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Utilization and patient characteristics for the trastuzumab reference and biosimilars, and other HER2 inhibitors in the United States

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BACKGROUND

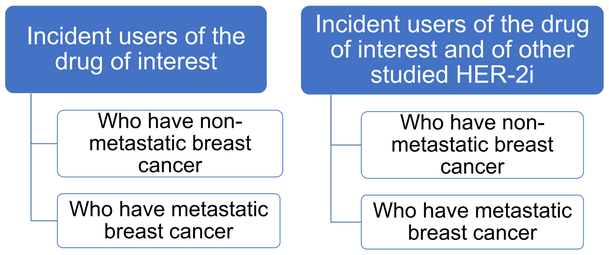
- Biologics have significantly improved treatment of conditions such as cancer and are one of the fastest growing segments of the prescription product market [1].
- Trastuzumab is a biologic agent used to treat human epidermal growth factor receptor-2 (HER2) positive breast cancer and other cancers.
- The reference trastuzumab (Herceptin®) was approved in 1998 in the US as the first HER2-targeted therapy.
- Trastuzumab biosimilars became available beginning in 2017, yet utilization information on these biosimilars is limited.

OBJECTIVE

To evaluate utilization plus patient baseline sociodemographic and clinical characteristics for the trastuzumab reference drug (Herceptin®), its biosimilars, and other HER2 inhibitors.

METHODS

- Data Source: Healthcare claims data within four commercial health plans participating in the FDA's Sentinel System and Biologics & Biosimilars Collective Intelligence Consortium (BBCIC) distributed research network from 01 October 2016 through 31 October 2022.
- Inclusion Criteria
  - Age ≥18 years on the first recorded dispensing or administration date for the study drug (index date);
  - Continuous medical and prescription drug insurance for ≥365 days prior to the index date (enrollment gap ≤45 days was allowed);
  - Incident use of a study drug (washout period: 365 days) during the study period.
- Study Cohort



- Patients could contribute multiple incident use episodes for different drugs if they met the eligibility criteria; within the same drug, only the first eligible episode was counted.
- Patient characteristics were evaluated during a pre-specified pre- and/or post-index period.

RESULTS

Table 1. Patient characteristics of incident episodes of trastuzumab products (incident to the drug itself) in the BBCIC Distributed Research Network, 01 October 2016 – 31 October 2022: All Patients

	Herceptin®	Kanjinti®	Kadcyla®	Ogiviri®	Nerlynx®	Trazimera®	Tykerb®	Enhertu®
Number of incident episodes	4,057	1,490	1,059	352	268	470	193	380
Demographic characteristics (on index date)								
Mean (SD) age (years)	60.2 (12.9)	62.5 (13.1)	59.6 (13.5)	61.4 (13.2)	53.5 (11.9)	64.2 (12.1)	61.1 (12.2)	62.9 (12.2)
Female, n (%)	3,755 (92.6)	1,392 (93.4)	1,026 (96.9)	332 (94.3)	268 (100.0)	430 (91.5)	180 (93.3)	315 (82.9)
Clinical characteristics (183 days prior to index drug dispensing) , n (%)								
Charlson/Elixhauser Combined Comorbidity Score, mean (SD)	1.3 (1.9)	1.5 (1.9)	1.9 (2.1)	1.5 (1.8)	1.0 (1.5)	1.7 (2.1)	1.9 (2.1)	2.5 (2.4)
Breast cancer - malignant neoplasm, n (%)	3,631 (89.5)	1,328 (89.1)	1,011 (95.5)	312 (88.6)	266 (99.3)	422 (89.8)	173 (89.6)	285 (75.0)
Metastatic disease, n (%)	1,515 (37.3)	620 (41.6)	722 (68.2)	156 (44.3)	84 (31.3)	210 (44.7)	176 (91.2)	345 (90.8)
Hypercholesterolemia, n (%)	550 (13.6)	214 (14.4)	97 (9.2)	38 (10.8)	<11 (NC)	65 (13.8)	16 (8.3)	25 (6.6)
Obesity, n (%)	879 (21.7)	360 (24.2)	190 (17.9)	83 (23.6)	44 (16.4)	119 (25.3)	29 (15.0)	55 (14.5)
Diabetes, n (%)	591 (14.6)	245 (16.4)	153 (14.4)	50 (14.2)	22 (8.2)	80 (17.0)	24 (12.4)	61 (16.1)
Hypertension, n (%)	1,590 (39.2)	648 (43.5)	392 (37.0)	136 (38.6)	54 (20.1)	201 (42.8)	72 (37.3)	134 (35.3)
Recorded History of (365 days prior to index drug dispensing) , n (%)								
Record of ER+ status	2,520 (62.1)	961 (64.5)	801 (75.6)	227 (64.5)	206 (76.9)	298 (63.4)	111 (57.5)	209 (55.0)
IHC or FISH test	3,610 (89.0)	1,206 (80.9)	787 (74.3)	272 (77.3)	54 (20.1)	380 (80.9)	87 (45.1)	173 (45.5)
Cancer-related radiation therapy	416 (10.3)	222 (14.9)	399 (37.7)	66 (18.8)	166 (61.9)	81 (17.2)	94 (48.7).	144 (37.9)
Lumpectomy/mastectomy	1,502 (37.0)	516 (34.6)	565 (53.4)	125 (35.5)	121 (45.1)	153 (32.6)	15 (7.8)	32 (8.4)
History of Use (7 days prior to through 30 days after index drug dispensing) , n (%)								
Any endocrine therapy	380 (9.4)	219 (14.7)	258 (24.4)	55 (15.6)	147 (54.9)	63 (13.4)	44 (22.8)	55 (14.5)
Pertuzumab	2,141 (52.8)	744 (49.9)	16 (1.5)	169 (48.0)	16 (6.0)	219 (46.6)	<11 (NC)	0 (0)

- NC: Not Calculated. Small number of counts (0<n<11) are suppressed (indicated as <11 in the table), and their proportions are not calculated.
- ER+: Estrogen-receptive positive; FISH: Fluorescence In Situ Hybridization; IHC: Immunohistochemistry; SD: standard deviation.
- Data availability varied by Research Partner (RP): RP1 – 6/30/2022; RP2 – 10/31/2022; RP3 – 6/30/2022; RP4 – 5/31/2022.
- Trastuzumab and hyaluronidase-oysk (Herceptin Hylecta®), trastuzumab-dttb (Ontruzant®), trastuzumab-pkrb (Herzuma®), and pertuzumab-trastuzumab-hyaluronidase-zzxf (Phesgo®) are not presented due to small numbers.

RESULTS

- Over 16 million eligible health plan members representing over 31 million person-years of data were evaluated.
- In the incident users of the drug itself, we identified 8,732 incident treatment episodes, of which, 4,057 (46%) episodes were with the reference (Herceptin®).
- In the incident users of the drug itself and of other studied HER2 inhibitors, we identified 5,984 incident treatment episodes, of which, 3,878 (65%) episodes were with the reference (Herceptin®).

Figure 1. Proportions of incident users by drug and year: Incident to itself

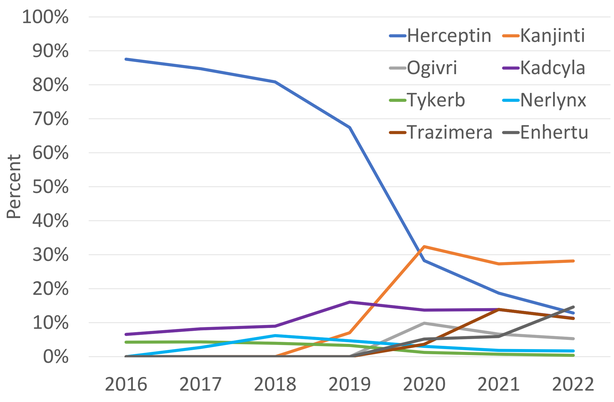


Figure 2. Proportions of incident users by drug and year: Incident to any HER2 inhibitors

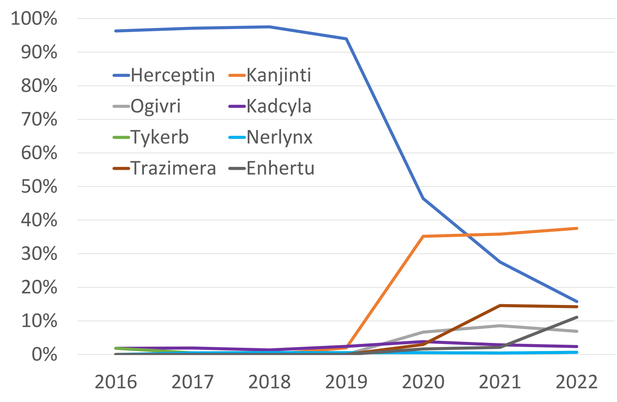


Figure 3. Proportions of incident users by drug and year: Incident to itself (metastatic breast cancer patients)

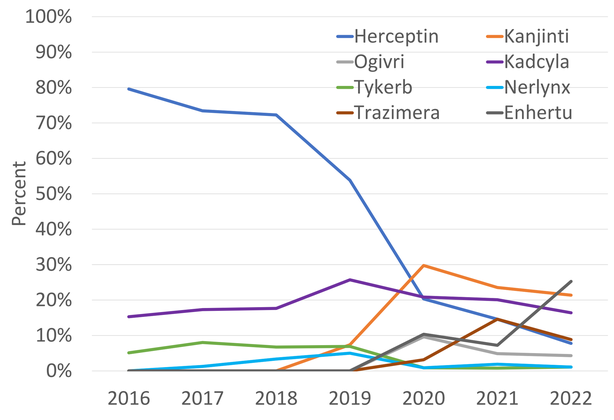
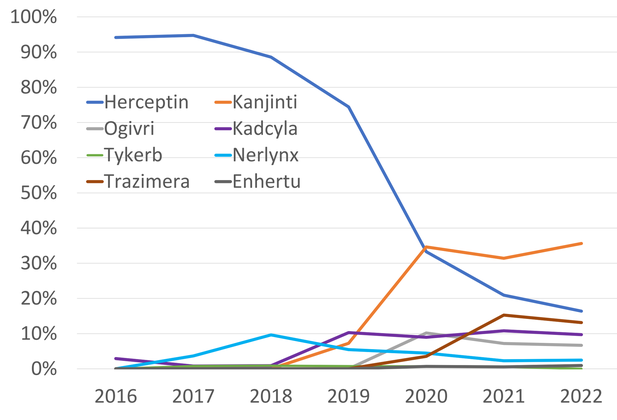


Figure 4. Proportions of incident users by drug and year: Incident to itself (non-metastatic breast cancer patients)



CONCLUSIONS

- Number of incident users of the reference (Herceptin®) decreased from 2017 to 2022; uptake of biosimilars such as trastuzumab-anns (Kanjinti®) and trastuzumab-qyyp (Trazimera®) increased since 2019.
- Although trends were similar among patients with and without metastatic disease, we observed greater use of ado-trastuzumab emtansine (Kadcyla®), lapatinib (Tykerb®), and fam-trastuzumab deruxtecan-nxki (Enhertu®) in patients with metastatic disease than those with non-metastatic disease, while others were more frequently used in non-metastatic disease patients.
- Limitations:
  - Full year data available until end of 2021 and partial year data in 2022 varying by Research Partner end dates at the time of this analysis;
  - Proportions of incident users calculated with use of an approximated number (5) for low counts (>0, <11) so some data points may not be accurately presented.

REFERENCES

[1] Biosimilars Facts. Available from: https://www.bbcic.org/resources/biosimilars-facts. Accessed on: 26 June 2023

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