

MVP/Preferred Care BENEFIT INTERPRETATION MANUAL
Age-Related Macular Degeneration (AMD) Treatments

Type of Policy

Medical

Codes

CPT: 67221, 67225

ICD-9: 362.52 (PRIMARY) AND 362.16 (SECONDARY), 115.02, 115.92, 360.21, 362.50

HCPCS: J3396 Visudyne® (Injection, verteporfin, 0.1 mg), J2503 Macugen® (Injection, pegaptanib sodium, 0.3 mg), J3490 Lucentis® (Unclassified biologics, ranibizumab, 0.5mg)

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Evidence Basis for Policy

Standard of Care. The procedure, device, or drug is accepted medical practice as evidenced by an abundance of scientific literature and well-designed clinical trials.

Description

The advanced or “wet” form of age-related macular degeneration is characterized by the growth of abnormal blood vessels. This is sometimes referred to as “choroidal neovascularization” or CNV and is associated with the expression of vascular endothelial growth factor in the retina and surrounding tissue. This factor is linked with the formation and growth of these CNV although there can be several types of CNV (minimally classic, classic, occult), the characteristics are similar. These blood vessels begin to leak fluid and blood which dries and forms a “disciform” scar. This scarring destroys central vision and the eye is left with peripheral vision only. Laser photocoagulation has been the mainstay of treatment for years. Both “hot” laser and “cold” laser (ocular photodynamic therapy) have been shown to be useful. A more recent strategy to treat the wet form of macular degeneration is to block the VEGF action by using anti-VEGF drugs which are injected directly into the eye.

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Indications/Criteria

Documentation Requirements

Medical necessity must be documented in the medical record and available upon request.

For Photodynamic Therapy, documentation should include results of a fluorescein angiogram and, if applicable, optical coherence tomography, which demonstrates classic or occult subfoveal choroidal neovascularization (CNV) and whether the member has previously undergone this procedure.

For Anti-VEGF Therapy, the patient's medical record should contain documentation supporting the diagnosis of "wet" macular degeneration, including a history, physical examination with measurement of visual acuity, and at least a baseline diagnostic fluorescein angiography or OCT. The medical record should support failure of another anti-VEGF therapy prior to treatment with Lucentis®.

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Ocular Photodynamic Therapy (OPT):

- Ocular Photodynamic Therapy with verteporfin is indicated for those members with predominately classic, subfoveal choroidal neovascularization (CNV) secondary to age-related macular degeneration. "Predominantly classic" subfoveal lesions are defined as those in which the area of classic CNV is at least 50% of the area of the entire lesion at baseline as determined by fluorescein angiograms.
- OPT is also covered for the treatment of age-related macular degeneration only when the patient has subfoveal occult with no classic CNV associated with AMD and subfoveal choroidal neovascular (CNV) lesions (where the area of classic CNV occupies at least 50% of the area of the entire lesion) and there is potential for visual acuity to deteriorate further to such a point that it would render the patient's functional vision worse than at the level prior to treatment. These indications are considered reasonable and necessary only when the following criteria are met:
 - the lesions are small (four disk areas or less in size) at the time of initial treatment or within the three months prior to initial treatment; and
 - the lesions have shown evidence of progression within the three months prior to initial treatment. Evidence of progression must be documented by deterioration of visual acuity (at least five letters on a standard eye examination chart), lesion growth (an increase in at least one disk area), or the appearance of blood associated with the lesion.
- Ocular Photodynamic Therapy with verteporfin is also indicated for members with Pathologic Myopia (PM) and Presumed Occular Histoplasmosis (OH) when the choroidal neovascularization lies under the geometric center of the foveal avascular zone.
- Members treated with verteporfin may need to be re-treated. All members having a re-treatment need to have a fluorescein angiogram performed prior to each treatment. Re-treatment is necessary if fluorescein angiograms show any sign of recurrence or persistence of leakage and the treating ophthalmologist believes that the therapy is indicated to reduce the risk of at least moderate vision loss compared to baseline visual acuity. Typically, treatment is not required greater than four (4) times per eye per year.

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Anti-Vascular Endothelial Growth Factor (VEGF) Therapy:

Anti-VEGF medications indicated for the treatment of patients with neovascular (wet) age-related macular degeneration. Treatment with anti-VEGF therapy is limited to fellowship-trained retinal specialists and requires prior authorization.

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Members with subfoveal sites of CNV 2° to age-related Macular Degeneration:

- Members with subfoveal choroidal neovascularization secondary to age-related macular degeneration with a visual acuity between 20/40 – 20/320.
- All angiography subtypes (minimally classic, classic, occult) with lesion sizes up to 12 disc areas (including blood, scar/atrophy, and neovascularization) with no greater than 50% of the lesion comprised of subretinal hemorrhage.
- Members with minimally classic or occult lesions with at least one of the following:
 - subretinal hemorrhage but not more than 50% of the lesion;
 - presence of lipid; or
 - loss of 15 or more letters (approximately three (3) lines on the eye chart) of visual acuity during the previous 12 weeks.

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Combination Therapies

Combination PDT and anti-VEGF therapy will be reviewed on a case-by-case basis. The medical record should support failure of anti-VEGF monotherapy prior to treatment with combination therapy.

The medical literature does not support the use of two anti-VEGF medications used in combination, and is, therefore, not covered.

Deleted: Treatment of neovascular (wet) age-related macular degeneration (AMD) with verteporfin, in combination with anti-angiogenesis drugs is not supported by clinical trial outcomes and is not a covered benefit. This is not true as more and more studies are coming out. In our practice we have been using combo RX and when you compare it to Lucentis at \$2300/dose X 12 mos it is about \$30,000/yr per patient. Our and others combo data show 1.6 PDT per year and 3.3 Avastin per year are equally efficacious to Lucentis monotherapy. If PC is concerned about using an FDA approved Rx-this will not happen for a variety of economic and political reasons. You can decide that Avastin in combination with PDT will not be covered but we will continue to offer it to our patients and they will continue to pay out of pocket for Avastin at a HUGE savings to PC.¶

Exclusions/Limitations

The following would not be medically indicated for photodynamic therapy:

- re-treatments greater than four (4) times a year per eye;
- photodynamic therapy for subfoveal choroidal neovascularization (CNV) from other causes such as angioid streaks and idiopathic causes are still under investigation;
- lesions outside the fovea (juxtafoveal or extrafoveal);
- atrophic or "dry" AMD or drusen;
- "off-label" use of verteporfin; or
- if the palliative effect of photodynamic therapy with verteporfin, which is to stem the inexorable loss of visual function is lost, photodynamic therapy would no longer be medically indicated for the member.

The following would not be medically indicated for anti-VEGF therapy:

- atrophy exceeding 25% OF THE TOTAL LESION;
- subfoveal scarring in the treatment eye;
- other potential causes of CNV:
 - myopia of eight (8) diopters or more;

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- ocular histoplasmosis;
- angioid streaks;
- choroidal rupture; and
- multifocal choroiditis;
- presence of retinal pigment epithelial tears/rips;
- diabetic retinopathy;
- acute ocular or periocular infection;
- likelihood of requiring cataract surgery within two (2) years; or
- upon review, drug coverage will be excluded unless the drug is recognized as safe and effective for treatment of the specific diagnosis for which the drug has been prescribed in one of the following:
 - the American Hospital Formulary Service Drug Information; or
 - the United States Pharmacopeia Drug Information; or
 - recommended by review article or editorial comment in a major peer reviewed professional journal and has been proven effective in at least two Phase II or Phase III well-designed clinical trials and well-conducted investigations.

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Deleted: (i) the American Medical Association Drug Evaluations;or

References

Literature (Search updated in 2007)

- Pegaptanib Sodium Injection (Macugen™), Eyetech Pharmaceuticals, Pfizer, Inc., Dermatologic and Ophthalmic Advisory Committee, August 27, 2004.
- Gragoudas Evangelos, Adamis Anthony, et al. Pegaptanib for Neovascular Age-Related Macular Degeneration. New England Journal of Medicine. 351:27 December 30, 2004.
- Macugen® (pegaptanib sodium injection), Package insert. Eyetech, Pfizer. FDA Approves New Drug Treatment for Age-Related Macular Degeneration. FDA News December 20, 2004. [On-Line] available: www.fda.gov/bbs/topics/news/2004/.
- Empire Medicare Services LCD: Ocular Photodynamic Therapy (OPT) (OP011E02). Effective: 4/1/03. Available: [On-Line] www.empiremedicare.com.
- Verteporfin Therapy of Subfoveal Choroidal Neovascularization in AMD: Meta: Analysis of Two-Year Safety Results in Three Randomized Clinical Trials, Retina, (Abstract) February 2004, 24.
- The Centers for Medicare & Medicaid Services (CMS), National Coverage Determination, Ocular Photodynamic Therapy, publication # 100-3, effective: 4/1/04. Available: [On-Line] www.cms.hhs.gov.
- Upstate Medicare Division, LMRP OP011E00, effective 8/17/03, Ocular Photodynamic Therapy (OPT). [On-Line] Available: www.umd.nycpic.com.
- American Academy of Ophthalmology, Preferred Practice Pattern: Age-Related Macular Degeneration. September, 2003.
- Aetna, (2002). Visudyne (Verteporfin) photodynamic therapy.
- Health Care Financing Administration (HCFA), (2001). Verteporfin(Visudyne™), The Coverage Issues Manual, Section 35-100 and Section 45-30, July 1, 2001. Medicare News Brief – New York 2001-6:pp. 25-26.
- FDA Updates (2001). Visudyne approved for pathologic myopia, presumed ocular histoplasmosis. Available: www.pharmscope.com/news.

Deleted: I would suggest that these treatments be limited to fellowship-trained retinal specialists unless access to a specialist is unavailable.¶
Combination Therapie

Wormalk, R., Evans, J., Smeeth, L. (2001). Photodynamic therapy for neovascular age-related macular degeneration. The Cochrane Library, 2. Available: www.medscape.com.

Centers for Medicare & Medicaid Services (CMS), (2001). Coverage Decision Memorandum for Ocular Photodynamic Therapy with Verteporfin for Macular Degeneration (#CAG-00066R). Available: www.cms.hhs.gov/coverage.

Centers for Medicare and Medicaid Services (CMS), 2002. Coverage Decision Memorandum for Ocular Photodynamic Therapy with Verteporfin for Macular Degeneration (#CAG 00066R2). www.cms.hhs.gov/coverage.

American Academy of Ophthalmology. (2000). Background on visudyne coding and payment history. *Federal Affairs. EyeNet*. (On-line) Available: www.eyenet.org.

American Academy of Ophthalmology. (2000). Photodynamic therapy using verteporfin for age-related macular degeneration. *Rapid Clinical Report. EyeNet*. (On-line) Available: www.eyenet.org.

ECRI (2000). Target Report #425: Photodynamic therapy (PDT) for wet age-related macular degeneration (AMD).

ECRI (2000). FDA clears combined laser/drug therapy to slow vision loss. *Health Technology Trends* vol.12(5):1-2.

Fine, S. L., Berger, J. W., Maguire, M. G., Ho, A. C. (2000). Age-related macular degeneration. *New England Journal of Medicine*, 342(7), 483-492.

Treatment of Age-related Macular Degeneration With Photodynamic Therapy (TAP) Study Group. (1999). Photodynamic therapy of subfoveal choroidal neovascularization in age-related macular degeneration with verteporfin: One-year results of two (2) randomized clinical trials-TAP report 1. *Archives of Ophthalmology*, 117, (Oct.), 1329-1345. (On-line) Available: www.archophthalmol.com.

[Visudyne® Prescribing Information Novartis October 2005.](#)
[Macugen® Prescribing Information Pfizer July 2006.](#)
[Lucentis® Prescribing Information Genentech 2006.](#)

Approvals & Review/Revisions

Medical:

Review:

Eye Advisory Team: 5/30/07

Approval:

Quality Improvement Committee: 10/8/07

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Note: For Preferred Care authorization requirements refer to Appendix A and Appendix B in the Referral/Precertification/Prior Authorization/Notification Administrative Policy. You may also refer to the "Prior Authorization/Precertification of Certain Prescription Drugs" for information on drugs that require precertification and prior authorization.. Both policies are available on the easylink for Providers at www.preferredcare.org.

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<http://www.allaboutvision.com/conditions/lucentis-vs-avastin.htm>

<http://content.nejm.org/cgi/content/full/355/14/1409>

<http://linkinghub.elsevier.com/retrieve/pii/S0161642005014375>

<http://www.retinajournal.com/pt/re/retina/abstract.00006982-200605000-00002.htm;jsessionid=GGwPYbgBWxsGcb3b2bCmFYy1sydWzbZqB4ckDm1zF3fFrJh1tycTl721371455!-949856145!8091!-1>

<http://linkinghub.elsevier.com/retrieve/pii/S0002939406003321>

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<http://linkinghub.elsevier.com/retrieve/pii/S0002939405012845>

<http://www.retinajournal.com/pt/re/retina/abstract.00006982-200605000-00002.htm;jsessionid=GGxL1dxyHpLc0JvMc7JWRgiG31Yp8vGKmxSpJ4H34CTRfQXttZ1L!-377544086!-949856144!8091!-1>

<http://linkinghub.elsevier.com/retrieve/pii/S0002939406002327>