How Payers Impact Clinical Care

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limited treatment options
reduced profitability
administrative costs
coverage restrictions
prior authorization
code bundling
narrow networks
payment rates

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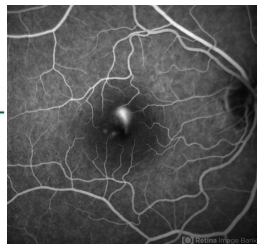
Case 1

- 45-year-old with symptomatic CSR, persistent despite 3-month period of observation



Eye

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Article | Open access | Published: 26 December 2022

Real world outcomes of photodynamic therapy for chronic central serous chorioretinopathy

Samir Khandhadia, Suresh Thulasidharan, Nguyen Thuy Vy Hoang, Sameh Alkhalili Ibrahim, Yanling Ouyang & Andrew Lotery

Eye 37, 2548–2553 (2023) | Cite this article

5235 Accesses | 7 Altmetric | Metrics

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What is the appropriate next step in this scenario

A. Ask your technician to set up for PDT laser as you plan to treat the patient right away?
B. Give the chart to your office manager to verify that insurance will pay prior to treatment?

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Procedure Denied

- Diagnosis considered investigational or unproven

aetna

B. *Non-Cancer Indications*

Aetna considers photodynamic therapy experimental, investigational, or unproven for any of the following indications because its effectiveness for these indications has not been established:

- Actinic cheilitis
- Actinic dermatitis
- Atopic dermatitis (eczematous dermatitis)
- Central serous chorioretinopathy
- Chronic rhinosinusitis
- Chronic ulcers (including diabetic ulcers)
- Condyloma (genital warts)
- Darier's disease (keratosis follicularis)
- Denture stomatitis
- Disseminated superficial actinic porokeratosis
- Dyspigmentation
- Endodontic infections
- Extra-mammary Paget's disease (e.g., Paget's disease of the vulva)
- Gingivitis
- Granulomatous dermatitis
- Halitosis
- Herpes labialis

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Health Care Delivery

- A payer in health insurance is an organization or entity that pays for healthcare services. This could be a health insurance company, government program or employer

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A Physician in Practice

Professional responsibility to provide ethical medical care

Financial responsibility to run a profitable business

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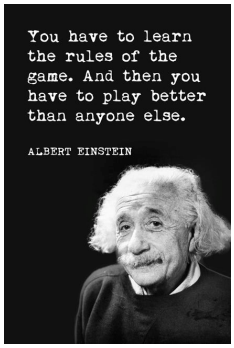

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This label may not be the latest approved by FDA.
For current labeling information, please visit https://www.fda.gov/drugsatfda

NDA 021119/S-034
Page 3

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use VISUDYNE safely and effectively. See full prescribing information for VISUDYNE.

VISUDYNE® (verteporfin for injection), for intravenous use
Initial U.S. Approval: 2000

INDICATIONS AND USAGE

VISUDYNE (verteporfin for injection) therapy is a photosensitizer indicated for the treatment of patients with predominantly classic subfoveal choroidal neovascularization due to age-related macular degeneration, pathologic myopia or presumed ocular histoplasmosis. (1)

DOSAGE AND ADMINISTRATION

- Recommended Dose: 6 mg/m² body surface area. (2.2)
- Reconstitution: Reconstitute each vial of VISUDYNE with 7 mL of Sterile Water for Injection to provide 7.5 mL containing 2 mg/mL of verteporfin. Reconstituted VISUDYNE must be protected from light and used within 4 hours. (2.3)
- Dilution: Dilute desired dose of reconstituted VISUDYNE with 5% Dextrose for Injection to a total infusion volume of 30 mL. (2.3)
- Infusion: Administer intravenously over 10 minutes at a rate of 3 mL/minute, using an appropriate syringe pump and in-line filter. (2.3)
- Light Administration: The recommended light dose is 50 J/cm² of neovascular lesion administered at an intensity of 600 mW/cm². The wavelength of the laser light should be 689±3 nm. This light dose is administered over 83 seconds, starting 15 minutes after the start of the VISUDYNE infusion. (2.4)

DOSAGE FORMS AND STRENGTHS

- For injection: 15 mg of verteporfin as a dark green lyophilized cake in a single-dose vial for reconstitution. (3)
- Each reconstituted vial provides 7.5 mL solution containing 2 mg/mL of verteporfin. (3)

CONTRAINDICATIONS

VISUDYNE (verteporfin for injection) is contraindicated for patients with porphyria or a known hypersensitivity to any component of this preparation. (4)

WARNINGS AND PRECAUTIONS

- Extravasation: If extravasation occurs, the infusion should be stopped immediately. The extravasation area must be thoroughly protected from direct light until swelling and discoloration have faded in order to prevent the occurrence of local burn. (5.1)
- Exposure to Sun or Direct Light: Following injection with VISUDYNE (verteporfin for injection), care should be taken to avoid exposure of skin or eyes to direct sunlight or bright indoor light for 5 days. (5.2)
- Anaphylactic Reactions: Immediately discontinue administration of VISUDYNE and initiate appropriate therapy if an anaphylactic or other serious allergic reaction occurs during or following infusion. (5.4)

ADVERSE REACTIONS

Most common adverse reactions (incidence >10%) are injection site reactions and visual disturbances. (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Bausch & Lomb Incorporated at 1-800-553-5340 or FDA at 1-800-FDA-1088 or

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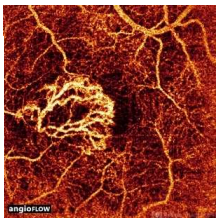
Case 2

- 77-year-old with new onset Neovascular AMD



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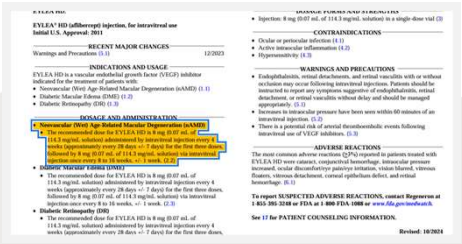

EYLEA® HD (aflibercept) injection, for intravitreal use
Initial U.S. Approval: 2011

RECENT MAJOR CHANGES
Warnings and Precautions (5.1) 12/2023

INDICATIONS AND USAGE
EYLEA HD is a vascular endothelial growth factor (VEGF) inhibitor indicated for the treatment of patients with:
- Neovascular (Wet) Age-Related Macular Degeneration (nAMD) (1.1)
- Diabetic Macular Edema (DME) (1.2)
- Diabetic Retinopathy (DR) (1.3)

DOSAGE AND ADMINISTRATION
- Neovascular (Wet) Age-Related Macular Degeneration (nAMD)
  - The recommended dose for EYLEA HD is 8 mg (0.07 mL of 114.3 mg/mL solution) administered by intravitreal injection every 4 weeks (approximately every 28 days +/- 7 days) for the first three doses, followed by 8 mg (0.07 mL of 114.3 mg/mL solution) via intravitreal injection once every 8 to 16 weeks, +/- 1 week. (2.2)
- Diabetic Macular Edema (DME)
  - The recommended dose for EYLEA HD is 8 mg (0.07 mL of 114.3 mg/mL solution) administered by intravitreal injection every 4 weeks (approximately every 28 days +/- 7 days) for the first three doses, followed by 8 mg (0.07 mL of 114.3 mg/mL solution) via intravitreal injection once every 8 to 16 weeks, +/- 1 week. (2.3)
- Diabetic Retinopathy (DR)
  - The recommended dose for EYLEA HD is 8 mg (0.07 mL of 114.3 mg/mL solution) administered by intravitreal injection every 4 weeks (approximately every 28 days +/- 7 days) for the first three doses,
- Injection: 8 mg (0.07 mL of 114.3 mg/mL solution) in a single-dose vial (3)

CONTRAINDICATIONS
- Ocular or periocular infection (4.1)
- Active intraocular inflammation (4.2)
- Hypersensitivity (4.3)

WARNINGS AND PRECAUTIONS
- Endophthalmitis, retinal detachment, and retinal vasculitis with or without occlusion may occur following intravitreal injections. Patients should be instructed to report any symptoms suggestive of endophthalmitis, retinal detachment, or retinal vasculitis without delay and should be managed appropriately. (5.1)
- Increases in intraocular pressure have been seen within 60 minutes of an intravitreal injection. (5.2)
- There is a potential risk of arterial thromboembolic events following intravitreal use of VEGF inhibitors. (5.3)

ADVERSE REACTIONS
The most common adverse reactions (≥5%) reported in patients treated with EYLEA HD were cataract, conjunctival hemorrhage, intraocular pressure increased, ocular discomfort/eye pain/eye irritation, vision blurred, vitreous floaters, vitreous detachment, corneal epithelium defect, and retinal hemorrhage. (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Regeneron at 1-855-393-3240 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

See 17 for PATIENT COUNSELING INFORMATION.

Revised: 10/2024

FDA Label

https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=BasicSearch.process

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What is the appropriate next step

A. You know for certain that Eylea HD is FDA approved for the diagnosis of NVAMD, therefore you grab a drug from the fridge and perform the intravitreal injection.

B. You pause and decide to give the chart to your manager to verify that insurance will pay prior to treatment.

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Policy Changes and Lack of Transparency

Private payers may not actively communicate changes to their policies or guidelines to providers in a clear and timely manner, making it difficult for providers to stay updated.

This lack of transparency can lead to situations where providers perform procedures or prescribe treatments that are later denied coverage due to a policy change, they were unaware of.

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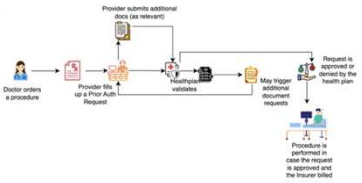
Prior Authorization

- Under medical and prescription drug plans, some treatments and medications may need approval from your health insurance carrier before you receive care



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Step therapy

Step Therapy Criteria

Eylea

Eylea, when prescribed for Neovascular (Wet) Age-Related Macular Degeneration, may be covered when any of the criteria listed below are satisfied:

- History of a trial of at least 3 consecutive doses given monthly, resulting in minimal clinical response to compounded Avastin (bevacizumab); **or**
- History of contraindication or adverse event(s) to compounded Avastin (bevacizumab); **or**
- Continuation of prior therapy within the past 365 days.

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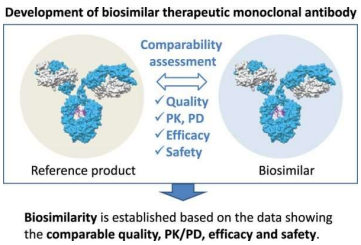
Biosimilars

- Ishii-Watabe A, Kuwabara T. Biosimilarity assessment of biosimilar therapeutic monoclonal antibodies. *Drug Metab Pharmacokinet*. 2019;34(1):64-70. doi:10.1016/j.dmpk.2018.11.004



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Out Of Pocket Costs Matter!

- Copay - A copay is a fixed amount you pay for a covered health care service, usually at the time you receive the service. Copays are a shared cost between you and your insurance company
- Deductible - A deductible is the amount of money you pay before your insurance covers the rest of a claim

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How Payers Impact Clinical Care

- Authorization requirements may affect the timeliness of care
- Payers may restrict or narrow treatment options

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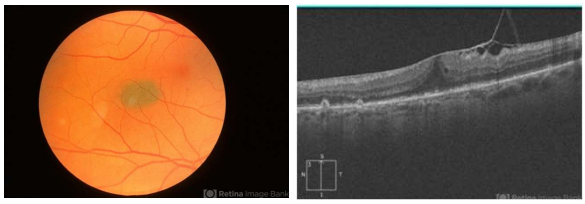
Case: 65-year-old male



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Bundled Codes and Mutually Exclusive Codes

- The National Correct Coding Initiative (NCCI) edits, which are used by Medicare and many commercial payers, often bundle certain procedures together, meaning they are considered to be part of the same service and only one code should be billed.
- In some cases, the procedures are considered mutually exclusive, meaning that one procedure is generally considered to provide the same information as the other, and therefore, both should not be billed.

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Local Coverage Determination (LCD):

Scanning Computerized Ophthalmic Diagnostic Imaging

L35038 Expand All | Collapse All

* Note: Please see next bullet if undergoing active treatment.

- No more than one (1) exam per month will be considered medically reasonable and necessary to manage the patient with retinal conditions undergoing active treatment, or in conditions suggestive of rapid deterioration. These conditions include wet AMD, choroidal neovascularization, macular edema, diabetic retinopathy (proliferative and non-proliferative), branch retinal vein occlusion, central retinal vein occlusion, and cystoid macular edema.

Frequency of allowable diagnostic services

https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?LCDId=35038

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What is the appropriate management of patients in this uncertain environment?

- Do what's right for the patient
- Follow established protocols for obtaining authorization
- Take guidance from your administrative support staff
- Talk to the patient in advance about possible out of pocket costs

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Thank you!

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Retina Group of Washington

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