

Medical Coverage Policy | Ocriplasmin for Symptomatic Vitreomacular Adhesion



EFFECTIVE DATE: 10|01|2015
POLICY LAST UPDATED: 04|05|2023

OVERVIEW

Ocriplasmin is a recombinant truncated form of human plasmin, a proteolytic enzyme that breaks down protein components at the vitreoretinal interface in the eye, used for symptomatic vitreomacular adhesion and vitreomacular traction. Ocriplasmin is injected into the affected eye (intravitreal) as a single dose and can induce vitreous liquefaction and separation from the retina.

MEDICAL CRITERIA

Not applicable

PRIOR AUTHORIZATION

Not applicable

POLICY STATEMENT

Medicare Advantage Plans

A single intravitreal injection of Ocriplasmin may be considered medically necessary for treatment of an eye with symptomatic vitreomacular adhesion (VMA) or vitreomacular traction.

The use of intravitreal Ocriplasmin is considered not covered in all other situations, including use of repeat injections of Ocriplasmin.

Commercial Products

A single intravitreal injection of Ocriplasmin may be considered medically necessary for treatment of an eye with symptomatic vitreomacular adhesion (VMA) or vitreomacular traction.

The use of intravitreal Ocriplasmin is considered not medically necessary in all other situations, including use of repeat injections of Ocriplasmin.

COVERAGE

Benefits may vary between groups and contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage or Subscriber Agreement for applicable medical and not medically necessary/not covered benefits/coverage.

BACKGROUND

The vitreous is a gel-like fluid within the eye that adheres completely to the surface of the retina. The consistency of the vitreous and its adhesion to the retina are maintained by several proteins including collagen, laminin, and fibronectin. With aging, the proteins in the vitreous break down, resulting in liquefaction of the vitreous and eventual separation of the vitreous from the retina, a process called posterior vitreous detachment (PVD).

The process of vitreous detachment usually proceeds without incident, but sometimes the separation is not complete. The adhesion usually remains at sites where the bonds between the vitreous and retina are the strongest. In some cases, the adhesion can cause visual symptoms. The traction caused by the adherent vitreous can cause deformation of the retina, edema, and full-thickness macular holes (FTMH). Although the

terms are sometimes used synonymously, the International Vitreomacular Traction Study Group has defined vitreomacular adhesion (VMA) as adhesion at the macula without detectable changes in retinal morphology and vitreomacular traction (VMT) as adhesion with retinal morphologic changes but without full-thickness defect.¹ Both VMA and VMT can be focal or diffuse.

Symptoms can vary, but may include diminished visual acuity, distorted vision (metamorphopsia), and central field defect. Individuals are usually observed until resolution or worsening, in which case vitrectomy is the standard treatment. Spontaneous release of VMA/VMT occurs in about 30% of cases over a period of 1 to 2 years, and observation is usually indicated because vitrectomy has risks and an almost certain occurrence of cataract in the years following the procedure.

Ocriplasmin is a recombinant product that is a shortened form of the protease plasmin. Early studies of ocriplasmin were conducted in individuals scheduled to have vitrectomy and established doses that showed some effect in inducing posterior vitreous detachment (PVD).

For individuals who have symptomatic vitreomacular adhesion or vitreomacular traction who receive intravitreal injection of ocriplasmin, the evidence includes 2 large, double-blind, placebo-controlled trials and other supporting studies. Relevant outcomes are symptoms, change in disease status, functional outcomes, quality of life, and treatment-related morbidity. Results of the pivotal randomized controlled trial, Randomized, Placebo Controlled, Double-masked, Multicenter Trial of Microplasmin Intravitreal Injection for Non-surgical Treatment of Focal Vitreomacular Adhesion (MIVI-TRUST), demonstrated an improvement in the resolution of vitreomacular adhesion and vitreomacular traction at 28 days (26.5% of ocriplasmin patients vs. 10.1% of placebo patients; number needed to treat [NNT], 6) and a lesser reduction in the proportion of patients undergoing vitrectomy (17.7% of patients vs. 26.6% of patients; NNT, 11). Results of this and other trials have also shown an increase in the proportion of patients who had clinically significant gains in visual acuity NNT, 17) and visual function. The randomized controlled trials did not find higher rates of important complications; however, postmarketing surveillance has identified some previously unknown adverse events for this enzymatic treatment. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

CODING

Medicare Advantage Plans and Commercial Products

The following HCPCS code is covered with one of the ICD-10 codes listed in the code range below:

J7316 Injection, Ocriplasmin, 0.125 mg

ICD-10-CM Diagnosis Code Range: H43.821-H43.829

RELATED POLICIES

Not applicable

PUBLISHED

Provider Update, June 2023

Provider Update, July 2022

Provider Update, June 2021

Provider Update, June 2020

Provider Update, August 2019

REFERENCES

1. Duker JS, Kaiser PK, Binder S, et al. The International Vitreomacular Traction Study Group classification of vitreomacular adhesion, traction, and macular hole. *Ophthalmology*. Dec 2013; 120(12): 2611-2619. PMID 24053995
2. Tzu JH, John VJ, Flynn HW, et al. Clinical Course of Vitreomacular Traction Managed Initially by Observation. *Ophthalmic Surg Lasers Imaging Retina*. May 2015; 46(5): 571-6. PMID 26057761

3. Jackson TL, Donachie PH, Sparrow JM, et al. United Kingdom National Ophthalmology Database Study of Vitreoretinal Surgery: report 1; case mix, complications, and cataract. *Eye (Lond)*. May 2013; 27(5): 644-51. PMID 23449509
4. Benz MS, Packo KH, Gonzalez V, et al. A placebo-controlled trial of microplasmin intravitreal injection to facilitate posterior vitreous detachment before vitrectomy. *Ophthalmology*. Apr 2010; 117(4): 791-7. PMID 20138368
5. de Smet MD, Gandorfer A, Stalmans P, et al. Microplasmin intravitreal administration in patients with vitreomacular traction scheduled for vitrectomy: the MIVI I trial. *Ophthalmology*. Jul 2009; 116(7): 1349-55, 1355.e1-2. PMID 19447497
6. Stalmans P, Delaey C, de Smet MD, et al. Intravitreal injection of microplasmin for treatment of vitreomacular adhesion: results of a prospective, randomized, sham-controlled phase II trial (the MIVI-IIT trial). *Retina*. Jul-Aug 2010; 30(7): 1122-7. PMID 20616687
7. Blue Cross and Blue Shield Association. Ocriplasmin for symptomatic vitreomacular adhesion. *Technol Eval Cent Assess Program Exec Summ*. Aug 2013; 28(5): 1-3. PMID 24066370
8. Stalmans P, Benz MS, Gandorfer A, et al. Enzymatic vitreolysis with ocriplasmin for vitreomacular traction and macular holes. *N Engl J Med*. Aug 16 2012; 367(7): 606-15. PMID 22894573
9. Gandorfer A, Benz MS, Haller JA, et al. Association between anatomical resolution and functional outcomes in the mivi-trust studies using ocriplasmin to treat symptomatic vitreomacular adhesion/vitreomacular traction, including when associated with macular hole. *Retina*. Jun 2015; 35(6): 1151-7. PMID 25741816
10. Kaiser PK, Kampik A, Kuppermann BD, et al. Safety profile of ocriplasmin for the pharmacologic treatment of symptomatic vitreomacular adhesion/traction. *Retina*. Jun 2015; 35(6): 1111-27. PMID 25635577
11. Novack RL, Staurengi G, Girach A, et al. Safety of intravitreal ocriplasmin for focal vitreomacular adhesion in patients with exudative age-related macular degeneration. *Ophthalmology*. Apr 2015; 122(4): 796-802. PMID 25435217
12. Drenser K, Girach A, Capone A. A RANDOMIZED, PLACEBO-CONTROLLED STUDY OF INTRAVITREAL OCRIPLASMIN IN PEDIATRIC PATIENTS SCHEDULED FOR VITRECTOMY. *Retina*. Mar 2016; 36(3): 565-75. PMID 26398685
13. Steel DHW, Patton N, Stappler T, et al. OCRIPLASMIN FOR VITREOMACULAR TRACTION IN CLINICAL PRACTICE: The INJECT Study. *Retina*. Feb 01 2021; 41(2): 266-276. PMID 32496343
14. Khanani AM, Duker JS, Heier JS, et al. Ocriplasmin Treatment Leads to Symptomatic Vitreomacular Adhesion/Vitreomacular Traction Resolution in the Real-World Setting: The Phase IV ORBIT Study. *Ophthalmol Retina*. Jan 2019; 3(1): 32-41. PMID 30935657
15. Hahn P, Chung MM, Flynn HW, et al. SAFETY PROFILE OF OCRIPLASMIN FOR SYMPTOMATIC VITREOMACULAR ADHESION: A Comprehensive Analysis of Premarketing and Postmarketing Experiences. *Retina*. Jun 2015; 35(6): 1128-34. PMID 25635575
16. Shah SP, Jeng-Miller KW, Fine HF, et al. Post-Marketing Survey of Adverse Events Following Ocriplasmin. *Ophthalmic Surg Lasers Imaging Retina*. Feb 2016; 47(2): 156-60. PMID 26878449
17. Chatziralli I, Theodossiadis G, Xanthopoulou P, et al. Ocriplasmin use for vitreomacular traction and macular hole: A meta-analysis and comprehensive review on predictive factors for vitreous release and potential complications. *Graefes Arch Clin Exp Ophthalmol*. Jul 2016; 254(7): 1247-56. PMID 27137631
18. National Institute for Health and Care Excellence (NICE). Ocriplasmin for treating vitreomacular traction [TA297]. 2017; <https://www.nice.org.uk/guidance/ta297>. Accessed February 20, 2023.
19. Flaxel CJ, Adelman RA, Bailey ST, et al. Idiopathic Epiretinal Membrane and Vitreomacular Traction Preferred Practice Pattern(R). *Ophthalmology*. Feb 2020; 127(2): P145-P183. PMID 31757497
20. Neffendorf JE, Kirthi V, Pringle E, et al. Ocriplasmin for symptomatic vitreomacular adhesion. *Cochrane Database Syst Rev*. Oct 17 2017; 10: CD011874. PMID 29040800

1

CLICK THE ENVELOPE ICON BELOW TO SUBMIT COMMENTS

This medical policy is made available to you for informational purposes only. It is not a guarantee of payment or a substitute for your medical judgment in the treatment of your patients. Benefits and eligibility are determined by the member's subscriber agreement or member certificate and/or the employer agreement, and those documents will supersede the provisions of this medical policy. For information on member-specific benefits, call the provider call center. If you provide services to a member which are determined to not be medically necessary (or in some cases medically necessary services which are non-covered benefits), you may not charge the member for the services unless you have informed the member and they have agreed in writing in advance to continue with the treatment at their own expense. Please refer to your participation agreement(s) for the applicable provisions. This policy is current at the time of publication; however, medical practices, technology, and knowledge are constantly changing. BCBSRI reserves the right to review and revise this policy for any reason and at any time, with or without notice. Blue Cross & Blue Shield of Rhode Island is an independent licensee of the Blue Cross and Blue Shield Association.

