Policy Name	Clinical Policy – Verteporfin (Visudyne)
Policy Number	1345.00
Department	Clinical Strategy
Subcategory	Medical Management
Original Approval Date	04/07/2021
Current MPC/CCO Approval Date	04/09/2025
Current Effective Date	07/01/2025

Company Entities Supported (Select All that Apply)
X Superior Vision Benefit Management
X Superior Vision Services
X Superior Vision of New Jersey, Inc.
X Block Vision of Texas, Inc. d/b/a Superior Vision of Texas
X Davis Vision
(Collectively referred to as 'Versant Health' or 'the Company'

Acronyms	
ARMD	Age Related Macular Degeneration
Anti-VEGF	Vascular Endothelial Growth Factor Receptor Antagonists
CNV	Choroidal Neovascularization
CSR or CSCR	Central Serous Chorioretinopathy or Central Serous Retinopathy
IVFA	Intravenous Fluorescein Angiography
PCV	Polypoidal Choroidal Vasculopathy
PDT	Photodynamic Therapy
POHS	Presumed Ocular Histoplasmosis Syndrome

PURPOSE

To provide the clinical criteria to support the indication(s) for verteporfin photodynamic therapy (PDT). Applicable procedure codes are also defined.

POLICY

A. BACKGROUND

Verteporfin (Visudyne) photodynamic therapy (PDT) selectively binds to chorioretinal vascular structures and, in response to subsequent laser therapy, results in occlusion of choroidal vascular anomalies[1] Despite its efficacy, PDT has been replaced largely by anti-VEGF agents.[2] However, PDT still has a role in patients who are unresponsive or intolerant to anti-VEGF agents, and for primary treatment of certain conditions.

B. Medically Necessary

1. PDT is effective in the treatment of the following retinal disorders:

    a. Age related macular degeneration due to classic choroidal neovascularization[3]
    b. Degenerative myopia with choroidal neovascularization[4]
    c. Central serous retinopathy[5]
    d. Chronic or acute central serous choroidopathy [6]
    e. Choroidal hemangioma[7]
    f. Choroidal Metastasis[8]
    g. Presumed Ocular Histoplasmosis Syndrome[9]
    h. Polypoidal choroidal vasculopathy[10]
    i. Peripapillary choroidal neovascularization and related disorders[11]
    j. Other choroidal vascular anomalies

2. Initial therapy may be medically necessary when the following criteria are met:

    a. Any of the above diagnoses are present; and,
    b. Patient is 18 years or older.

3. Some patients will require retreatment at three (3) month intervals. Retreatment may be medically necessary when:

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[1] Newman, 2016
[2] Rosenfeld, 2006, Kim, 2006, Brown, 2009, Wong, 2015, and Kang, 2013
[3] Schmidt-Erfurt, 2007, Bressler, 2001, Blumenkranz, 2002, Blinder, 2003, Rosenfeld, 2004, Larsen, 2012.
[4] Wolf, 2014, Wong, 2015
[5] Chan, 2008.
[6] Yannuzzi, 2003, Ober, 2005, Erikitola, 2014, Chan, 2008, Senturk, 2011, Fujita 2011,12, Ergun, 2004
[7] Alshehri, 2023, Tsipursky, 2011, Ho, 2018, Boixadera, 2009, Blasi, 2010, Porrini, 2003, Singh, 2004, Shields, 2020
[8] Shields, 2020 (2 articles).
[9] Busquets, MA, 2003, Ramaiya, 2013
[10] Uyama, 2002, Eandi, 2007
[11] Jutley, 2011, Rosenblatt, 2005

a. All requirements for initial therapy are still present; and,
b. Clinical evidence of continued leakage including test results, as applicable.

4. The combined therapies of PDT plus Anti-VEGF therapy or PDT plus corticosteroid therapy have demonstrated increased efficacy with fewer injections. Therefore, the combined therapies of PDT and Anti-VEGF or PDT and corticosteroid therapy may be considered medically necessary.[12] [13]

C. Not Medically Necessary

All single and combination therapy treatment plans may be considered not medically necessary if there is not a clear diagnostic differentiation of the conditions listed.

D. Documentation

Medical necessity must be supported by adequate and complete documentation in the patient's medical record that describes the procedure and the medical rationale. For early retreatment, medical documentation of test results may be required. For any retrospective review, a full operative report and the medical plan of care is needed.

All items must be available upon request to initiate or sustain previous payments. Every page of the record must be legible and include appropriate patient identification information (e.g., complete name, date(s) of service). Services provided or ordered must be authenticated by the physician, in a handwritten or electronic signature. Stamped signatures are not acceptable.

E. Procedural Detail

CPT and HCPCS Codes	
J3396	Injection, verteporfin, 0.1 mg
67221	Destruction of localized lesion of choroid (e.g., choroidal neovascularization) photodynamic therapy (includes intravenous infusion)
67225	Destruction of localized lesion of choroid (e.g., choroidal neovascularization); photodynamic therapy, second eye, at single session (List separately in addition to code for primary eye treatment)

[12] Tozer, 2013, Koh, 2012, Antoszyk, 2008, Tong, 2016, Piermarocchi, 2008, Maberley, 2009, Piri, 2014.
[13] Koh, 2012

responsible for determining what services or treatments to provide to their patients. Patients (members) should always consult their doctor before making any decisions about medical care.

Subject to applicable law, compliance with this clinical policy is not a guarantee of coverage or payment. Coverage is based on the terms of an individual's particular benefit plan document, which may not cover the service(s) or procedure(s) addressed in this clinical policy. The terms of the individual's specific benefit plan are always determinative.

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RELATED POLICIES	
1317	Intravitreal Injections
1326	Laser Photocoagulation

DOCUMENT HISTORY		
Approval Date	**Revision**	**Effective Date**
04/07/2021	PTD therapy was removed from policy 1317 and republished as a separate policy.	09/01/2021
04/06/2022	Annual review; no criteria changes.	07/01/2022

04/12/2023	Add 3 indications for use; delete requirement for OCT or IVFA for initial treatment, add option of ICG test to retreatment criteria.	10/01/2023
04/03/2024	Annual review; no criteria changes.	06/01/2024
04/09/2025	Remove improvement in vision as a requirement for retreatment.	07/01/2025

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