Medical benefit drug policies are a source for BCBSM and BCN medical policy information only. These documents are not to be used to determine benefits or reimbursement. Please reference the appropriate certificate or contract for benefit information. This policy may be updated and therefore subject to change.

**Effective Date: 11/7/2019**

**Intravitreal Injections for Retinal Conditions**

- **Eylea®** (aflibercept)
- **Lucentis®** (ranibizumab)
- **Macugen®** (pegaptanib)

**FDA approval:** Various  
**HCPCS:** Lucentis: J2778; Eylea: J0178; Macugen: J2503  
**Benefit:** Medical

**Policy:**

*Requests must be supported by submission of chart notes and patient specific documentation.*

<table>
<thead>
<tr>
<th><strong>Drug</strong></th>
<th><strong>Criteria</strong></th>
</tr>
</thead>
</table>
| **Eylea:** (aflibercept) | 1. Prescribed by an ophthalmologist  
2. Diagnosis of neovascular (wet) age related macular degeneration (AMD)  
OR  
3. Diagnosis of macular edema due to retinal vein occlusion (RVO)  
OR  
4. Diagnosis of diabetic macular edema (DME)  
OR  
5. Diabetic retinopathy (DR)  
AND  
6. Treatment with bevacizumab has been ineffective, not tolerated or contraindicated  
AND  
7. Trial and failure of the preferred products as specified in the BCBSM/BCN utilization management medical drug list  
a. No trial and failure of bevacizumab is required for those with a diagnosis of diabetic macular edema when visual acuity in the affected eye(s) is less than or equal to 20/50 |

**Quantity Limitations and Authorization Period**

1. **Initial Authorization Period:** Up to 1 year  
2. **Wet AMD:** 2 mg administered via intravitreal injection every 4 weeks for the first 12 weeks, followed by 2 mg every 8 weeks  
3. **Macular edema due to RVO:** 2 mg monthly  
4. **DME & DR:** 2 mg administered via intravitreal injection every 4 weeks for the first 5 injections, followed by 2 mg every 8 weeks  
5. **Authorization may be reviewed at least annually to confirm maintenance or improvement of visual acuity**  
   [e.g. stabilization or gain of Snellen and/or ETDRS letters; stabilization or gain of ETDRS-DRSS score]
Lucentis: (ranibizumab)

1. Prescribed by an ophthalmologist
   AND
2. Diagnosis of neovascular (wet) age related macular degeneration (AMD)
   OR
3. Diagnosis of macular edema due to retinal vein occlusion (RVO)
   OR
4. Diagnosis of diabetic macular edema (DME)
   OR
5. Diabetic retinopathy (DR)
   OR
6. Myopic choroidal neovascularization (mCNV)
   AND
7. Treatment with bevacizumab has been ineffective, not tolerated or contraindicated
   AND
8. Trial and failure of the preferred products as specified in the BCBSM/BCN utilization management medical drug list

Quantity Limitations and Authorization Period

1. Initial Authorization Period: Up to 1 year
2. Macular edema due to RVO/AMD: 0.5 mg administered via intravitreal injection every 4 weeks
3. DME & DR: 0.3 mg administered via intravitreal injection every 4 weeks
4. mCNV: 0.5 mg administered via intravitreal injection every 4 weeks for up to three months
5. Authorization may be reviewed at least annually to confirm maintenance or improvement of visual acuity [e.g., stabilization or gain of Snellen and/or ETDRS letters; stabilization or gain of ETDRS-DRSS score]

Macugen: (pegaptinib)

1. Prescribed by an ophthalmologist
   AND
2. Diagnosis of neovascular (wet) age related macular degeneration (AMD)
   AND
3. Treatment with bevacizumab has been ineffective, not tolerated or contraindicated
   AND
4. Trial and failure of the preferred products as specified in the BCBSM/BCN utilization management medical drug list

Quantity Limitations and Authorization Period

1. Initial authorization period: 3 months
2. 0.3 mg administered via intravitreal injection once every 6 weeks.
3. Authorization may be reviewed at least annually to confirm maintenance or improvement of visual acuity [e.g. stabilization or gain of Snellen or ETDRS letters]

*ETDRS: Early Treatment Diabetic Retinopathy Study; ETDRS-DRSS: Early Treatment Diabetic Retinopathy Study Diabetic Retinopathy Severity Scale

A. Eylea, Lucentis, and Macugen are considered investigational when used for all other conditions, including but not limited to:
   a. Used in combination with other intravitreal VEGF inhibitors
   b. Choroidal retinal neovascularization, secondary to pathologic myopia (Lucentis)
   c. Diabetic macular edema (DME) (Macugen)
Therapeutic considerations:

A. FDA approved indication/Diagnosis

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Eylea</th>
<th>Lucentis</th>
<th>Macugen</th>
</tr>
</thead>
<tbody>
<tr>
<td>Neovascular (wet) Age-Related Macular Degeneration (AMD)</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Macular Edema Following Retinal Vein Occlusion</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Diabetic Macular Edema (DME)</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Diabetic Retinopathy</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Myopic choroidal neovascularization (mCNV)</td>
<td></td>
<td></td>
<td>X</td>
</tr>
</tbody>
</table>

*Please refer to most recent prescribing information.

B. Background Information

a. The use of intravitreal injections technique has been widely used by ophthalmologists to treat various ocular diseases; the diseases include but are not limited to: neovascular age related macular degeneration, diabetic macular edema, and macular edema due to retinal vein occlusions. This procedure, which consists of injecting the drug directly into the center of the eye, can be done in the outpatient setting with the use of local anesthetics; hospitalization is not necessary.

b. The current intravitreal anti-VEGFs on the market include: aflibercept, bevacizumab, pegaptinib, and ranibizumab. These drugs work by binding to the growth factors to suppress the formation of irregular blood vessels. Bevacizumab is the best value VEGF inhibitor for the treatment of ocular conditions.

C. Efficacy

*Please refer to most recent prescribing information.

D. Medication Safety Considerations

Black Box Warning: No

*Please refer to most recent prescribing information.
E. Dosing and Administration

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Eylea</th>
<th>Lucentis</th>
<th>Macugen</th>
</tr>
</thead>
<tbody>
<tr>
<td>Neovascular (wet) Age-Related Macular Degeneration (AMD)</td>
<td>2 mg ever 4 weeks for 12 Weeks, then 2 mg every 8 weeks thereafter</td>
<td>0.5 mg every 4 weeks</td>
<td>0.3 mg every 6 weeks</td>
</tr>
<tr>
<td>Macular Edema Following Retinal Vein Occlusion (RVO)</td>
<td>2 mg monthly</td>
<td>0.5 mg every 4 weeks</td>
<td>N/A</td>
</tr>
<tr>
<td>Diabetic Macular Edema (DME)</td>
<td>2 mg every 4 weeks for 5 injections, then 2 mg every 8 weeks thereafter</td>
<td>0.3 mg every 4 weeks</td>
<td>N/A</td>
</tr>
<tr>
<td>Diabetic Retinopathy</td>
<td>2 mg every 4 weeks for 5 injections, then 2 mg every 8 weeks thereafter</td>
<td>0.3 mg every 4 weeks</td>
<td>N/A</td>
</tr>
<tr>
<td>Myopic Choroidal Neovascularization (mCNV)</td>
<td>N/A</td>
<td>0.5 mg every 4 weeks</td>
<td>N/A</td>
</tr>
</tbody>
</table>

*Please refer to most recent prescribing information.

F. How supplied

<table>
<thead>
<tr>
<th>Drug</th>
<th>How Supplied</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eylea</td>
<td>2 mg/0.05 mL vial</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>Lucentis</td>
<td>0.3 mg/0.05 mL vial</td>
</tr>
<tr>
<td></td>
<td>0.3 mg/0.05 mL prefilled syringe</td>
</tr>
<tr>
<td></td>
<td>0.5 mg/0.05 mL vial</td>
</tr>
<tr>
<td></td>
<td>0.5 mg/0.05 mL prefilled syringe</td>
</tr>
<tr>
<td>Macugen</td>
<td>0.3 mg/0.09 mL vial</td>
</tr>
</tbody>
</table>

*Please refer to most recent prescribing information.

References:

5. Blue Cross Blue Shield association : Medical Policy: Visudyne® (Verteporfin)
6. Blue Cross Blue Shield Association : Pharmacy and Therapeutic Committee on July 15, 2010: Avastin
7. Lucentis [prescribing information]. South San Francisco, CA Genentech, Inc; March 2018.

This policy and any information contained herein is the property of Blue Cross Blue Shield of Michigan and its subsidiaries, is strictly confidential, and its use is intended for the P&T committee, its members and BCBSM employees for the purpose of coverage determinations.


<table>
<thead>
<tr>
<th>#</th>
<th>Date</th>
<th>Change Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.1</td>
<td>Effective Date: 01/01/2020</td>
<td>PA added to BCBS for Eylea and Lucentis</td>
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<tr>
<td>2.0</td>
<td>Effective Date: 11/7/2019</td>
<td>Updated initial approval lengths</td>
</tr>
<tr>
<td>1.9</td>
<td>Effective Date: 08/15/2019</td>
<td>Updated policy to reflect new Eylea indication (DR)</td>
</tr>
<tr>
<td>1.8</td>
<td>Effective Date: 11/01/2018</td>
<td>Updated policy to reflect new Eylea criteria for DME with visual acuity less than or equal to 20/50</td>
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<tr>
<td>1.7</td>
<td>Effective Date: 08/09/2018</td>
<td>Annual Review of Medical Policy</td>
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<tr>
<td>1.6</td>
<td>Effective Date: 08/10/2017</td>
<td>Updated policy to reflect new Lucentis indication (mCNV) AND (DR)</td>
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<td>1.5</td>
<td>Effective Date: 07/05/2017</td>
<td>PA added to MAPPO and BCNA for Eylea, Lucentis, and Macugen.</td>
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<td>1.4</td>
<td>Effective Date: 02/09/2017</td>
<td>Annual Review; No criteria changes. Updated template.</td>
</tr>
<tr>
<td>1.3</td>
<td>Effective Date: 08/13/2015</td>
<td>Updated policy to reflect new Eylea indication (DR) &amp; updated renewal criteria</td>
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<td>1.2</td>
<td>Effective Date: 05/07/2015</td>
<td>Updated policy to reflect new Lucentis indication(DR) &amp; updated template</td>
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<tr>
<td>1.1</td>
<td>Effective Date: 05/08/2014</td>
<td>Yearly update</td>
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<tr>
<td>1.0</td>
<td>Effective Date: 11/08/2012</td>
<td>New Policy. PA added to BCN for Eylea and Lucentis.</td>
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</table>

* The prescribing information for a drug is subject to change. To ensure you are reading the most current information it is advised that you reference the most updated prescribing information by visiting the drug or manufacturer website or [http://dailymed.nlm.nih.gov/dailymed/index.cfm](http://dailymed.nlm.nih.gov/dailymed/index.cfm).