Pegaptanib Sodium

NDC CODE(S) 68782-0001-XX MACUGEN 0.3MG/0.09ML Solution (BAUSCH HEALTH)

DESCRIPTION

Pegaptanib sodium is a selective vascular endothelial growth factor (VEGF) antagonist. VEGF is a secreted protein that selectively binds and activates its receptors located primarily on the surface of vascular endothelial cells. It induces angiogenesis, and increases vascular permeability and inflammation, all of which are thought to contribute to the progression of the neovascular (wet) form of age-related macular degeneration (AMD), a leading cause of blindness.

Pegaptanib is an aptamer, a pegylated modified oligonucleotide. It adopts a three-dimensional conformation that enables it to bind to extracellular VEGF and is effective at suppressing pathological neovascularization.

POLICY

- Pegaptanib sodium for the treatment of the following is considered ***medically necessary*** if the medical appropriateness criteria are met. **(See Medical Appropriateness below.)**
  - Diabetic macular edema
  - Diabetic retinopathy
  - Neovascular (wet) age-related macular degeneration

- Pegaptanib sodium for the treatment of other conditions/diseases is considered ***investigational.***

MEDICAL APPROPRIATENESS

INITIAL APPROVAL

- Pegaptanib sodium is considered **medically appropriate** if **ALL** of the following criteria are met:
  - Individual is 18 years of age or older
  - Free from ocular and/or periocular infections
  - Therapy will not be used with other ophthalmic VEGF inhibitors (i.e., aflibercept, ranibizumab, brolucizumab-dbll, bevacizumab, etc.)
  - Definitive diagnosis of **ANY ONE** of the following
    - Diabetic macular edema
    - Diabetic retinopathy
    - 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

- Pegaptanib sodium is considered **medically appropriate** for renewal if **ALL** of the following criteria are met:
  - Individual continues to meet initial approval criteria
  - Continued administration is necessary for the maintenance treatment of the condition
  - Individual had a beneficial response to therapy

- Absence of unacceptable toxicity from the agent. Examples of unacceptable toxicity include the following: endophthalmitis, increase in intraocular pressure, anaphylaxis/anaphylactoid reactions, etc.

INDICATION(S)	DOSAGE & ADMINISTRATION
All indications	0.3 mg intravitreally once every 6 weeks into the eye to be treated** ***NOTE: The safety and efficacy of administration to both eyes concurrently have not been established*

LENGTH OF AUTHORIZATION

Coverage 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. *Pegaptanib sodium*. Retrieved November 3, 2020 from Lexi-Comp Online with AHFS.

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

U. S. Food and Drug Administration. (2011, July). Center for Drug Evaluation and Research. *Macugen® (pegaptanib sodium injection) intravitreal injection*. Retrieved November 4, 2020 from http://www.accessdata.fda.gov/drugsatfda_docs/label/2011/021756s018lbl.pdf.

EFFECTIVE DATE 4/2/21

ID_MRx