NICE National Institute for Health and Care Excellence

Putting NICE guidance into practice

Costing report: Aflibercept for treating diabetic macular oedema (TA346)

Published: July 2015

Summary

Aflibercept solution for injection is recommended as an option for treating visual impairment caused by diabetic macular oedema only if:

- the eye has a central retinal thickness of 400 micrometres or more at the start of treatment and
- the company provides aflibercept with the discount agreed in the patient access scheme.

The Department of Health and Bayer Pharma have agreed that aflibercept will be available to the NHS with a patient access scheme which makes it available with a discount. The size of the discount is commercial in confidence. It is the responsibility of the company to communicate details of the discount to the relevant NHS organisations. Any enquiries from NHS organisations about the patient access scheme should be directed to Bayer Pharma, lesley.gilmour@bayer.com.

6,205 people in England may be eligible for treatment with aflibercept solution for injection each year. The annual cost associated with implementing the guidance is estimated as £26 million in England.

This equates to 12 people and a cost of £48,407 per 100,000 population.

This technology is commissioned by clinical commissioning groups. Providers are NHS hospital trusts and outsourced services.

This report is supported by a costing template. **The costing template is based on the list price and can be amended locally to take into account the patient access scheme discount.**

1 Introduction

1.1 NICE technology appraisal guidance covers the use of new and existing medicines and treatments within the NHS in England. Unless otherwise directed by the Department of Health, NHS bodies should make funding available for treatments recommended by NICE within 3 months of publication of the guidance.

1.2 **The Department of Health and Bayer Pharma have agreed that aflibercept will be available to the NHS with a patient access scheme which makes it available with a discount. The size of the discount is commercial in confidence. It is the responsibility of the company to communicate details of the discount to the relevant NHS organisations. Any enquiries from NHS organisations about the patient access scheme should be directed to Bayer Pharma, lesley.gilmour@bayer.com.**

1.3 This report, which has been provided to support the implementation of guidance, is supported by a costing template. The template aims to help organisations in England, Wales and Northern Ireland plan for the financial implications of implementing the NICE guidance. **The costing template is based on the list price and can be amended locally to take into account the patient access scheme discount.**

1.4 This technology is commissioned by clinical commissioning groups. Providers are NHS hospital trusts and outsourced services.

2 Background

2.1 Diabetic macular oedema is a frequent complication associated with diabetic retinopathy, and is the most common cause of visual impairment in people with diabetes mellitus.

2.2 Aflibercept solution for injection (Eylea, Bayer Pharma) is a soluble vascular endothelial growth factor (VEGF) receptor fusion protein that binds to all forms of VEGF-A, VEGF-B, and the placental growth factor. Aflibercept is given by intravitreous injection.

3 Guidance

3.1 The guidance states that:

Aflibercept solution for injection is recommended as an option for treating visual impairment caused by diabetic macular oedema only if:

- the eye has a central retinal thickness of 400 micrometres or more at the start of treatment and
- the company provides aflibercept with the discount agreed in the patient access scheme.

3.2 People whose treatment with aflibercept is not recommended in this NICE guidance, but was started within the NHS before this guidance was published, should be able to continue aflibercept until they and their NHS clinician consider it appropriate to stop.

4 Assumptions made

4.1 The costing model makes the following assumptions:

- There are 2,593,695 people in England aged 18 and over with diabetes mellitus (Health and Social Care Information Centre).
- There are 1,686 people in England presenting each year with visual impairment because of diabetic macular oedema with a central retinal thickness of 400 micrometres or more.
- A further 4,519 people from the prevalent population have disease that will progress from having a retinal thickness of less than 400 micrometres to more than 400 micrometres each year.

- This gives a total of 6,205 people in England who may be eligible for treatment with aflibercept solution for injection each year (see the costing template for details of how this has been calculated).
- Current practice is based on the predicted uptake for the main comparator, ranibizumab, used in the cost impact calculations in NICE's technology appraisal guidance on ranibizumab for treating diabetic macular oedema.
- Future practice is based on expert clinical opinion. It is estimated that 10% (620) receive laser treatment, 55% (3,413) receive aflibercept monotherapy, 25% (1,551) receive ranibizumab monotherapy, 5% (310) receive combination therapy with laser and aflibercept, 2% (125) receive combination therapy with laser and ranibizumab, and 3% (186) receive no active treatment.
- Some people will have diabetic macular oedema that will not respond to treatment. It is assumed that they will only have 3 injections in each eye treated before moving to laser treatment as monotherapy in year 2. It is estimated that 8% (440) of people treated with aflibercept monotherapy, ranibizumab monotherapy or combination therapy will not respond.
- It is assumed that 53.5% of people will need treatment in one eye and 46.5% of people will need treatment in both eyes.
- It is assumed that all treatment and monitoring appointments can be shared when both eyes are treated.
- The estimated number of treatment and monitoring appointments is based on the company's submission and amendments in the Evidence Review Group report.
- It is assumed that all treatment visits double as monitoring visits.
- It is assumed that a course of treatment lasts for 3 years.

5 Costing summary

5.1 Table 1 shows the annual cost associated with implementing the guidance is estimated as £26 million in England after 5 years, based on the standard assumptions in the model.

Table 1 Cost of implementation for England using NICE assumptions

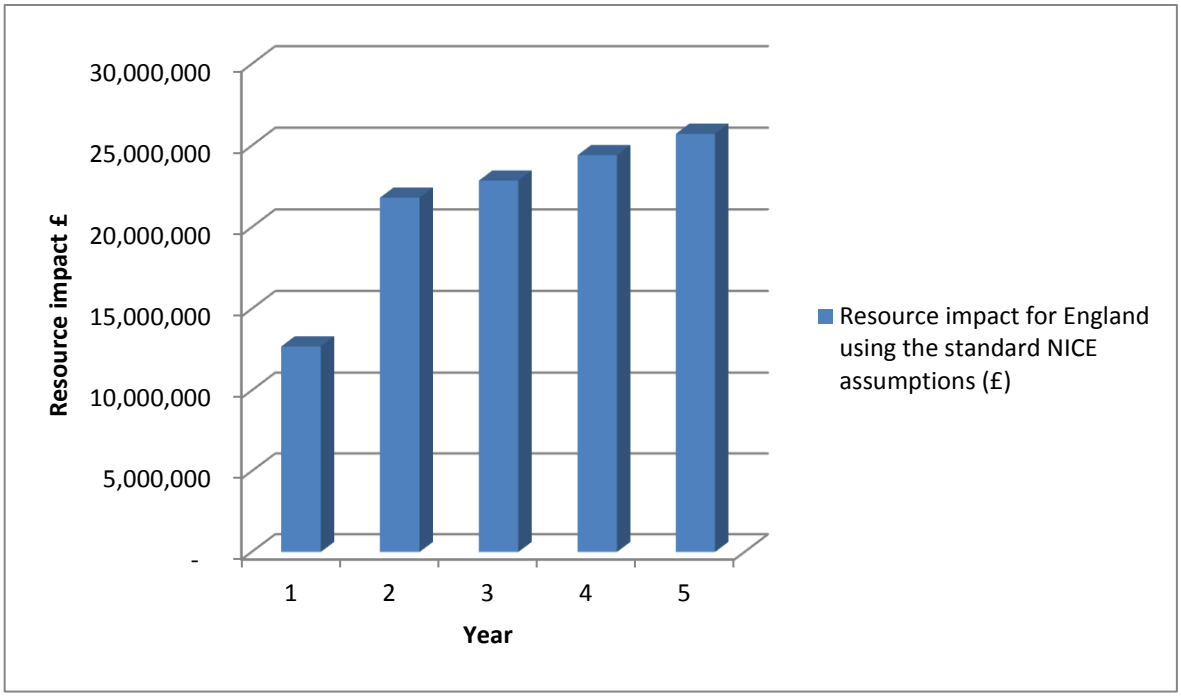
	Cost (£) – based on the list price
Current practice	
Treatment in year 1	43,464,149
Treatment in year 2	22,927,549
Treatment in year 3	13,355,118
Total cost of current practice	**79,746,816**
Future practice	
Treatment in year 1	53,568,757
Treatment in year 2	32,375,940
Treatment in year 3	15,246,253
Total cost of future practice	**101,190,950**
Total incremental cost excluding VAT (£)	**21,444,134**
VAT adjustment	4,276,924
Total incremental cost including VAT (£)	**25,721,058**

5.2 Costs over time are shown in table 2 and figure 1 below. These are based on company estimates of the increase in market share for aflibercept over 5 years. The resource impact for England using the standard NICE assumptions increases from £13 million in the first year to £26 million after 5 years.

Table 2 Projected uptake over 5 years

Year	1	2	3	4	5
Aflibercept	19%	46%	58%	64%	69%
Ranibizumab	81%	54%	42%	36%	31%
Resource impact for England (£)	12,698,508	21,814,293	22,856,097	24,418,803	25,721,058

Figure 1 Resource impact per for England using the standard NICE assumptions



6 Implications for commissioners

6.1 Aflibercept solution for injection falls within programme budgeting category 8: problems of vision.

7 Other considerations

7.1 The Committee acknowledged that the summary of product characteristics for aflibercept and ranibizumab states a reduced dosing interval after the first 12 months, and agreed that there is uncertainty around the average number of aflibercept injections that a person would receive after the first 12 months. Reducing the number of aflibercept injections in year 2 has been explored in the sensitivity analysis.

7.2 To be consistent with the ERG the costing template estimates 12 monitoring appointments for ranibizumab in the first year. However the ranibizumab summary of product characteristics has been recently revised to permit a monitoring schedule in the first year that is more flexible and is more in line with that of aflibercept. In the short to medium term the number of ranibizumab monitoring visits in the first year may tend to converge with that of aflibercept. Therefore reducing the number of monitoring appointments to 8 has been explored in the sensitivity analysis.

8 Summary of sensitivity analysis

8.1 Future practice is based on expert clinical opinion. Inputting the company estimates for future practice reduces the resource impact from £26 million to £16 million.

8.2 Reducing the number of aflibercept injections in year 2 to 4 reduces the resource impact from £26 million to £18 million.

8.3 Reducing the number of monitoring appointments for ranibizumab in year 1 from 12 to 8 increases the resource impact by £763,000. This is because less monitoring appointments for ranibizumab reduces the cost of the comparator and so increases the cost of implementing the guidance.

About this costing report

This costing report accompanies the NICE technology appraisal guidance on aflibercept for treating diabetic macular oedema and should be read in conjunction with it. See terms and conditions on the NICE website.

Issue date: July 2015

This report is written in the following context

This report represents the view of NICE, which was arrived at after careful consideration of the available data and through consulting healthcare professionals. The report is an implementation tool and focuses on the recommendations that were considered to have a significant impact on national resource use.

Assumptions used in the report are based on assessment of the national average. Local practice may be different from this, and the impact should be estimated locally.

Implementation of the guidance is the responsibility of local commissioners and providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity and foster good relations. Nothing in this costing tool should be interpreted in a way that would be inconsistent with compliance with those duties.