

<b>POLICY TITLE</b>	<b>OCRIPLASMIN FOR SYMPTOMATIC VITREOMACULAR ADHESION</b>
<b>POLICY NUMBER</b>	<b>MP-2.181</b>

<b>Original Issue Date (Created):</b>	<b>4/1/2014</b>
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**POLICY**

A single intravitreal injection of ocriplasmin may be considered **medically necessary** for treatment of an eye with symptomatic vitreomacular adhesion or vitreomacular traction.

The use of intravitreal ocriplasmin is considered **investigational** in all other situations, including use of repeat injections of ocriplasmin as there is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure.

**Policy Guidelines**

The precise patient indications for treatment are not certain. The eligibility criteria for the key randomized controlled trial (RCT) included the following:

- Individual's age is equal to or greater than 18 years;
- Optical coherence tomography (OCT) demonstrates all of the following:
  - There is vitreous adhesion within 6-mm of the fovea (center of macula); and
  - There is elevation of the posterior vitreous cortex (outer layer of the vitreous).
- Individual has best-corrected visual acuity of 20/25 or less in the eye to be treated with ocriplasmin
- Individual does not have any of the following:
  - proliferative diabetic retinopathy;
  - neovascular age-related macular degeneration;
  - retinal vascular occlusion;
  - aphakia;
  - high myopia (greater than -8 diopters);
  - uncontrolled glaucoma;
  - macular hole greater than 400 μm in diameter;
  - vitreous opacification;
  - lenticular or zonular instability;
  - history of retinal detachment in either eye;
  - prior vitrectomy in the affected eye;

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- prior laser photocoagulation of the macula in the affected eye; or
- prior treatment with ocular surgery, intravitreal injection or retinal laser photocoagulation in the previous 3 months.

Clinical input suggested that not all of the trial exclusion criteria should be absolute exclusions. However, there was not a consensus on the recommended exclusion criteria (see Rationale section on clinical input received through physician specialty societies and academic medical centers).

***Cross-reference:***

**MP-2.103** Off Label Use of Medications

**I. PRODUCT VARIATIONS**

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This policy is applicable to all programs and products administered by Capital BlueCross unless otherwise indicated below.

**FEP-** Refer to FEP Medical Policy Manual MP-5.90.05, Jetrea. The FEP Medical Policy Manual can be found at: [www.fepblue.org](http://www.fepblue.org).

**II. DESCRIPTION/BACKGROUND**

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Vitreous is a gel-like fluid within the eye that adheres completely to the surface of the retina. The consistency of 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 vitreous and eventual separation of 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 incomplete. 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.<sup>1</sup> 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. Patients 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

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usually indicated because vitrectomy has risks and an almost certain occurrence of cataract in the years following the procedure.<sup>2,3</sup>

Ocriplasmin is a recombinant product that is a shortened form of the protease plasmin. Early studies of ocriplasmin were conducted in patients scheduled to have vitrectomy and established doses that showed some effect in inducing PVD. Studies by Benz et al, de Smet et al, and Stalmans et al led to the design and conduct of the pivotal clinical trials described in the Rationale section below.<sup>4-6</sup>

**Regulatory Status**

In October 2012, ocriplasmin (Jetrea®; ThromboGenics, Iselin, NJ) received U.S. Food and Drug Administration approval for the treatment of symptomatic vitreomacular adhesion. No contraindications were noted. In the Warnings and Precautions section of the prescribing information, it was noted that a higher percentage of subjects treated with ocriplasmin in the clinical trials had worsening of visual acuity of 3 or more lines than subjects in the control group. Transient injection-associated effects such as inflammation occurred in a higher percentage of subjects treated with ocriplasmin than control subjects. Alcon has obtained exclusive distribution rights for Jetrea® in the United States.

**III. RATIONALE**

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The most recent literature update was performed through January 8, 2018.

Medical policies assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function—including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

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**INTRAVITREAL INJECTION FOR VITREOMACULAR ADHESION OR VITREOMACULAR TRACTION**

This medical policy was informed by a TEC Assessment (2013), which concluded that ocriplasmin is associated with higher rates of resolution of vitreomacular adhesions (VMAs), closure of macular holes, lower rates of vitrectomy, and improvement in some measures of visual acuity, without increases in major adverse events, when compared with watchful waiting with vitrectomy as indicated.<sup>7</sup> The Assessment concluded that use of ocriplasmin led to improvement in health outcomes.

The principal evidence supporting ocriplasmin for symptomatic VMA are the RCT results published by Stalmans et al (2012) for the MIVI-TRUST study group.<sup>8</sup> The study presented pooled results of 2 identically designed, double-blind, placebo-controlled randomized trials. Patients enrolled in the trial met strict inclusion and exclusion criteria: they were not currently scheduled to have vitrectomy, but, according to assessment by their physicians, 84% were expected to need a vitrectomy if their conditions did not improve. Overall, 652 eyes were treated, 464 with ocriplasmin and 188 with placebo. The principal study end point (resolution of VMA at 28 days) was met by 26.5% of ocriplasmin-treated patients and by 10.1% of placebo-treated patients (number needed to treat, 6.1). Other 28-day secondary end points (posterior vitreal detachment, closure of macular holes) also favored ocriplasmin.

Secondary outcomes measured beyond 28 days were also better in ocriplasmin-treated eyes. By 6 months, 17.7% of ocriplasmin-treated subjects had undergone vitrectomy vs 26.6% of placebo-treated subjects. Visual improvement varied depending on how data were analyzed but generally favored ocriplasmin. Measured as a categorical improvement of 3 or more lines on the Early Treatment of Diabetic Retinopathy Study chart, ocriplasmin-treated subjects showed greater improvement than placebo-treated subjects. Absolute gains in both groups were modest (needed to treat, 17)—eg, in the analysis that only considered those who did not undergo vitrectomy (9.7% and 3.7%, respectively). A higher proportion of patients in the ocriplasmin group had a clinically meaningful ( $\geq 5$  point) improvement on 25-item National Eye Institute Visual Function Questionnaire scores (36.0% vs 27.2%,  $p=0.03$ ), and fewer ocriplasmin-treated patients had a clinically meaningful worsening in their visual function compared with the placebo group (15.0% vs 24.3%,  $p=0.005$ ).<sup>9</sup> Resolution of VMA at 28 days, regardless of treatment group, was associated with greater improvement in visual acuity at all time points (7.5-letter improvement vs 2.1-letter improvement,  $p<0.001$ ).<sup>10</sup> Serious adverse events in ocriplasmin-injected eyes (7.7%) did not differ significantly from placebo-injected eyes (10.7%).<sup>11</sup> The most common adverse events reported in patients treated with ocriplasmin include eye floaters, bleeding of the conjunctiva, eye pain, flashes of light (photopsia), blurred vision, vision loss, retinal edema (swelling), and macular edema.

In a phase 2 randomized, sham-controlled trial, Novack et al (2015) assessed 100 patients with exudative age-related macular degeneration.<sup>12</sup> The trial was primarily intended to evaluate the efficacy but also reported adverse events. Adverse events were higher in the ocriplasmin group, and serious adverse events in the study eye were observed in 10.7% of ocriplasmin-injected eyes compared with 0% sham-treated eyes. The efficacy in releasing VMAs was numerically similar to the MIVI-TRUST trial, but the difference between active and sham treatments was not

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statistically significant (24.3% vs 12.0%, p=0.26); the phase 2 trial had insufficient power to detect a significant difference. Visual acuity was similar in both groups.

In a phase 2, sham-controlled, randomized trial, Dresner et al (2016) evaluated 22 pediatric patients scheduled to undergo vitrectomy.<sup>13</sup> The trial was intended to test whether ocriplasmin would permit a faster surgical procedure and fewer complications. Use of ocriplasmin in pediatric patients is not currently recommended. The primary outcome was the proportion of eyes with posterior vitreous detachment at the beginning of vitrectomy or after suction. This outcome was observed in 50% of the ocriplasmin group and 62.5% of the placebo group. This result did not support any potential benefit of ocriplasmin.

Hahn et al (2015), in a report commissioned by the American Society of Retina Specialists, assessed adverse events based on regulatory reports of 999 injections administered during clinical trials and voluntary reports of adverse events from 4387 doses administered postmarketing.<sup>14</sup> This report described the incidence, in a small percentage of patients, of significant and permanent vision loss, electroretinogram changes, dyschromatopsia, retinal tear/detachment, lens subluxation, impaired pupillary reflex, loss or disruption of the ellipsoid zone, vascular attenuation or vasoconstriction, and nyctalopia (night blindness). The rates of these adverse events could not be determined with certainty due to the voluntary and possibility incomplete nature of reporting.

Shah et al (2016) surveyed 2465 retinal physicians about ocriplasmin use and adverse events—270 (11%) completed questionnaires (reporting on 1056 treated eyes).<sup>15</sup> The most common adverse events reported included acute visual acuity decline (17.0%), retinal detachment or submacular fluid (10.2%), dyschromatopsia (9.1%), progression to macular hole (8.7%), retinal detachment (2.7%), retinal tear (2.0%), and afferent pupillary defect (1.8%). Reported adverse event rates were higher than those in clinical trial data (e.g., incidence of decline in visual acuity in trials was 7.7%). However, the survey-based estimates would likely to be influenced by the high rate of physician nonresponse.

Finally, Chatziralli et al (2016) conducted a meta-analysis ocriplasmin for vitreomacular traction.<sup>16</sup> Results from 19 studies were pooled—RCT, cohort, case-control, or cross-sectional designs were included. No study quality (risk of bias) appraisal was performed. Factors predictive for vitreomacular traction release were adhesion diameter, age less than 65 years, female, and lack of a phakic lens. The pooled rate of macular hole closure was 33% (95% confidence interval, 26% to 39%;  $I^2=0\%$ ; 13 studies). Adverse event rates were summarized for 874 eyes, including acute decrease in visual acuity (17.4%), subretinal fluid (8.8%), dyschromatopsia (0.9%), progression to macular hole (5.0%), retinal detachment/tear (1.8%), and afferent pupillary defect (0.1%). Except for decreased acute visual acuity, adverse event rates were considerably lower than those from the Shah survey. While some factors were associated with response, implications are limited by the study-level nature of the meta-analysis.

**SUMMARY OF EVIDENCE**

For individuals who have symptomatic VMA 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,

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functional outcomes, quality of life, and treatment-related morbidity. Results of the principal randomized controlled trial (MIVI-TRUST) demonstrated an improvement in the resolution of VMA and vitreomacular traction at 28 days (26.5% of ocriplasmin patients vs 10.1% of placebo patients; number needed to treat, 6) and a lesser reduction in the proportion of patients undergoing vitrectomy (17.7% of patients vs 26.6% of patients; needed to treat, 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 (needed to treat, 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 a meaningful improvement in the net health outcome.

**CLINICAL INPUT FROM PHYSICIAN SPECIALTY SOCIETIES AND ACADEMIC MEDICAL CENTERS**

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

In response to requests, input was received from 1 physician specialty society and 1 academic medical center while this policy was under review in 2013. Input suggested that not all of the MIVI-TRUST trial exclusion criteria should be absolute. However, there was no consensus on which exclusion criteria should be removed. Individual reviewers suggested removing the following criteria: macular hole greater than 400 μm, proliferative diabetic retinopathy, vitreous opacification, aphakia, high myopia, neovascular age-related macular degeneration, history of retinal detachment, and uncontrolled glaucoma. In addition, it was suggested that ocriplasmin might be beneficial for the treatment of macular holes and vitreous hemorrhage.

**PRACTICE GUIDELINES AND POSITION STATEMENTS**

In 2013, the National Institute for Health and Care Excellence issued guidance on ocriplasmin for treating vitreomacular traction (VMT).<sup>17</sup> The Institute recommended ocriplasmin as an option for treating VMT in adults, only if:

- “an epiretinal membrane is not present **and**
- “they have a stage II full-thickness macular hole with a diameter of 400 micrometres or less **and/or**
- “they have severe symptoms.”

As of February 2017, this guidance was placed on the “static guidance list.”

**American Academy of Ophthalmology**

The American Academy of Ophthalmology’s 2016 preferred practice pattern on the idiopathic epiretinal membrane and VMT offered the following recommendations:

“The treating physician should discuss the option of treating patients who have VMT with ocriplasmin and compare the treatment with observation, a gas bubble injected into the

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vitreous, or vitrectomy surgery. *(good quality, strong recommendation)* The discussion should include the relevant risks versus benefits for each of these options. *(good quality, strong recommendation)*<sup>18</sup>

**U.S. PREVENTIVE SERVICES TASK FORCE RECOMMENDATIONS**

Not applicable.

**MEDICARE NATIONAL COVERAGE**

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

**ONGOING AND UNPUBLISHED CLINICAL TRIALS**

Some currently unpublished trials that might influence this review are listed in Table 1.

**Table 1. Summary of Key Trials**

<b>NCT No.</b>	<b>Trial Name</b>	<b>Planned Enrollment</b>	<b>Completion Date</b>
<b>Unpublished</b>			
NCT02035748 <sup>a</sup>	Assessment of Anatomical and Functional Outcomes in Patients Treated With Ocriplasmin for Vitreomacular/Symptomatic Vitreomacular Adhesion (VMT/sVMA)	400	Sep 2015 (completed)
NCT02322229 <sup>a</sup>	Assessment of Anatomical and Functional Outcomes in Subjects Treated With Ocriplasmin for Vitreomacular Traction/Symptomatic Vitreomacular Adhesion (VMT/sVMA)	62	May 2016 (completed)
NCT02079883 <sup>a</sup>	Ocrlasmin Research to Better Inform Treatment (ORBIT)	540	May 2016 (completed)

**IV. DEFINITIONS**

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N/A

**V. BENEFIT VARIATIONS**

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The existence of this medical policy does not mean that this service is a covered benefit under the member's contract. Benefit determinations should be based in all cases on the applicable contract language. Medical policies do not constitute a description of benefits. A member's individual or group customer benefits govern which services are covered, which are excluded, and which are subject to benefit limits and which require preauthorization. Members and providers should consult the member's benefit information or contact Capital BlueCross for benefit information.

**VI. DISCLAIMER**

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*Capital BlueCross medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and*

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*treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. Capital BlueCross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.*

**VII. CODING INFORMATION**

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**Note:** This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

**Covered when medically necessary:**

CPT Codes®							
67028							

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HCPCS Code	Description
J7316	Injection, ocriplasmin, 0.125 mg

ICD-10-CM Diagnosis Code	Description
H43.821	Disorders of vitreous body ; Vitreomacular adhesion, right eye
H43.822	Disorders of vitreous body ; Vitreomacular adhesion, left eye
H43.823	Disorders of vitreous body ; Vitreomacular adhesion, bilateral

**VIII. REFERENCES**

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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):644-651. PMID 23449509



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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):791-797. PMID 20138368
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**IX. POLICY HISTORY**

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<b>MP -2.181</b>	<b>CAC 11/26/13</b> New policy; BCBSA adopted. A single intravitreal injection of ocriplasmin may be considered medically necessary for treatment of an eye with symptomatic vitreomacular adhesion (VMA). All other indications are considered investigational. FEP variation added. Policy coded.
	<b>12/20/2013-</b> New 2014 Code updates made.
	<b>CAC 11/25/14</b> Consensus review. No change to policy statements. References and rationale updated. No change to policy statements. Coding Reviewed- Updated the ICD 10 range.
	<b>02/3/2015-</b> Unlisted code removed from the policy.
	<b>CAC 11/24/15</b> Consensus review. No change to the policy statements. Reference and rationale update. Coding reviewed.
	<b>CAC 9/27/16</b> Consensus review. No change to the policy statements. Reference and rationale update. Coding reviewed. Variation reformatting.
	<b>CAC 9/26/17</b> Minor revision. Vitreomacular traction added to the medically necessary indications. FEP policy number updated to 5.90.05. Rationale and Reference sections updated. Coding Review.
	<b>6/19/18</b> Consensus review. Policy statements unchanged. Description/Background, Rationale and Reference sections updated.

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