Visudyne® (verteporfin)
(Intravenous)

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I. Length of Authorization

Coverage will be provided for 1 infusion per eye every 3 months and may be renewed.

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

- Visudyne 15 mg single-dose vial: 1 vial every 3 months per eye

B. Max Units (per dose and over time) [HCPCS Unit]:

- 300 billable units every 3 months

(Max units are based on administration to both eyes)

III. Initial Approval Criteria [1]

Coverage is provided in the following conditions:

- Patient is at least 18 years of age; **AND**

Universal Criteria

- Must be used with activation process via light from a nonthermal diode laser; **AND**
- Must not be used in combination with any anti-angiogenic agents (e.g., bevacizumab, aflibercept, ranibizumab, pegaptanib, brolucizumab, faricimab, etc.); **AND**
- Patient does not have porphyria; **AND**

Classic Subfoveal Choroidal Neovascularization (CNV) †

- Patient's condition is associated with one of the following:
  - Neovascular age-related macular degeneration (AMD); **OR**
  - Ocular histoplasmosis; **OR**
  - Pathologic myopia

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Φ Orphan Drug

IV. Renewal Criteria [1]

Coverage can be renewed based upon the following criteria:

- Patient continues to meet the universal and other indication-specific relevant criteria identified in section III; **AND**
- Disease response with treatment as indicated by an improvement in lines of visual acuity from baseline and/or reduction in the number of episodes of severe visual acuity loss; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: extravasation, severe decrease in visual acuity, anaphylactic/serious allergic reactions, etc.

V. Dosage/Administration [1]

Indication	Dose
Classic Subfoveal Choroidal Neovascularization (CNV)	Administer 6 mg/m^2 body surface area via IV infusion over 10 minutes at a rate of 3 mL/minute. One week after the first course, if no significant toxicity occurs, the second eye can be treated, if necessary. Approximately 3 months later, the eye(s) can be evaluated for re-treatment. ***Note:** If the patient has already received previous Visudyne therapy in one eye with an acceptable safety profile, both eyes can be treated concurrently after a single administration of Visudyne. The more aggressive lesion should be treated first, at 15 minutes after the start of infusion. Immediately at the end of light application to the first eye, the laser settings should be adjusted to introduce the treatment parameters for the second eye, with the same light dose and intensity as for the first eye, starting no later than 20 minutes from the start of infusion.*

VI. Billing Code/Availability Information

HCPCS Code:

- J3396 – Injection, verteporfin, 0.1 mg: 1 billable unit = 0.1 mg

NDC:

- Visudyne 15 mg single-dose vial: 24208-5600-xx

VII. References

1. Visudyne [package insert]. Bridgewater, NJ; Bausch & Lomb; February 2023. Accessed May 2024.
2. National Coverage Determination (NCD) for VERTEPORFIN (80.3.1). Centers for Medicare & Medicaid Services, Inc. Updated 01/2018 with effective date 01/2018. Accessed May 2024.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
B39.4	Histoplasmosis capsulata, unspecified
B39.5	Histoplasmosis duboisii
B39.9	Histoplasmosis, unspecified
H32	Chorioretinal disorders in diseases classified elsewhere
H35.3210	Exudative age-related macular degeneration, right eye, stage unspecified
H35.3211	Exudative age-related macular degeneration, right eye, with active choroidal neovascularization
H35.3212	Exudative age-related macular degeneration, right eye, with inactive choroidal neovascularization
H35.3213	Exudative age-related macular degeneration, right eye, with inactive scar
H35.3220	Exudative age-related macular degeneration, left eye, stage unspecified
H35.3221	Exudative age-related macular degeneration, left eye, with active choroidal neovascularization
H35.3222	Exudative age-related macular degeneration, left eye, with inactive choroidal neovascularization
H35.3223	Exudative age-related macular degeneration, left eye, with inactive scar
H35.3230	Exudative age-related macular degeneration, bilateral, stage unspecified
H35.3231	Exudative age-related macular degeneration, bilateral, with active choroidal neovascularization
H35.3232	Exudative age-related macular degeneration, bilateral, with inactive choroidal neovascularization
H35.3233	Exudative age-related macular degeneration, bilateral, with inactive scar
H35.3290	Exudative age-related macular degeneration, unspecified eye, stage unspecified
H35.3291	Exudative age-related macular degeneration, unspecified eye, with active choroidal neovascularization
H35.3292	Exudative age-related macular degeneration, unspecified eye, with inactive choroidal neovascularization
H35.3293	Exudative age-related macular degeneration, unspecified eye, with inactive scar
H35.711	Central serous chorioretinopathy, right eye
H35.712	Central serous chorioretinopathy, left eye
H35.713	Central serous chorioretinopathy, bilateral
H35.719	Central serous chorioretinopathy, unspecified eye
H44.20	Degenerative myopia, unspecified eye
H44.21	Degenerative myopia, right eye
H44.22	Degenerative myopia, left eye
H44.23	Degenerative myopia, bilateral

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

The preceding information is intended for non-Medicare coverage determinations. Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determinations (NCDs) and/or Local

Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes		
Jurisdiction	**NCD/LCA/LCD Document (s)**	**Contractor**
All Jurisdictions	NCD (80.3.1)	All Contractors

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC