Intravitreal Targeted Treatment of Diabetic Retinal Disease: Diabetic Macular Edema (DME)

CMS Office of Clinical Standards and Quality
Coverage and Analysis Group
Division of Items and Devices

Purpose of the Meeting

CMS has called this meeting of the MEDCAC panel to review the available evidence for Intravitreal Targeted Treatment of Diabetic Retinal Disease: Diabetic Macular Edema (DME).

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CMS is most interested in meaningful changes to beneficiaries' visual function that enable their independent accomplishment of routine daily activities. We also seek the panel's input on the preferred measures for determining progression in clinical trials of DME treatment.

Voting Scale

For the voting questions, use the following scale identifying level of confidence - with 1 representing the lowest or no confidence, 3 representing intermediate confidence and 5 representing a high level of confidence.

1 Low Confidence	**2**	**3 Intermediate Confidence**	**4**	**5 High Confidence**

Discussion Question #1

1. In a 2005 MEDCAC on wet age-related macular degeneration (WAMD), the following commonly used outcomes or intermediate endpoint measures were discussed:

a. Visual acuity
b. VFQ 25
c. Dilated eye exam (to assess retinal damage)
d. Grade of diabetic retinopathy (DR)
e. Amsler grid
f. Extent/progression as measured by retinal photography

Question 1 (cont'd)

g. Fluorescein angiography (to assess blood flow/leakage in retina and choroid)
h. Visual fields
i. Ocular coherence tomography (OCT) (to assess retinal thickening, other damage)

Please discuss the suitability of these measures for assessing DME treatment-related health outcomes, i.e., benefits and harms.

Question 2

2. How confident are you that there is adequate evidence to determine whether or not DME management using intravitreal targeted anti-VEGF treatment improves patient health outcomes compared to DME management without intravitreal targeted anti-VEGF treatment?

Question 3

3. If the result of Question 2 is at least intermediate (mean vote ≥ 2.5), how confident are you that there is adequate evidence to conclude that DME management using intravitreal targeted anti-VEGF treatment improves patient health outcomes compared to DME management without intravitreal targeted anti-VEGF treatment?

Discussion for Question 3

Please discuss any patient characteristics, treatment regimens, or other factors that may have important impacts on the degree of patient benefit or harm from these treatments.

Question 4

4. If the result of Question 3 is at least intermediate (mean vote ≥ 2.5), how confident are you that there is also adequate evidence to determine whether or not there are clinically meaningful differences in health outcomes among the available intravitreal targeted anti-VEGF treatments for the management of DME?

Question 5

5. If the result of Question 4 is at least intermediate (mean vote ≥ 2.5), how confident are you that there is adequate evidence to conclude that there are clinically meaningful differences in the health outcomes when comparing the following available intravitreal targeted anti-VEGF treatments?

Discussion for Question 5

- Ranibizumab vs Pegaptanib
- Bevacizumab vs Pegaptanib
- Ranibizumab vs Bevacizumab

Please discuss whether your conclusions are based on evidence of:

a. Different benefits with similar harms
b. Similar benefits with different harms
c. Different benefits and different harms

Question 6

6. How confident are you that the conclusions above are generalizable to:

- Medicare beneficiaries?
- Community-based settings?

Discussion Question #7

7. To what extent are the conclusions above generalizable to the management of other forms of diabetic retinal vascular disease beyond DME?

Discussion Question #8

8. Are there significant gaps in the evidence base on the management of diabetic macula edema?

Discussion Question #9

9. What study designs would support the narrowing or closure of these gaps?