Ranibizumab

NDC CODE(S) 50242-0080-XX LUCENTIS 0.5MG/0.05ML Solution (GENENTECH)
50242-0082-XX LUCENTIS 0.3MG/0.05ML Solution (GENENTECH)
50242-0082-XX LUCENTIS 0.3MG/0.05ML Solution Prefilled Syringe (GENENTECH)

DESCRIPTION

Ranibizumab is a vascular endothelial growth factor (VEGF) inhibitor. It is a fragment of a monoclonal antibody which binds to and inhibits the biologic activity of VEGF-A. VEGF-A has been shown to cause neovascularization and leakage in models of ocular angiogenesis and vascular occlusion. It is thought to contribute to the pathophysiology of neovascular age-related macular degeneration, macular edema following retinal vein occlusion, diabetic retinopathy and diabetic macular edema. The binding of ranibizumab to VEGF-A prevents the interaction of VEGF-A with its receptors on the surface of endothelial cells, reducing endothelial cell proliferation, vascular leakage, and new blood vessel formation

POLICY

- Ranibizumab for the treatment of the following is considered ***medically necessary*** if the medical appropriateness criteria are met. **(See Medical Appropriateness below.)**
  - Diabetic Macular Edema (DME)
  - Diabetic Retinopathy (DR)
  - Neovascular (Wet) Age-Related Macular Degeneration (AMD)
  - Macular Edema Following Retinal Vein Occlusion (RVO)
  - Myopic Choroidal Neovascularization (mCNV)
- Ranibizumab for the treatment of other conditions/diseases is considered ***investigational.***

MEDICAL APPROPRIATENESS

INITIAL APPROVAL

- Ranibizumab is considered **medically appropriate** if **ALL** of the following criteria are met:
  - Individual is 18 years of age or older
  - Individual is free of ocular and/or peri-ocular infections
  - Therapy will not be used with other ophthalmic VEGF inhibitors (i.e., aflibercept, pegaptanib, brolucizumab-dbll, bevacizumab, etc.)
  - Definitive diagnosis of **ANY ONE** of the following
    - Diabetic Macular Edema (DME)
    - Diabetic Retinopathy (DR)
    - Macular Edema Following Retinal Vein Occlusion (RVO)
    - Myopic Choroidal Neovascularization (mCNV)
    - Neovascular (Wet) Age-Related Macular Degeneration (AMD) and **BCBST requirement:** Documentation of prior trial and failure of **ANY ONE** of the following:
      - Bevacizumab
      - Bevacizumab-awwb
      - Bevacizumab-bvzr

RENEWAL CRITERIA

- Ranibizumab is considered **medically appropriate** for renewal if **ALL** of the following criteria are met:

- Individual continues to meet initial approval criteria
- Absence of unacceptable toxicity from the agent. Examples of unacceptable toxicity include the following: e.g., endophthalmitis and retinal detachments, increase in intraocular pressure, arterial thromboembolic events, etc.
- Individual had a beneficial response to therapy and **ANY ONE** of the following:
  - Continued administration is necessary for the maintenance treatment of the condition
  - In myopic choroidal neovascularization ONLY continued administration is necessary due to disease activity such as a drop in vision, visual symptoms (e.g., metamorphopsia), or the presence of intra-/sub-retinal fluid or active leakage

INDICATION(S)	DOSAGE & ADMINISTRATION
Diabetic macular edema and Diabetic retinopathy (DR)	0.3 mg intravitreally per affected eye once a month (approximately 28 days)
AMD* and macular edema following RVO	0.5 mg intravitreally per affected eye once a month (approximately 28 days)
Myopic Choroidal Neovascularization (mCNV)	0.5 mg intravitreally per affected eye once a month (approximately 28 days) for up to 3 months Patients may be retreated if needed.
* Individuals with AMD may be treated with 3 monthly doses followed by less frequent dosing (4-5 doses on average in the following 9 months) or one dose every 3 months after 4 monthly doses. Patients should be assessed regularly.	

LENGTH OF AUTHORIZATION

Coverage for myopic choroidal neovascularization (mCNV) will be provided for 3 months and may be renewed

Coverage for all other indications will be provided annually and may be renewed

Refer to **DOSAGE LIMITS** below

APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

BlueCross BlueShield of Tennessee's Medical Policy complies with Tennessee Code Annotated Section 56-7-2352 regarding coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is recognized in one of the statutorily recognized standard reference compendia or in the published peer-reviewed medical literature.

IMPORTANT REMINDER

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the Medical Policy and a health plan, the express terms of the health plan will govern.

ADDITIONAL INFORMATION

For appropriate chemotherapy regimens, dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) published by the National Comprehensive Cancer Network®, Drugdex Evaluations of Micromedex Solutions at Truven Health, or The American Hospital Formulary Service Drug Information).

SOURCES

Lexi-Comp Online. (2020, March). AHFS DI. *Ranibizumab.* Retrieved November 3, 2020 from Lexi-Comp Online with AHFS.

MICROMEDEX Healthcare Series. Drugdex Drug Evaluations. (2020, August). *Ranibizumab*. Retrieved November 3, 2020 from MICROMEDEX Healthcare Series.

U. S. Food and Drug Administration. (2017, April). Center for Drug Evaluation and Research. *Lucentis® (ranibizumab)*. Retrieved November 4, 2020 from https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/125156s114lbl.pdf.

EFFECTIVE DATE 4/2/21

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