BlueCross BlueShield of Alabama

Name of Blue Advantage Policy:

Ocriplasmin for Symptomatic Vitreomacular Adhesion

Policy #: 535
Latest Review Date: March 2023
Category: Surgery

BACKGROUND:

Blue Advantage *medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:*

1. *Safe and effective;*
2. *Not experimental or investigational*;*
3. *Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*
   - *Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;*
   - *Furnished in a setting appropriate to the patient's medical needs and condition;*
   - *Ordered and furnished by qualified personnel;*
   - *One that meets, but does not exceed, the patient's medical need; and*
   - *At least as beneficial as an existing and available medically appropriate alternative.*

Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill* ***Original Medicare* *for covered services that are related to* ***clinical trials*** *that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).*

POLICY:

Blue Advantage will treat a **single intravitreal injection of ocriplasmin** as a **covered benefit** for treatment of an eye with symptomatic vitreomacular adhesion (VMA) or vitreomacular traction (VMT) when the following are met:

- 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 (> −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;
    - Prior laser photocoagulation of the macula in the affected eye;
    - Prior treatment with ocular surgery, intravitreal injection or retinal laser photocoagulation in the previous three months.

Blue Advantage will treat the **use of intravitreal ocriplasmin** as a **non-covered benefit** and as **investigational** in all other situations, including use of repeat injections of ocriplasmin.

Blue Advantage does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Advantage administers benefits based on the members' contract and medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

DESCRIPTION OF PROCEDURE OR SERVICE:

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.

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

Treatment
Symptoms of vitreomacular adhesion or vitreomacular traction can vary and 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 one to two 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, conducted in individuals scheduled to have vitrectomy, established doses that showed some effect in inducing posterior vitreous detachment.

KEY POINTS:
This policy is updated regularly with searches of the PubMed database. The most recent literature update was performed through December 19, 2022.

Summary of Evidence
For individuals who have symptomatic vitreomacular adhesion or vitreomacular traction who receive intravitreal injection of ocriplasmin, the evidence includes two 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, MIVI-TRUST, demonstrated an improvement in the resolution of vitreomacular adhesion and vitreomacular traction at 28 days (26.5% of ocriplasmin individuals vs. 10.1% of placebo individuals; NNT, six) and a lesser reduction in the proportion of individuals undergoing vitrectomy (17.7% of individuals vs. 26.6% of individuals; NNT, 11). Results of this and other trials have also shown an increase in the proportion of individuals who had clinically significant gains in visual acuity (NNT, 17) and visual function. The RCTs did not find higher rates of important complications; however, post marketing 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.

Practice Guidelines and Position Statements
The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

National Institute for Health and Care Excellence
In 2013(minor update in September 2020), the National Institute for Health and Care Excellence issued guidance on ocriplasmin for treating vitreomacular traction (VMT). The Institute recommended ocriplasmin as an option for treating vitreomacular 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."

[Ocriplasmin for treating vitremacular traction. N…. 7.]

American Academy of Ophthalmology
In 2019, the American Academy of Ophthalmology's preferred practice pattern on the idiopathic epiretinal membrane and vitreomacular traction stated the following:

"A Cochrane review of 932 eyes in four studies concluded that although ocriplasmin is useful in the treatment of symptomatic [vitreomacular adhesion], up to 20% of eyes treated with ocriplasmin will still require additional treatment with pars plana vitrectomy within six months. (I+, Good quality, Strong recommendation) There were more ocular adverse events in eyes in the ocriplasmin group than in the control treatment group (sham or placebo injection)."

U.S. Preventive Services Task Force Recommendations
Not applicable.

KEY WORDS:
Intravitreal Injection, Ocriplasmin, Jetrea, vitreomacular adhesion, VMA, vitreomacular traction, VMT

APPROVED BY GOVERNING BODIES:
On October 17, 2012, ocriplasmin (Jetrea®; ThromboGenics) was approved by the FDA for the treatment of symptomatic vitreomacular adhesion.

BENEFIT APPLICATION:
Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

CURRENT CODING:

CPT Codes:

67028	Intravitreal injection of a pharmacologic agent (separate procedure)

HCPCS Codes:

J7316	Injection, ocriplasmin, 0.125 mg

REFERENCES:

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POLICY HISTORY:

Adopted for Blue Advantage, August 2013
Available for comment August 22 through October 5, 2013
Medical Policy Group, August 2014
Medical Policy Group, August 2014
Medical Policy Group, March 2016
Medical Policy Group, March 2017
Medical Policy Group, March 2018

Medical Policy Group, March 2019
Medical Policy Group, March 2020
Medical Policy Group, March 2021
Medical Policy Group, March 2022
Medical Policy Group, March 2023

This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member's plan in effect as of the date services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.

This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield's administration of plan contracts.