

# Age-Related Macular Degeneration (AMD)

Medicare Coverage Advisory Committee

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# Review Team

- Stuart Caplan, RN, MAS
- Ross Brechner, MD, MS(stat), MPH
- Kimberly Long
- Michelle Atkinson
- Louis Jacques, MD
- Steve E. Phurrough, MD, MPA

# Today's Presentation

- AMD treatment and outcome measures
- Evidence review and data analysis
- History of Medicare coverage
- MCAC panel questions
- Presentations

# MCAC Panel Materials

- Draft AHRQ technology assessment
- Copies of articles reviewed
- Written testimony of presenters
- Evidence summary
- Questions for the panel

# AMD in the Medicare Population

- Leading cause of blindness age >65
- NEI estimates 165,000 cases/year
- 7.1% prevalence over age 75
- 1.2 million total prevalence

# AMD Therapies

- No cure
- Several FDA-approved therapies:
  - 1) Ocular photodynamic therapy (OPT/PDT) with verteporfin
  - 2) Anti-angiogenesis therapy
  - 3) Laser photocoagulation
  - 4) Vitamins and other treatments
- Various early trials of other therapies

# FDA/CMS Status: OPT with Verteporfin

- Predominantly classic AMD-related subfoveal choroidal neovascularization (CNV)
- Occult with no classic or minimally classic CNV is off-label
- January 2004: CMS covers broader than FDA label when certain clinical conditions are met

# NCD for OPT with verteporfin

The National Coverage Determination on OPT with verteporfin can be found on the CMS coverage website:

<http://www.cms.hhs.gov/mcd/viewdecisionmemo.asp?id=101>



# FDA/CMS Status pegaptanib sodium

- Anti-vascular endothelial growth factor (anti-VEGF)
- FDA-approved for all AMD-related CNV
- CMS is silent on national coverage
- Coverage at contractor discretion

# FDA/CMS Status: Other therapies

## Non FDA-approved, Noncovered by CMS

- Anecortave acetate
- Ranibizumab
- Other therapies in clinical trials

## Contractor discretion

- Bevacizumab, off-label
- Triamcinolone acetonide, off label
- Laser photocoagulation
- Combined FDA-approved therapies

# Panel Questions

# Panel Question 1

Each of the following have been reported as measures of disease activity or outcome in AMD. Some are direct measures of visual outcome, unambiguously representing visual aspects of patient well-being.

# Panel Question 1 (continued)

Others are intermediate endpoints, meaning that they are intended to predict visual outcomes, even if they are not direct measures of outcome themselves.

# Panel Question 1 (continued)

For each of the measures below, how confident are you that it is valid as a measure of visual outcome? If it is not a valid measure of visual outcome, how confident are you that it is a valid intermediate endpoint?

# Panel Question 1 (continued)

1. Visual acuity
2. VFQ 25
3. Extent of CNV
4. Amsler grid
5. Drusen extent/progression

# Panel Question 1 (continued)

6. Geographic atrophy
7. Glare recovery
8. Contrast sensitivity
9. Fluorescein angiography
10. Visual fields
11. Ocular coherence tomography



# Panel Question 1B

Which other currently available outcome/intermediate measures should be considered?

## Panel Question 1C

As new technologies arise, will new outcome/intermediate measures be needed to demonstrate benefit in the treatment of AMD?

# Panel Question 1D

What are the appropriate chronological criteria for “short-term” and “long-term” outcomes for AMD treatments?

## Panel Question 2

At present, usual and approved care for AMD includes photodynamic therapy with verteporfin, laser photocoagulation, intravitreal injection of pegaptanib, and oral vitamins/antioxidants/zinc.

# Panel Question 2 A&B

How confident are you that:

- A. There is sufficient evidence to assess the health benefit of these modalities compared to watchful waiting?
- B. There are modalities other than photodynamic therapy with verteprofin, laser photocoagulation, intravitreal injection of pegaptanib, and vitamins that provide a health benefit when compared to watchful waiting?

## Panel Question 3

Based on evidence reviewed, how confident are you that the treatments such as photodynamic therapy with verteporfin, laser photocoagulation, intravitreal injection of pegaptanib, and oral vitamins, antioxidants & zinc will positively affect the outcomes listed in Question 1?

# Panel Question 4A

Based on evidence reviewed, how confident are you that the approved treatment modalities such as photodynamic therapy with verteporfin, laser photocoagulation, intravitreal injection of pegaptanib, and oral vitamins, antioxidants & zinc used singly or in combination, produce clinically significant net health benefits in the treatment of AMD?

## Panel Question 4B

Based on evidence reviewed, how confident are you that the *other* treatment modalities, used singly or in combination, produce clinically significant net health benefits in the treatment of AMD?



# Panel Question 5

What are the knowledge gaps in current evidence pertaining to the usual care and outcome measurements of AMD?

# Panel Question 6

What trial designs will support the development of sufficient evidence to determine the appropriate treatment of AMD?

## Panel Question 7

Based on the evidence presented, how likely is it that studies using valid measures of outcomes in treatment of AMD will result in conclusions that can be generalized to the Medicare population?

Ross Brechner, MD, MS(stat), MPH