

Medical Drug Clinical Criteria

Subject:	Jetrea (Ocriplasmin)		
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Overview

This document addresses the use of Jetrea (ocriplasmin), a recombinant truncated form of human plasmin (proteolytic enzyme) that breaks down protein components such as laminin, fibronectin and collagen in the vitreous body and vitreoretinal interface (VRI) in the eye.

Jetrea is FDA approved to treat symptomatic vitreomacular adhesion (VMA). VMA is a condition in which the vitreous gel adheres to the retina in an abnormally strong manner. This may cause vitreomacular traction that becomes symptomatic. Symptoms typically include distorted vision, blurring of visual acuity, and defects in the central visual field. Macular distortion, edema, and the formation of macular holes may result from vitreomacular traction. Optical coherence tomography (OCT) is utilized to assess and document the status of the VMA. In symptomatic VMA, the posterior vitreous cortex separates from the back of the eye, appearing elevated when compared to the adhesion in the central macular area. Epiretinal membranes (ERMs) consist of fibrocellular proliferation on the surface of the retina which may lead to macular traction and similar visual symptoms.

Treatment for symptomatic VMA may include observation, a gas bubble injected into the vitreous, vitrectomy surgery, or Jetrea injection. Jetrea is injected into the affected eye (intravitreal) as a single dose and can induce vitreous liquefaction and separation from the retina. The America Academy of Ophthalmology (AAO) Preferred Practice Pattern on Idiopathic Epiretinal Membrane and Vitreomacular Traction (2019) notes that “resolution of the VMA may be achieved more often in younger patients (<65 years), eyes without an ERM, eyes with a full-thickness macular hole and associated VMA, phakic eyes, and eyes with a focal VMA of 1500 µm or less.” The clinical trial appearing in the FDA label (Stalmans 2012) excluded individuals with certain underlying conditions (e.g. diabetic retinopathy, uncontrolled glaucoma), as well as those with some prior procedures (e.g. laser photocoagulation, ocular surgery).

Repeat injections of Jetrea (ocriplasmin) in the same eye are not recommended. For treatment of bilateral VMA, a waiting period of at least 7 days is recommended before treatment of the contralateral eye.

Jetrea injection was discontinued by the manufacturer. Criteria will remain active until 05/2022 as claims can adjudicate several years after agent discontinuation.

Clinical Criteria

When a drug is being reviewed for coverage under a member’s medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

Jetrea (ocriplasmin)

Requests for Jetrea (ocriplasmin) may be approved if the following criteria are met:

- I. Individual is 18 years of age or older; **AND**
- II. Individual is using for treatment of an eye with symptomatic vitreomacular adhesion (VMA); **AND**
- III. Documentation is provided that the posterior segment optical coherence tomography (OCT) demonstrates the following (Stalmans 2012):
 - A. There is vitreous adhesion within 6-mm of the fovea (center of macula); **AND**
 - B. There is elevation of the posterior vitreous cortex (outer layer of the vitreous);

AND

- IV. Documentation is provided that individual has best-corrected visual acuity of 20/25 or worse in the eye to be treated with ocriplasmin (Stalmans 2012); **AND**
- V. Individual does **not** have any of the following (Stalmans 2012):

- A. Proliferative diabetic retinopathy; **OR**
- B. Neovascular age-related macular degeneration; **OR**
- C. Retinal vascular occlusion; **OR**
- D. Aphakia (absence of the lens of the eye); **OR**
- E. High myopia (more than -8 diopters); **OR**
- F. Uncontrolled glaucoma; **OR**
- G. Macular hole greater than 400 µm in diameter; **OR**
- H. Vitreous opacification; **OR**
- I. Lenticular or zonular instability; **OR**
- J. History of retinal detachment in either eye; **OR**
- K. Prior vitrectomy in the affected eye; **OR**
- L. Prior laser photocoagulation of the macula in the affected eye; **OR**
- M. Prior treatment with ocular surgery, intravitreal injection or retinal laser photocoagulation in the previous 3 months.

Requests for Jetrea (ocriplasmin) may not be approved for the following:

- I. All indications not included above; **OR**
- II. Repeat intravitreal injections of Jetrea (ocriplasmin) in the affected eye

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

CPT

67028 Intravitreal injection of a pharmacologic agent [when specified as intravitreal injection of ocriplasmin, in conjunction with the HCPCS code listed below]
**Inclusion of this code in the clinical policy is informational only and does not denote a requirement for pre or post service medical necessity review.*

HCPCS

J7316 Injection, ocriplasmin, 0.125 mg [Jetrea]

ICD-10 Diagnosis

H35.00-H35.9 Retinal Disorders
 H40.001-H40.9 Glaucomas
 H43.821-H43.829 Vitreomacular adhesion
 H54.0X33-H54.52A2 Blindness and low vision

Document History

Reviewed: 03/14/2022

Document History:

- 03/14/2022 – Annual Review: No changes. Coding Reviewed: No changes.
- 08/01/2021 – Administrative update to add documentation.
- 03/15/2021 – Annual Review: No changes. Coding Reviewed: No changes.
- 03/16/2020 – Annual Review: Wording and formatting changes. Coding reviewed: Added H35.00-H35.9, H40.001-H40.9
- 05/22/2019 – Coding reviewed: Added ICD-10 dx H54.0X33-H54.52A2.
- 03/18/2019 – Annual Review: No changes. Coding Reviewed: No changes
- 11-16-2018 – Select Review: Initial review of Jetrea (Ocriclasmin); Minor wording and formatting changes. HCPCS and ICD-10 coding review: no changes.

References

1. American Academy of Ophthalmology Retina/Vitreous Panel. Preferred Practice Pattern Guidelines. For additional information visit the AAO website: Accessed on March 4, 2022.
 - a. Idiopathic epiretinal membrane and vitreomacular traction. October 2019.
 - b. Idiopathic macular hole. October 2019.

2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2022. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
3. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: March 4, 2022.
4. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
5. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2022; Updated periodically.
6. Stalmans P, Benz MS, Gandorfer A, et al.; MIVI-TRUST Study Group. Enzymatic vitreolysis with ocriplasmin for vitreomacular traction and macular holes. N Engl J Med. 2012; 367(7):606-615.

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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