**EYLEA/LUCENTIS/MACUGEN**

<table>
<thead>
<tr>
<th>Brand Name</th>
<th>Generic Name</th>
<th>Length of Authorization</th>
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<tbody>
<tr>
<td>Eylea</td>
<td>aflibercept</td>
<td>Per Medical Guidelines</td>
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<tr>
<td>Lucentis</td>
<td>ranibizumab</td>
<td>Per Medical Guidelines</td>
</tr>
<tr>
<td>Macugen</td>
<td>pegaptanib sodium</td>
<td>Per Medical Guidelines</td>
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</table>

**Approvable Criteria**

1. Will this be prescribed and administered by a retinal specialist?
   - If yes, continue to #2.
   - If no, do not approve.
2. Is the member diagnosed with neovascular (wet) age-related macular degeneration (AMD)
   or diabetic macular edema (DME)?
   - If yes, continue to #4.
   - If no, continue to #3 for Lucentis and Eylea requests.
3. *(For Lucentis and Eylea requests only)* Is the member diagnosed with macular edema
   following retinal vein occlusion?
   - If yes, continue to #4.
   - If no, continue to #5.
4. Has there been a documented treatment failure of Avastin (bevacizumab)*?
   - If yes, approve for 6 months per dosing schedule below.
   - If no, do not approve.
5. *(For Lucentis only)* Is the member diagnosed with myopic choroidal neovascularization
   (mCNV)?
   - If yes, approve for 3 months per dosing schedule below.
   - If no, do not approve.

**SPECIALTY PHARMACY PRODUCT**

* Based upon clinical evidence from peer-reviewed medical literature, intravitreal injection of Avastin has been proven effective and is medically appropriate for these off-label indications.

Continued on following page...
Eylea Notes:
- **Usual Dose:**
  - For AMD: 2mg (0.05mL) intravitreal injection every 4 weeks for the first 12 weeks, followed by 2mg (0.05mL) once every 8 weeks.
  - For macular edema following retinal vein occlusion: 2mg (0.05mL) intravitreal injection every 4 weeks.
  - For DME: 2mg (0.05mL) intravitreal injection every 4 weeks for the first 5 injections, followed by 2mg (0.05mL) every 8 weeks.
  - Additional efficacy was not demonstrated when Eylea was dosed every 4 weeks compared to every 8 weeks for AMD and DME.

Lucentis Notes:
- **Usual Dose:**
  - For AMD and macular edema following retinal vein occlusion: 0.5mg (0.05mL) intravitreal injection once a month
  - For DME: 0.3mg (0.05mL) intravitreal injection once a month for diabetic macular edema.
  - For mCNV: 0.5mg (0.05mL) intravitreal injection once a month for up to 3 months.
  - Although less effective, treatment may be reduced to 3 once monthly doses, followed by less frequent dosing (i.e., an average of 4 to 5 injections over the subsequent 9 months). Visual acuity can be expected to be maintained with the less frequent dosing, as compared to monthly dosing, which would result in a 1-2 letter gain. Alternatively, patients may also receive 4 once monthly injections followed by 1 injection every three months. Compared to continued monthly dosing, extending the dosing interval to every 3 months will lead to an approximate 5-letter (1 line) loss of visual acuity benefit, on average, over the subsequent 9 months.
  - If used in bilateral eyes, a new vial must be used and sterile field, syringe, gloves, drapes, eyelid speculum, filter, and injection needles must be changed prior to administration to the other eye.*

Macugen Notes:
- **Usual Dose for AMD and DME:** 0.3mg (0.09mL) intravitreal injection once every 6 weeks.
- **Duration of Therapy:** Safety and efficacy beyond two years has not been demonstrated.
- **Macugen is indicated only for monotherapy.**
- **The safety and efficacy of therapy administered to both eyes concurrently have not been studied.**
- **Macugen is not FDA-approved for the treatment of macular edema.**

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* Reference: