

Real-World Utilization and Impact of Multigene Expression Tests and Chemotherapy Use in Early-Stage Breast Cancer: A German Claims Data Analysis



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Background

Evaluation of multigene test use and its impact on chemotherapy decisions in early-stage HR+/HER2- breast cancer (German claims data).

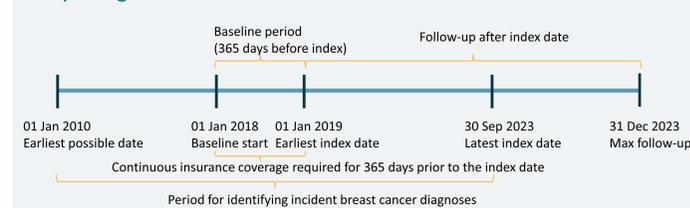
Study Context

Following a diagnosis of early-stage breast cancer, prognosis assessment and selection of appropriate (neo-)adjuvant therapies remain key clinical challenges. In Germany, multigene expression tests for early-stage breast cancer have been reimbursed within statutory health insurance since January 2020, following a decision by the Federal Joint Committee (G-BA) to incorporate these assays into routine care. This study uses German routine claims data to evaluate the real-world utilization of multigene expression tests and their association with chemotherapy decision-making in routine early-stage breast cancer care. This study utilizes an anonymized database provided by GWQ ServicePlus AG, which aggregates claims data from 20 small and medium-sized statutory health insurance (SHI) companies. The dataset encompasses a population of up to 7.8 million observable insured individuals (covering the period from January 2010 to December 2023).

Methods

Retrospective cohort study using anonymized German health insurance data from 2019 – 2023 from selected payor organizations, representing about 10% of the SHI market.

Study Design + Observation Period



Inclusion Criteria

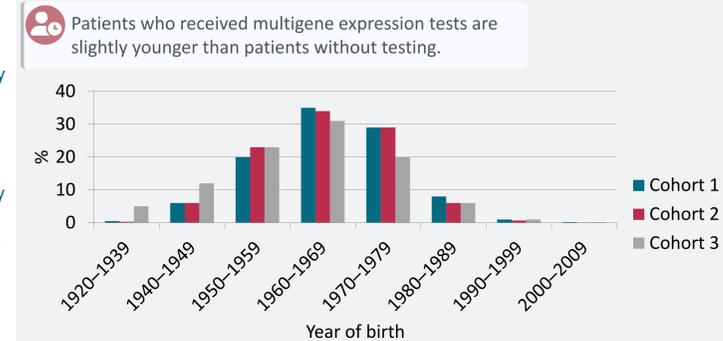
- Female patients with a breast cancer diagnosis (ICD-10 C50*)
- At least two documented outpatient diagnoses or one inpatient diagnosis
- Continuous insurance coverage for 365 days prior to the index date
- No prior malignancy diagnoses (except C43, C44, C84.9)

Cohorts

Cohort	Utilization of Multigene Expression Tests
1	Patients with incident breast cancer who received Oncotype DX® test (EBM 19506) during the observation period.
2	Patients with incident breast cancer who received EndoPredict®, MammaPrint®, or Prosigna® (EBM 19503, 19504, 19505) during the observation period.
3	Patients with incident breast cancer who did not receive any of the above-mentioned tests during the observation period.

Population Characteristics

The cohorts show broadly comparable menopausal status distributions. Patients who received multigene expression tests tended to be slightly younger and to have fewer comorbidities than those without testing. Descriptive differences were also observed in tumor burden and treatment characteristics, with lower frequencies of metastases and use of targeted therapies among tested patients.



Patients with multigene expression tests show differences in tumor and therapy-related characteristics.

Characteristic	Oncotype DX® (n=421)	Other tests (n=179)	No tests (n=12,808)
Lymph node positivity (≤180 d)	17.1%	32.4%	18.5%
Distant metastasis (≤180 d)	7.6%	7.8%	9.0%
HR+ status	95.7%	87.2%	69.5%
HER2+ status	1.2%	2.8%	11.2%
Targeted therapy	2.9%	2.8%	4.4%

Patients who received multigene expression tests are slightly healthier than patients without testing.

Comorbidity	Oncotype DX® (n = 421)	Other tests (n = 179)	No tests (n = 12,808)
Obesity	8.6%	11.2%	10.7%
Anxiety	18.5%	21.8%	20.5%
Depression	17.3%	18.4%	18.6%
Cardiac disease	33.0%	34.6%	41.6%
Thyroid disorder	28.3%	30.2%	30.1%
Osteoporosis	4.0%	5.6%	5.9%

The distribution of menopausal status is similar across cohorts.

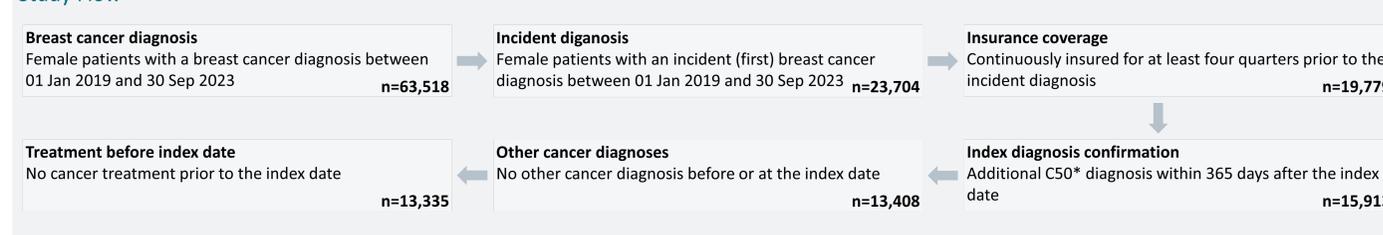
Menopausal status	Oncotype DX® (n = 421)	Other tests (n = 179)	No tests (n = 12,808)
Postmenopausal	85.7%	90.5%	86.6%
Premenopausal	12.1%	7.3%	12.6%
Inconsistent / unclear	2.1%	<5%	0.7%

Results

Patient Selection

A waterfall model illustrates the stepwise selection of patients from 63,518 to a final cohort of 13,335.

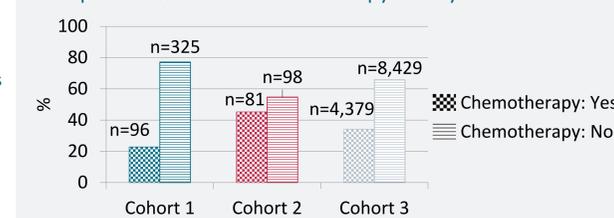
Study Flow



Chemotherapy Rates by Cohort

Adjuvant chemotherapy use varied across cohorts and reflects differences in underlying clinical characteristics rather than treatment effects.

Descriptive Overview of Chemotherapy Use by Cohort



Clinical Context and Interpretation

- Multigene expression testing cohorts predominantly comprised HR-positive and HER2-negative tumors, consistent with guideline-concordant test use
- While rates of distant metastasis were comparable between cohorts, higher proportion of HER-positive and targeted therapy were present in the no-test cohort
- Cohorts were not matched or adjusted; findings should therefore be interpreted descriptively
- Further analysis will apply additional exclusion criteria and confounder adjustment.

Utilization of Multigene Expression Tests

The results reveal a low overall use of multigene expression tests in routine early-stage breast cancer care in Germany.

Number of Multigene Expression Tests in the dataset



Key Findings

- Multigene expression testing was increasingly utilized after its introduction into routine statutory health insurance care, with notable differences in uptake across patient cohorts.
- The Oncotype DX® test represented the largest observed share of MGA in the analyzed 2023 claims dataset (75%).
- EndoPredict® is the second most frequently used test, accounting for approximately 17%.

Conclusions

The results emphasize the value of real-world data in assessing how multigene expression testing is incorporated into everyday clinical decision-making.

Overall utilization of multigene expression tests	Overall use of multigene expression tests was low but increasing; however, utilization may be underestimated, as Ambulatory Specialized Care (ASV)-reimbursed tests are not captured in the database.
Frequency of used multigene expression tests	Oncotype DX® was the most frequently multigene expression tests in 2023, and its use was associated with a lower observed frequency of chemotherapy in routine early-stage breast cancer care.

Methodological considerations

- The analysis characterizes real-world care patterns. Cohorts were not matched or adjusted; comparative interpretations (including budget impact) should therefore be made with caution.
- Differences in tumor and therapy-related characteristics, particularly between test and no-test cohorts, may reflect underlying population heterogeneity.
- Results are based on a representative German claims dataset (~7.5% of SHI patients, 2023) and reflect billed services; privately insured/self-paid testing and other SHI organizations are not captured