



# Oral Breast Cancer Therapy Interventions in an Integrated Health System Specialty Pharmacy: Analysis of Patient Acceptance Rate of Clinical Pharmacist Interventions in an Outpatient Setting

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## PURPOSE

This study was designed to analyze patient acceptance rate and reported outcomes on pharmacist provided interventions for patients on oral targeted breast cancer therapies in a mail order integrated health system specialty pharmacy and to further promote specialized, oncolytic pharmacists as integral members of the interdisciplinary team.

## METHODS

Patients utilizing oral breast cancer therapy were included in this retrospective, multi-centered study conducted from October 1, 2023 to February 29, 2024. Interventions were categorized as medication reconciliation, drug therapy adherence, administration, disease state monitoring, side effect management, drug safety, immunization recommendation, other, and multiple categories.

## RESULTS

Forty-seven patients were included for analysis with a 70 percent acceptance rate by patients of specialty pharmacist intervention recommendations. Thirty-nine (83%) of participants were of the age 65-years-old or younger. Twenty-two (47%) of the patients were on an oral breast cancer therapy for more than 3 months with an average of 2 clinician outreaches needed per intervention. The time from clinical intervention made to clinician follow up was less than 2 weeks in 45 percent of the patients, with 40 percent of the patients indicated as not needing a follow up. Medication reconciliation (34%) was the most common category selected for clinical interventions, followed by multiple interventions conducted in one patient encounter (24%), drug safety (19%), side effect management (13%), drug therapy adherence (4%), administration (4%) and other (2%). Abemaciclib (40%) was the most common oral breast cancer therapy managed with a reported intervention.

## CONCLUSION

This study provides statistical and clinical evidence of interventions that pharmacists are providing, the patient acceptance rate of these interventions, and the impact on patient outcomes. Further studies would benefit from a longer study duration to assess efficacy of clinical intervention training and oncology patient therapeutic outcomes.



## INTRODUCTION

The National Breast Cancer Foundation reports an estimated 310,720 women and 2,800 men will be diagnosed with invasive breast cancer in 2024. The average age for diagnosis is 62 years old for United States women.<sup>1</sup> The proportion of patients receiving their cancer care outside of the hospital setting has increased 25 percent from 2014 to 2020, allowing for greater ease of medication administration.<sup>2</sup> As oral cancer therapies are becoming more common, patients are left to manage their medication administration and adverse events independently at their home. Additionally, a high proportion of patients who have cancer are at an advanced age and may be at higher risk for polypharmacy, comorbidities, and renal impairment.<sup>3</sup>

Oral breast cancer therapies are administered in neoadjuvant and adjuvant cases in patients with non-metastatic (early) or metastatic (late) breast cancer diagnosis.<sup>4</sup> During the study period, the most commonly filled oral breast cancer specialty medications included CDK 4/6 Inhibitors such as ribociclib and abemaciclib, which are first line endocrine based therapies (in combination with aromatase inhibitors) for treatment of advanced or metastatic hormone receptor-positive/human epidermal growth factor receptor 2 negative (HR+/HER2-) breast cancer.<sup>5,6</sup> Alpelisib, an  $\alpha$ -selective phosphatidylinositol 3-kinase (PI3K) inhibitor, is indicated for males and postmenopausal females with advanced or metastatic HR+/HER2- breast cancer with a PIK3CA mutation.<sup>7</sup> Everolimus is used in postmenopausal women with advanced HR+/HER2- breast cancer.<sup>8</sup> Capecitabine may be used alone or in combination treatment regimens for advanced breast cancer or in the adjuvant setting in early-stage triple-negative breast cancer.<sup>9</sup>

Oral targeted therapies have narrow therapeutic index, wide pharmacokinetic variability, and dose response relationships which call for multiple clinical assessments to ensure effectiveness and avoid toxicity.<sup>10</sup>

Oncology pharmacists have the education and training to collaboratively manage therapeutics throughout the continuum of care from the time of diagnosis, through treatment decisions, as well as supporting the patient and their caregivers with managing cancer therapeutics and treatment related symptoms.<sup>11</sup> Pirolli et al defined pharmacist interventions (PIs) as professional activities taken by a pharmacist directed towards a medication-taking behavior or a change with medication therapy. Even with the knowledge of the importance of PI documentation, many studies show the underrepresentation of PIs reported.<sup>12</sup> Pharmacist-led programs allow for oncolytic therapeutic interventions, include medication reconciliation utilizing multiple medication databases, drug-drug interaction identification, adherence instruction, and recommendation and advice to oncology team members regarding prescribing practices and reduction of medication dosing burden or costs.<sup>13</sup>

This study aimed to evaluate the patient acceptance rate of specialty pharmacist's interventions provided to adult patients utilizing targeted oral breast cancer therapies. Acceptance is defined by the patient as confirming they implemented the action(s) recommended by the pharmacist. Additional areas of interest are to summarize the category type of PIs and compare documented intervention volumes pre-and post-implementation of new intervention documentation process training.

## METHODS

**Study Setting.** Lumicera Health Services is a specialty pharmacy that assists in operating several health system specialty pharmacies. The specialized, oncology pharmacists support the integrated health system of Sisters of Saint Mary (SSM). Through these collaborations pharmacists have the ability to utilize electronic health records (EHR). Lumicera is ACHC and URAC dual-accredited, mail-order, with five locations across the United States serving patients nationwide. Lumicera services are based off the core principles of integrity, transparency, and stewardship for which they have earned the Accreditation Commission for Health Care (ACHC) Oncology Distinction.

This study was a multi-center, retrospective chart review of documentation relating to telephonic oncology interventions from October 1, 2023, to February 29, 2024. Institutional Review Board (IRB) approval was obtained October 18, 2023, through SSM Health of Wisconsin IRB. Procedures followed were in accordance with the ethical standards of SSM committee on human experimentation. In an effort to improve patient care and comply with Version 5.0 URAC accreditation standards, at the time of study commencement Lumicera was in the process of updating documentation requirements for pharmacists to identify and report clinical interventions.

**Pharmacist Interventions.** PI categories and “select when” prompts were determined by interviewing pharmacists on their workflow process from the point of prescription intake, through patient consultations and monitoring, and to the dispensing of the product from Lumicera. Additionally, the primary investigator evaluated prior documented PIs conducted within the internal software and utilized the URAC webinar video on tracking clinical intervention outcomes.<sup>14</sup> PI categories were defined as: medication reconciliation, drug therapy adherence, administration, disease state monitoring, side effect management, drug safety, immunization recommendations, other, and multiple categories (Table 1).

Lumicera’s analytics team collaborated with investigators to develop a pharmacist intervention clinical dashboard to standardize data capture of PIs conducted. The dashboard allowed for real time data capture of patient name, medication utilized, intervention category selected, indicated follow up period, intervention resolution status, and if resolved, PI acceptance status. If a follow-up was determined to be appropriate by the pharmacist at the initial patient encounter, they would select their determined follow-up interval and the dashboard would then provide notification to the pharmacist via email on the scheduled follow-up day. Pharmacists could additionally select an intervention as left message or resolved. Selecting resolved prompted a further drop down to select whether the intervention was accepted or not accepted. The clinical intervention dashboard could only be accessed by clinical staff using Lumicera issued devices.



**TABLE 1: PHARMACIST INTERVENTION CATEGORIES**

| Category                            | Select When...                                                                                                                                                                                                                                                                                                                                                                  |
|-------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Medication Reconciliation</b>    | <ul style="list-style-type: none"> <li>• Identifying loading dose needs</li> <li>• Incorrect signature</li> <li>• Incorrect therapy indication</li> <li>• Therapeutic duplication</li> <li>• Medication costs</li> <li>• Changing dose/managing dose</li> <li>• Medication accessibility/availability</li> <li>• Discontinuation of therapy</li> <li>• Drug omission</li> </ul> |
| <b>Drug Therapy Adherence</b>       | <ul style="list-style-type: none"> <li>• Missed dose advising</li> <li>• Providing an adherence tool (only document if requiring follow up)</li> <li>• Drug holiday</li> <li>• Difficulties tracking med administration days</li> <li>• Underutilization of medication</li> <li>• Over utilization of medication</li> </ul>                                                     |
| <b>Administration</b>               | <ul style="list-style-type: none"> <li>• Drug form change (pen vs syringe or tab vs liquid)</li> <li>• Adjusting med timing with or without food at refill</li> <li>• Adjusting injection administration technique at refill</li> </ul>                                                                                                                                         |
| <b>Disease State Monitoring</b>     | <ul style="list-style-type: none"> <li>• Lab/imaging recommendations (Calcium, CBC, BMP, MRI, etc.)</li> <li>• Medication therapy effectiveness</li> <li>• Symptoms monitoring: <ul style="list-style-type: none"> <li>» Validated Disease State Assessment Scores</li> <li>» Mental Health/PHQ9</li> <li>» MS Symptoms</li> </ul> </li> </ul>                                  |
| <b>Side Effect Management</b>       | <ul style="list-style-type: none"> <li>• Supportive care recommendations</li> <li>• Side effect mitigation (pharmacotherapy options)</li> </ul>                                                                                                                                                                                                                                 |
| <b>Drug Safety</b>                  | <ul style="list-style-type: none"> <li>• Serious Adverse Event</li> <li>• Unexpected Drug Reactions</li> <li>• Contraindication</li> <li>• Drug-drug interaction</li> <li>• Drug-food interaction</li> <li>• Pregnancy precaution</li> <li>• Expired/improperly stored medication</li> <li>• Hazardous handling/disposal</li> </ul>                                             |
| <b>Immunization Recommendations</b> | <ul style="list-style-type: none"> <li>• Specific vaccine recommendation</li> <li>• Vaccine administration timing during therapy duration</li> </ul>                                                                                                                                                                                                                            |
| <b>Other</b>                        | <ul style="list-style-type: none"> <li>• Social determinants of health: <ul style="list-style-type: none"> <li>» Patient Advocacy</li> <li>» Transportation</li> <li>» Financial Assistance</li> <li>» Cultural and Health Literacy Assistance</li> </ul> </li> <li>• Any other wonderful work not performed as stated above</li> </ul>                                         |
| <b>Multiple Categories</b>          | To be selected if two or more interventions are occurring in one instance                                                                                                                                                                                                                                                                                                       |

**Eligible patients included women and men 18 years or older, with an active diagnosis of breast cancer as determined by ICD10**

Pharmacists were trained asynchronously via a recorded presentation on the new documentation process, descriptions of each clinical intervention category, how to utilize the dashboard, and further follow-up protocols for the proposed intervention. Clinical documentation of interventions performed within the patient chart was reviewed to assess intervention category recommendations made by the pharmacist with the patient, the timeframe for follow-up as determined by the pharmacist, and the patient acceptance rate of the intervention recommendations. Additionally, the primary investigator analyzed data from pre-intervention documentation training October 1 to December 31, 2023, and post-intervention documentation training January 7 to February 29, 2024, for number of interventions and accuracy of reported interventions, as defined by PI categories of medication reconciliation, drug therapy adherence, administration, disease state monitoring, side effect management, immunization, recommendation, other, and multiple intervention categories in one patient encounter (Table 1).

**Inclusion and exclusion criteria.** Eligible patients included women and men 18 years, or older, with an active diagnosis of breast cancer as determined by ICD10, an active prescription for oral breast cancer therapy dispensed by Lumicera, and a documented PI. Patients were excluded if pregnant or breastfeeding at time of intervention and/or follow-up, known hypersensitivity to prescribed breast cancer therapy or any component of the formulation, or PIs involving prescription clarifications of therapy which had not yet reached the patient.



TABLE 2: PATIENT CHARACTERISTICS (N=47)

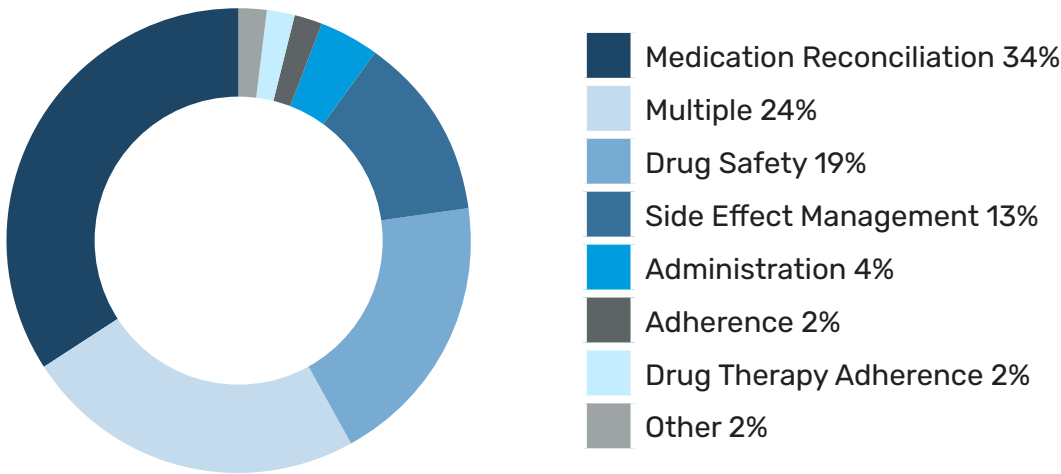
| Characteristic                              | N (%)    |
|---------------------------------------------|----------|
| Age                                         |          |
| < 65 years old                              | 39 (83%) |
| 65-75 years old                             | 6 (13%)  |
| > 75 years old                              | 2 (4%)   |
| Medication on Enrollment                    |          |
| Capecitabine                                | 13 (28%) |
| Everolimus                                  | 2 (4%)   |
| Ribociclib                                  | 12 (26%) |
| Alpelisib                                   | 1 (2%)   |
| Abemaciclib                                 | 19 (40%) |
| Duration on Therapy at Time of Intervention |          |
| New to Therapy                              | 7 (15%)  |
| ≤ 3 months                                  | 18 (38%) |
| > 3 months                                  | 22 (47%) |
| Intervention Outcomes                       |          |
| Time to Follow Up                           |          |
| No follow up needed                         | 19 (40%) |
| <2 weeks                                    | 21 (45%) |
| 1 month                                     | 2 (4%)   |
| 2 months                                    | 2 (4%)   |
| Lost to follow up                           | 3 (6%)   |
| Average Number of Outreaches per Patient    | 2        |

RESULTS

**Patient Characteristics.** Between October 1, 2023, and February 29, 2024, forty-seven patients met the inclusion criteria and were included for analysis, with three participants lost to follow up (Table 2). Thirty-nine (83%) were 65 years old or younger. Twenty-two (47%) of the patients were on therapy for more than 3 months, with an average of two pharmacist outreaches needed per intervention. The time designated from PI made to pharmacist follow-up was less than 2 weeks in 45 percent of the patients, with 40 percent of patient interventions indicated as not needing a follow up.

**Pharmacist Interventions.** The acceptance rate of PI recommendations was 70% as defined by patient confirming they implemented the action(s) recommended by the pharmacist. PIs were primarily conducted on abemaciclib (19 PIs, 40%), followed by capecitabine (13, 28%), ribociclib (12, 26%), everolimus (2, 4%) and alpelisib (1, 2%). Medication reconciliation (34%) was the most common category selected for PIs made, followed by multiple interventions conducted in one patient encounter (24%), drug safety (19%), side effect management (13%), drug therapy adherence (4%), administration (4%) and other (2%) (Figure 1). The total number of oral breast cancer therapy interventions conducted pre-pharmacist intervention documentation training was 94, with 23 (25%) defined as accurately reported interventions by meeting criteria established in Table 1. The total number of documented interventions post-pharmacist intervention documentation training was 67, with 49 (73%) accurately reported interventions. This resulted in an increase of 113 percent change in accuracy of documentation from pre- to post-intervention training.

FIGURE 1: INTERVENTION CATEGORIES FOR ORAL BREAST CANCER THERAPY



## DISCUSSION

Specialty oncology pharmacists are positioned to work closely with medical and nursing staff to ensure the availability of specialty oncolytic therapies, verify appropriate dosing, assess patient safety, provide education and materials as appropriate, and monitor adherence.<sup>17</sup> Telephonic consultations allow access for ongoing reassessments and monitoring throughout the continuum of cancer therapy with patients nationwide in the comfort of an outpatient setting. Given the steady increase in prescribing of outpatient oral oncology cancer therapies, this study provides evidence to the integral role clinical pharmacists have in therapy, as illustrated by 70 percent of patients accepting PI recommendations.

The predominate age category of patients who received PIs was less than 65 years old, which is representative of the average age of U.S. women being diagnosed with breast cancer at the age of 62.<sup>1</sup> PIs occurred most frequently with abemaciclib (40%), which is the predominant oral oncology therapy to treat breast cancer dispensed by all Lumicera locations. The rate of interventions is unsurprising, given the results of the adjuvant abemaciclib trial, where 44% of patients taking abemaciclib required a dose reduction due to side effects.<sup>16</sup>

The majority of PIs were identified early in therapy, for patients new to therapy (15%) and those on therapy for three months or less (38%). Although the overall duration of therapy was not directly studied based on the short trial period, PIs provided early on in oral breast cancer therapy could be integral to patient's ability to continue therapy. The duration on therapy was greater than 3 months in 47 percent of the patient population during the study period. However, pharmacy-reported duration of therapy can be influenced by other external factors, such as change in insurance mid-therapy or a temporary drug holiday.

Medication reconciliation was the prevalent intervention category. Examples of interventions conducted in this category included verifying dose reductions and cycle lengths to modify quantity dispensed appropriately and informing/requesting dose changes due to patient reported side effects. Additionally, many oral breast cancer therapies have complex administration schedules, such as cycle dosing with ribociclib and capecitabine, as well as a high frequency of dose adjustments required due to side effects and neutropenia.<sup>15</sup>



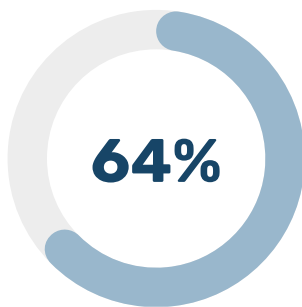
**This study provides evidence to the integral role clinical pharmacists have in therapy.**

# 13,365

oncologists  
are engaged in  
patient care



of oncologists  
are available in  
rural areas



of counties in the  
US don't have  
physicians who  
specialized in  
oncology practices

The usefulness of the PI dashboard allowed for a streamlined data analytics tool and a centralized source for pharmacists to reference for follow-up date reminders to enhance longitudinal care with patients. Providing PI documentation training raised awareness around interventions conducted throughout the time of prescription intake to dispensing at Lumicera and increased reporting of accurate PIs by 133 percent post training.

According to the American Society of Clinical Oncology (ASCO) 2022 State of the Oncology Workforce in America, 13,365 oncologists are engaged in patient care, with 22.0 percent of oncologists nearing retirement (aged 64+) and 13.9 percent of oncologists 40 and under. Of these oncologists in practice, 10.5 percent are available in rural areas.<sup>18</sup> Furthermore, 64 percent of counties in the United States do not have physicians who specialized in oncology practice, requiring patients to travel farther to receive cancer care and/or seek physicians not specialized with oncologic practices.<sup>19</sup> Oncology pharmacists are readily available to their patients and have been shown to increase patient satisfaction and enhance learning outcomes, which ultimately leads to improved medication adherence and disease-based outcomes.<sup>20</sup> Activities of the oncology pharmacist include changing/managing dose of oncologic therapy, identifying drug-drug interactions, providing supportive care and side effect mitigation recommendations, counseling on hazardous drug handling/disposal, and providing disease state monitoring as well as adherence tools. The complexity of oncologic therapy and further development of targeted and immunotherapy medications require the need for specially trained practitioners to help ensure the safety of self-administration of these treatments, make recommendations as deemed appropriate and can function as physician extenders.<sup>15</sup>

Pharmacists are notable members of the interdisciplinary team, assisting with gaining access to needed oncologic therapies and acting as a liaison between the provider and the patient in a variety of inpatient and outpatient settings. Per the American Society of Health-System Pharmacists (ASHP), state governments are employing pharmacists to provide patients with access to essential healthcare needs for which pharmacists are practicing at the top of their licenses to support Medicare program demands for which healthcare systems are not reimbursed for. Advancing legislation for pharmacist provider status will allow for enhanced health care services and access to medication

related education and training health care services in rural and underserved settings.<sup>21</sup> With the discrepancy between retiring oncolytic practitioners and younger practitioners entering the workforce, oncology pharmacists are uniquely positioned to fulfill this essential healthcare gap. This study provides evidence of the utilization and acceptance of pharmacist recommendations in the outpatient setting throughout the continuum of breast cancer treatment, which may allow for safer outpatient treatment. Obtaining National Provider status for oncology pharmacists will solidify their role in the interdisciplinary team to collaboratively manage therapeutics as well as supporting the individualized needs of the cancer patient and their caregivers.

## **LIMITATIONS**

The limitations with this single institution study were shorter time to follow up, small patient sample, and limited data capture. Of note, retrospective review of patient data may allow for selection bias which is inherent to this type of analysis. Pharmacists were trained during the middle of the study period in an asynchronous manner which did not allow for consistent intervention reporting.

## **FUNDING**

This study did not receive any funding or grants from Lumicera or any other outside public agencies or non-profit sectors.

## **CONCLUSION**

This study provides statistical and clinical evidence of interventions that pharmacists are providing, the patient acceptance rate of these interventions, and the impact on patient outcomes. PIs were accepted by patients in 70% of instances, with the majority of interventions conducted in the medication reconciliation category. Further studies would benefit from a longer study duration to assess efficacy of clinical intervention training and oncology patient therapeutic outcomes. Study outcomes are relevant to support clinical pharmacists becoming frontline practitioners in oncology practice and for the advancement of National legislation for provider status.

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