Patient characteristics and utilization for bevacizumab in ophthalmology and oncology in a distributed research network

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Background:

- Bevacizumab is an anti-angiogenic agent approved in 2004 for various oncologic indications. Biosimilars bevacizumab-awwb and bevacizumab-bvzr were launched in 2017 and 2019, respectively
- Bevacizumab is not approved by the FDA for ophthalmologic conditions
- Real-world data on utilization for bevacizumab biosimilars and ophthalmologic conditions is limited

Objective:

- To evaluate utilization patterns and patient sociodemographic and clinical characteristics for the originator bevacizumab relative to its biosimilars for labeled and off-label oncology and ophthalmology conditions

Methods:

- Retrospective cohort study using the Biologics and Biosimilars Collective Intelligence Consortium (BBCIC) distributed database from January 1, 2010, to December 31, 2020
- The data captured users 21 years of age and older
- Oncology indications: colon, lung, and gynecologic (cervical, uterine, and ovarian) cancers
- Ophthalmology indications: neovascular age-related macular degeneration (AMD), retinal vein occlusion (RVO), choroidal neovascularization (CNV), and proliferative diabetic retinopathy (PDR)
- Biosimilar data was analyzed collectively due to limited data availability

Results:

- For overall oncology indications, bevacizumab users had a mean age of 62.9 years, were primarily female, and had a Charlson/Elixhauser Combined Comorbidity Score of 7.4
- For ophthalmology indications, bevacizumab users had a mean age of 69 years, were primarily female, and had a Charlson/Elixhauser Combined Comorbidity Score ranging from 0.8 to 2.9
- Overall bevacizumab product utilization increased over time for CNV, RVO, and PDR but decreased for AMD after 2016
- Biosimilar utilization began in mid-2019 and full year data was only available for 2020; biosimilars contributed to 6.9% of total episodes for AMD compared to <1% for CNV, RVO, and PDR

References:

- American Academy of Ophthalmology, Summary Points, 2015
- Kodjikian, K., Souied, E., Mimoun, G., et al., 2013
- Holfinger, S., Miller, A., & Roa, L., 2016
- Moja, L., Lucenteforte, E., Kwag, K., et al., 2014
- US Food and Drug Administration, FDA-2014-D-1525, 2015

- **Bevacizumab biosimilar utilization made up 43.1% of all bevacizumab product use in 2020 in oncology**
- **Bevacizumab product utilization increased for retinal vein occlusion, choroidal neovascularization, and proliferative diabetic retinopathy, while decreasing for neovascular macular degeneration due to FDA draft guidance released in 2015**

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Table 1. Patient characteristics of bevacizumab product users in oncology from 2010 to 2020

	Number/Mean	Percent/Standard Deviation
Number of unique patients	23,066	--
Number of dispensings	24,044	--
Mean Age (years)	63	12
Number of females	14,261	62
Mean Charlson/Elixhauser Combined Comorbidity Score	7.4	3.0

Table 2. Patient characteristics of bevacizumab product users in ophthalmology from 2010 to 2020

	AMD	RVO	CNV	PDR
Number of unique patients	7,211	8,115	3,974	38,386
Number of dispensings	27,908	40,478	17,767	182,361
Mean Age (years)	79	72	57	61
Number of females	4,383	4,131	2,418	16,687
Mean Charlson/Elixhauser Combined Comorbidity Score	2.9	1.4	0.8	2.8

Table 3. Episodes of bevacizumab utilization from 2019 to 2020 by indication (N = 84,853)

Ophthalmologic Indication	Originator (N = 84,231)	Biosimilars (N = 622)
Age-Related Macular Degeneration	3,103 (93.1%)	230 (6.9%)
Choroidal Neovascularization	5,946 (99.9%)	5 (0.1%)
Retinal Vein Occlusion	16,912 (99.7%)	59 (0.3%)
Proliferative Diabetic Retinopathy	58,270 (99.4%)	328 (0.6%)

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Figure 1. Number of episodes of bevacizumab products per 10,000 eligible member-years by ophthalmologic indication and year

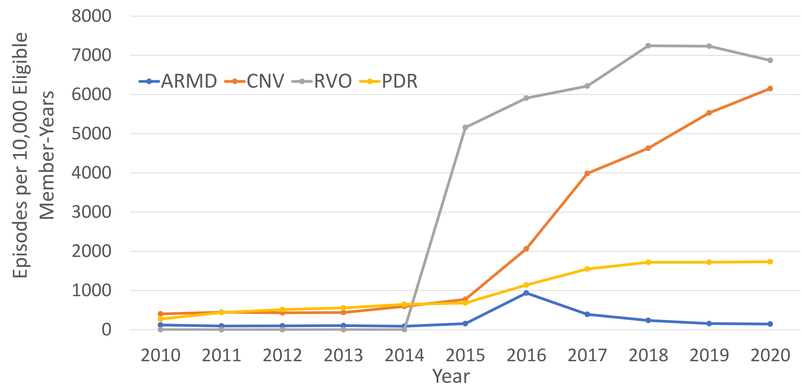
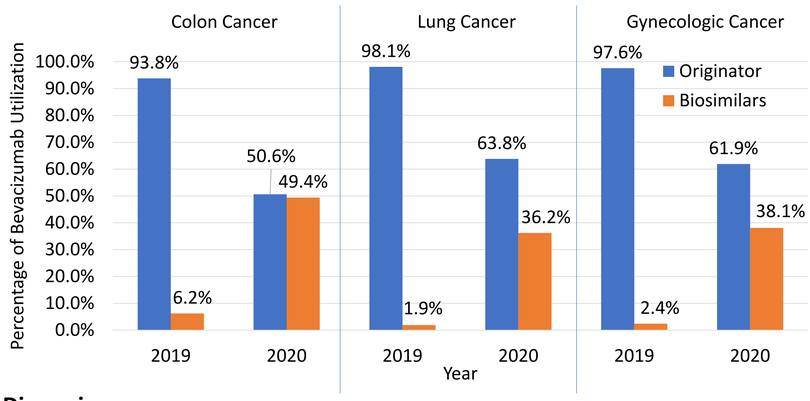


Figure 2. Percentage of bevacizumab utilization from 2019 to 2020 by oncology indication



Discussion:

- There was a notable increase in bevacizumab utilization for AMD between 2015 to 2016. This increase may be due bevacizumab being the cost-effective option compared to other anti-angiogenic drugs with a similar safety profile
- In 2015, FDA released draft guidance for mixing, diluting, or repackaging biological products outside the scope of an approved biological license. This guidance makes it difficult for ophthalmologists to order and store bevacizumab which may eliminate the ability of an ophthalmologist to use bevacizumab
- Biosimilar utilization represented a lower proportion of all bevacizumab use but is expected to increase in the future as more data becomes available