Antiangiogenic Therapy for Ophthalmic Conditions  

Policy Number: M-0044

Pegaptinib (Macugen®)
Ranibizumab (Lucentis®)
Bevacizumab (Avastin®)

Payment will not be made for any use of these drugs outside of the criteria without prior authorization. The member may not be billed unless the member explicitly agrees in writing to be responsible for the charges in accordance with the contract/provider manual. Prior authorization will only be given if the provider demonstrates the intended use meets Medicare coverage guidelines.

Coverage Guidelines:

**Pegaptinib**

FDA
Age related macular degeneration, Neovascular (Wet)
Off-Label
Diabetic macular edema

**Ranibizumab**

FDA
Exudative age-related macular degeneration
Macular retinal edema - Thrombosis of retinal vein (Macular Edema Following Retinal Vein Occlusion)
Off-Label
Diabetic macular edema

**Bevacizumab**

Off-label
Age related macular degeneration, Secondary to choroidal neovascularization
Branch retinal vein occlusion with macular edema
Central retinal vein occlusion with macular edema
Diabetic macular edema
Neovascular glaucoma; Adjunct
Retinopathy of prematurity
Coding Information:

HCPCS Code(s)

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>J2503</td>
<td>INJECTION, PEGAPTNIB SODIUM, 0.3 MG</td>
</tr>
<tr>
<td>J2778</td>
<td>INJECTION, RANIBIZUMAB, 0.1 MG</td>
</tr>
<tr>
<td>J9035</td>
<td>INJECTION, BEVACIZUMAB, 10 MG</td>
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</table>

ICD-9 Code(s)

**Bevacizumab (J9035), and Pegaptanib (J2503)**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>115.92</td>
<td>HISTOPLASMOSIS RETINITIS UNSPECIFIED</td>
</tr>
<tr>
<td>362.02</td>
<td>PROLIFERATIVE DIABETIC RETINOPATHY</td>
</tr>
<tr>
<td>362.06</td>
<td>SEVERE NONPROLIFERATIVE DIABETIC RETINOPATHY</td>
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<tr>
<td>362.07</td>
<td>DIABETIC MACULAR EDEMA</td>
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<tr>
<td>362.16</td>
<td>RETINAL NEOVASCULARIZATION NOS</td>
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<tr>
<td>362.35</td>
<td>CENTRAL RETINAL VEIN OCCLUSION</td>
</tr>
<tr>
<td>362.36</td>
<td>VENOUS TRIBUTARY (BRANCH) OCCLUSION OF RETINA</td>
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<tr>
<td>362.52</td>
<td>EXUDATIVE SENILE MACULAR DEGENERATION OF RETINA</td>
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<tr>
<td>362.53</td>
<td>CYSTOID MACULAR DEGENERATION OF RETINA</td>
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<tr>
<td>363.43</td>
<td>ANGIOD STREAKS OF CHOROID</td>
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<tr>
<td>365.63</td>
<td>GLAUCOMA ASSOCIATED WITH VASCULAR DISORDERS OF EYE</td>
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</tbody>
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**Ranibizumab (J2778)**

<table>
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<tr>
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<th>Description</th>
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<tbody>
<tr>
<td>362.07</td>
<td>DIABETIC MACULAR EDEMA</td>
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<td>362.35</td>
<td>CENTRAL RETINAL VEIN OCCLUSION</td>
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<tr>
<td>362.52</td>
<td>EXUDATIVE SENILE MACULAR DEGENERATION OF RETINA</td>
</tr>
</tbody>
</table>

Limitations:

1. **Pegaptanib (Macugen®):**
   
   **FDA:**
   
   Neovascular (wet) age-related macular degeneration.
   
   **Off-label use:**
   
   - A. Diabetic macular edema;
   - B. Central retinal vein occlusion;
   - C. Venous tributary (branch) occlusion;
   - D. Histoplasmosis retinitis;
   - E. Proliferative diabetic retinopathy;
   - F. Severe nonproliferative diabetic retinopathy;
   - G. Retinal neovascularization;
   - H. Cystoid macular degeneration;
   - I. Angioid streaks of choroid; and
   - J. Glaucoma associated with vascular disorders.
2. Ranibizumab (Lucentis®):
   FDA:
   A. Neovascular (wet) age-related macular degeneration.
   B. Macular edema following retinal vein occlusion (RVO).
   Off-label use:
   Note that CMS did not have this, yet Diabetic macular edema is listed in Micromedex.

3. Bevacizumab (Avastin®):
   Off-label use:
   A. Neovascular (wet) age-related macular degeneration
   B. Diabetic macular edema;
   C. Central retinal vein occlusion;
   D. Venous tributary (branch) occlusion;
   E. Histoplasmosis retinitis;
   F. Proliferative diabetic retinopathy;
   G. Severe nonproliferative diabetic retinopathy;
   H. Retinal neovascularization;
   I. Cystoid macular degeneration;
   J. Angioid streaks of choroid; and
   K. Glaucoma associated with vascular disorders.

1. For labeled indications, the dose and frequency of administration should be consistent with the FDA approved package insert.
2. For Bevacizumab (Avastin®), providers are reminded to use the following HCPCS guidelines:
   a. Part B: J9035 (bill one unit per eye)

Background:

Ranibizumab is in a class of medications called vascular endothelial growth factor A (VEGF-A) antagonists. It works by stopping abnormal blood vessel growth and leakage in the eye(s) that may cause vision loss in people with wet AMD.

Bevacizumab is in a class of medications called antiangiogenic agents. It works by stopping the formation of blood vessels that bring oxygen and nutrients to tumors. This may slow the growth and spread of tumors.

Pegaptanib injection is in a class of medications called vascular endothelial growth factor (VEGF) antagonists. It works by stopping abnormal blood vessel growth and leakage in the eye(s) that may cause vision loss in people with wet AMD.
**Black Box Warning:**

**Avastin® BBW warning:**

Gastrointestinal perforation, some cases fatal, has occurred in up to 2.4% of bevacizumab-treated patients. Discontinue bevacizumab if gastrointestinal perforation or wound dehiscence occurs. Discontinue at least 28 days prior to elective surgery. Do not initiate bevacizumab for at least 28 days after surgery and until the surgical wound is fully healed. Severe or fatal hemorrhage, including hemoptysis, gastrointestinal bleeding, CNS hemorrhage, and vaginal bleeding, have occurred up to 5-fold more frequently in bevacizumab-treated patients. Do not administer bevacizumab to patients with serious hemorrhage or recent hemoptysis.

**Definitions:**

**HCPCS Code**—Healthcare Common Procedure Coding System - A system of letter and number codes assigned to procedures, medications, supplies and equipment used for pricing and billing.

**ICD-9 Code**—International Classification of Disease, 9th edition. A standardized classification of disease, injuries, and causes of death, by etiology and anatomic localization and codified into a 6-digit number, which allows clinicians, statisticians, politicians, health planners and others to speak a common language, both US and internationally.

**References:**


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