Coverage Summary

Age Related Macular Degeneration (AMD) Therapy
(Macugen®, Lucentis®, Avastin®, EYLEA®)

Approved by: UnitedHealthcare Medicare Benefit Interpretation Committee  Last Review Date: 06/21/2017

Related Medicare Advantage Policy Guidelines:
- Avastin (Bevacizumab)
- Coverage of Drugs and Biologicals for Label and Off-Label Uses
- Eylea (Aflibercept)
- Lucentis (Ranibizumab)
- Macugen (Pegaptanib)

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The benefit information in this Coverage Summary is based on existing national coverage policy, however Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable.

I. COVERAGE

Coverage Statement: Age Related Macular Degeneration (AMD) Therapy: (Avastin®, Lucentis®, Macugen® and EYLEA® are covered when the Medicare criteria are met.

Guidelines/Notes:
1. Avastin® (Bevacizumab) (CPT/HCPCS Code C9257 and J9035)
   - Medicare does not have a National Coverage Determination (NCD) for Avastin® (Bevacizumab)
   - Local Coverage Determinations (LCDs) exist and compliance with these policies is required where applicable. For state-specific LCDs, see the LCD Availability Grid (Attachment A).
• **For states with no LCDs**, refer to the [UnitedHealthcare Drug Policy for Ophthalmologic Policy Vascular Endothelial Growth Factor (VEGF) Inhibitors](#) for coverage guidelines with individual consideration for the following diagnoses:
  - cystoid macular degeneration
  - venous tributary (branch) occlusion
  - nonproliferative diabetic retinopathy

  (IMPORTANT NOTE: After searching the Medicare Coverage Database, if no state LCD or Local Article is found, then use the above referenced policy.)

• **Committee approval date:** June 21, 2017
• **Accessed June 6, 2017**

2. **Lucentis® (Ranibizumab) (HCPCS code J2778)**
   - Medicare does not have a National Coverage Determination (NCD) for Lucentis® (Ranibizumab).
   - Local Coverage Determinations (LCDs) exist and compliance with these policies is required where applicable. See the [LCD Availability Grid (Attachment B)](#) for state specific LCDs.
   - **For states with no LCDs**, refer to the UnitedHealthcare Drug Policy for Ophthalmologic Policy Vascular Endothelial Growth Factor (VEGF) Inhibitors for coverage guidelines.

   (IMPORTANT NOTE: After searching the Medicare Coverage Database, if no state LCD or Local Article is found, then use the above referenced policy.)

• **Committee approval date:** June 21, 2017
• **Accessed June 6, 2017**

3. **Macugen® (Pegaptanib) (HCPCS code J2503)**
   - Medicare does not have a National Coverage Determination (NCD) for Macugen® (Pegaptanib).
   - Local Coverage Determinations (LCDs) exist and compliance with these policies is required where applicable. For state-specific LCDs, see the LCD Availability Grid (Attachment C).

   **For states with no LCDs**, refer to the UnitedHealthcare Drug Policy for Ophthalmologic Policy Vascular Endothelial Growth Factor (VEGF) Inhibitors for coverage guidelines.

   (IMPORTANT NOTE: After searching the Medicare Coverage Database, if no state LCD or Local Article is found, then use the above referenced policy.)

• **Committee approval date:** June 21, 2017
• **Accessed June 6, 2017**

4. **EYLEA® (Aflibercept) (HCPCS code J0178)**
   - Medicare does not have a National Coverage Determination (NCD) for EYLEA® (Aflibercept).

   **Local Coverage Determinations (LCDs)/Local Articles exist for Aflibercept (e.g., EYLEA™). Compliance with these policies is required where applicable. See the LCD Availability Grid (Attachment D) for state specific LCDs/Articles.**

   **For states with no LCDs/Local Articles**, refer to the UnitedHealthcare Drug Policy for Ophthalmologic Policy Vascular Endothelial Growth Factor (VEGF) Inhibitors for coverage guidelines.

   (IMPORTANT NOTE: After searching the Medicare Coverage Database, if no state LCD or Local Article is found, then use the above referenced policy.)
II. DEFINITIONS

Age Related Macular Degeneration (AMD):
Macular degeneration, often called age-related macular degeneration (AMD), is an eye disorder associated with aging and results in damaging sharp and central vision. Central vision is needed for seeing objects clearly and for common daily tasks such as reading and driving. AMD affects the macula, the central part the retina that allows the eye to see fine details. There are two forms of AMD—wet and dry.

Wet AMD is when abnormal blood vessel behind the retina start to grow under the macula, ultimately leading to blood and fluid leakage. Bleeding, leaking, and scarring from these blood vessels cause damage and lead to rapid central vision loss. An early symptom of wet AMD is that straight lines appear wavy.

Dry AMD is when the macula thins overtime as part of aging process, gradually blurring central vision. The dry form is more common and accounts for 70–90% of cases of AMD and it progresses more slowly than the wet form. Over time, as less of the macula functions, central vision is gradually lost in the affected eye. Dry AMD generally affects both eyes. One of the most common early signs of dry AMD is drusen.

Drusen are tiny yellow or white deposits under the retina. They often are found in people aged 60 years and older. The presence of small drusen is normal and does not cause vision loss. However, the presence of large and more numerous drusen raises the risk of developing advanced dry AMD or wet AMD.

It is estimated that 1.8 million Americans aged 40 years and older are affected by AMD and an additional 7.3 million with large drusen are at substantial risk of developing AMD. The number of people with AMD is estimated to reach 2.95 million in 2020. AMD is the leading cause of permanent impairment of reading and fine or close-up vision among people aged 65 years and older. Centers for Disease Control and Prevention. Vision Health Initiative (VHI); available at http://www.cdc.gov/features/healthyvisionmonth/index.html. (Accessed June 6, 2017)

III. REFERENCES

See above.

IV. REVISION HISTORY

6/21/2017 Annual review; no updates.

11/15/2016 Re-review with the following update:
Guideline 1 [Avastin® (Bevacizumab)] - updated default guideline for states with no LCDs to include the following 2 additional diagnoses for individual consideration (IC): venous tributary (branch) occlusion and nonproliferative diabetic retinopathy.

06/21/2016 Annual review with the following recommended update:
Updated the LCD Availability grids to include the condensed LCD links.

07/21/2015 Annual review with the following update:
Guideline 1 [Avastin® (Bevacizumab) (CPT/HCPCS Code C9257 and J9035)]
Removed the following language (for internal use only):
“This diagnosis is addressed as covered in all the available LCDs, but not addressed in the UnitedHealthcare Drug Policy.”

03/12/2015 Formatting change only.

10/21/2014 Annual review with the following updates:
- Guideline # 1 Avastin® (Bevacizumab) - Changed the default guidelines for states with no LCDs from LCD for Drugs and Biologicals: Antiangiogenic Therapy for Ophthalmic Conditions (L30555) to UnitedHealthcare Drug Policy for Ophthalmologic Policy Vascular Endothelial Growth Factor (VEGF) Inhibitors with individual consideration for the diagnosis of cystoid macular degeneration.
- Guideline # 2 Lucentis® (Ranibizumab) - Changed the default guidelines for states with no LCDs from LCD for Drugs and Biologicals: Antiangiogenic Therapy for Ophthalmic Conditions (L30555) to UnitedHealthcare Drug Policy for Ophthalmologic Policy Vascular Endothelial Growth Factor (VEGF) Inhibitors.
- Guideline # 3 Macugen® (Pegaptanib)- Changed the default guidelines for states with no LCDs from LCD for Drugs and Biologicals: Antiangiogenic Therapy for Ophthalmic Conditions (L30555) to UnitedHealthcare Drug Policy for Ophthalmologic Policy Vascular Endothelial Growth Factor (VEGF) Inhibitors.
- Guideline # 4 EYLEA® (Aflibercept) - Changed the default guidelines for states with no LCDs from LCDs for Drugs and Biologicals (L25820) and related Articles (A46091) to UnitedHealthcare Drug Policy for Ophthalmologic Policy Vascular Endothelial Growth Factor (VEGF) Inhibitors.
- Definitions - Updated the definition of Age Related Macular Degeneration (AMD) based on the Centers for Disease Control and Prevention, Vision Health Initiative (VHI)

08/20/2013 Annual review, no updates.

08/20/2012 Annual review; updated to include Guidelines #2 - Aflibercept (EYLEA™).

V. ATTACHMENT(S)

<table>
<thead>
<tr>
<th>Attachment A - LCD Availability Grid</th>
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<tbody>
<tr>
<td>Avastin® (Bevacizumab)</td>
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<tr>
<td>(CPT/HCPCS C9257 and J9035)</td>
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<td>CMS website accessed June 6, 2017</td>
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IMPORTANT NOTE: Use the applicable LCD based on member’s residence/place of service AND type of service.

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<th>LCD ID</th>
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<td>FL, PR, VI</td>
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<td>L33394/ A52370</td>
<td>Drugs and Biologicals, Coverage of, for Label and Off-Label Uses</td>
<td>A and B MAC</td>
<td>National Government Services, Inc.</td>
<td>CT, IL, MA, ME, MN, NH, NY, RI, VT, WI</td>
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### Attachment A - LCD Availability Grid
**Avastin® (Bevacizumab)**
(CPT/HCPCS C9257 and J9035)
CMS website accessed June 6, 2017

**IMPORTANT NOTE:** Use the applicable LCD based on member’s residence/place of service AND type of service.

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<td>Billing and Coding Information Regarding Uses, Including Off-Label Uses, of Anti-Vascular Endothelial Growth Factor (anti-VEGF), for The Treatment of Ophthalmological Diseases</td>
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<td>Novitas Solutions, Inc.</td>
<td>AR, CO, DC, DE, LA, MD, MS, NJ, NM, OK, PA, TX</td>
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**End of Attachment A**

### Attachment B - LCD Availability Grid
**Lucentis® (Ranibizumab)**
(HCPCS code J2778)
CMS website accessed June 1, 2017

**IMPORTANT NOTE:** Use the applicable LCD based on member’s residence/place of service AND type of service.

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**End of Attachment B**
## Attachment C - LCD Availability Grid

**Macugen® (Pegaptanib)**
(HCPCS code J2503)

CMS website accessed June 6, 2017

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**End of Attachment C**

## Attachment D - LCD Availability Grid

**EYLEA® (Aflibercept)**
(CPT code J0178)

CMS website accessed June 6, 2017

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**End of Attachment D**