6ER- 038 Can we reduce costs with the use of aflibercept 8mg in neovascular age-related macular degeneration (nAMD) and diabetic macular edema (DME)? An economic analysis from Spain

Calleja-Hernández, MA[1]; Gismero-Moreno, S[2]; Puigcerver-Huerta, M[3]; González-Pueyo, D[3]

[1]Hospital Universitario Virgen de las Nieves, Granada, Spain, [2]Hospital Universitario Costa del Sol, Marbella, Spain, [3]Bayer Hispania SL, Barcelona, Spain

Background and importance

Treatment burden in neovascular age-related macular degeneration (nAMD) and diabetic macular edema (DME) is an issue for patients and healthcare systems in Spain[1-3]. Newly approved treatment options, such as aflibercept 8mg, have the potential to be administered at longer treatment intervals and potentially reduce overall treatment burden and cost.

Aim and objectives

Estimate the overall treatment costs and economic savings with the use of aflibercept 8mg (AFL-8) compared to faricimab 6mg (FAR) and aflibercept 2mg (AFL-2).

Materials and methods

Clinical trial data of phase III studies PULSAR[4-6], PHOTON[7-9] (AFL-8), ALTAIR[10] (AFL-2), TENAYA, LUCERNE, RHINE, YOSEMITE[11-15] (FAR) were used to determine the mean number of injections through 2 years *(Table 1)*. Being aware that, in the first year, the treatment burden is greater due to the required loading doses, for the purposes of this analysis, the average number of injections over two years has been considered in order to obtain a more reliable value for injections/year that reflects the patient's reality. The comparator arm or study with the best response in terms of treatment extensions was selected[4-15].

Table 1. Average nº of injections per presentation.

Drug	nAMD injections	DME injections	Avg. nº injections (2 years)[a]	Avg. nº injections / year
AFL-2	10,40	11,40	**10,90**	**5,45**
FAR	10,50	11,50	**11,00**	**5,50**
AFL-8	8,20	7,80	**8,00**	**4,00**

Table 2. List Public Price in Spain per presentation.

Drug	List Price
AFL-2	742€ [31]
FAR	843,18€ [32]
AFL-8	843,18€ [33]

Table 3. Administration and monitoring cost per injection.

Process	Cost	Total cost
Ophthalmologic visit	115,09 €	**277,45 €**
Intravitreal injection	13,52 €	
OCT test	148,84 €	

[a] Avg nº of injections was calculated assuming 50-50 patient split between DME and AMD.

A cost-minimization analysis was performed assuming a similar efficacy or non-inferior efficacy within all treatments analyzed and considering the drug cost *(Table 2)* and costs related to monitoring and administration for FAR, AFL-2 and AFL-8 *(Table 3)* in a one-hundred eyes treatment for all presentations. For FAR, the lowest list price was considered. The calculated administration and monitoring cost is 277,45€ per injection *(Table 3)*, the same for all treatments and indications[16-30]. 100% adherence was assumed.

Results

Based on these preliminary considerations regarding injections per year, the list price of each alternative and the cost per administration (i.e. indirect costs), the following table shows the annual treatment cost for the three alternatives compared, as well as the savings generated by AFL-8 if it is estimated that 100 eyes will be treated with this new drug *(Table 4)*.

Table 4. Annual treatment cost of each presentation and savings generated by aflibercept 8mg.

Drug	€/unit	€/Inj.	Inj. / year	Annual treatment cost	Indirect costs	€/year	Diff. vs. AFL-8	Savings (100 eyes) with 8 mg	Savings (%) with 8mg
AFL-2	742,00 €	742,00 €	5,45	4.043,90 €	1.512,10 €	**5.556,00 €**	- 1.073,48 €	**- 107.348,25 €**	**19,32%**
FAR	843,18 €	843,18 €	5,50	4.637,49 €	1.525,98 €	**6.163,47 €**	- 1.680,95 €	**- 168.094,60 €**	**27,27%**
AFL-8	843,18 €	843,18 €	4,00	3.372,72 €	1.109,80 €	**4.482,52 €**	-	-	

In summary, AFL-8 represents a potential saving of 19.32% compared to AFL-2, which means a saving of 107.348,25€ if 100 eyes were treated with AFL-8, and a saving of 27.27% compared to FAR, which means a saving of 168.094,50€ if 100 eyes were treated with Aflibercept 8mg.

Conclusions and relevance

Treatment with AFL-8 allowed for the extension of treatment intervals in clinical trials and appears to be potentially the most economical option for the treatment of nAMD and DME. AFL-8 has the potential to meaningfully reduce costs by decreasing the number of injections and associated visits, and these findings reinforce AFL-8 as potentially the most efficient treatment option.

References

1- Servicio de Salud. Libro blanco de la oftalmología: calidad asistencial. https://serv.es/wp-content/descargasWP/LIBRO-BLANCO-OFTEX-CALIDAD-ASISTENCIAL_vf.pdf; **2-** Pina Marín, B., Gajate Paniagua, N. M., Gómez-Baldó, L., & Gallego-Pinazo, R. (2022). Burden of disease assessment in patients with neovascular age-related macular degeneration in Spain: Results of the AMD-MANAGE study. European journal of ophthalmology, 32(1), 385–394. https://doi.org/10.1177/11206721211001716; **3-** Ruiz-Moreno, J. M., Gámez Lechuga, M., Calvo, P., Merino, M., Martín Lorenzo, T., Maravilla-Herrera, P., Gil Jiménez, B., & Abraldes, M. J. (2024). Burden of Disease Study of Patients with Diabetic Macular Oedema in Spain. Ophthalmology and therapy, 13(7), 1937–1953. https://doi.org/10.1007/s40123-024-00959-2; **4-** Lanzetta P, Korobelnik JF, Heier JS, Leal S, Holz FG, Clark WL, et al. Intravitreal aflibercept 8 mg in neovascular age-related macular degeneration (PULSAR): 48-week results from a randomised, double-masked, non-inferiority, phase 3 trial. Lancet. 2024;403(10432):1141-52. doi: 10.1016/s0140-6736(24)00063-1.; **5-** Spitzer MS. Intravitreal aflibercept 8 mg injection in patients with neovascular age-related macular degeneration: 48-week results from the Phase 3 PULSAR trial. Investigative Ophthalmology & Visual Science. 2023;64(8):461-; **6-** Lanzetta P, Schulze A, Schmidt-Ott U, Zhang X, Berliner A, Chu K, et al. Intravitreal aflibercept 8 mg injection in patients with neovascular age-related macular degeneration: 60-week and 96-week results from the Phase 3 PULSAR trial. EURETINA Congress; Amsterdam 2023; **7-** Brown DM, Boyer DS, Do DV, Wykoff CC, Sakamoto T, Win P, et al. Intravitreal aflibercept 8 mg in diabetic macular oedema (PHOTON): 48-week results from a randomised, double-masked, non-inferiority, phase 2/3 trial. Lancet. 2024;403(10432):1153-63. doi: 10.1016/s0140-6736(23)02577-1; **8-** Wykoff C. Aflibercept 8 mg for Diabetic Macular Edema: 96-Week Results From the Phase 2/3 PHOTON Trial. EURETINA Congress; Amsterdam 2023; **9-** Do DV. Aflibercept 8 mg for Diabetic Macular Edema: 48-Week Results From the Phase 2/3 PHOTON Trial. Investigative Ophthalmology & Visual Science. 2023;64(8):2814-; **10-** Ohji M et al. Efficacy and Safety of Intravitreal Aflibercept Treat-and-Extend Regimens in Exudative Age-Related Macular Degeneration: 52- and 96-Week Findings from ALTAIR: A Randomized Controlled Trial. Adv Ther. 2020 Mar;37(3):1173-1187. doi: 10.1007/s12325-020-01236-x. Epub 2020 Feb 3. PMID: 32016788; PMCID: PMC7089719; **11-** Khanani AM et al TENAYA and LUCERNE: Two-Year Results from the Phase 3 Neovascular Age-Related Macular Degeneration Trials of Faricimab with Treat-and-Extend Dosing in Year 2. Ophthalmology. 2024 Feb 19:S0161-6420(24)00134-9. doi: 10.1016/j.ophtha.2024.02.014.; **12-** Heier JS, Khanani AM, Quezada Ruiz C, Basu K, Ferrone PJ, Brittain C, et al. Efficacy, durability, and safety of intravitreal faricimab up to every 16 weeks for neovascular age-related macular degeneration (TENAYA and LUCERNE): two randomised, double-masked, phase 3, non-inferiority trials. Lancet. 2022;399(10326):729-40; **13-** Wong TY et al. Faricimab Treat-and-Extend for Diabetic Macular Edema: Two-Year Results from the Randomized Phase 3 YOSEMITE and RHINE Trials. Ophthalmology. 2024 Jun;131(6):708-723. doi: 10.1016/j.ophtha.2023.12.026. Epub 2023 Dec 28. PMID: 38158159; **14-** Wykoff CC, Abreu F, Adamis AP, Basu K, Eichenbaum DA, Haskova Z, et al. Efficacy, durability, and safety of intravitreal faricimab with extended dosing up to every 16 weeks in patients with diabetic macular oedema (YOSEMITE and RHINE): two randomised, double-masked, phase 3 trials. Lancet. 2022;399(10326):741-55); **15-** Ohji M et al. Efficacy and Safety of Intravitreal Aflibercept Treat-and-Extend Regimens in Exudative Age-Related Macular Degeneration: 52- and 96-Week Findings from ALTAIR: A Randomized Controlled Trial. Adv Ther. 2020 Mar;37(3):1173-1187. doi: 10.1007/s12325-020-01236-x. Epub 2020 Feb 3. PMID: 32016788; PMCID: PMC7089719; ***16-*** *Consejería de Sanidad (2016) RESOLUCIÓN de 29 de junio de 2016. Boletín Oficial de Castilla y León, nº 132, 11 de Julio de 2016;* ***17-*** *Servicio de Salud (2017). Resolución de 15 de noviembre de 2017. Diario Oficial de Castilla-La Mancha núm. 226, 22 de noviembre de 2017;* ***18-*** *Consejería de Sanidad (2017). Orden 727/2017 de 7 de agosto de 2017. Boletín Oficial de la Comunidad de Madrid núm. 198, 21 de agosto de 2017;* ***19-*** *Consejería de Sanidad y Servicios Sociales (2023). Resolución de 16 de enero de 2023. Diario Oficial de Extremadura, número 14 de 20 de enero de 2023;* ***20-*** *Consejería de Administración Pública y Hacienda (2014) Orden 17/2014, de 16 de noviembre de 2014. Boletín Oficial de la Rioja, nº 156, 19 diciembre 2014;* ***21-*** *Servicio Navarro de Salud-Osasunbidea (2019). RESOLUCIÓN 1564/2018, de 20 de diciembre. Boletín Oficial de Navarra, número 14, 22 de enero de 2019;* ***22-*** *Presidencia de la Generalitat (Valencia) (2018). Ley 20/2017, de 28 de diciembre, de tasas. Boletín Oficial del Estado, nº 38, 12 de febrero 2018;* ***23-*** *Consejería de Sanidad y Servicios Sociales (2023). Resolución de 16 de enero de 2023. Diario Oficial de Extremadura, número 14 de 20 de enero de 2023;* ***24-*** *Departament de salut (2020). Orden SLT/63/2020, de 8 de marzo. Diari Oficial de la Generalitat de Catalunya, número 8134 del 15 de mayo del 2020;* ***25-*** *Instituto catalán de la salud (2022). Resolución SLT/3911/2022 de 14 de diciembre. Diari Oficial de la Generalitat de Catalunya, número 8816 de 20 de diciembre de 2022;* ***26-*** *Presidencia de la Generalitat (Valencia) (2018). Ley 20/2017, de 28 de diciembre, de tasas. Boletín Oficial del Estado, nº 38, 12 de febrero 2018;* ***27-*** *Consejería de Sanidad y Asuntos Sociales (2014) Orden de 17/11/2014. Diario Oficial de Castilla-La Mancha, nº 226, 21 noviembre 2014;* ***28-*** *Osakidetza-Servicio Vasco de Salud (2022). Acuerdo del Consejo de Administración de 22 de diciembre de 2022. Boletín Oficial del País Vasco, 22 de diciembre de 2022;* ***29-*** *Departament de salut (2020). Orden SLT/63/2020, de 8 de marzo. Diari Oficial de la Generalitat de Catalunya, número 8134 del 15 de mayo del 2020;* ***30-*** *Instituto catalán de la salud (2022). Resolución SLT/3911/2022 de 14 de diciembre. Diari Oficial de la Generalitat de Catalunya, número 8816 de 20 de diciembre de 2022;* **31-** CIPM 3rd March. 2022. Available in: https://www.sanidad.gob.es/areas/farmacia/precios/comisionInteministerial/acuerdosNotasInformativas/docs/20220404_ACUERDOS_CIPM_222.pdf; **32-** CIPM 24th July 2023. Available in: https://www.sanidad.gob.es/areas/farmacia/precios/comisionInteministerial/acuerdosNotasInformativas/docs/ACUERDOS_CIPM_236.pdf; 33- CIPM 20th November 2025. Available in: https://www.sanidad.gob.es/areas/farmacia/precios/comisionInteministerial/acuerdosNotasInformativas/docs/ACUERDOS_CIPM_252.pdf;

This communication has been promoted by Bayer Hispania.