Reference number(s)
1984-A

Standard Medicare Part B Management Visudyne

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Visudyne	verteporfin

Indications

FDA-approved Indications[1]

Visudyne for injection is indicated for the treatment of patients with predominantly classic subfoveal choroidal neovascularization due to age-related macular degeneration, pathologic myopia, or presumed ocular histoplasmosis.

Compendial Uses[2]

Non-melanoma skin cancer

Nationally Covered Indication[3]

CMS covers Visudyne for age-related macular degeneration in specific circumstances. See coverage criteria section 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.

© 2025 CVS Caremark. All rights reserved.

This document contains confidential and proprietary information of CVS Caremark and cannot be reproduced, distributed or printed without written permission from CVS Caremark. This document contains prescription brand name drugs that are trademarks or registered trademarks of pharmaceutical manufacturers that are not affiliated with CVS Caremark.

Exclusions

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

Coverage Criteria

Neovascular (Wet) Age-related Macular Degeneration[1,3]

- Authorization of 12 months may be granted for treatment of neovascular age-related macular degeneration when any of the following criteria are/is met:
    - 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.
    - The member has subfoveal occult with no classic CNV associated with AMD and meets both criteria below:
        - 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.
        - 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.
    - 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:
        - 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.
        - 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.

© 2025 CVS Caremark. All rights reserved.

This document contains confidential and proprietary information of CVS Caremark and cannot be reproduced, distributed or printed without written permission from CVS Caremark. This document contains prescription brand name drugs that are trademarks or registered trademarks of pharmaceutical manufacturers that are not affiliated with CVS Caremark.

Pathologic Myopia Associated with Classic Subfoveal Choroidal Neovascularization[1]

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

Presumed Ocular Histoplasmosis Associated with Classic Subfoveal Choroidal Neovascularization[1]

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

Non-melanoma Skin Cancer[2]

- Authorization of 12 months may be granted for the treatment of non-melanoma skin cancer.

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:

- The member is currently receiving therapy with requested medication.
- None of the exclusions delineated in exclusions section are met.
- The requested medication is being used to treat an indication enumerated in coverage criteria section.
- The medication has been effective for treating the diagnosis or condition.

Summary of Evidence

The contents of this policy were created after examining the following resources:

- The prescribing information for Visudyne.
- The available compendium
    - National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
    - Micromedex DrugDex
    - American Hospital Formulary Service- Drug Information (AHFS-DI)
    - Lexi-Drugs
    - Clinical Pharmacology

© 2025 CVS Caremark. All rights reserved.

This document contains confidential and proprietary information of CVS Caremark and cannot be reproduced, distributed or printed without written permission from CVS Caremark. This document contains prescription brand name drugs that are trademarks or registered trademarks of pharmaceutical manufacturers that are not affiliated with CVS Caremark.

- American Academy of Ophthalmology Retinal/Vitreous Panel. Preferred Practice Pattern® Guidelines. Age-Related Macular Degeneration.
- National Coverage Determination: Verteporfin

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Visudyne are covered in addition to non-melanoma skin cancer

Explanation of Rationale

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

Support for using Visudyne to treat non-melanoma skin cancer can be found in the Micromedex DrugDex database. Use of information in the DrugDex database for off-label use of drugs and biologicals in an anti-cancer chemotherapeutic regimen is supported by the Medicare Benefit Policy Manual, Chapter 15, section 50.4.5 (Off-Label Use of Drugs and Biologicals in an Anti-Cancer Chemotherapeutic Regimen).

Predominantly classic subfoveal choroidal neovascularization due to age-related macular degeneration is covered according to the conditions outlined in National Coverage Determination Manual section 80.3.1 (Verteporfin).

References

1. Visudyne [package insert]. Charleston, SC: Alcami Carolinas Corporation; February 2023.
2. Micromedex Solutions [database online]. Truven Health Analytics, Greenwood Village, Colorado, USA. Available at: http://www.micromedexsolutions.com/. Accessed December 16, 2024.
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 December 16, 2024.
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

© 2025 CVS Caremark. All rights reserved.

This document contains confidential and proprietary information of CVS Caremark and cannot be reproduced, distributed or printed without written permission from CVS Caremark. This document contains prescription brand name drugs that are trademarks or registered trademarks of pharmaceutical manufacturers that are not affiliated with CVS Caremark.