more weeks (Smith et al., 2022; Smith et al., 2023). Ultimately, these delays may impact survival and contribute to worse morbidity and mortality for patients with ovarian cancer.

Given the efficacy of PARP inhibitors and their integration into standard of care for patients with ovarian cancer with BRCA mutations or somatic HRD, understanding barriers to FDA-approved PARP inhibitor usage is important to facilitating evidence-based care delivery. Our objective was to examine the prevalence of prior authorization for PARP inhibitors in ovarian cancer overall, by frontline maintenance or in the recurrent setting, and by genetic status.

2. Methods

The University of Pennsylvania's Institutional Review Board reviewed and exempted this study (#848983).

We performed a retrospective cross-sectional study of patients with ovarian cancer prescribed a PARP inhibitor within the University of Pennsylvania oncology practices from December 2018 through May 2021. In the frontline setting, the FDA first approved a PARP inhibitor for maintenance therapy for patients with BRCA mutations and advanced ovarian cancer in December 2018 and for all patients with advanced ovarian cancer in April 2020 (Liang and Huh, 2018). In the recurrent setting, the FDA approved PARP inhibitor for treatment in December 2014 (an indication now withdrawn) and for maintenance therapy after platinum-sensitive recurrence in March 2017. Since the University of Pennsylvania was a site for several of the trials leading to PARP inhibitor approval, we limited the study period to post-FDA approval of frontline maintenance to have the largest population of patients (FDA, 2022; FDA, 2023). Our academic practice consists of 8 gynecologic oncology attendings, 3 of whom provide chemotherapy, 4 medical oncologists, and 3 nurse practitioners across 4 clinical sites in eastern Pennsylvania and New Jersey, associated with 2 hospitals.

Data were extracted from PennMedicine's Oncology Research and Quality Improvement Datamart (ORQID), a clinical data repository which sources data from multiple databases, including the PennMedicine Epic Clarity database (Epic Systems Corporation, Verona, WI) and the PennMedicine Cancer Registry. A custom query was developed to identify ovarian cancer patients using ICD-10 (C48.0, C48.1, C48.2, C48.8, C56.1, C56.2, C56.9, C57.0, C57.00, C57.01, C57.02, C79.60, C79.61, C79.62, D07.39, Z15.01, Z15.02, Z80.41, Z84.81, Z85.43) and ICD-O-3 (C56.9) codes (Supplemental Table 1). Relevant, targeted therapy medication orders (olaparib, niraparib, rucaparib, veliparib) were queried from the PennMedicine electronic health record (EHR). Manual chart review was used when needed to fill in absent values. The extracted patients were then manually reviewed to ensure the PARP inhibitor prescription was for ovarian cancer and not another primary site of malignancy.

Using a standardized search strategy, we reviewed the EHR of all

Table 1
Characteristics of Patients with Ovarian Cancer Prescribed PARP Inhibitors, December 2018 to December 2021.

	All patients (n = 215)	Patients with Prior Authorization (n = 116)	Patients Not Experiencing Prior Authorization (n = 64)	p-value
	N (%)	N (%)		
Age in years (Median)	65 (IQR 58–71)	64 (IQR 58–71)	67 (IQR 59–72)	0.0001
Insurance type				
Uninsured	0 (0)	0 (0)	0 (0)	–
Medicaid	17 (9)	7 (6)	9 (15)	0.05
Traditional Medicare	62 (31)	30 (26)	20 (33)	0.32
Medicare Advantage	15 (8)	8 (7)	5 (8)	0.74
Private insurance	106 (53)	70 (61)	26 (43)	0.03
Race				
White	163 (76)	90 (78)	47 (73)	0.84
African American or Black	22 (10)	12 (10)	7 (11)	0.90
Asian	16 (7)	7 (6)	7 (11)	0.24
Other/Multiple races/ Unknown	14 (7)	7 (6)	3 (5)	0.71
Histology				
Serous	186 (87)	105 (91)	57 (89)	0.76
Endometrioid	7 (3)	5 (4)	1 (2)	–
Clear Cell	5 (2)	3 (3)	1 (2)	–
Other or unknown	17 (8)	3 (3)	5 (8)	–
Stage				
I	12 (6)	6 (5)	5 (8)	0.21
II	16 (7)	11 (10)	3 (5)	–
III	129 (60)	73 (63)	37 (58)	–
IV	43 (20)	24 (21)	14 (22)	–
Unknown	15 (7)	2 (2)	5 (8)	–
Germline Genetics				
BRCA 1/2 positive	60 (28)	41 (35)	13 (20)	0.11
Other HRD-germline mutation	12 (6)	7 (6)	4 (6)	0.48
No HRD germline mutation	118 (55)	64 (55)	36 (56)	0.02
Unknown	27 (13)	11 (9)	6 (9)	0.02
Somatic Mutations				
BRCA 1/2 positive	33 (15)	24 (21)	6 (9)	0.08
Other HRD-somatic mutation	22 (10)	11 (9)	8 (13)	–
No HRD somatic mutation	67 (31)	34 (29)	22 (34)	–
Unknown	93 (43)	47 (41)	28 (44)	–
Recurrence Status				
Recurrent	99 (46)	55 (47)	30 (47)	0.11
Nonrecurrent	104 (48)	60 (52)	30 (47)	–
Unknown	12 (6)	1 (1)	4 (6)	–

P-value compares chi-squared difference between patients experiencing and not experiencing prior authorization for PARP inhibitors. IQR = Interquartile range. HRD mutations include BRCA 1, BRCA 2, ATM, BRIP1, PALB2, RAD51C, and RAD51D. Germline and somatic mutations may not add to 100%, given patients with multiple germline and/or somatic mutations.

patients with ovarian cancer and a prescription for a PARP inhibitor during the study period. We developed our search terms from a registry of patients experiencing prior authorization that had been developed for quality improvement and maintained in one clinic (Supplemental Table 2). Using previously published methodology, we validated the search terms through chart reviews using examples of these identified patients who experienced prior authorization (Smith et al., 2022; Smith et al., 2023).

Our primary outcome was the occurrence of prior authorization for PARP inhibitor at any point during their care (i.e., prior authorization could occur at first prescription or refills). We assessed the prevalence of prior authorization for PARP inhibitors overall, by frontline or recurrent maintenance, and by BRCA or HRD status. For patient who experienced prior authorization, we then assessed the associated approval and appeal rates.

Our secondary outcomes were the occurrence of prior authorization for other components of patients' ovarian cancer care and the correlation of PARP inhibitor prior authorization with FDA indication. Olaparib currently has FDA approval for (1) frontline maintenance therapy in patients with BRCA germline or somatic mutation who have complete or partial response to first-line platinum therapy, (2) frontline maintenance in combination with bevacizumab for patients with HRD germline or somatic mutation, and (3) recurrent maintenance therapy in all platinum-sensitive patients (Olaparib FDA Label, 2023). Niraparib has FDA approval for (1) frontline maintenance therapy in all patients who have complete or partial response to first-line platinum therapy and (2) recurrent maintenance therapy in all platinum-sensitive patients (Niraparib FDA Label, 2023). Rucaparib has FDA approval for recurrent maintenance therapy in all platinum-sensitive patients (Rucaparib FDA Label, 2023).

We abstracted patient-reported race, age, and insurance from the EHR. Ethnicity was not included due to small numbers of Hispanic or Latino patients in the sample. Insurance was categorized into primary insurance type: private insurance, Medicare fee-for-service, Medicare Advantage, Medicaid, or uninsured. When insurance type was not clear from the plan name, insurance was cross-checked using state Medicaid and Medicare insurance lists and federal Medicare Advantage lists (Pennsylvania Statewide Managed Care Map, 2021; Department of Human Services, 2021; Medicare.gov: the official U.S. government site for Medicare | Medicare. Accessed November 15, 2021).

We reported descriptive statistics for each outcome with 95 % confidence interval and range where appropriate. We compared characteristics of patients experiencing prior authorization to those who did not using chi-squared tests for categorical variables and z-tests for continuous variables. We used univariate and multivariate generalized linear models regression analyses with a Poisson distribution to analyze the risk of patients experiencing prior authorization by insurance, race, and genetic status. We used a general linearized model with a Poisson distribution to obtain these risk ratios. Analyses were conducted with Stata 17 (StataCorp, College Station, TX).

3. Results

We identified 215 unique patients with ovarian cancer who were prescribed a PARP inhibitor between December of 2018 and May of 2021 (Fig. 1). 67 % (95 %CI 60–73 %) received more than one prescription for a PARP inhibitor during the study period. The median age was 65 years old (range 34–90). There were 163 patients (76 %) who identified as White, 22 (10 %) as Black or African American, 16 (7 %) as Asian and 14 (7 %) as other or multiple races (Table 1). The majority of patients had advanced stage disease classified as stage III or IV (172 patients, 80 %) and serous histology (186 patients, 87 %). 99 (46 %) patients were prescribed a PARP inhibitor for recurrent maintenance therapy, and 104 (48 %) for frontline maintenance. The majority of patients were prescribed olaparib (122, 57 %) followed by niraparib (65, 30 %), rucaparib (27, 13 %), and veliparib (1). Seven patients (4 %) were prescribed, but never started their PARP inhibitor: 3 never started due to cost, 2 never started per patient preference, and 2 never started due to rapid progression of disease. 27 (13 %) of patients never had germline genetic testing, and 97 (45 %) never had somatic genetic testing. Of note, 70 % (49) of patients with a germline HRD mutation never had somatic testing, while 25 % (29) patients with negative germline testing never had somatic testing. 60 (28 %) of patients prescribed a PARP inhibitor had a germline BRCA mutation, 33 (15 %) a somatic BRCA mutation, 12 (6 %) had another HRD germline mutation, 13 (6 %) had somatic HRD, and 97 (45 %) had no known germline or somatic mutation (including unknown).

A total of 180 patients (84 %) had a PARP inhibitor prescription and information on prior authorization; the other 35 patients were patients who were seeking a second opinion and had been prescribed a PARP inhibitor outside the health system. Of patients with a PARP inhibitor prescription and information on prior authorization, 116 patients (64 %, 95 %CI 57–71) experienced prior authorization for their PARP inhibitor. 110 (52 %, 95 %CI 45–59) experienced prior authorization for other components of their gynecologic oncology care, largely for surveillance imaging. Of patients in the frontline setting, 60 of 90 patients (67 %, 95 %CI 56–76) experienced prior authorization for FDA-approved PARP maintenance. For frontline maintenance, 78 %(95 %CI 57–90) of patients experienced prior authorization for niraparib and 73 % (95 %CI 59–84) for olaparib (Table 2). Of patients prescribed PARP maintenance after cancer recurrence, 55 of 85 (65 %, 95 %CI 54–74) experienced prior authorization. For recurrent maintenance, 67 % (95 %CI 46–82) experienced prior authorization for olaparib and 68 % (95 %CI 53–80)

Table 2
Prescriptions and Prior Authorization by FDA indication.

	Niraparib		Olaparib		Rucaparib	
	Prescription	Prior authorization	Prescription	Prior authorization	Prescription	Prior authorization
Frontline maintenance						
All comers	31	21 (78 %)	60	38 (74 %)	–	–
HRD+	7	4 (67 %)	41	31 (82 %)	–	–
BRCA+	5	3 (75 %)	39	31 (86 %)	–	–
Recurrent maintenance						
All comers	32	18 (67 %)	54	32 (68 %)	13	5 (45 %)
HRD+	7	4 (57 %)	25	18 (75 %)	5	2 (22 %)
BRCA+	3	1 (33 %)	22	16 (76 %)	5	2 (22 %)

HRD + includes BRCA + patients.
Of note, rucaparib is not approved for frontline maintenance in the United States in any population.

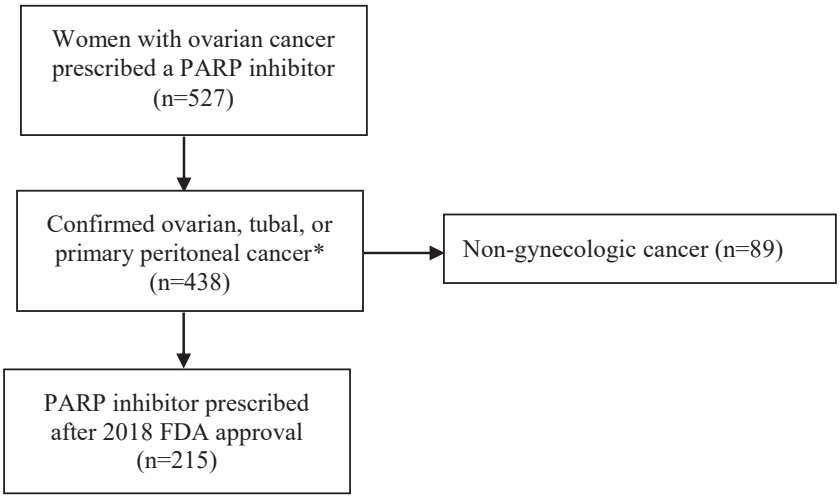

Fig. 1. Flow diagram of study selection.

for niraparib.

Of patients with germline BRCA mutations, 41 of 54 (76 %) experienced prior authorization for PARP inhibitors. Of patients with documented germline or somatic BRCA mutations, 55 of 77 (71 %) experienced prior authorization. In the frontline setting, 21 (84 %) of patients with germline BRCA mutations experienced prior authorization for their PARP inhibitor; 11 (79 %) of patients with somatic BRCA mutations experienced prior authorization. Of patients who were HRD-positive and not BRCA mutated, 11 (58 %) experienced prior authorization for PARP inhibitors (Table 2).

In regression analyses, having private insurance was associated with higher risk of prior authorization in univariate (RR 1.28, 95 %CI 1.02–1.61), but not multivariate analyses controlled for race and genetic status, when compared to traditional Medicare. Having a somatic or germline BRCA mutation was associated with a higher risk of prior authorization in univariate and multivariate analyses than not having a BRCA mutation (adjusted RR 1.35, 95 %CI 1.09–1.67) (Table 3). Race was not associated with prior authorization for PARP inhibitors in univariate or multivariate analyses.

Table 3
Association of Experiencing Prior Authorization for PARP Inhibitors with Insurance type and Race.

	Univariate	Multivariate
	Risk ratio (95 %CI)	Risk ratio (95 %CI)
Insurance type		
Medicaid	0.64 (0.37–1.14)	1.20 (0.82–1.75)
Private insurance	1.28 (1.02–1.61)*	1.17 (0.89–1.54)
Medicare Advantage	0.93 (0.60–1.45)	0.89 (0.52–1.51)
Medicare fee-for-service	0.88 (0.68–1.14)	Reference
Race		
Black	0.98 (0.68–1.41)	0.89 (0.60–1.33)
Asian	0.76 (0.45–1.30)	1.31 (0.99–1.73)
Other or multiple race	1.09 (0.72–1.67)	–
White	1.03 (0.74–1.45)	Reference
Genetics		
BRCA Germline	1.18 (0.95–1.46)	–
BRCA Germline or Somatic	1.28 (1.03–1.58)*	1.35 (1.09–1.67)*
Any HRD	1.25 (1.02–1.55)*	–
No Germline or Somatic HRD	0.82 (0.66–1.03)	Reference

Traditional Medicare was used as the reference as prior authorization is not allowed in traditional Medicare. White race was used as reference for its larger sample size. Age was not included, given collinearity with Medicare insurance (available mostly with patients age 65 years and older).
Multivariable log-binomial regression analyses were adjusted for both insurance and race.
* Significant to p-value of < 0.05, ** Significant to p-value of < 0.01.

For patients to obtain prescribed PARP inhibitors after prior authorization, 102/116 (89 %, 95 %CI 83–94) required one appeal, 8 cases required two appeals, and 5 cases required 3 appeals. 5 patients had their PARP inhibitor denied after 3 appeals, even though 4 of these prescriptions were congruent with FDA approved indications (the remaining was for frontline olaparib in HRD-negative patient). In the denial letters, 2 stated PARP inhibitors were limited to HRD-positive or BRCA patients, 2 stated PARP inhibitors were not medically necessary, and 1 stated the patient was not taking contraception and thus not eligible. Two of these patients were ultimately approved for an alternative PARP inhibitor, 1 received their PARP inhibitor through prescription assistance programs, and 2 never started PARP inhibitor due to out-of-pocket costs, leading to a significant change in care (e.g., no PARP inhibitor) for 2 of 116 prior authorizations or 2 % of the time. The mean time from PARP inhibitor prescription to PARP inhibitor start was 22 days (95 %CI 13–30) for patients who experienced prior authorization compared to 12 days (95 %CI 5–19) for patients who did not experience prior authorization.

4. Discussion

In this cohort of ovarian cancer patients prescribed FDA-approved PARP inhibitors, 64 % experienced prior authorization for their PARP inhibitor. Patients with somatic or germline BRCA mutations—those most likely to benefit from PARP inhibitors—were more likely to experience prior authorization than patients without BRCA mutations. Prior authorizations led to patients not receiving PARP inhibitor in 2 % of cases. They were also associated with a 10-day delay from prescription to medication start, compared to patients who did not experience PARP inhibitor prior authorization.

Our previous work found that 25 % of patients experience prior authorization for other components of gynecologic oncology care (Smith et al., 2022). Patients prescribed PARP inhibitors experienced more than double this rate of prior authorization in our study. The prior authorization rate for PARP inhibitors also remained higher than for other components of cancer care for the patients in our study. Moreover, the higher rate of prior authorization for BRCA-positive patients is surprising, given the greater clinical benefit of PARP inhibitors in this population (Armstrong et al., 2022). This may reflect a longer period of prescribing for PARP inhibitors during the study (i.e., the earlier FDA approval of PARP inhibitors for BRCA mutation positive patients provided more opportunity for prior authorizations).

Patients with germline HRD mutations, such as BRCA or BRIP1, are

diagnosed with ovarian cancer at younger ages when patients are more likely to have employer-based private insurance. While we did not see a difference by insurance in this study, we previously found high rates of prior authorization in certain private insurance plans (Smith et al., 2023). The higher rate of prior authorization could reflect genetic-agnostic prior authorization policies that may flag patients receiving more care (e.g., BRCA mutation positive patients may use more health care, given other cancer risks and recommended screening). The Genetic Information Nondiscrimination Act allows for insurers to promote targeted therapies with a positive benefit, and insurers may want to consider prior authorization policy changes that facilitate PARP inhibitor access for the BRCA-positive population, i.e., patients most likely to benefit (Radford et al., 2013).

Studies in other cancers have similarly found low correspondence between FDA approvals and patient receipt of medication and high approval rates after prior authorization (Dickens and Pollock, 2017; Tran et al., 2019) Yet each prior authorization request adds 30–60 min on average to clinical staff workload (Dickens and Pollock, 2017; Niccolai et al., 2017). A 10-day delay from PARP inhibitor prescription to patient receipt after prior authorization may not have a clinical impact on cancer recurrence, but it creates anxiety and work for patients and clinicians (Chino et al., 2023). Early prescription of PARP inhibitor, such as with cycle 5–6 of chemotherapy, may reduce time from chemotherapy end to PARP inhibitor start. Reforms at the state and federal level to reduce prior authorization for guideline-concordant care, improve response times, and standardize length of authorizations are needed for equitable, efficient oncologic care across insurance types (Bills in 30 states show momentum to fix prior authorization | American Medical Association, 2023) For patients with Medicare, Medicare Part B prohibits prior authorization for IV chemotherapies, and this exemption from prior authorization could be expanded to oral chemotherapy agents like PARP inhibitors that fall under Medicare Part D (Schwartz et al., 2021).

Limitations of our study include the retrospective nature and reliance on review of the electronic medical record. It is possible that prior authorization processes were documented in a way that our search terms were not able to capture, which could result in an underestimation of the prevalence of prior authorization. We were not able to capture the out-of-pocket costs of PARP inhibitors to patients or receipt of prescription assistance programs, factors that may have allowed patients whose PARP inhibitor was not approved to obtain the prescribed therapy. Furthermore, given some patients were seen for second opinions or transfer of care, genetic testing results were not available for all patients, which could result in an underestimation of prevalence within the HRD-positive population. However, we had a greater prevalence of germline genetic mutations in our patient population than national averages (37 % vs. 25 %), which better allows us to examine prior authorization rates by genetic mutations (Alhilli and Pederson, 2021). Lastly, our population and practice setting is a tertiary care center with three affiliated hospitals in an urban environment with significant resources devoted to prior authorization appeals at both the clinic and pharmacy level. For patients starting oral cancer therapies, such as PARP inhibitors, prescriptions are usually sent to a central pharmacy where multiple staff members are devoted to dealing with insurers and prior authorization, improving processing times and likely approval rates. Therefore, prior authorization appeals and approvals may be lower than less resourced settings.

Two-thirds of patients experienced prior authorization for FDA approved therapies in ovarian cancer. Paradoxically, patients most likely to have an overall survival benefit from PARP inhibitors were more likely to experience prior authorization. Prior authorization reform is needed to reduce unnecessary burdens on delivery of evidence-based cancer care.

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CRediT authorship contribution statement

Anna Jo Bodurtha Smith: Writing – review & editing, Validation, Funding acquisition, Data curation, Conceptualization. **Annie Apple:** Writing – original draft, Formal analysis, Data curation. **Audra Hugo:** Writing – review & editing, Formal analysis, Data curation, Conceptualization. **Ashley Haggerty:** Writing – review & editing, Supervision, Funding acquisition, Formal analysis. **Emily M. Ko:** Writing – review & editing, Supervision, Methodology, Funding acquisition, Formal analysis, Conceptualization.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.gore.2024.101335.

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