Real-World Extended Dosing Assessment for Eye(s) New to Faricimab-svoa Therapy

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Background

- Age-related macular degeneration and diabetic macular edema are the leading causes of blindness and visual impairment, affecting 1.8 million people in the United States.[1]
- Ophthalmic vascular endothelial growth factor inhibitors (OVEGFIs) are first-line treatments for retinal diseases and are injected intravitreally into the affected eye to reduce leakage and growth of vessels, improving visual acuity.[2,3]
- OVEGFIs are a top 10 medical drug spend category for both commercial and Medicare with annual single eye treatment costs ranging widely from $1,000 to over $20,000, depending on the drug and dosing frequency (every 4 to 8 weeks).[4,5]
- In January 2022, faricimab-svoa was approved, enabling extended dosing up to every 16 weeks after four monthly loading doses. However, faricimab-svoa is more costly than most competitor products when not used at an extended dose beyond every 8 weeks.
- Discerning real-world dosing frequency of OVEGFIs is a challenge due to claim variation in the sidedness of eye(s) treated (i.e., left, right, or both eyes).
- Understanding faricimab-svoa dosing at the eye level can more accurately assess real-world dosing to inform management strategies.

Objectives

Using medical claims from a population consisting of approximately 13.9 million commercially insured lives and 670,000 Medicare lives:

- Assess extended dosing for eyes new to faricimab-svoa therapy by analyzing medical drug claim data and assigning eye sidedness (i.e., left, right or both eyes) to claims using billed units, procedure modifier codes and ICD-10 codes.

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Academy of Managed Care Pharmacy (AMCP) Annual Meeting, October 14–18, 2024, Las Vegas, NV

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Methods

All analyses were conducted using medical claims from a population consisting of approximately 13.9 million commercially insured lives and 670,000 Medicare lives.

Identification of members newly initiating faricimab-svoa therapy

- Members' first faricimab-svoa (index) claims were identified during the identification period of Jan. 28, 2022 to Dec. 31, 2022, using Healthcare Common Procedure Coding System (HCPCS) codes (C9097, J2777) and National Drug Codes (50242009686, 50242009601, 50242009677).
- To be included in the analysis, each member had a 365-day pre-index and post-index continuous enrollment requirement.
- Members meeting continuous enrollment requirement post-index faricimab-svoa claims were assigned sidedness (i.e., left, right or both eyes) using medical drug claim fields:
  - Units billed equaling the treatment of two eyes (e.g., 120) were assigned both eyes (i.e., right eye and left eye).
  - Procedure modifier code of LT for left eye and RT for right eye.
  - ICD-10 diagnosis code descriptions (e.g., H35.531 – age-related macular degeneration, right eye).
- Members having one or more claim(s) not assigned sidedness were excluded from the analysis.
- Members not having a faricimab-svoa in the pre-index period were identified as newly initiating therapy.

Diagnosis and treatment type assignment of newly initiating members

- Newly initiating members were then assigned a diagnosis of age-related macular degeneration or diabetic macular edema based on the ICD-10 codes on their faricimab-svoa claims.
- Newly initiating faricimab-svoa members were identified as treatment experienced if they had pre-index claim(s) with a HCPCS code (C9257, J0179, Q5124, Q5128, J0178, J2778, J2779, C9093, J9035) for another OVEGFI. Previous therapy was identified for treatment experienced members. Members without a pre-index claim were identified as treatment naïve.
- The proportion of members by line of business, diagnosis, and treatment type was determined.

Dose assessment

- Resulting members' claims were examined at the eye level (i.e., right or left) to assess for dosing milestones:
  - Eye(s) having more than four faricimab-svoa claims were defined as achieving maintenance phase.
  - Extended dosing was defined as eyes reaching maintenance phase and having greater than 63 days between their most recent two claims.
- The proportion of members achieving each milestone was summarized along with the average days between claims for those members reaching maintenance phase and categorized by dosing extension and non-dose extension.

Figure 1

Member attrition

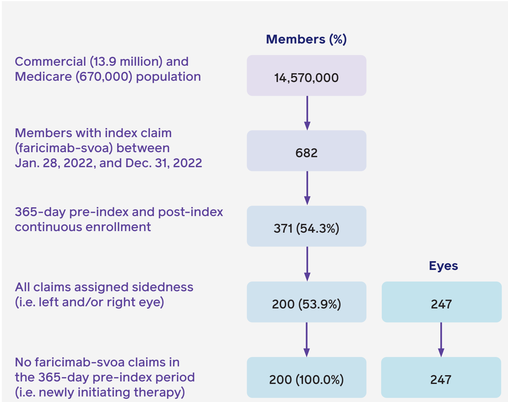

Table 2

Previous therapy for treatment experienced eyes

Drug	Members	Members %	Eyes	Eyes %
Bevacizumab	34	18.7%	41	18.1%
Brolucizumab	7	3.8%	11	4.8%
Aflibercept	125	68.7%	157	69.2%
Ranibizumab	16	8.8%	18	7.9%

Members were identified by their first (index) faricimab-svoa claim between Jan. 28, 2022, and Dec. 31, 2022. Members were included in the analysis if they had 365 days of pre-index and post-index continuous enrollment and had each of their faricimab-svoa claims sidedness (i.e., right, left or both eyes) identified using units, procedure modifier codes or diagnosis description. Previous treatment was identified for members having an ophthalmic vascular endothelial growth factor inhibitor claim in the pre-index period. The claim most recent to their index claim was identified as the member's previous treatment.

Table 1

Characteristics

Category	Type	Members	Members %	Eyes	Eyes %
All	All	200	100.0%	247	100.0%
Line of Business	Medicare	125	62.5%	153	61.9%
	Commercial	75	37.5%	94	38.1%
Diagnosis	Age-Related Macular Degeneration	145	72.5%	167	67.6%
	Diabetic Macular Edema	52	26.0%	75	30.4%
	Other	3	1.5%	5	2.0%
Treatement Type	Treatment Experienced	182	91.0%	227	91.9%
	Treatment Naïve	18	9.0%	20	8.1%

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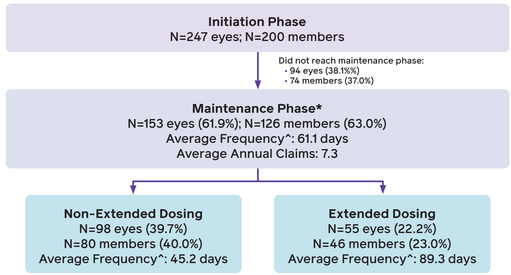
Figure 2

Dosing assessment



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Results

Analytic population identification (Figure 1)

- A total of 682 members with a faricimab-svoa medical claim were identified from Jan. 28 2022, to Dec. 31, 2022.
- After applying continuous enrollment criteria, 371 (54.3%) of 682 members met criteria for analysis.
- 200 (53.9%) of 371 members had all faricimab-svoa claims assigned sidedness (i.e. left eye and/or right eye).
- All 200 members were new to faricimab-svoa therapy due to its approval in January 2022.
- There were 247 unique eye(s) identified among the 200 members which were used for dosing assessment.

Analyzable eye characteristics (Table 1 & Table 2)

- Majority of eyes assessed were from the Medicare line of business (153 of 247 or 61.9%), treated age-related macular degeneration (167 of 247 or 67.6%), and were treatment experienced (227 of 247 eyes or 91.9%).
- 69.1% (157 of 227) of treatment experience eyes were previously treated with aflibercept and 18.0% (41 of 227) with bevacizumab. The remaining 12.7% (29 of 227) were treated with brolucizumab and ranibizumab.

Dosing assessment (Figure 2)

- 153 (61.9%) of 247 eyes newly initiating faricimab-svoa therapy reached maintenance phase.
- Extended dosing occurred in 55 (22.2%) of 247 eyes with average days between most recent two claims of 89.3 days.
- Non-Extended dosing occurred in 98 (39.7%) of 247 eyes with average days between most recent two claims of 45.2 days. Of the 153 eyes meeting maintenance phase evaluation criteria, 55 (35.9%) were categorized as extended dosing.
- 94 (38.0%) of 247 eyes did not reach maintenance phase and therefore could not have their dosing assessed.
- 10 (4%) of 247 eyes reached the maximum extended dosing interval of 16 weeks or greater (>105 days, incorporating 7-day scheduling buffer).

Conclusions

- Less than 2 out of 3 eyes newly initiating faricimab-svoa therapy reached maintenance phase, and approximately 1 out of 5 received extended dosing during the first year of treatment.
- Only 1 in 25 eyes reached the maximum extended dosing interval of 16 weeks or greater.
- This low proportion of extended dosing provides a key insight into faricimab-svoa's competitiveness in the category which may influence its position and importance in management strategies such as step therapy.
- The use of value-based contracts providing remuneration when extended dosing is not achieved would improve faricimab-svoa's proposition in this competitive category while meeting the varying treatment needs of patients.
- Similar dosing assessments should be conducted with newly launched extended dose drugs, such as aflibercept high dose, to better understand real-world usage to inform drug management strategies.
- Dosing assessments will become even more important with the launch and use of ranibizumab and aflibercept biosimilars which will likely reduce competitor therapy costs.

Limitations

- Administrative medical claims have the potential to be miscoded and include assumptions of members' actual drug use and diagnoses.
- The population in this study was identified one year post faricimab-svoa approval, which could be different than populations identified in subsequent time periods (e.g. severity, treatment experience, indication mix).
- Switching from faricimab-svoa to another OVEGFI product was not assessed and therefore some of the members identified as not reaching maintenance faricimab-svoa may have been due to switching to another OVEGFI product.
- Reasons for longer dosing frequencies could not be determined but were assumed to be due to dosing extension vs nonadherence.

References

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