Reference number(s)
1984-A

STANDARD MEDICARE PART B MANAGEMENT

VISUDYNE (verteporfin)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indications
Predominantly classic subfoveal choroidal neovascularization due to age-related macular degeneration, pathologic myopia, or presumed ocular histoplasmosis.

B. Compendial Uses
Non-melanoma skin cancer

C. Nationally Covered Indication
CMS covers Visudyne for age-related macular degeneration in specific circumstances. See Section III for more information.

All other indications will be assessed on an individual basis. Submissions for indications other than those enumerated in this policy should be accompanied by supporting evidence from Medicare approved compendia.

II. EXCLUSIONS

A. The following exclusion applies to all requests for Visudyne
Use of Visudyne is excluded when it is not used in conjunction with ocular photodynamic therapy or not administered intravenously

B. The following exclusions apply to requests for Visudyne for age-related macular degeneration (AMD)
1. Treatment of juxtafoveal or extrafoveal CNV lesions (lesions outside the fovea)
2. Inability to obtain a fluorescein angiogram
3. Atrophic or “dry” AMD

III. CRITERIA FOR INITIAL APPROVAL

A. Neovascular (wet) age-related macular degeneration
Authorization of 12 months may be granted for treatment of neovascular age-related macular degeneration when any of the following criteria are/is met:
1. The member has predominately classic subfoveal choroidal neovascularization (CNV) lesions, where the area of classic CNV occupies at least 50% of the area of the entire lesion, at the initial visit as determined by a fluorescein angiogram.

2. The member has subfoveal occult with no classic CNV associated with AMD and meets both criteria below:
   i. The lesions are small (4 disk areas or less in size) at the time of initial treatment or within the 3 months prior to initial treatment.
   ii. The lesions have shown evidence of progression within the 3 months prior to initial treatment. Evidence of progression must be documented by deterioration of visual acuity (at least 5 letters on a standard eye examination chart), lesion growth (an increase in at least 1 disk area), or the appearance of blood associated with the lesion.
3. The member has subfoveal minimally classic CNV, where the area occupies less than 50% of the area of the entire lesion, associated with AMD and meets both criteria below:
   i. The lesions are small (4 disk areas or less in size) at the time of initial treatment or within the 3 months prior to initial treatment.
   ii. The lesions have shown evidence of progression within the 3 months prior to initial treatment. Evidence of progression must be documented by deterioration of visual acuity (at least 5 letters on a standard eye examination chart), lesion growth (an increase in at least 1 disk area), or the appearance of blood associated with the lesion.

B. Pathologic myopia associated with classic subfoveal choroidal neovascularization
Authorization of 12 months may be granted for treatment of pathologic myopia associated with classic subfoveal choroidal neovascularization.

C. Presumed ocular histoplasmosis associated with classic subfoveal choroidal neovascularization
Authorization of 12 months may be granted for the treatment of presumed ocular histoplasmosis associated with classic subfoveal choroidal neovascularization.

D. Non-melanoma skin cancer[2]
Authorization of 12 months may be granted for the treatment of non-melanoma skin cancer.

IV. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

Authorization for 12 months may be granted when all of the following criteria are met:
A. The member is currently receiving therapy with Visudyne.
B. None of the exclusions delineated in section II are met.
C. Visudyne is being used to treat an indication enumerated in Section III.
D. The medication has been effective for treating the diagnosis or condition.

V. REFERENCES

1. Visudyne [package insert]. Charleston, SC: Alcami Carolinas Corporation; September 2020.
2. Micromedex Solutions [database online]. Truven Health Analytics, Greenwood Village, Colorado, USA. Available at: http://www.micromedexsolutions.com/. Accessed February 11, 2021.
3. National Coverage Determination (NCD) for Verteporfin (80.3.1). Version 2. https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=350&ncdver=2&DocID=80.3.1&SearchType=Advanced&bc=EAAAAAgAAAAA& Accessed February 12, 2021.
4. American Academy of Ophthalmology Retinal/Vitreous Panel. Preferred Practice Pattern® Guidelines. Age-Related Macular Degeneration. San Francisco, CA: American Academy of Ophthalmology; 2019. Available at: https://www.aao.org/preferred-practice-pattern/age-related-macular-degeneration-ppp.