NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Technology appraisals

Patient access scheme submission template

October 2009

1 Introduction

The 2009 Pharmaceutical Price Regulation Scheme (PPRS) (www.dh.gov.uk/en/Healthcare/Medicinespharmacyandindustry/Pharmaceuticalpriceregulationscheme/2009PPRS) is a non-contractual scheme between the Department of Health and the Association of the British Pharmaceutical Industry. The purpose of the 2009 PPRS is to ensure that safe and cost-effective medicines are available on reasonable terms to the NHS in England and Wales. One of the features of the 2009 PPRS is to improve patients' access to medicines at prices that better reflect their value through patient access schemes.

Patient access schemes are arrangements which may be used on an exceptional basis for the acquisition of medicines for the NHS in England and Wales. Patient access schemes propose either a discount or rebate that may be linked to the number, type or response of patients, or a change in the list price of a medicine linked to the collection of new evidence (outcomes). These schemes help to improve the cost effectiveness of a medicine and therefore allow the National Institute for Health and Care Excellence (NICE) to recommend treatments which it would otherwise not have found to be cost effective. More information on the framework for patient access schemes is provided in the 2009 PPRS (www.dh.gov.uk/en/Healthcare/Medicinespharmacyandindustry/Pharmaceuticalpriceregulationscheme/2009PPRS.

Patient access schemes are proposed by a pharmaceutical company and agreed with the Department of Health, with input from the Patient Access Schemes Liaison Unit (PASLU) within the Centre for Health Technology Evaluation at NICE.

2 Instructions for manufacturers and sponsors

This document is the patient access scheme submission template for technology appraisals. If manufacturers and sponsors want the National Institute for Health and Care Excellence (NICE) to consider a patient access scheme as part of a technology appraisal, they should use this template. NICE can only consider a patient access scheme after formal referral from the Department of Health.

The template contains the information NICE requires to assess the impact of a patient access scheme on the clinical and cost effectiveness of a technology, in the context of a technology appraisal, and explains the way in which background information (evidence) should be presented. If you are unable to follow this format, you must state your reasons clearly. You should insert 'N/A' against sections that you do not consider relevant, and give a reason for this response.

Please refer to the following documents when completing the template:

- 'Guide to the methods of technology appraisal' (http://publications.nice.org.uk/guide-to-the-methods-of-technology-appraisal-2013-pmg9)
- 'Specification for manufacturer/sponsor submission of evidence' (http://www.nice.org.uk/aboutnice/howwework/devnicetech/singletechnologyappraisalsubmissiontemplates.jsp) and
- Pharmaceutical Price Regulation Scheme 2009 (www.dh.gov.uk/en/Healthcare/Medicinespharmacyandindustry/Pharmaceuticalpriceregulationscheme/2009PPRS).

For further details on the technology appraisal process, please see NICE's 'Guide to the single technology appraisal (STA) process' and 'Guide to the multiple technology appraisal (MTA) process' (http://www.nice.org.uk/aboutnice/howwework/devnicetech/technologyappraisalprocessguides/technology_appraisal_process_guides.jsp). The

‘Specification for manufacturer/sponsor submission of evidence’ provides details on disclosure of information and equality issues.

Make the submission as brief and informative as possible. Only mark information as confidential when absolutely necessary. Sufficient information must be publicly available for stakeholders to comment on the full content of the technology appraisal, including details of the proposed patient access scheme. Send submissions electronically to NICE in Word or a compatible format, not as a PDF file.

Appendices may be used to include additional information that is considered relevant to the submission. Do not include information in the appendices that has been requested in the template. Appendices should be clearly referenced in the main submission.

When making a patient access scheme submission, include:

- an updated version of the checklist of confidential information, if necessary
- an economic model with the patient access scheme incorporated, in accordance with the ‘Guide to the methods of technology appraisal’ (http://publications.nice.org.uk/guide-to-the-methods-of-technology-appraisal-2013-pmg9).

If you are submitting the patient access scheme at the end of the appraisal process, you should update the economic model to reflect the assumptions that the Appraisal Committee considered to be most plausible. No other changes should be made to the model.

3 Details of the patient access scheme

3.1 Please give the name of the technology and the disease area to which the patient access scheme applies.

Name of the technology: Aflibercept 40mg/ml solution for injection (Eylea)

Disease area: Macula oedema secondary to central retinal vein occlusion (CRVO) and neovascular wet age-related macular degeneration (AMD) (already recommended by NICE guidance in TA294)

3.2 Please outline the rationale for developing the patient access scheme.

To provide aflibercept solution for injection to the NHS in a more cost effective manner.

3.3 Please describe the type of patient access scheme, as defined by the PPRS.

The PAS is a commercially confidential discount on the list price of aflibercept 40mg/ml solution for injection (Eylea), reduced from the list price at market introduction of £816 plus VAT to a discounted confidential net price of [redacted] plus VAT per vial.

3.4 Please provide specific details of the patient population to which the patient access scheme applies. Does the scheme apply to the whole licensed population or only to a specific subgroup (for example, type of tumour, location of tumour)? If so:

- How is the subgroup defined?
- If certain criteria have been used to select patients, why have these have been chosen?
- How are the criteria measured and why have the measures been chosen?

The patient access scheme applies to aflibercept solution for injection for the treatment macular oedema secondary to CRVO and of all adults with neovascular wet AMD.

3.5 Please provide details of when the scheme will apply to the population specified in 3.4. Is the scheme dependent on certain criteria, for example, degree of response, response by a certain time point, number of injections? If so:

- Why have the criteria been chosen?
- How are the criteria measured and why have the measures been chosen.

As above.

3.6 What proportion of the patient population (specified in 3.4) is expected to meet the scheme criteria (specified in 3.5)?

As above.

3.7 Please explain in detail the financial aspects of the scheme. How will any rebates be calculated and paid?

The PAS will operated as a simple discount scheme, where aflibercept 40mg/ml will be made available with a variable discount from list price (currently [redacted]) to maintain a fixed purchase price of [redacted] plus VAT per vial. The discount will be applied at the point of invoice. The population of patients covered by the PAS is adults with macula oedema secondary to CRVO and neovascular wet AMD in line with the licenced indication. However to avoid the need for individual patient tracking it is confirmed that the same level of discount would be made available for purchases of aflibercept 40mg/ml solution when used in all other future indications.

3.8 Please provide details of how the scheme will be administered. Please specify whether any additional information will need to be collected, explaining when this will be done and by whom.

Straight discount scheme

3.9 Please provide a flow diagram that clearly shows how the scheme will operate. Any funding flows must be clearly demonstrated.

The patient access scheme will allow the NHS to obtain aflibercept solution for injection at a price lower than the list price, subject to a confidentiality agreement. The discount will be applied at the point of invoice so no change to the flow of funds is anticipated.

3.10 Please provide details of the duration of the scheme.

The scheme will run until or after NICE publish their guidance following the review of the appraisal.

3.11 Are there any equity or equalities issues relating to the scheme, taking into account current legislation and, if applicable, any concerns identified during the course of the appraisal? If so, how have these been addressed?

No

3.12 If available, please list any scheme agreement forms, patient registration forms, pharmacy claim forms/rebate forms, guides for pharmacists and physicians and patient information documents. Please include copies in the appendices.

The agreement will be between Bayer plc and the hospital trust subject to a confidentiality agreement.

3.13 In the exceptional case that you are submitting an outcome-based scheme, as defined by the PPRS, please also refer to appendix B.

4 Cost effectiveness

4.1 If the population to whom the scheme applies (as described in sections 3.4 and 3.5) has not been presented in the main manufacturer/sponsor submission of evidence for the technology appraisal (for example, the population is different as there has been a change in clinical outcomes or a new continuation rule), please (re-)submit the relevant sections from the 'Specification for manufacturer/sponsor submission of evidence' (particularly sections 5.5, 6.7 and 6.9). You should complete those sections both with and without the patient access scheme. You must also complete the rest of this template.

The patient access scheme (PAS) applies to aflibercept solution for injection for the treatment of all adults with macular oedema (MO) secondary to central retinal vein occlusion (CRVO). A cost-effectiveness analysis comparing aflibercept to ranibizumab was presented in Chapter 7 of 'Specification for manufacturer/sponsor submission of evidence'.

4.2 If you are submitting the patient access scheme at the end of the technology appraisal process, you should update the economic model to reflect the assumptions that the Appraisal Committee considered to be most plausible. No other changes should be made to the model.

The scheme is presented together with the submission to NICE.

4.3 Please provide details of how the patient access scheme has been incorporated into the economic model. If applicable, please also provide details of any changes made to the model to reflect the assumptions that the Appraisal Committee considered most plausible.

No changes have been made to the cost-effectiveness model (CEM) and/or the budget impact model (BIM).

The type of patient access scheme presented in this document is a 'Financially-based scheme', where the list price of aflibercept is reduced by [redacted] (price after discount [redacted] per drug injection).

The CEM is an excel-based model with the flexibility to allow the user setting up the model to either consider the patient access scheme or not before calculation of results. The BIM includes a similar option.

4.4 Please provide the clinical effectiveness data resulting from the evidence synthesis and used in the economic model which includes the patient access scheme.

There are no changes to the clinical effectiveness data compared to those presented in the base-case analysis.

4.5 Please list any costs associated with the implementation and operation of the patient access scheme (for example, additional pharmacy time for stock management or rebate calculations). A suggested format is presented in table 1. Please give the reference source of these costs. Please refer to section 6.5 of the 'Specification for manufacturer/sponsor submission of evidence'.

The PAS will allow the NHS to obtain aflibercept solution for injection at a price lower than the list price, subject to a confidentiality agreement. The discount will be applied at the point of invoice so no change to the flow of funds is anticipated.

There are no costs associated with the implementation and operation of the PAS since it is a 'Financially-based scheme' – straight discount scheme.

4.6 Please provide details of any additional treatment-related costs incurred by implementing the patient access scheme. A suggested format is presented in table 2. The costs should be provided for the intervention both with and without the patient access scheme. Please give the reference source of these costs.

Table 1 below provides a summary of treatment-related costs incurred by implementing the PAS, with and without PAS respectively, using assumptions from the base-case analyses.

Table 1. Additional treatment-related costs for the intervention without and with the patient access scheme (PAS)

	Without PAS	With PAS
Injections	8.3	8.3
Monitoring	9.25	9.25
Drug cost (£)	816	[redacted]
Administration cost (£), of which:	233.24	233.24
• Outpatient visit (£) (52.38%)	79.74	79.74
• Day case visit (£) (47.62%)	402.08	402.08
Total monitoring cost (£), of which*:	197	197
• Visual acuity visit (£)	79.74	79.74
• OCT (£)	117.26	117.26
Total (£)	10,531	[redacted]

* At baseline visit, an additional £117.26 is incurred by patients to reflect the cost of fluorescein angiography.

The "Total" row at the bottom of the table is a simplification of the yearly costs incurred by implementing the PAS.

Summary results

Base-case analysis

4.7 Please present in separate tables the cost-effectiveness results as follows.[1]

- the results for the intervention without the patient access scheme
- the results for the intervention with the patient access scheme.

A suggested format is shown below (table 3).

Table 2 and Table 3 below report the CEM results without and with PAS respectively.

[1] For outcome-based schemes, please see section 5.2.8 in appendix B.

Table 2. Base-case cost-effectiveness results without PAS

	Aflibercept	Ranibizumab
Intervention cost (£)	[redacted]	[redacted]
Other costs (£)	[redacted]	[redacted]
Total costs (£)	[redacted]	[redacted]
Difference in total costs (£)	[redacted]	[redacted]
LYG	18.977	18.976
LYG difference	N/A	0.001
QALYs	[redacted]	[redacted]
QALY difference	N/A	0.054
ICER (£)	N/A	[redacted]

LYG: life-year gained; QALY: quality-adjusted life-year; ICER: incremental cost-effectiveness ratio.

Table 3. Base-case cost-effectiveness results with PAS

	Aflibercept	**Ranibizumab**
Intervention cost (£)	[redacted]	[redacted]
Other costs (£)	[redacted]	[redacted]
Total costs (£)	[redacted]	[redacted]
Difference in total costs (£)	N/A	-2,937
LYG	18.977	18.976
LYG difference	N/A	0.001
QALYs	[redacted]	[redacted]
QALY difference	N/A	0.054
ICER (£)	N/A	AFB dominant

AFB: aflibercept; LYG: life-year gained; QALY: quality-adjusted life-year; ICER: incremental cost-effectiveness ratio.

4.8 Please present in separate tables the incremental results as follows. [2]

- the results for the intervention without the patient access scheme
- the results for the intervention with the patient access scheme.

List the interventions and comparator(s) from least to most expensive. Present the incremental cost-effectiveness ratios (ICERs) in comparison with baseline (usually standard care), and

[2] For outcome-based schemes, please see section 5.2.9 in appendix B.

the incremental analysis ranking technologies in terms of dominance and extended dominance. A suggested format is presented in table 4.

Aflibercept was cost-effective compared to ranibizumab in the base-case cost-effectiveness analysis when the list price of £816.00 per injection was used, providing higher total costs ([redacted]) and slightly higher QALYs [redacted] vs. [redacted]) per patient in a lifetime horizon.

Aflibercept dominated ranibizumab when the [redacted]% discount was applied (£[redacted] per drug injection) decreasing total costs per patient from £[redacted] in scenario without PAS to £[redacted] in scenario with PAS.

The incremental results without PAS and with PAS are summarised respectively in Table 4 and Table 5 below:

Table 4: Base-case incremental results without PAS

Technologies	Total costs (£)	Total LYG	Total QALYs	Incremental costs (£)	Incremental LYG	Incremental QALYs	ICER (£) versus baseline (QALYs)
Aflibercept	[redacted]	18.977	[redacted]	-	-	-	-
Ranibizumab	[redacted]	18.976	[redacted]	[redacted]	0.001	0.054	[redacted]

LYG: life-year gained; QALY: quality-adjusted life-year; ICER: incremental cost-effectiveness ratio.

Table 5: Base-case incremental results with PAS

Technologies	Total costs (£)	Total LYG	Total QALYs	Incremental costs (£)	Incremental LYG	Incremental QALYs	ICER (£) versus baseline (QALYs)
Aflibercept	[redacted]	18.977	[redacted]	-	-	-	
Ranibizumab	[redacted]	18.976	[redacted]	-2,937	0.001	0.054	AFB Dominant

LYG: life-year gained; QALY: quality-adjusted life-year; ICER: incremental cost-effectiveness ratio.

Sensitivity analyses

4.9 Please present deterministic sensitivity analysis results as described for the main manufacturer/sponsor submission of

evidence for the technology appraisal. Consider using tornado diagrams.

A deterministic sensitivity analysis was performed using the same methodology applied in the base-case analysis included in the manufacturer submission. An ICER approach was undertaken since aflibercept was shown to be cost-effective versus ranibizumab in the base-case scenario. The willingness to pay threshold (WTP) that was used for the analysis (£20,000 per QALY).

Parameters tested included clinical inputs (e.g. RR of gaining ≥ 15 letters with ranibizumab compared with aflibercept and rate of post-trial BCVA progression), resource use inputs (primarily frequency of monitoring and injections), as well as cost inputs (e.g. cost of drug administration, cost of drug monitoring) and discount rates (for more details please refer to the manufacture submission).

Results of the deterministic sensitivity analysis for the base-case scenario without PAS and with PAS are presented in two tornado diagrams, respectively Figure 1 and Figure 2 below. Note the tornado diagram was designed to hide ICERs when aflibercept is dominant or dominated. This is why for several parameters, only one bar, showing either results of the “low” or the “high” variation, can be seen.

Figure 1. Tornado plot – ICER of aflibercept vs. ranibizumab, 1 year of treatment, lifetime horizon (without PAS)

[redacted]

Results in Figure 1 above (no PAS) indicate that the ICER is most sensitive to frequency of injections with ranibizumab in Year 1, the RR of gaining ≥ 15 letters with ranibizumab compared with aflibercept, the frequency of injections with aflibercept in Year 1 and the rate of monitoring patients with both ranibizumab and aflibercept in Year 1. Additional drivers of the results were the utility values.

In the diagram below, the bars of the diagram that are not shown indicate that:

- aflibercept is dominant when using the lower values for the Year 1 frequency of administration with ranibizumab, the lower rate of aflibercept administration visits in month 7-12 and the higher rate of Year 1 monitoring visits for patients treated with ranibizumab.

- aflibercept is dominated when using the higher RR value.

When the PAS is implemented, the base-case analysis showed that aflibercept is dominant. Therefore for the sensitivity analysis, a net monetary benefit (NMB) approach was preferred. The tornado diagram generated using this approach is presented in Figure 2 below.

Figure 2. Tornado plot – NMB of aflibercept vs. ranibizumab, 1 year of treatment, lifetime horizon (with PAS)

[redacted]

The analysis generated a NMA of £4,011. When varying the values of the parameters, aflibercept was systematically cost-effective.

4.10 Please present any probabilistic sensitivity analysis results, and include scatter plots and cost-effectiveness acceptability curves.

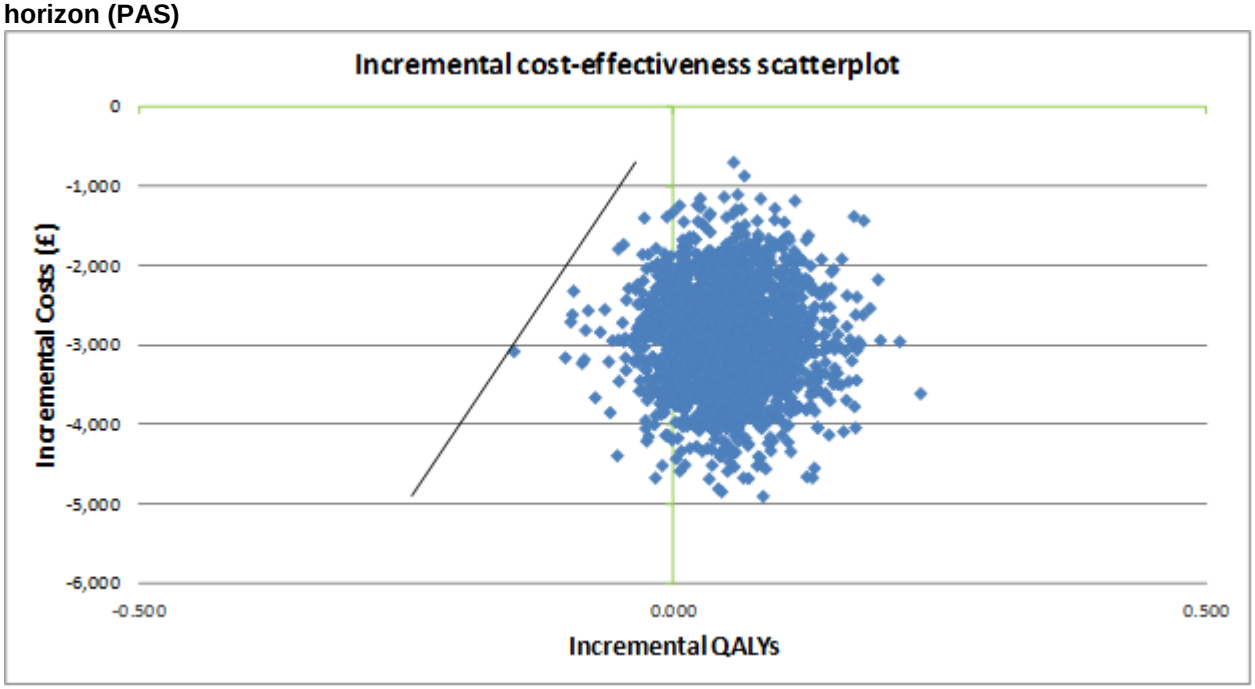
A probabilistic sensitivity analysis was performed in the same way as for the base-case analysis presented in NICE's 'Specification for manufacturer/sponsor submission of evidence'. Two thousand iterations were run showing that aflibercept is 88.50% likely to dominate ranibizumab and

11.50% likely to be less effective and less costly. The cost-effectiveness plane in Figure 3 shows how most of the iterations lie in the south quadrants.

Table 6. Probabilistic sensitivity analysis with PAS

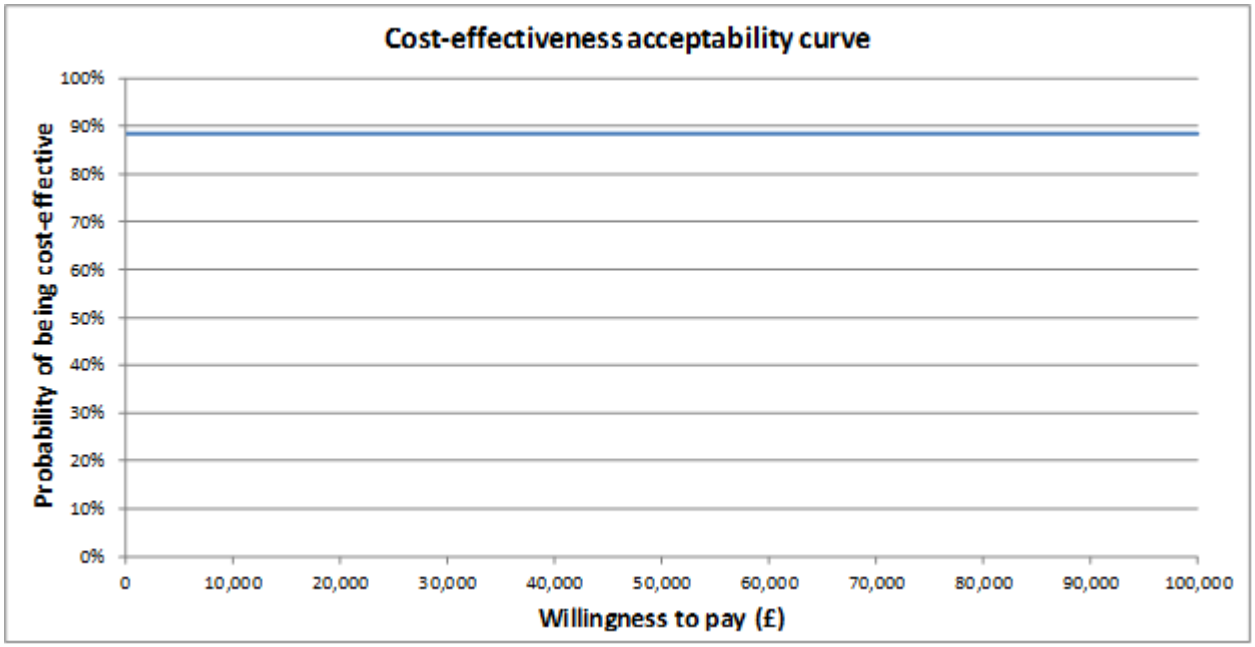
Dominant	More effective & more costly	Less effective & less costly	Dominated
88.50%	0.00%	11.50%	0.00%

Figure 3 . Scatterplot for aflibercept vs. ranibizumab, 1 year of treatment, lifetime horizon (PAS)



The CE plane (Figure 4) shows that assuming a willingness to pay threshold of £20,000/QALY, there is an 88.50% chance that aflibercept is deemed cost-effective vs. ranibizumab.

Figure 4. CE plane for aflibercept vs. ranibizumab, 1 year of treatment, lifetime horizon (PAS)



4.11 Please present scenario analysis results as described for the main manufacturer/sponsor submission of evidence for the technology appraisal.

Analyses were performed comparing aflibercept at the discounted price of £[redacted] ([redacted]% discount) per drug injection to different scenarios of ranibizumab prices per drug injection. Ranibizumab price (£742.17) was tested in discount scenarios ranging from -10% to -50% in 5% increments.

Aflibercept dominated ranibizumab in the base case scenario. Decreasing ranibizumab price per injection did not change the trend in results except with a 50% discount, in which case aflibercept is still cost-effective (ICER: £5,871).

Table 7: Scenario analyses with patient access scheme Ranibizumab: -10%

Technologies	Total costs (£)	Total LYG	Total QALYs	Incremental costs (£)	Incremental LYG	Incremental QALYs	ICER (£) versus baseline (QALYs)
Aflibercept	[redacted]	18.977	[redacted]	-	-	-	-
Ranibizumab	[redacted]	18.976	[redacted]	-2,286	0.001	0.054	AFB Dominant

Table 8: Scenario analyses with patient access scheme Ranibizumab: -15%

Technologies	Total	Total	Total	Increme	Increme	Increme	ICER (£)

	costs (£)	LYG	QALYs	ntal costs (£)	ntal LYG	ntal QALYs	versus baseline (QALYs)
Aflibercept	[redacted]	18.977	[redacted]	-	-	-	-
Ranibizumab	[redacted]	18.976	[redacted]	-1,961	0.001	0.054	AFB Dominant

Table 9: Scenario analyses with patient access scheme Ranibizumab: -20%

Technologies	Total costs (£)	Total LYG	Total QALYs	Incremental costs (£)	Incremental LYG	Incremental QALYs	ICER (£) versus baseline (QALYs)
Aflibercept	[redacted]	18.977	[redacted]	-	-	-	-
Ranibizumab	[redacted]	18.976	[redacted]	-1,636	0.001	0.054	AFB Dominant

Table 10: Scenario analyses with patient access scheme Ranibizumab: -25%

Technologies	Total costs (£)	Total LYG	Total QALYs	Incremental costs (£)	Incremental LYG	Incremental QALYs	ICER (£) versus baseline (QALYs)
Aflibercept	[redacted]	18.977	[redacted]	-	-	-	-
Ranibizumab	[redacted]	18.976	[redacted]	-1,311	0.001	0.054	AFB Dominant

Table 11: Scenario analyses with patient access scheme Ranibizumab: -30%

Technologies	Total costs (£)	Total LYG	Total QALYs	Incremental costs (£)	Incremental LYG	Incremental QALYs	ICER (£) versus baseline (QALYs)
Aflibercept	[redacted]	18.977	[redacted]	-	-	-	-
Ranibizumab	[redacted]	18.976	[redacted]	-985	0.001	0.054	AFB Dominant

Table 12: Scenario analyses with patient access scheme Ranibizumab: -35%

Technologies	Total costs (£)	Total LYG	Total QALYs	Incremental costs (£)	Incremental LYG	Incremental QALYs	ICER (£) versus baseline (QALYs)
Aflibercept	[redacted]	18.977	[redacted]	-	-	-	-
Ranibizumab	[redacted]	18.976	[redacted]	-660	0.001	0.054	AFB Dominant

Table 13: Scenario analyses with patient access scheme Ranibizumab: -40%

Technologies	Total costs (£)	Total LYG	Total QALYs	Incremental costs (£)	Incremental LYG	Incremental QALYs	ICER (£) versus baseline (QALYs)
Aflibercept	[redacted]	18.977	[redacted]	-	-	-	-
Ranibizumab	[redacted]	18.976	[redacted]	-335	0.001	0.054	AFB Dominant

Table 14: Scenario analyses with patient access scheme Ranibizumab: -45%

Technologies	Total costs (£)	Total LYG	Total QALYs	Incremental costs (£)	Incremental LYG	Incremental QALYs	ICER (£) versus baseline (QALYs)
Aflibercept	[redacted]	18.977	[redacted]	-	-	-	-
Ranibizumab	[redacted]	18.976	[redacted]	-10	0.001	0.054	AFB Dominant

Table 15: Scenario analyses with patient access scheme Ranibizumab: -50%

Technologies	Total costs (£)	Total LYG	Total QALYs	Incremental costs (£)	Incremental LYG	Incremental QALYs	ICER (£) versus baseline (QALYs)
Aflibercept	[redacted]	18.977	[redacted]	-	-	-	-
Ranibizumab	[redacted]	18.976	[redacted]	315	0.001	0.054	5,871

4.12 If any of the criteria on which the patient access scheme depends are clinical variable (for example, choice of response measure, level of response, duration of treatment), sensitivity analyses around the individual criteria should be provided, so that the Appraisal Committee can determine which criteria are the most appropriate to use.

Not applicable.

Impact of patient access scheme on ICERs

4.13 For financially based schemes, please present the results showing the impact of the patient access scheme on the ICERs for the base-case and any scenario analyses. A suggested format is shown below (see table 5). If you are submitting the patient access scheme at the end of the appraisal process, you must include the scenario with the assumptions that the Appraisal Committee considered to be most plausible.

The same five scenario analyses presented in NICE's 'Specification for manufacturer/sponsor submission of evidence' were performed using the discounted price for aflibercept.

Comparative results with and without PAS are presented in Table 17 below. As expected and given the suggested PAS consists on a commercially

confidential discount on the list price of aflibercept, results obtained in the current analyses for aflibercept vs. ranibizumab produce higher savings compared to results in the 'Specification for manufacturer/sponsor submission of evidence' demonstrating dominance of aflibercept over ranibizumab in all scenarios.

Table 16. Results showing the impact of patient access scheme on ICERs

Scenario	ICER	
	Without PAS	**With PAS**
0 - Base-case	[redacted]	AFB Dominant
1 – Treatment duration of 2 years	[redacted]	AFB Dominant
2 – Treatment duration of 4 years	[redacted]	AFB Dominant
3 – Literature-based utilities (Czoski Murray)	[redacted]	AFB Dominant
4 – Inclusion of AEs	[redacted]	AFB Dominant
5 – Aflibercept vs. dexamethasone comparison	[redacted]	£3,236/QALY

For the comparison of aflibercept vs. dexamethasone, aflibercept was cost-effective both with list price (ICER: £[redacted]/QALY; incremental cost: £[redacted]; incremental QALY: 0.189)) and with discounted PAS price (ICER: £3,236/QALY; incremental cost: £612; incremental QALY: 0.189).

5 Appendices

5.1 Appendix A: Additional documents

5.1.1 If available, please include copies of patient access scheme agreement forms, patient registration forms, pharmacy claim forms/rebate forms, guides for pharmacists and physicians, patient information documents.

Not applicable

5.2 Appendix B: Details of outcome-based schemes

5.2.1 If you are submitting a proven value: price increase scheme, as defined in the PPRS, please provide the following information:

- the current price of the intervention
- the proposed higher price of the intervention, which will be supported by the collection of new evidence
- a suggested date for when NICE should consider the additional evidence.

Not applicable