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Real world data on the adoption of trastuzumab biosimilars in the treatment of HER2-positive breast cancer.

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BACKGROUND

Biosimilars for trastuzumab were introduced into the US market for the treatment of HER2 positive breast cancer in 2019, with the goal of providing the clinical benefit of the brand product at a lower price (increased value). Adoption of trastuzumab biosimilars may be affected by multiple factors, including physician confidence in biosimilar efficacy and efficacy across stages, practice reimbursement, payer medical policy/redirection. To look at the adoption of trastuzumab biosimilars in the US medical oncology community, we queried a database of submitted treatment plans for patients with breast cancer.

METHODS

The Eviti® Connect decision support tool allows prospective treatment plan review for payers, capturing detailed information on the clinical features of the proposed treatment plan and the insured patient. The final analysis reviewed approved treatment plans submitted from June 2019 through October 31, 2020 (the abstract included earlier quarters), filtered to include only those that included trastuzumab, trastuzumab-hyaluronidase-oysk (both considered brand) or trastuzumab biosimilars.

The rate of biosimilar use was then calculated after stratifying the filtered treatment plans by various criteria. For the initial analysis, treatments plans were stratified by stage of disease (0-III Vs IV/recurrent). To identify changes in biosimilar use over time, the rate was then estimated over each quarter over the time period within each cohort. To look for the potential effect of payer drug policy, treatment plans were then stratified by presence vs. absence of payer policy favoring biosimilar use.

Finally, the economic impact of the observed pattern of biosimilar use was assessed. The stage-stratified patient populations were assigned costs based on the following assumptions:

- patients with stage I-III disease were assumed to receive 1 year of trastuzumab therapy between neoadjuvant and/or adjuvant therapy (18 doses);
- patients with stage IV/recurrent disease were assumed to receive 11 months of therapy (16 cycles) based on reported median PFS, TTP reported in various chemotherapy regimens with trastuzumab.

METHODS (Cont'd)

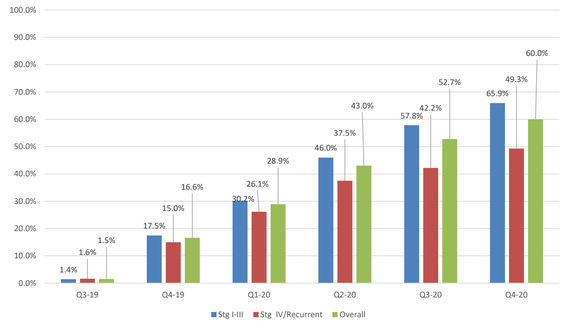
The trastuzumab dose was normalized dose of 440 mg for trastuzumab/trastuzumab biosimilars or 600 mg of trastuzumab-hyaluronidase; costs using the July 1, 2020 CMS pricing for these drugs at the average cost/cycle/patient for brand therapy and biosimilar therapy is $4502 and $3618, respectfully.

RESULTS

Table 1: Submitted plans and biosimilar use by stage at treatment

Stage at treatment	Submitted plans	Plans with biosimilar		Patients
Stages 0- III	6657	2271	34.0 (95% CI: 32.9-35.1)	4505
Stage IV/recurrent	3312	904	27.0 (95% CI: 25.5-28.5)	1933
TOTAL	9981	3175	31.7 (95% CI: 30.7-32.6)	6438

Figure 1: Biosimilar use over time



RESULTS

Table 2: Biosimilar use by presence/absence of payer policy

Payer policy favors biosimilar	Submitted plans	Plans with biosimilar	% biosimilar	Patients
Yes	896	372	41.5 (95% CI: 38.4-44.9)	673
No	9085	2803	30.9 (95% CI: 29.9-31.8)	5765

Over this interval, 9981 treatment plans were submitted for the treatment of 6438 patients (Table 1). Some patients had multiple treatment plans as they received either adjuvant and neoadjuvant therapy, therapy for localized and recurrent disease, or multiple lines of therapy in the metastatic/recurrent setting. The choice of brand over biosimilar does not appear to be based on curative vs noncurative therapy, as biosimilar use was actually higher in the curative setting (34% Vs 27%).

Adoption has increased over time across all stages of disease (Figure 1).

Use of biosimilars does appear to increase when the payer policy favors their use (41.5% Vs 30.9% - Table 2). As biosimilars were being introduced at different times during this time period and payer policy would likely lag behind these introduction, it is likely that the observed difference in biosimilar use by payer policy is underestimated.

The potential economic effect from the observed utilization rate is estimated (Table 3).

Table 3: Estimated savings associated with observed biosimilar use

Brand trastuzumab price	$4,502.00	-	
Average trastuzumab biosimilar price	$3,618.00		
Savings from biosimilar use/dose	$884.00		
Stage I-III		Stage IV/recurrent	
- number of patients	4502 x	- number of treatment plans	3312 x
- biosimilar use rate	34% x	- biosimilar use rate	27% x
- savings/biosimilar dose	$884.00 x	- savings/biosimilar dose	$884.00 x
- #/doses	18	- #/doses	16
Estimated savings	$24,356,180.00		$12,648,130.00

CONCLUSIONS

Within our data set, adoption of trastuzumab biosimilars for the treatment of patients with breast cancer has been significant.

This adoption does not appear to have been affected by patient selection by stage of disease as a proxy of goals of care.

Payer policy does appear to increase biosimilar utilization. Its impact may be underestimated in our analysis due to the introduction of new biosimilars during this time period and likely lag time between drug introduction and any modification of payer drug policies.

The estimated societal savings with trastuzumab biosimilar use in breast cancer is significant. Future estimates should use more rigorous models with stratification by use with hormonal therapy, chemotherapy, combinations with pertuzumab, or single agent, and the corresponding durations of therapy.

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