



Implementation of Guidelines Concordant Treatment Options in Patients with HR (Hormone Receptor Positive) and HER 2 neu Negative Advanced Breast Cancer

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Introduction: The management of patients with advanced HR positive, HER 2 neu negative breast cancer patients has changed quite a lot since development of the inhibitors of cyclin dependent kinases 4 and 6 (CDK4/6). Since this class of drug was made available in 2015 and onwards, uptake of these drugs in management has not been uniform, despite efficacy and meaningful improvement in the outcome of patient's treatment with this class of drugs in combination with ER blockers. Prior to the availability of these drugs, management of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative (HR+/HER2-) advanced breast cancer was typically treated with more of a palliative form of chemotherapy. The treatment paradigm prior to CDK 4/6 for HR+/HER2- advanced breast cancer involved sequencing endocrine therapy, targeted therapy, and/or chemotherapy to prolong patients' lives, delay disease progression, and minimize cancer-related symptoms. The CDK4/6 inhibitors are rapidly transforming this treatment landscape. There are currently three CDK4/6 inhibitors that have been approved by the US Food and Drug Administration: palbociclib, ribociclib, and abemaciclib¹⁻⁵.

Despite the plethora of research available for the optimal application of the CDK 4/6 in the management of advanced HR positive HER 2 negative breast cancer patients, there is significant variation in the utilization pattern of these drugs. Even six years after approval of these drugs, a question still remains, how can the treatment with inhibitors of CDK4/6s be optimized for patients with breast cancer?

We share a case study of the Carolina blood and cancer care as to how we optimized guidelines concordant utilization of the CDK4/6 in the management of advanced breast cancer that are HR positive/HER 2 negatives. We acknowledge data acquisition from the Pfizer MSL team to support analytics and allow us to use IQVIA data.

Methods: A retrospective analysis of fully adjudicated pharmacy and medical claims data from the IQVIA (anonymized Patient Longitudinal Data; Longitudinal Access and Adjudication Data format- LAAD). The dataset includes HIPAA-compliant anonymized information on diagnostic codes, diagnostic tests, prescribed treatments, and procedures. This dataset covers ~18 million US cancer patients, ~10,000 oncologists, and includes data across all 50 states (60 - 85% capture rate). It also includes access to data from 2012 onward, with treatment patterns reported starting in 2015. Data for Medicaid, commercial, Medicare, Medicare Part D, and cash transactions from February 2012 onwards are included in this dataset.

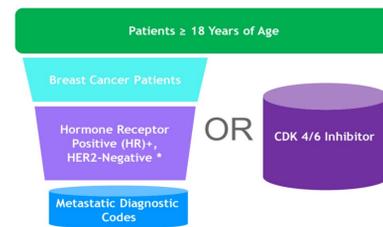
Inclusion Criteria

- Patient greater than OR equal to 18 years of age on first breast cancer
- Breast Cancer Diagnosis (Diagnosis codes for Breast Cancer on two medical service claims separated by at least 30days), AND
- HR-positive At least one (1) claims for ER+ disease (ICD9/ICD10codes) OR hormonal product (HR+ Drug List) AND
- Metastatic Breast Cancer At least two (2) medical claim s with any secondary metastatic 1CD9/ICD10codes on 2 separate calendar days, AND
- Continuous Visibility: At least one (1) medical Or pharmacy claim or both- before and after the Index Date and or for 6 months

Exclusion Criteria

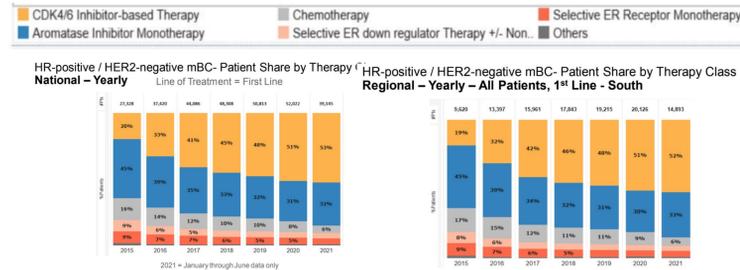
- HER2-positive
- At least one (1) medical or pharmacy claim during the data period for a drug used to treat HER2+ Breast Cancer

Methods and data source: Patient Selection Criteria

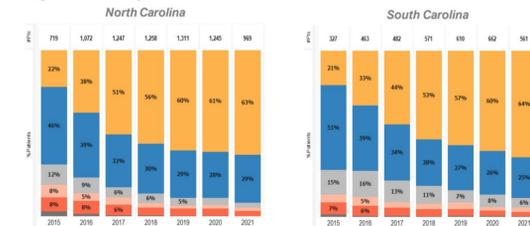


Methods & Data Source: Classification of Treatment Categories

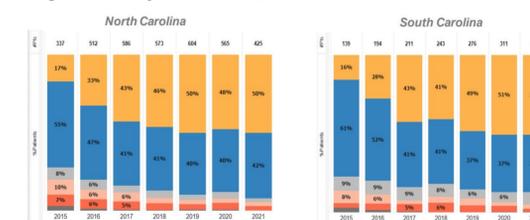
Acknowledgn	Treatment Categories	
1.Palbociclib (Ibrar) 2.Verzenio, Abema 3.Ibrance: Palbocic https://bit.ly/35YK 4.Ibrance: Palbocic 5.Kisqali: Ribocicli 6.National Compre 7.National Institute 8.Institute of Medi 9.Arndt JV, Netsh L 10.Gregory, KE, Dif 11.Whyte JL, Engel 12.Elyse Swallow, J 13.Tang, DH, LIN, C	CDK4/6 inhibitor-based Therapy	palbociclib, ribociclib, abemaciclib (includes combination products)
	Aromatase Inhibitor Monotherapy	anastrozole, exemestane, letrozole
	Selective Estrogen Receptor Down Regulator	fulvestrant
	Selective Estrogen Receptor Modulator	toremifene, tamoxifen
	Chemotherapy	capecitabine, carboplatin, docetaxel, doxorubicin, doxorubicin liposome, epirubicin, eribulin, gemcitabine, idarubicin, ixabepilone, paclitaxel, paclitaxel protein-bound, vinorelbine
	Others	entrectinib, talazoparib, olaparib, everolimus, pembrolizumab, alpelisib, Larotrectinib, ethinyl estradiol, fluoxymesterone



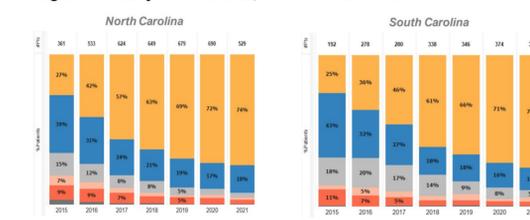
HR-positive / HER2-negative mBC- Patient Share by Therapy Class Regional - Yearly - All Patients, 1st Line



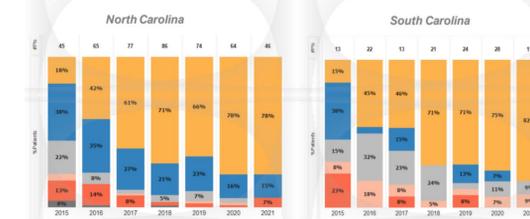
HR-positive / HER2-negative mBC- Patient Share by Therapy Class Regional - Yearly - All Patients, 1st Line - Medicare and Medicare Part D



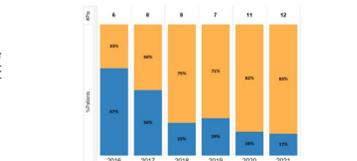
HR-positive / HER2-negative mBC- Patient Share by Therapy Class Regional - Yearly - All Patients, 1st Line - Commercial



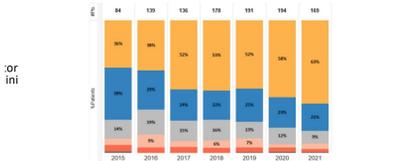
HR-positive / HER2-negative mBC- Patient Share by Therapy Class Regional - Yearly - All Patients, 1st Line - Medicaid



HR-positive / HER2-negative mBC- Patient Share by Therapy Class Yearly - All Patients, 1st Line - Carolina Blood and Cancer



HR-positive / HER2-negative mBC- Patient Share by Therapy Class Yearly - All Patients, 1st Line - South Carolina Community Practices



Limitations

- The data used in this analysis were captured primarily for the purpose of claim filing and may not be representative of patients outside of the dataset, specifically those patients not receiving treatment.
- Administrative claims data used in this database is constrained by codes available and may include coding errors and missing data.
- Patients were included in the analysis only if enough information was available to determine eligibility based on the methods outlined herein. Patients who received no treatment during the specified time frame are not represented in the data presented.
- The intended purpose of this data is for quality improvement and not intended to inform clinical decision making or for research purposes. Causality or predictability of future use should not be implied.
- The results summarized in this report are not necessarily indicative of efficacy, safety, or tolerability of the included products. No product claims, including comparative claims, can be made from this report.
- Assuming that all patients who received a CDK4/6 inhibitor in this analysis have HR+/HER2- mBC likely overestimates the actual number and proportion of metastatic breast cancer patients receiving a CDK4/6 inhibitor and underrepresents patients treated with other therapies.
- Patient cohorts comprised of less than 6 patients will not be displayed

Potential Filters:

- Age Groups (years)
 - 18-49
 - 50-59
 - 60-64
 - 65-69
 - 70-74
 - 75-79
 - >80
- Methods of Payment
 - Commercial
 - Medicare
 - Medicare Part D
 - Medicaid
 - Cash
- Geography
 - National
 - Regional
 - State
 - Metropolitan Statistical Area (MSA)
 - Institution/local Level (as defined by)
- Practice Type
 - Integrated Health Delivery Networks
 - Academic Centers
 - Large Group Practices

- All, New or Continuing patients

- Male, Female, or all patients

- Time frame (e.g., monthly, quarterly, rolling year, year-over-year comparisons, other relevant time frame)

Discussion:

At the Carolina Blood and Cancer Care Associates (CBCCA) we have implemented a rigorous and vigorous process to implement adherence to guidelines-based treatment as often as possible since 2014. One of the reasons for this strategy is to remain in compliance with our participation in multiple value-based care pilots including an oncology care model (OCM) and commercial payers. This involved regularly schedule meeting of all the providers, review of all new cases on weekly bases. We also did not differentiate between payers and implemented our policy of universal approach. As a result, compared to our peers across the country, where there was wide variation based on age, type of insurance, commercial versus Medicare or Medicaid, our approach was universal and since 2015, we have adhered to guidelines concordant treatment.

A limitation of this study is the sample size.

Drug Lists	
HR-Positive Drug List	HER2-Positive Drug List (Exclusion)
Abemaciclib	Ado-Trastuzumab Emtansine
Anastrozole	Lapatinib
Ethinyl estradiol	Margetuximab-CMKB
Everolimus	Neratinib
Exemestane	Pertuzumab
Fluoxymestron	Trastuzumab
Fulvestrant	Trastuzumab-ANNS
Letrozole	Trastuzumab-DKST
Palbociclib	Trastuzumab-DTTB
Ribociclib	Trastuzumab Deruxtecan Lyophilisate
Ribociclib/letrozole	Trastuzumab-PKRB
Tamoxifen	Tucatinib
Toremifene	