

Real-World Use of Aflibercept 8 mg in Eyes With Neovascular Age-Related Macular Degeneration (nAMD) or Diabetic Macular Edema (DME): Analysis of the Academy IRIS[®] Registry (ILLUMIN-8)

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Disclosures

- Quan Dong Nguyen has served on the scientific advisory boards of Belite Bio, Genentech, Keenova, Kriya, Osanni, and Regeneron Pharmaceuticals, Inc.
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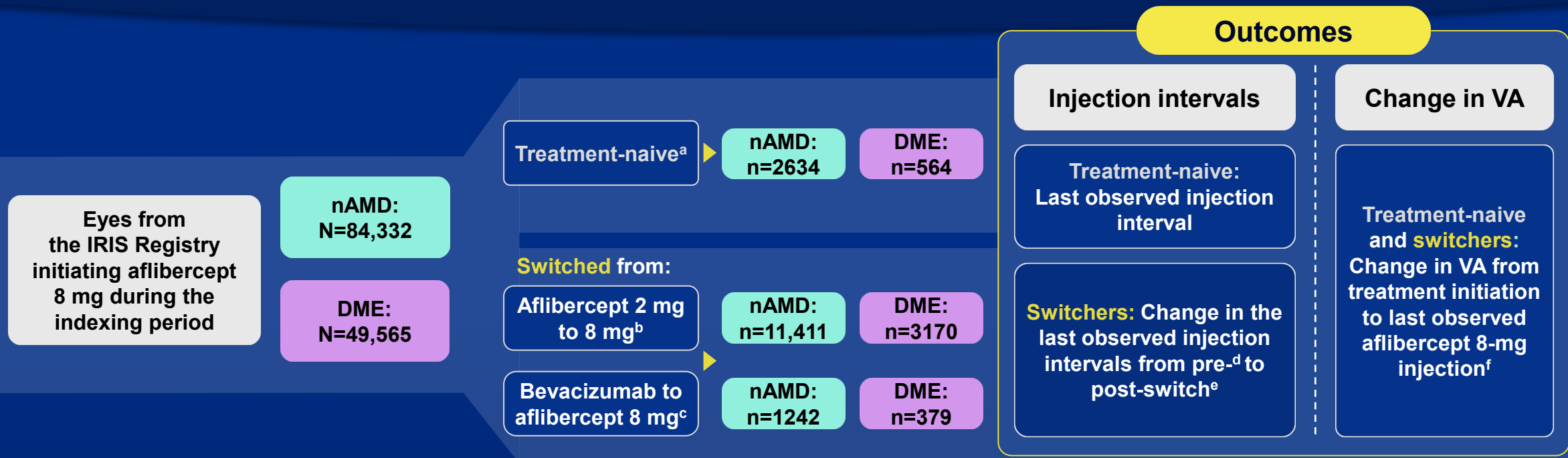
Background and Objectives

- Aflibercept 8 mg at extended dosing intervals demonstrated visual and anatomic improvements that were comparable to those of aflibercept 2 mg every 8 weeks with fewer injections through 96 weeks in the pivotal PULSAR (nAMD) and PHOTON (DME) trials^{1,2}
- Although real-world analyses have shown that aflibercept 8 mg maintains visual acuity while extending dosing intervals in both treatment-naïve and previously treated patients with nAMD or DME,³ longer-term outcome data remain limited

ILLUMIN-8 aims to describe real-world treatment outcomes in patients with nAMD or DME from the Academy IRIS[®] Registry⁴ who were:

- **Treatment-naïve and initiated aflibercept 8 mg**
- **Previously treated with aflibercept 2 mg or bevacizumab and switched to aflibercept 8 mg**

Study Design



Eligibility criteria

- Aged ≥50 years with nAMD or ≥18 years with DME at the aflibercept 8-mg initiation date (index date)^g
- Initiated aflibercept 8 mg during the indexing period (August 18, 2023, to March 31, 2025), and no other anti-VEGF or other treatments for nAMD or DME (intravitreal steroids and laser therapy) on the index date
- Received ≥1 aflibercept 8-mg injection(s) after the initial dosing phase,^h with the last injection >12 months post-index date
- No diagnosis of DME/DR (for nAMD), nAMD (for DME), or RVO during the baseline period (12 months prior to index date) or on the index date

^aEyes that did not receive treatment with anti-VEGF, intravitreal steroid, or laser therapy during baseline period or on index date. ^bEyes switched within 16 weeks prior to the index date with a last pre-switch injection interval ≥6 weeks. ^cEyes switched within 16 weeks prior to the index date. ^d≥12 months prior to the index date. ^eEyes were stratified by last injection interval before switching (6 to ≤8, >8 to ≤10, >10 to ≤12, >12 to ≤16, and >16 weeks). ^fAssessed in eyes treated with aflibercept 8 mg, with VA available at the index date and at the last injection, stratified by VA ≤65 ETDRS letters or >65 ETDRS letters at the index date. ^gFor patients with both eyes treated on the index date and eligible for inclusion, 1 eye was randomly selected. ^hFirst 3 injections or 90 days, whichever occurred first. DR, diabetic retinopathy; ETDRS, Early Treatment Diabetic Retinopathy Study; RVO, retinal vein occlusion; VA, visual acuity; VEGF, vascular endothelial growth factor.

Patient Demographics and Clinical Characteristics at the Index Date



	Treatment-naïve		Switchers from aflibercept 2 mg		Switchers from bevacizumab	
	nAMD (n=2634)	DME (n=564)	nAMD (n=11,411)	DME (n=3170)	nAMD (n=1242)	DME (n=379)
Age, mean (SD), years	80.6 (6.5)	67.8 (10.1)	80.8 (6.8)	66.5 (10.9)	80.4 (7.1)	63.5 (11.4)
Male, n (%)	922 (35.0)	330 (58.5)	4278 (37.5)	1720 (54.3)	453 (36.5)	198 (52.2)
Race and ethnicity, n (%)^a						
Non-Hispanic White	1886 (86.9)	297 (64.7)	8171 (84.3)	1825 (66.6)	842 (83.9)	190 (59.0)
Non-Hispanic Black or African American	25 (1.2)	50 (10.9)	116 (1.2)	309 (11.3)	11 (1.1)	31 (9.6)
Hispanic or Latino	35 (1.6)	35 (7.6)	157 (1.6)	193 (7.0)	24 (2.4)	34 (10.6)
Other ^b	225 (10.4)	77 (16.8)	1246 (12.9)	412 (15.0)	126 (12.6)	67 (20.8)
Bilateral nAMD or DME^c, n (%)	782 (29.7)	517 (91.7)	5543 (48.6)	2885 (91.0)	451 (36.3)	336 (88.7)
Eyes with available VA, n (%)	2605 (98.9)	560 (99.3)	11,382 (99.7)	3166 (99.9)	1240 (99.8)	379 (100)
VA, mean (SD), ETDRS letters^d	57.8 (22.5)	64.7 (18.1)	62.3 (21.3)	69.3 (15.0)	60.8 (21.9)	66.8 (17.6)

^aData from patients with missing values were excluded when calculating percentages. ^bOther includes Asian, Pacific Islander, or Other. ^cBilaterality of nAMD or DME was defined from the laterality information recorded in the diagnosis codes for nAMD or DME during the baseline period or on the index date. Patients were considered as bilateral if they have a diagnosis code for bilaterality or have separate diagnosis codes for left eye and right eye ^dMeasured at least 15 days before initiating aflibercept 8 mg. SD, standard deviation.

Follow-Up Information and Treatment Patterns With Aflibercept 8 mg



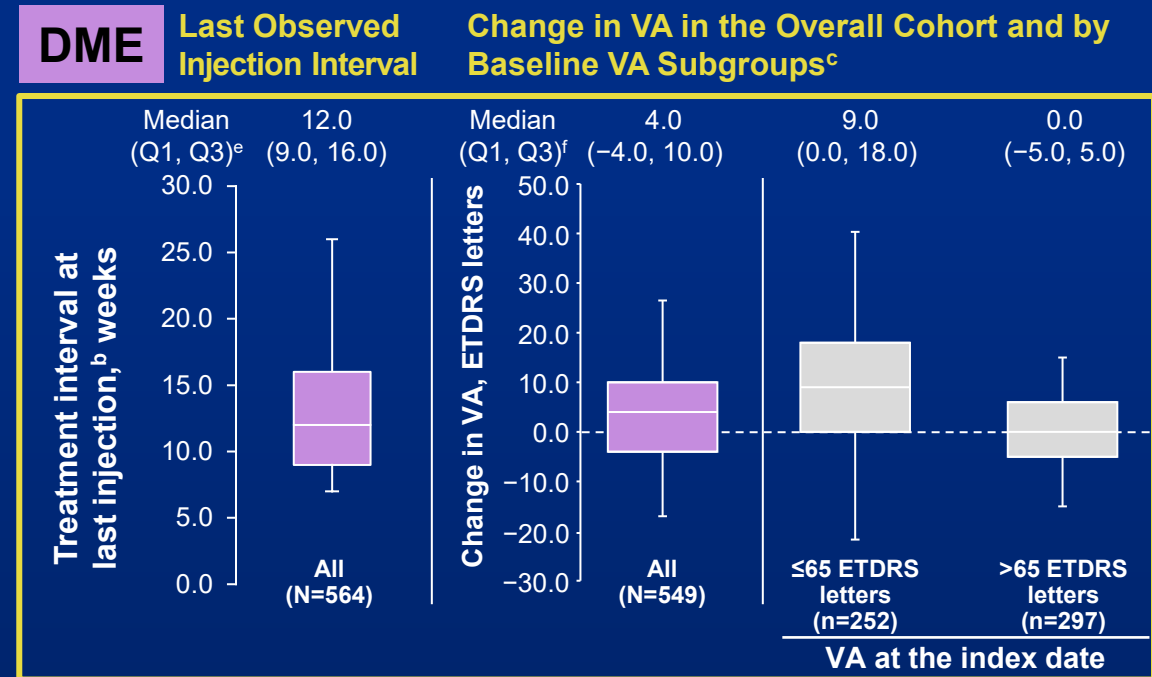
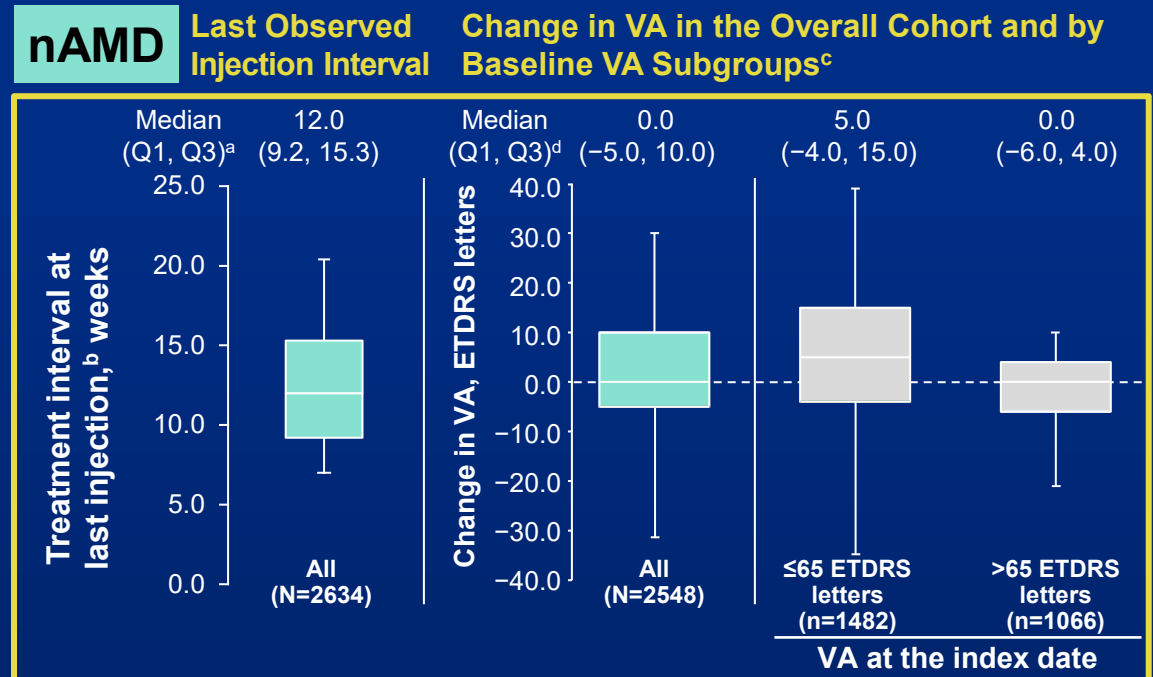
	Treatment-naïve		Switchers from aflibercept 2 mg		Switchers from bevacizumab	
	nAMD (n=2634)	DME (n=564)	nAMD (n=11,411)	DME (n=3170)	nAMD (n=1242)	DME (n=379)
Post-index follow-up, weeks						
Median (Q1, Q3)	76.3 (64.1, 93.3)	74.1 (63.1, 89.1)	86.1 (71.6, 101.3)	82.1 (68.4, 96.5)	80.0 (67.6, 94.3)	76.9 (65.1, 92.1)
Mean (SD)	79.6 (18.7)	77.5 (17.7)	86.9 (18.9)	83.4 (18.0)	81.7 (17.7)	78.8 (17.1)
Eyes that received ≥3 aflibercept 8-mg injections during the initial dosing phase,^{a,b} n (%)	1862 (70.7)	330 (58.5)	1538 (13.5)	452 (14.3)	420 (33.8)	151 (39.8)
Number of aflibercept 8-mg injections during the initial dosing phase,^{a,b} mean (SD)	2.7 (0.6) (n=2634)	2.5 (0.7) (n=564)	1.9 (0.6) (n=11,411)	1.9 (0.6) (n=3170)	2.2 (0.6) n=1242	2.3 (0.6) n=379
Number of aflibercept 8-mg injections during the follow-up period,^a mean (SD)	9.0 (2.3)	8.4 (2.4)	8.9 (2.7)	8.4 (2.5)	8.9 (2.6)	8.4 (2.4)

^aIncluding the index date. Index date was the date of the first aflibercept 8-mg injection. ^bInitial dosing phase was defined as the first 3 injections or 90 days, whichever occurred first. Q, quartile.



Treatment-Naive nAMD and DME: Injection Interval and Change in VA at >12 Months With Aflibercept 8 mg

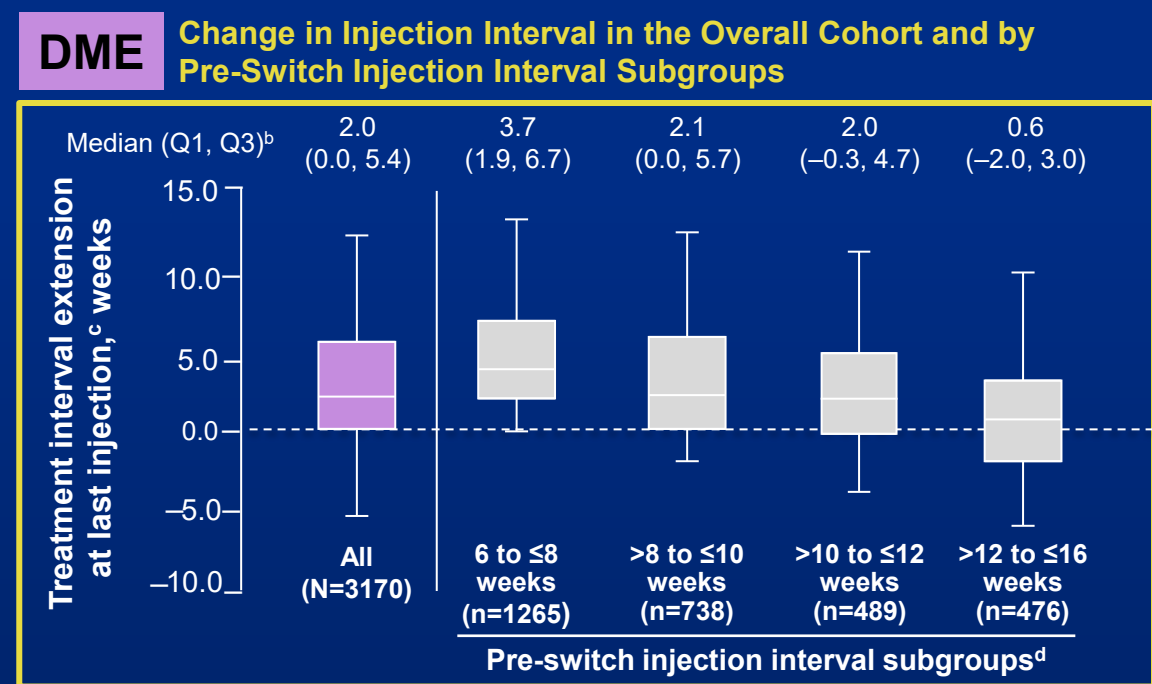
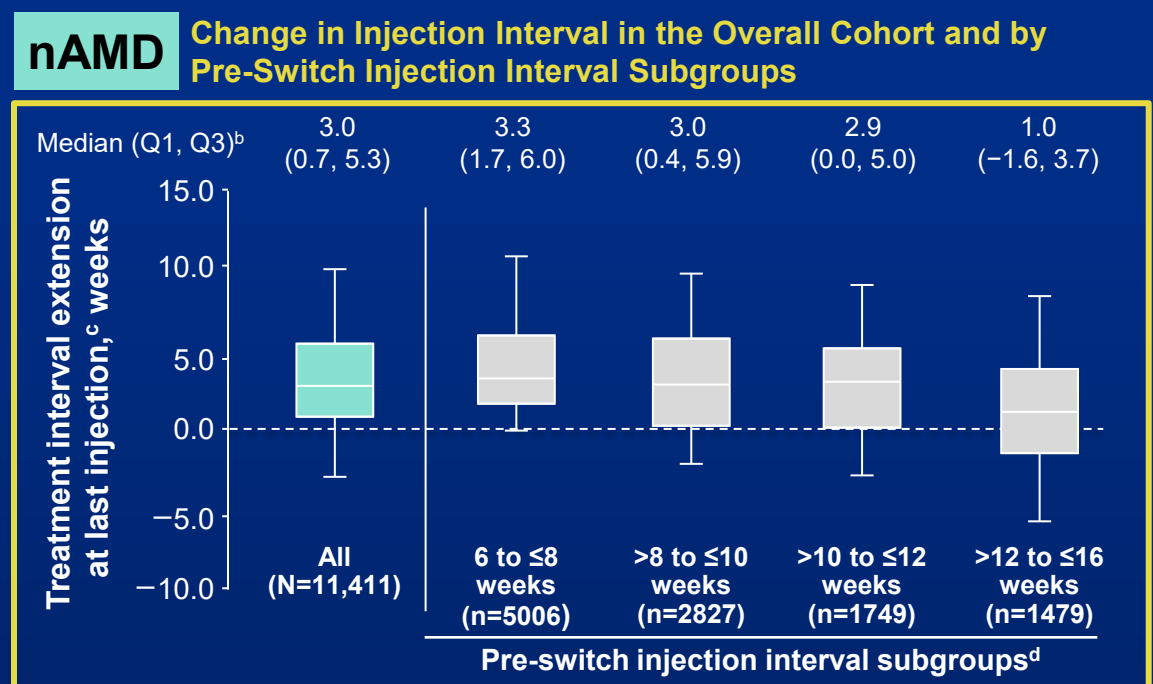
- The median last observed injection interval after initiating aflibercept 8 mg was 12.0 weeks for both nAMD and DME
- Median VA at index date was maintained during follow-up, with visual improvements observed for eyes with lower VA at index date



Boxes show median (middle line) and Q1 and Q3 (upper and lower bounds); whiskers show the 5th and 95th percentiles. ^aThe mean (SD) last observed injection interval was 12.8 (4.6). ^b>12 months post-index date. ^cFrom the index date to last injection. ^dMean change (SD) in VA was 1.3 (18.5) in the overall cohort, 4.4 (21.3) in eyes with VA of ≤65 ETDRS letters at index date, and -2.9 (12.3) in eyes with VA of >65 ETDRS letters at index date. ^eThe mean (SD) last observed injection interval was 13.4 (5.8). ^fMean change (SD) in VA was 3.9 (16.2) in the overall cohort, 9.4 (19.5) in eyes with VA of ≤65 ETDRS letters at index date, and -0.7 (10.8) in eyes with VA of >65 ETDRS letters at index date.

Switching From Aflibercept 2 mg to 8 mg: Injection Interval and Change in VA at >12 Months

- For both nAMD and DME, eyes switched from aflibercept 2 mg to 8 mg had injection intervals extended by 2.0-3.0 weeks versus the last pre-switch interval, while maintaining VA during follow-up^a



Boxes show median (middle line) and Q1 and Q3 (upper and lower bounds); whiskers show the 5% and 95% percentiles. ^aThe median (Q1, Q3) change in VA from index date to last injection was 0 (-7, 4) letters in eyes with nAMD and 0 (-5, 5) letters in eyes with DME in the overall cohort switched from aflibercept 2 mg to 8 mg. In VA subgroups with ≤65 and >65 ETDRS letters, eyes with nAMD had a median (Q1, Q3) change in VA of 0 (-8, 5) and 0 (-6, 0) letters, respectively, and eyes with DME had 0.5 (-4, 9) and 0 (-5, 0), respectively. ^bMean change (SD) in the injection interval in eyes with nAMD was 3.0 (4.6) in the overall cohort, and 4.2 (3.8), 3.4 (4.0), 2.7 (3.8), and 1.2 (4.3) in eyes with pre-switch interval injections of 6 to ≤8 weeks, >8 to ≤10 weeks, >10 to ≤12 weeks, and >12 to ≤16 weeks, respectively. In eyes with DME, the mean change (SD) in the injection interval was 2.7 (5.8) in the overall cohort, and 4.6 (4.5), 3.3 (4.8), 2.5 (4.6), and 1.1 (5.0) in eyes with pre-switch interval injections of 6 to ≤8 weeks, >8 to ≤10 weeks, >10 to ≤12 weeks, and >12 to ≤16 weeks, respectively. ^c>12 months post-index date. ^dThe number of eyes in each subgroup do not add up to the number of all eyes, because 350 patients with nAMD and 202 patients with DME had a pre-switch interval of >16 weeks. This subgroup is not shown on the figure.

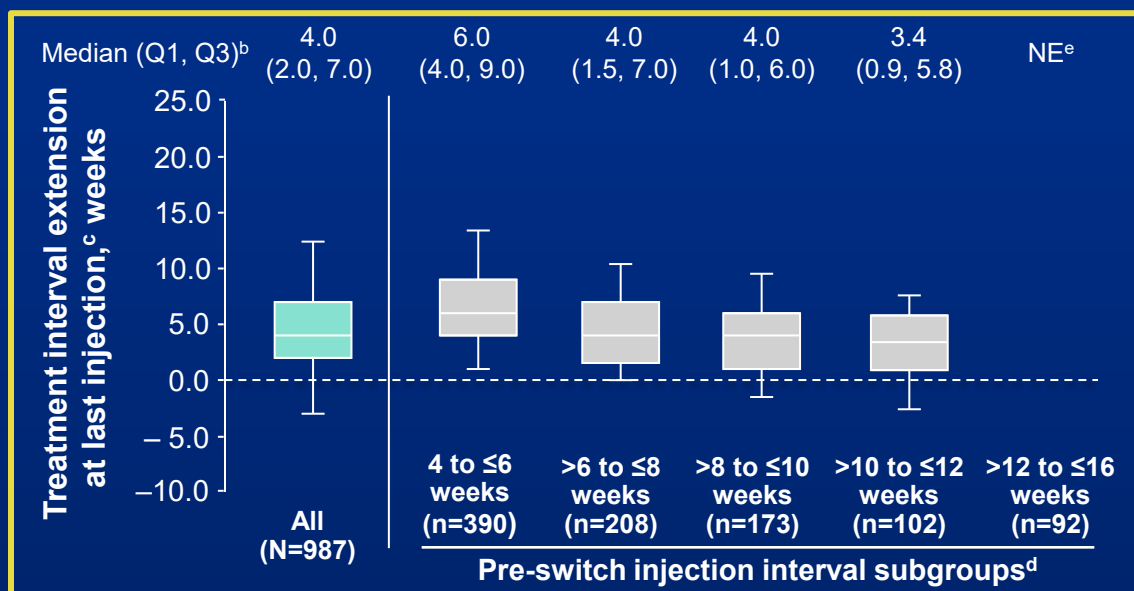
Switching From Bevacizumab to Aflibercept 8 mg: Injection Interval and Change in VA at >12 Months



- For both nAMD and DME, eyes switched from bevacizumab to aflibercept 8 mg had injection intervals extended by 4.0-5.0 weeks versus the last pre-switch interval, while maintaining VA during follow-up^a

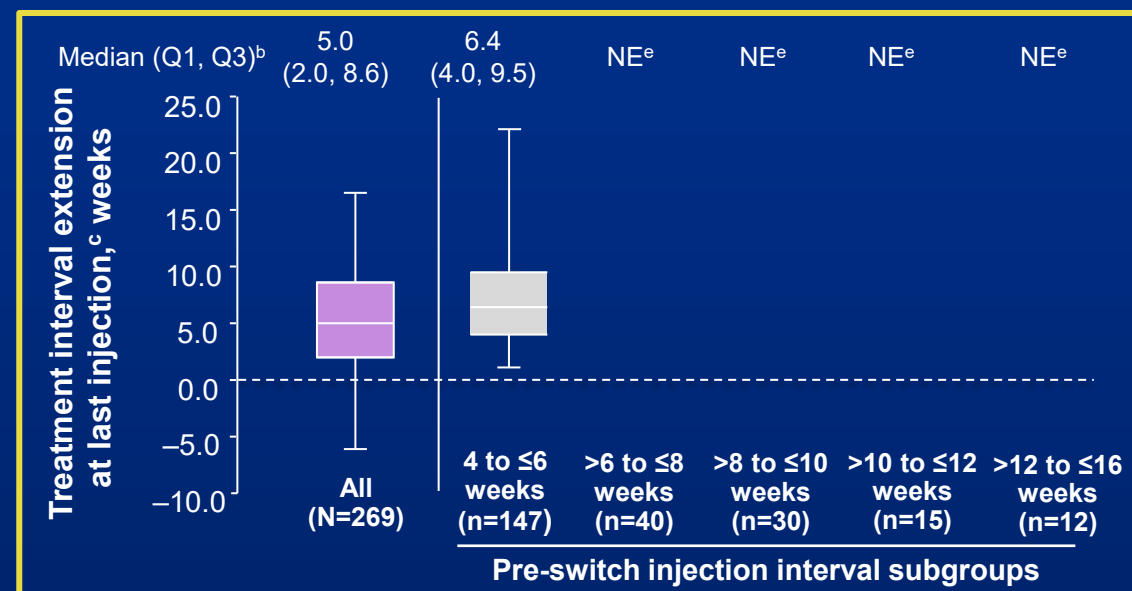
nAMD

Change in Injection Interval in the Overall Cohort and by Pre-Switch Injection Interval Subgroups



DME

Change in Injection Interval in the Overall Cohort and by Pre-Switch Injection Interval Subgroups



Boxes show median (middle line) and Q1 and Q3 (upper and lower bounds); whiskers show the 5% and 95% percentiles. ^aThe median (Q1, Q3) change in VA from index date to last injection was 0 (−6, 5) letters in eyes with nAMD and 0 (−5, 6) letters in eyes with DME in the overall cohort switched from bevacizumab to aflibercept 8 mg. In VA subgroups with ≤65 and >65 ETDRS letters, eyes with nAMD had a median (Q1, Q3) change in VA of 0 (−6, 8) and 0 (−6, 0) letters, respectively, and eyes with DME had 5 (0, 15) and 0 (−5, 4) respectively. ^bMean change (SD) in the injection interval in eyes with nAMD was 4.5 (4.9) in the overall cohort, and 6.7 (4.1), 4.5 (4.1), 3.8 (3.8), 3.0 (3.2), and 0.8 (4.9) in eyes with pre-switch injection intervals of 4 to ≤6 weeks, >6 to ≤8 weeks, >8 to ≤10 weeks, >10 to ≤12, and >12 to ≤16 weeks, respectively. In eyes with DME, the mean change (SD) in the injection interval was 4.8 (7.8) in the overall cohort, and 7.7 (5.8) in eyes with pre-switch interval injections of 4 to ≤6 weeks. ^c>12 months post-index date. ^dThe number of eyes in each subgroup do not add up to the number of all eyes, because 3 patients with nAMD had a pre-switch interval of <4 weeks and 19 had a pre-switch interval of >16 weeks. ^eThe change in injection interval for the pre-switch injection interval subgroup is not shown on the figure because it was not evaluable (sample size <100). NE, not evaluable.

Conclusions and Limitations

- In this real-world analysis of eyes with ≥ 12 months of aflibercept 8-mg treatment, treatment-naïve eyes with nAMD or DME had a median last observed injection interval beyond 1 year of 12.0 weeks, with VA maintained overall
 - Treatment-naïve eyes with low baseline VA (≤ 65 ETDRS letters) showed the greatest visual improvement
- In previously treated eyes, switching to aflibercept 8 mg from 2 mg resulted in an extension of 3.0 (nAMD) or 2.0 (DME) weeks in the injection interval compared with the last pre-switch injection interval
 - Switching to aflibercept 8 mg from bevacizumab resulted in an extension of 4.0 (nAMD) or 5.0 (DME) weeks
- These findings should be interpreted in the context of an early real-world electronic medical record analysis, including VA measures that were not always BCVA, and a potential lack of complete treatment history