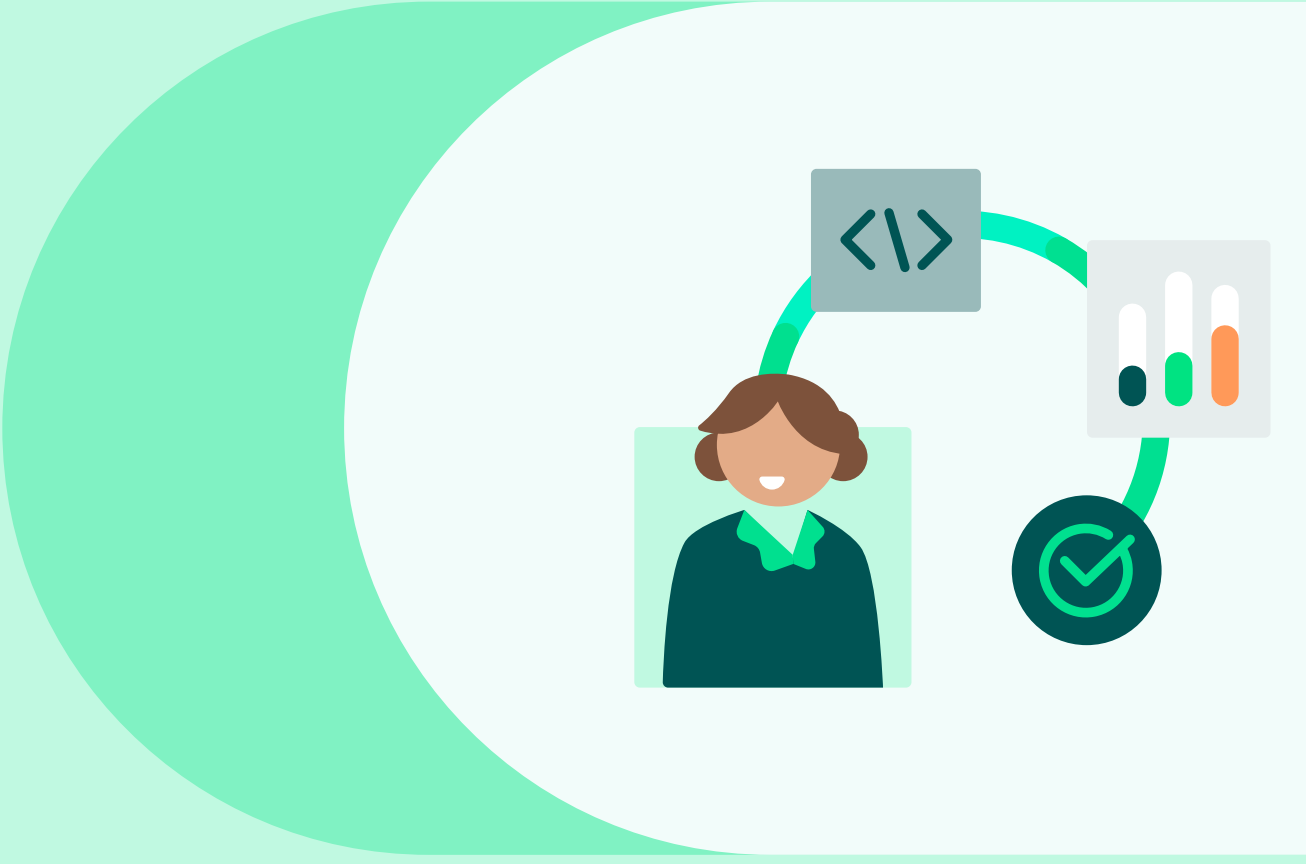
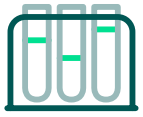
FinThrive

White Paper

Barriers to Personalized Oncology Treatment

The Implications of Insurance Denials for HRD Testing in PARP Inhibitor Therapy





Abstract

Precision or personalized oncology has emerged as an approach for disease treatment and prevention that considers individual variability in genes, environment and lifestyle for each person undergoing treatment.[1] This treatment approach enables patients to receive targeted therapy tailored to their unique genetic makeup. However, third-party payer denials of genomic tests needed to identify the particular genomic scars pose a critical barrier to the appropriate use of these therapies.

Introduction

The emergence of Poly (ADP-ribose) Polymerase (PARP) inhibitors has transformed the therapeutic landscape for patients with Breast Cancer gene (BRCA)-mutated and homologous recombination deficiency (HRD)-positive cancers. However, access to these life-extending therapies is compromised when the patient's insurance company denies coverage for the HRD testing that is the essential biomarker for identifying patients appropriate for PARP inhibitor treatment and justifying the medical necessity of this treatment.

This paper explores trends in third-party payer denials for genomic testing necessary for patients to access tailored treatment based on the unique genetic and molecular profile of their tumor.

In this paper, FinThrive's Data Insights team used hospital chargemaster and medical claims data from 2023 and 2024 to identify if HRD and BRCA biomarker testing are being denied by third-party payers; thus, impacting patient access to precision therapies.

1 U.S. National Library of Medicine: What is precision Medicine?

What Is a Denial?

Understanding how a denial originates, how it can be appealed and when it would be considered "final" is essential to any analysis of the impact of denials on patient access to care. For the purposes of this study, FinThrive's Data Insights team analyzed claim denials at both the initial and final phases of treatment. Key to understanding this analysis is not just how a denial may be appealed but when a denial originates.

A denial does not truly occur until the hospital or physician submits a claim to the insurance company seeking reimbursement for services provided. While the prior authorization process often refers to a service being "denied," this actually means the insurance company has failed to authorize the service. In many cases, the patient never receives the service, and subsequently, a claim is never submitted. For this reason, FinThrive's Data Insights team does not have access to information related to instances where prior authorization was not granted.

What FinThrive's Data Insights team was able to examine was claim submission and payer adjudication data from remittance advice transactions. The process of denying a claim begins when the service provider submits the claim for reimbursement. The insurance company adjudicates the claim and determines what it believes is its payment responsibility based upon the patient's particular insurance plan requirements. When the insurance company's initial adjudication of the claim results in a denial, the service provider and patient can appeal that determination. FinThrive's analysis for this study evaluated both the rate of initial denials and the frequency of subsequent adjudication that resulted in reimbursement. Available data does not indicate whether the subsequent adjudication is the direct result of an appeal. However, the data does show if an additional claim was filed. If there is no subsequent claim but the payer adjudicates the original claim, this is presumed to be the result of an appeal.

The prior authorization process often references the denial of services. However, a denial does not truly occur until the hospital or physician submits a claim to the insurance company seeking reimbursement for services provided.

Insurance Landscape and Coverage Denials

Despite the scientific rationale, HRD and BRCA testing are not uniformly covered by insurance companies in the United States. Even if a patient's insurance plan covers this testing, the payer may still deny the test as not medically necessary. While coverage is a key element for insurance reimbursement, simply because something is covered, it does not necessarily mean it will be reimbursed. For this reason, the analysis in this study not only reviewed the frequency at which HRD and BRCA testing is denied, but also the reason for the denial.

Data Analysis – Claims for Period 2023 and 2024

Ovarian Cancer patients with HRD and BRCA tests

* 4 patients had both 81445 and 81455 billed
* 1 patient had both 81408 and 81479 billed

Testing	Procedure Code	Total Claims		# HRD Line Item Denials/Adjustments		# HRD Final Reimbursement Denials or Claims Adjustments		HRD Reimbursement (with or without denial/appeal)	HRD Final Denials	HRD Reimbursement (with or without initial denial)	HRD Final Denial or Underpayment
		# Claims	# Patients	# Claims	# Patients	# Claims	# Patients	# Patients	# Patients	# Patients	# Patients
BRCA	81162	313	248	180	152	114	46	142	106	140	108
BRCA	81163	4	4	3	1	2	1	4	0	3	1
BRCA	81166	3	3					3	0	3	0
BRCA	81165	1	1	0	0			1	0	1	0
Subtotal		**321**	**256**	**183**	**153**	**116**	**47**	**150**	**106**		
HRD	81307	2	1	1	1	1	1	0	1	0	1
HRD	81408	1	1	1	1	0	0	1	0	1	0
HRD	81445	55	47	53	34	10	9	25	22	25	22
HRD	81455	37	21	26	12	8	6	15	6	15	6
HRD	81479	15	14	13	9	10	7	7	7	7	7
HRD	0037U	2	2	0	0			2	0	2	0
Subtotal		**112**	**86**	**94**	**57**	**29**	**23**	**52**	**34**		
Total		**433**	**342**	**277**	**210**	**145**	**70**	**202**	**140**	**197**	**145**

The table above displays the total number of claims for each CPT code related to HRD and BRCA testing. The denial analysis demonstrates an initial denial rate of 64%. Following the appeal of the initial denial, the final denial rate drops to 33%. This shows that the payers agree the denials are inappropriate more than 50% of the time.

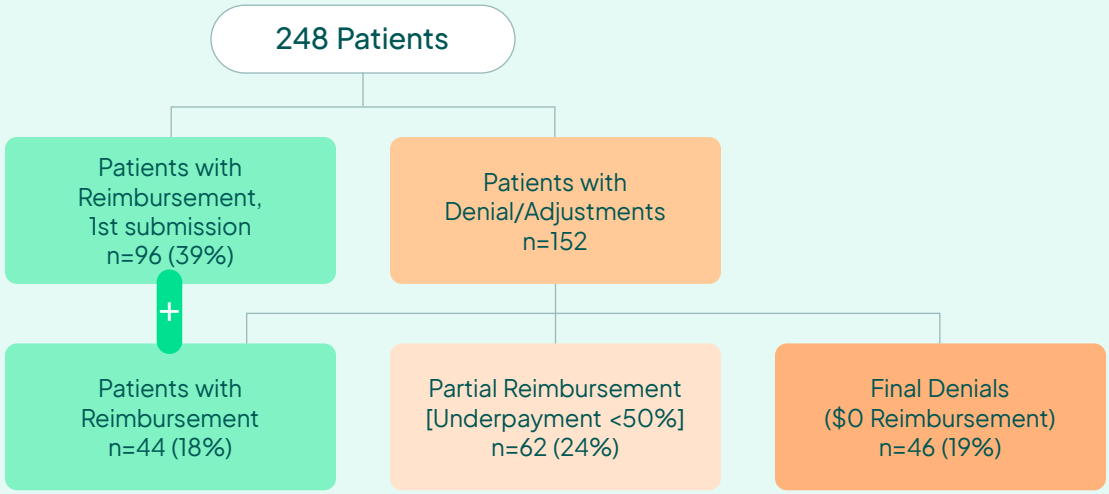
The Line Item Denials/ Adjustments represent the total denials or adjustments for each CPT code across all claims and patients. This analysis included looking at each denial reason given for each claim and whether a claim for the service was submitted multiple times for the same patient.

The HRD Final Reimbursement Denials represent the total denials or adjustments in which the FinThrive dataset indicates no reimbursement after the reasonable appeal timeframe has lapsed. The data demonstrates instances where an initial denial was received, but reimbursement was later received. These are denials that were overturned. The final denial column represents what a service provider would consider a true denial, as any attempts to appeal have been unsuccessful.

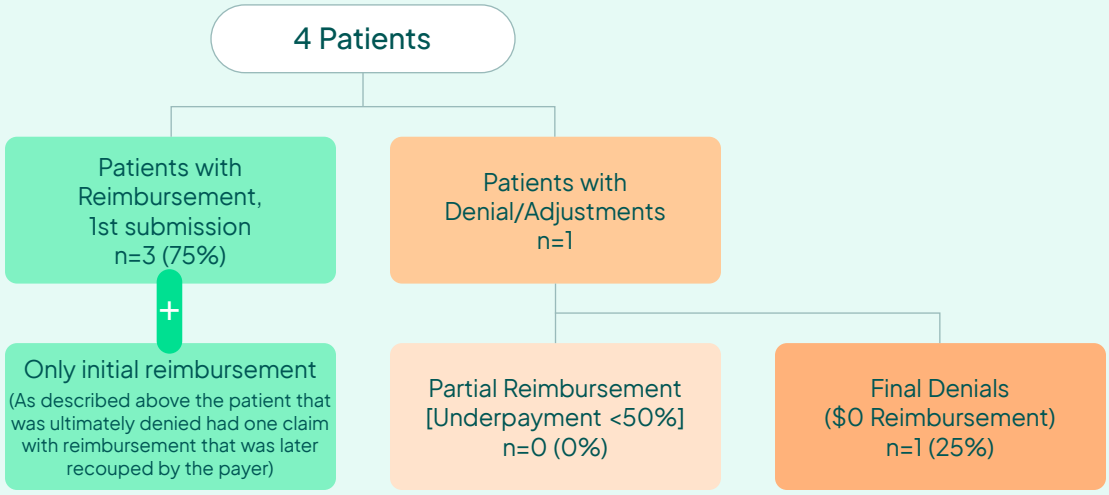
BRCA Testing

2023–2024
Gynecologic Cancer Diagnoses
Patients with Biomarker

BRCA 81162



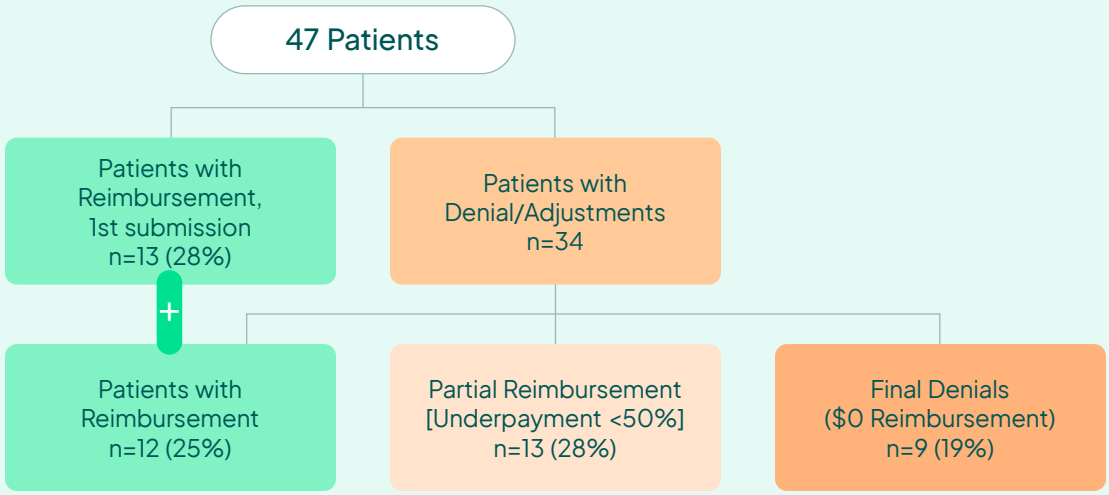
BRCA 81163



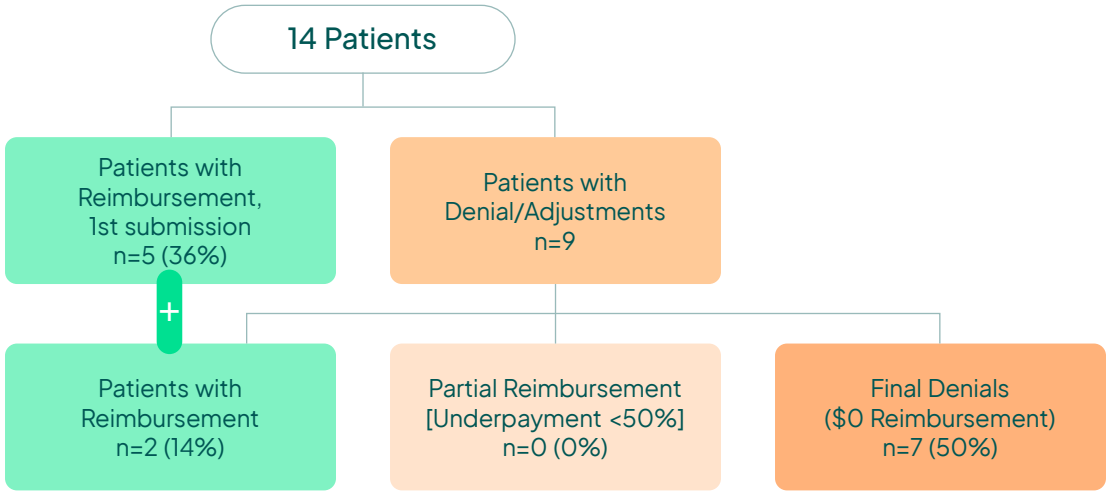
HRD Testing

2023–2024
Gynecologic Cancer Diagnoses
Patients with Biomarker

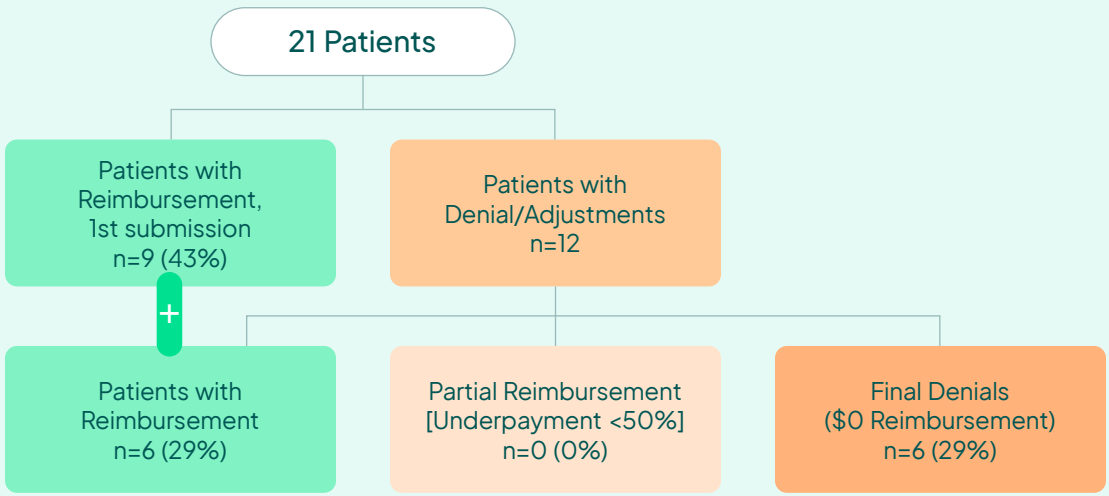
HRD 81445



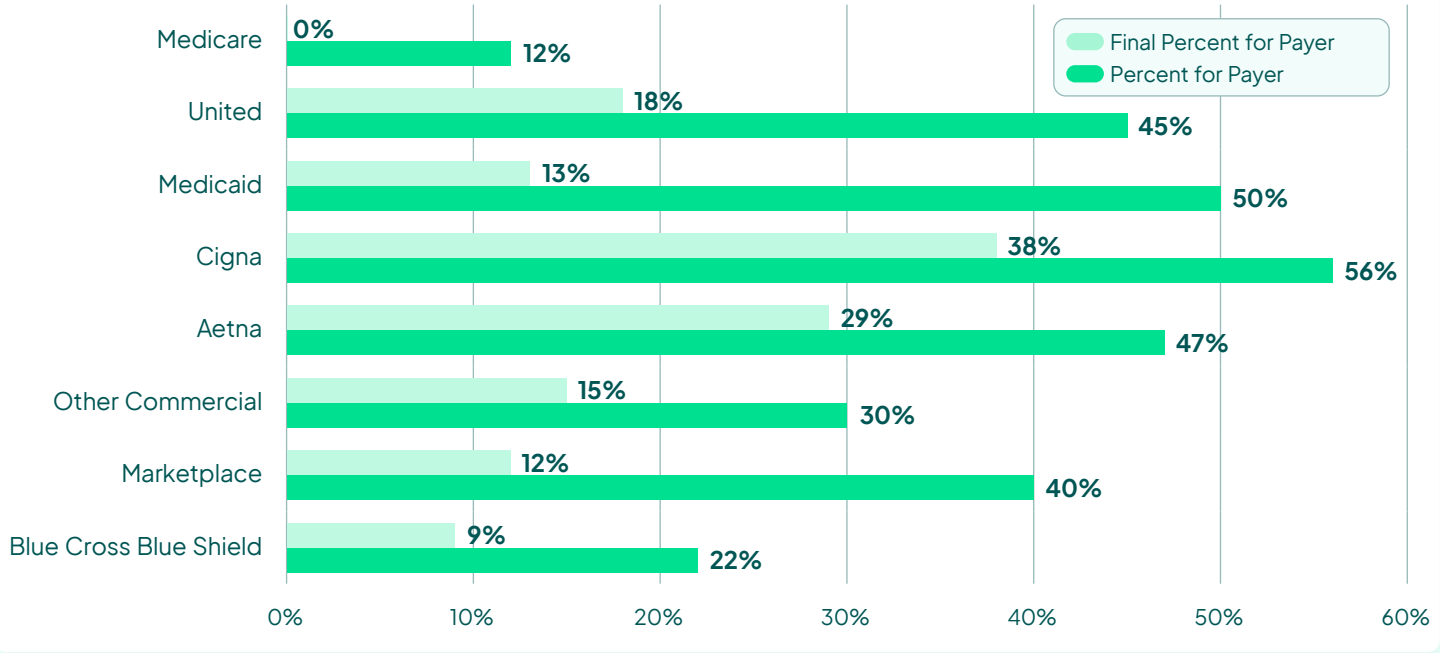
HRD 81479



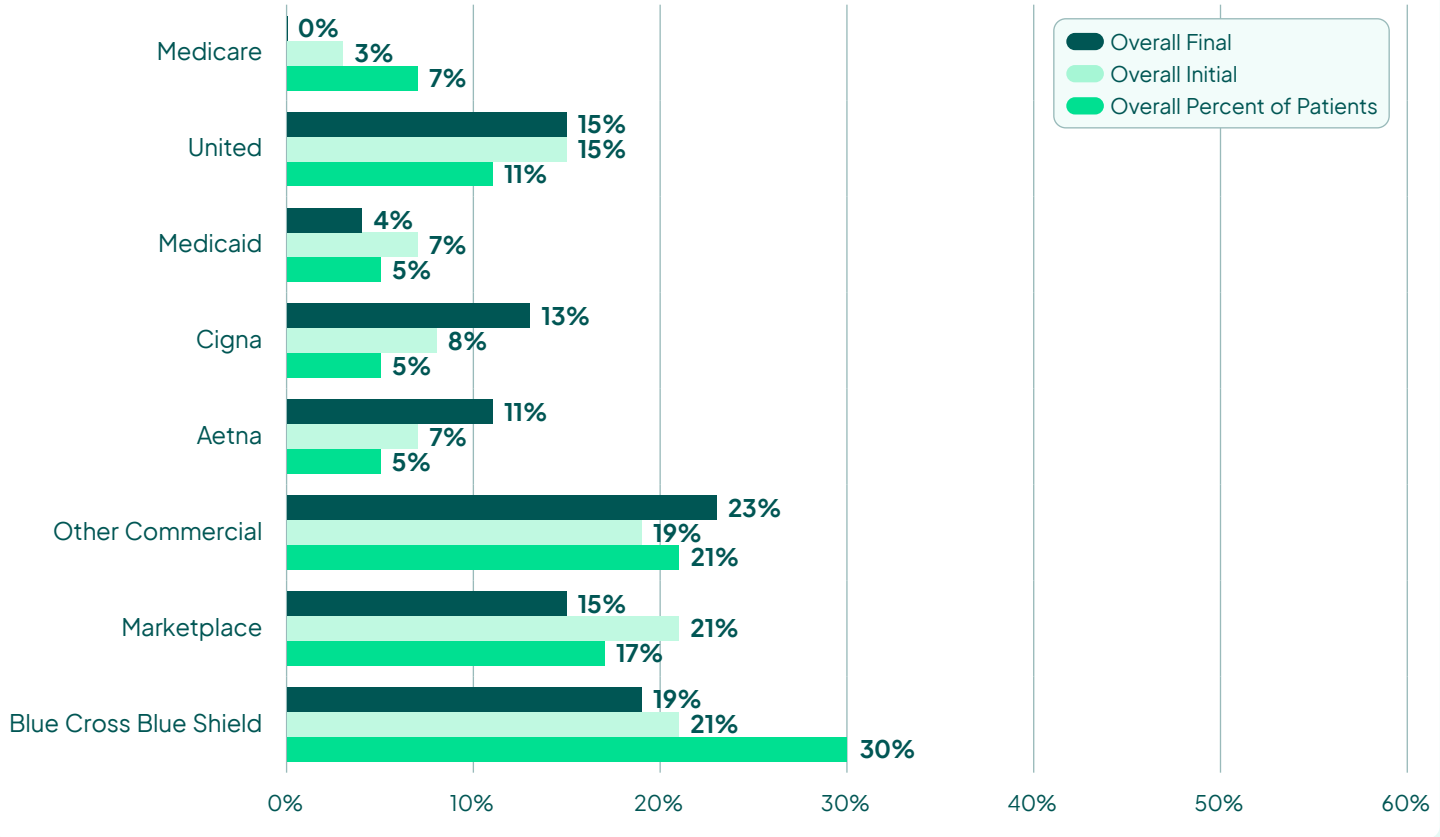
HRD 81455



HRD/BRCA Payer Denial Percentage



Overall Percentage of Patients and Denials



Summary

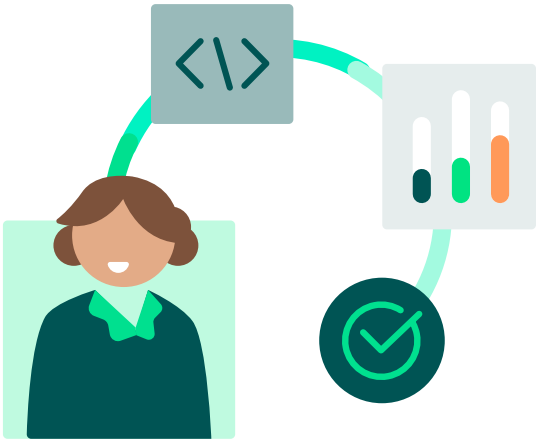
Third-party payer denials are an ongoing concern across healthcare provider revenue cycles. Health insurance companies deny coverage for medical services, procedures and medications as part of their cost-containment strategies. For services like HRD testing, the cost-containment strategy is two-fold: (1) denying the expense for the test, and (2) without these genetic test results, the targeting therapies can be denied because the medical necessity cannot be demonstrated. The key takeaway is that certain payers issue an initial denial when, if appealed, that denial will be overturned more than 50% of the time. This trend not only increases the cost of healthcare but also delays necessary treatment for patients, as these genetic results are often required to justify the appropriate targeted therapy.

Other key takeaways from the above data analysis include:

- There is a significantly higher denial rate between commercial insurance payers and governmental payers (Medicare and Medicaid)
- The denial overturn rate suggests that payers are placing an increased administrative burden on providers by denying these genetic tests and ultimately reimbursing for the tests if the provider exercises their appeal rights
- The denial reasons given by payers vary, with the most common reasons being “experimental treatment” and “medical necessity”

Certain payers issue an initial denial and, if appealed, overturn their own determination more than 50% of the time.

Lessons Learned



The shift toward precision oncology has highlighted the importance of genetic biomarkers in guiding therapy selection. PARP inhibitors have reshaped treatment protocols for various cancers, particularly those with DNA repair deficiencies. While BRCA mutations have served as the primary biomarker guiding PARP inhibitor use, clinical data support that HRD plays a role in predicting response.

Insurance denials of HRD and BRCA testing present a bottleneck in the delivery of precision cancer care and impact patient access to targeted therapies. Without the genomic testing that third-party payers are denying, healthcare providers do not have the clinically essential data that is not only necessary to develop the appropriate patient-specific treatment protocol but to justify to that same third-party payer the medical necessity for the treatment.

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