



**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)

J2503	INJECTION, PEGAPTANIB SODIUM, 0.3 MG
J2778	INJECTION, RANIBIZUMAB, 0.1 MG
J9035	INJECTION, BEVACIZUMAB, 10 MG

ICD-9 Code(s)

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

115.92	HISTOPLASMOSIS RETINITIS UNSPECIFIED
362.02	PROLIFERATIVE DIABETIC RETINOPATHY
362.06	SEVERE NONPROLIFERATIVE DIABETIC RETINOPATHY
362.07	DIABETIC MACULAR EDEMA
362.16	RETINAL NEOVASCULARIZATION NOS
362.35	CENTRAL RETINAL VEIN OCCLUSION
362.36	VENOUS TRIBUTARY (BRANCH) OCCLUSION OF RETINA
362.52	EXUDATIVE SENILE MACULAR DEGENERATION OF RETINA
362.53	CYSTOID MACULAR DEGENERATION OF RETINA
363.43	ANGIOID STREAKS OF CHOROID
365.63	GLAUCOMA ASSOCIATED WITH VASCULAR DISORDERS OF EYE

**Ranibizumab (J2778)**

362.07	DIABETIC MACULAR EDEMA
362.35	CENTRAL RETINAL VEIN OCCLUSION
362.36	VENOUS TRIBUTARY (BRANCH) OCCLUSION OF RETINA
362.52	EXUDATIVE SENILE MACULAR DEGENERATION OF RETINA

**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. Angloid 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, 9<sup>th</sup> 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:

1. Macugen® [package insert.]. Gilead Sciences, Inc. Cedar Knolls, NJ; 8/2008. <http://www.macugen.com/macugenUSPI.pdf>. Accessed June 15, 2012.
2. Macugen® In: Micromedex 2.0. Greenwood Village (CO): Thompson Reuters. [updated 12/12/11; accessed 06/25/12]. [http://www.thomsonhc.com.ezproxy.samford.edu/micromedex2/librarian/ND\\_T/evidencexpert/ND\\_PR/evidencexpert/CS/3582E5/ND\\_AppProduct/evidencexpert/DUPLICATIONSHIELD\\_SYNC/B26FA0/ND\\_PG/evidencexpert/ND\\_B/evidencexpert/ND\\_P/evidencexpert/PFActionId/evidencexpert.DisplayDrugpointDocument?docId=928352&contentSetId=100&title=Pegaptanib+Octasodium&servicesTitle=Pegaptanib+Octasodium&topicId=dosingAndIndicationsSection&subtopicId=fdaSection](http://www.thomsonhc.com.ezproxy.samford.edu/micromedex2/librarian/ND_T/evidencexpert/ND_PR/evidencexpert/CS/3582E5/ND_AppProduct/evidencexpert/DUPLICATIONSHIELD_SYNC/B26FA0/ND_PG/evidencexpert/ND_B/evidencexpert/ND_P/evidencexpert/PFActionId/evidencexpert.DisplayDrugpointDocument?docId=928352&contentSetId=100&title=Pegaptanib+Octasodium&servicesTitle=Pegaptanib+Octasodium&topicId=dosingAndIndicationsSection&subtopicId=fdaSection).
3. Lucentis® In: Micromedex 2.0. Greenwood Village (CO): Thompson Reuters. [updated 01/27/12; accessed 06/15/12]. [http://www.thomsonhc.com.ezproxy.samford.edu/micromedex2/librarian/ND\\_T/evidencexpert/ND\\_PR/evidencexpert/CS/7D9160/ND\\_AppProduct/evidencexpert/DUPLICATIONSHIELD\\_SYNC/F36A76/ND\\_PG/evidencexpert/ND\\_B/evidencexpert/ND\\_P/evidencexpert/PFActionId/evidencexpert.DisplayDrugpointDocument?docId=928565&contentSetId=100&title=Ranibizumab&servicesTitle=Ranibizumab&topicId=dosingAndIndicationsSection&subtopicId=fdaSection](http://www.thomsonhc.com.ezproxy.samford.edu/micromedex2/librarian/ND_T/evidencexpert/ND_PR/evidencexpert/CS/7D9160/ND_AppProduct/evidencexpert/DUPLICATIONSHIELD_SYNC/F36A76/ND_PG/evidencexpert/ND_B/evidencexpert/ND_P/evidencexpert/PFActionId/evidencexpert.DisplayDrugpointDocument?docId=928565&contentSetId=100&title=Ranibizumab&servicesTitle=Ranibizumab&topicId=dosingAndIndicationsSection&subtopicId=fdaSection)

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4. Lucentis® [package insert]. Genentech, Inc. South San Francisco, CA; [revised 6/2010.; accessed 06/15/12]. <http://www.gene.com/gene/products/information/pdf/lucentis-prescribing.pdf>.
5. Avastin® In: Micromedex 2.0. Greenwood Village (CO): Thomson Reuters. [updated 06/05/12; accessed 06/15/12]. [http://www.thomsonhc.com.ezproxy.samford.edu/micromedex2/librarian/ND\\_T/evidencexpert/ND\\_PR/evidencexpert/CS/A4AF90/ND\\_AppProduct/evidencexpert/DUPLICATIONSHIELDSYNC/E14D57/ND\\_PG/evidencexpert/ND\\_B/evidencexpert/ND\\_P/evidencexpert/PFActionId/evidencexpert.DisplayDrugpointDocument?docId=928020&contentSetId=100&title=Bevacizumab&servicesTitle=Bevacizumab&topicId=dosingAndIndicationsSection&subtopicId=fdaSection](http://www.thomsonhc.com.ezproxy.samford.edu/micromedex2/librarian/ND_T/evidencexpert/ND_PR/evidencexpert/CS/A4AF90/ND_AppProduct/evidencexpert/DUPLICATIONSHIELDSYNC/E14D57/ND_PG/evidencexpert/ND_B/evidencexpert/ND_P/evidencexpert/PFActionId/evidencexpert.DisplayDrugpointDocument?docId=928020&contentSetId=100&title=Bevacizumab&servicesTitle=Bevacizumab&topicId=dosingAndIndicationsSection&subtopicId=fdaSection).
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7. Local Coverage Determination (LCD) for for Drugs and Biologicals: Antiangiogenic Therapy for Ophthalmic Conditions (L30555) (Revision 4). Available at: <http://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=30555&ContrId=213&ver=15&ContrVer=1&Date=01%2f01%2f2012&DocID=L30555&bc=iAAAAAgAQAAA&>. Accessed November 7. 2012.

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