Blue Cross Blue Shield Blue Care Network of Michigan

Nonprofit corporations and independent licensees of the Blue Cross and Blue Shield Association

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: 08/15/2019

Brolucizumab (RTH258)

FDA approval: Anticipated 3rd Quarter 2019
HCPCS: N/A
Benefit: Medical

Policy:

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

A. Coverage of the requested drug is provided when all the following are met:
   a. Prescribed by an ophthalmologist
   b. Diagnosis of neovascular (wet) age related macular degeneration (AMD)
   c. Trial and failure of bevacizumab
   d. Trial and failure, intolerance, or a contraindication to the preferred products as listed in the BCBSM/BCN utilization management medical drug list

B. Quantity Limitations, Authorization Period and Renewal Criteria
   a. Quantity Limit: FDA approved dosing
   b. Initial Authorization Period: 6 months
   c. Renewal Criteria: Maintenance or improvement of visual acuity [i.e. stabilization or gain of Snellen and/or ETDRS letters; stabilization or gain of ETDRS-DRSS score]
   d. Renewal Authorization Period: 1 year

***Note: Coverage may differ for Medicare Part B members based on any applicable criteria outlined in Local Coverage Determinations (LCD) or National Coverage Determinations (NCD) as determined by Center for Medicare and Medicaid Services (CMS). See the CMS website at http://www.cms.hhs.gov/. Determination of coverage of Part B drugs is based on medically accepted indications which have supported citations included or approved for inclusion determined by CMS approved compendia.

Therapeutic considerations:

A. **FDA approved indication / Diagnosis**
   a. The treatment of wet age-related macular degeneration (AMD)

*Please refer to most recent prescribing information.
https://www.accessdata.fda.gov/scripts/cder/daf/

B. **Background Information**
   a. Estimates suggest that by 2020, 1.5 to 1.75 million people in the US will be living with wet AMD
   b. Wet AMD is the leading cause of severe vision loss and legal blindness in people over the age of 65 in North America
   c. The disease occurs when abnormal blood vessels form underneath the macula, the area of the retina responsible for sharp, central vision
   d. These blood vessels are fragile and leak fluid, disrupting the normal retinal architecture and ultimately causing damage to the macula
   e. As the disease progresses, patients may experience loss of central vision, resulting in an inability to complete daily tasks
   f. Without treatment, vision can rapidly deteriorate and may lead to blindness
   g. The American Academy of Ophthalmology state early detection and treatment of AMD to arrest the deterioration in vision may help preserve patients' quality of life and independence
   h. Anti-VEGF therapies have become first-line therapy for treating and stabilizing most cases of wet AMD
   i. Guidelines do not recommend use of one anti-VEGF over another
   j. Brolucizumab has not yet been addressed by the current treatment guidelines

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**
   a. Dosing: 6 mg every 12 weeks by intravitreal injection

Please refer to most recent prescribing information.

F. **How supplied**
   a. Unknown at this time

References:

1. Novartis Press Release. Novartis announces FDA filing acceptance and priority review of brolucizumab (RTH258) for patients with wet AMD. April 15, 2019. Available at: https://www.novartis.com/news/media-releases/novartis-announces-fda-filing-acceptance-and-priority-review-brolucizumab-rth258-patients-wet-amd Accessed on: June 5, 2019.
2. American Academy of Ophthalmology. Age-related macular degeneration preferred practice patterns. January 2015. Available at: https://www.aao.org/preferred-practice-pattern/age-related-macular-degeneration-ppp-2015. Accessed on: June 6, 2019.
3. van Lookeren, Campagne M, et al. Mechanisms of age-related macular degeneration and therapeutic opportunities. J Pathol. 2014; 232(2): 151-64.

4. Dugel PU, Koh A, Ogura Y, et al. HAWK and HARRIER: Phase 3 multicenter, randomized, double-masked trials of brolucizumab for neovascular age-related macular degeneration. Presented at: The American Academy of Ophthalmology 2017 Annual Meeting on November 10, 2017. New Orleans.
5. Clinicaltrials.gov. Efficacy and safety of RTH258 versus aflibercept. (NCT02307682) Available at: https://clinicaltrials.gov/ct2/show/NCT02307682?term=NCT02307682&rank=1. Accessed on June 5, 2019.
6. Clinicaltrials.gov. Efficacy and safety of RTH258 versus aflibercept – study 2. (NCT02434328) Available at: https://clinicaltrials.gov/ct2/show/NCT02434328?term=NCT02434328&rank=1. Accessed on June 5, 2019.
7. Wong, WL, et al. Global prevalence of age-related macular degeneration and disease burden projection for 2020 and 2040: a systematic review and met analysis. Lancet Glob Health. 2014 Feb; 2(2): e106-16.
8. World Health Organization. Priority eye diseases: age-related macular degeneration. Available at http://www.who.int/blindness/causes/priority/en/index7.html. Accessed on June 5, 2019.

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<tr><td>BCN</td><td>No</td></tr>
<tr><td>MAPPO</td><td>No</td></tr>
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L. **How supplied**
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References:

9. Novartis Press Release. Novartis announces FDA filing acceptance and priority review of brolucizumab (RTH258) for patients with wet AMD. April 15, 2019. Available at: https://www.novartis.com/news/media-releases/novartis-announces-fda-filing-acceptance-and-priority-review-brolucizumab-rth258-patients-wet-amd Accessed on: June 5, 2019.
10. American Academy of Ophthalmology. Age-related macular degeneration preferred practice patterns. January 2015. Available at: https://www.aao.org/preferred-practice-pattern/age-related-macular-degeneration-ppp-2015. Accessed on: June 6, 2019.
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12. Dugel PU, Koh A, Ogura Y, et al. HAWK and HARRIER: Phase 3 multicenter, randomized, double-masked trials of brolucizumab for neovascular age-related macular degeneration. Presented at: The American Academy of Ophthalmology 2017 Annual Meeting on November 10, 2017. New Orleans.
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14. Clinicaltrials.gov. Efficacy and safety of RTH258 versus aflibercept – study 2. (NCT02434328) Available at: https://clinicaltrials.gov/ct2/show/NCT02434328?term=NCT02434328&rank=1. Accessed on June 5, 2019.
15. Wong, WL, et al. Global prevalence of age-related macular degeneration and disease burden projection for 2020 and 2040: a systematic review and met analysis. Lancet Glob Health. 2014 Feb; 2(2): e106-16.
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Blue Cross Blue Shield/Blue Care Network of Michigan
Medication Authorization Request Form

Eylea® (aflibercept): J0178, Lucentis® (ranibizumab): J2778, Macugen® (pegaptanib): J2503, Beovu® (brolucizumab-dbll): J3490/J3590

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This form is to be used by participating physicians to obtain coverage for Eylea, Lucentis, Macugen, or Beovu. For commercial members only, please complete this form and submit via fax to 1-877-325-5979. If you have any questions regarding this process, please contact BCBSM Provider Relations and Servicing or the Medical Drug Helpdesk at 1-800-437-3803 for assistance.

PATIENT INFORMATION	PHYSICIAN INFORMATION
Name	**Name**
ID Number	**Specialty**
D.O.B. ☐Male ☐Female	**Address**
Diagnosis	**City /State/Zip**
Drug Name	**Phone/Fax: P**: ( ) - **F**: ( ) -
Dose and Quantity	**NPI**
Directions	**Contact Person**
Date of Service(s)	**Contact Person Phone / Ext.**

STEP 1: DISEASE STATE INFORMATION

1. Is this request for: ☐ Initiation ☐ Continuation *Date patient started therapy:* _____
2. Please provide the NPI number for the place of administration: _____
3. **Initiation AND Continuation of therapy:**
   a. What is the patient's diagnosis?
      ☐ Neovascular (wet) age-related macular degeneration (AMD)
      ☐ Macular edema due to retinal vein occlusion (RVO)
      ☐ Diabetic macular edema (DME)
         i. Is the patient's visual acuity in the affected eye(s) equal to or worse than 20/50? (For Eylea only)
            ☐ Yes ☐ No
      ☐ Diabetic retinopathy (DR)
      ☐ Myopic choroidal neovascularization (mCNV)
      ☐ Other, Please specify: _____
   b. Has the patient tried Avastin therapy? ☐ Yes ☐ No
      i. If yes, what was the response?
      _____
   c. Has the patient failed treatment with other anti–VEGF therapy? ☐ Yes ☐ No
      i. If yes, List what treatment(s) patient failed:
      _____
4. **Continuation of therapy:**
   a. How has the patient's condition changed while on therapy?
      ☐ Improved; Please describe: _____
      ☐ Stable; Please describe: _____
      ☐ Worsened; Please describe: _____
      ☐ Other; Please describe: _____

Please add any other supporting medical information necessary for our review

Coverage will not be provided if the prescribing physician's signature and date are not reflected on this document.

☐ Request for expedited review: I certify that applying the standard review time frame may seriously jeopardize the life or health of the member or the member's ability to regain maximum function

Physician's Name **Physician Signature** **Date**

Step 2: Checklist	☐ Form Completely Filled Out ☐ Attached chart notes	☐ Pertinent test results
Step 3: Submit	**By Fax: BCBSM Specialty Pharmacy Mailbox 1-877-325-5979**	**By Mail: BCBSM Specialty Pharmacy Program P.O. Box 312320, Detroit, MI 48231-2320**

4/16/2018;10/11/2018; 11/4/2019