Reimbursement Policy

Jetrea (Ocriplasmin)

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<th>Policy Number</th>
<th>Approved By</th>
<th>Current Approval Date</th>
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<tr>
<td>JET07232014RP</td>
<td>UnitedHealthcare Medicare Reimbursement Policy Committee</td>
<td>07/23/2014</td>
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IMPORTANT NOTE ABOUT THIS REIMBURSEMENT POLICY

This policy is applicable to UnitedHealthcare Medicare Advantage Plans offered by UnitedHealthcare and its affiliates.

You are responsible for submission of accurate claims. This reimbursement policy is intended to ensure that you are reimbursed based on the code or codes that correctly describe the health care services provided.

UnitedHealthcare reimbursement policies use Current Procedural Terminology (CPT®*), Centers for Medicare and Medicaid Services (CMS), or other coding guidelines. References to CPT or other sources are for definitional purposes only and do not imply any right to reimbursement.

This reimbursement policy applies to all health care services billed on CMS 1500 forms and, when specified, to those billed on UB04 forms (CMS 1450). Coding methodology, industry-standard reimbursement logic, regulatory requirements, benefits design and other factors are considered in developing reimbursement policy.

This information is intended to serve only as a general resource regarding UnitedHealthcare’s reimbursement policy for the services described and is not intended to address every aspect of a reimbursement situation. Accordingly, UnitedHealthcare may use reasonable discretion in interpreting and applying this policy to health care services provided in a particular case. Further, the policy does not address all issues related to reimbursement for health care services provided to UnitedHealthcare enrollees. Other factors affecting reimbursement may supplement, modify or, in some cases, supersede this policy. These factors may include, but are not limited to: legislative mandates, the physician or other provider contracts, and/or the enrollee’s benefit coverage documents. Finally, this policy may not be implemented exactly the same way on the different electronic claims processing systems used by UnitedHealthcare due to programming or other constraints; however, UnitedHealthcare strives to minimize these variations.

UnitedHealthcare may modify this reimbursement policy at any time by publishing a new version of the policy on this Website. However, the information presented in this policy is accurate and current as of the date of publication.

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Application

This reimbursement policy applies to services reported using the Health Insurance Claim Form CMS-1500 or its electronic equivalent or its successor form, and services reported using facility claim form CMS-1450 or its electronic equivalent or its successor form. This policy applies to all products, all network and non-network
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physicians, and other health care professionals.
The HCPCS/CPT code(s) may be subject to Correct Coding Initiative (CCI) edits. This policy does not take precedence over CCI edits. Please refer to the CCI for correct coding guidelines and specific applicable code combinations prior to billing UnitedHealthcare. It is not enough to link the procedure code to a correct, payable ICD-9-CM diagnosis code. The diagnosis must be present for the procedure to be paid. Compliance with the provisions in this policy is subject to monitoring by pre-payment review and/or post-payment data analysis and subsequent medical review. The effective date of changes/additions/deletions to this policy is the committee meeting date unless otherwise indicated. CPT codes and descriptions are copyright 2010 American Medical Association (or such other date of publication of CPT). All rights reserved. CPT is a registered trademark of the American Medical Association. Applicable FARS/DFARS restrictions apply to Government use. Fee schedules, relative value units, conversion factors, and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein. Current Dental Terminology (CDT), including procedure codes, nomenclature, descriptors, and other data contained therein, is copyright by the American Dental Association, 2002, 2004. All rights reserved. CDT is a registered trademark of the American Dental Association. Applicable FARS/DFARS apply.

Summary

Overview
Jetrea® (Ocriplasmin) is a proteolytic enzyme (or proteinase) that breaks down the long chain proteins into peptides and eventually into amino acids. Its activity is directed against the protein components of the vitreous body and the vitreoretinal interface where it dissolves the vitreomacular adhesions. Ocriplasmin is a truncated version of human plasmin produced by recombinant DNA technology created in yeast Pichia pastoris. Jetrea® (Ocriplasmin) is approved for the treatment of specific ocular conditions with the intent to prevent the need for surgery.

Reimbursement Guidelines
A single intravitreal injection of ocriplasmin is considered medically necessary for treatment of an eye* with symptomatic vitreomacular adhesion (VMA) when all of the following criteria are met:

1. Individual’s age is equal to or greater than 18 years;
2. Optical Coherence Tomography (OCT) (See Scanning Computerized Ophthalmic Diagnostic Imaging (SCODI)) demonstrates all of the following:
   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).
3. Individual has best-corrected visual acuity of 20/25 or less in the eye to be treated with ocriplasmin;
4. Individual does not have any of the following:
   a. proliferative diabetic retinopathy;
   b. neovascular age-related macular degeneration;
   c. retinal vascular occlusion;
   d. aphakia;
   e. high myopia (more than −8 diopters);
   f. macular hole greater than 400 μm in diameter;
   g. vitreous opacification;
   h. lenticular or zonular instability;
   i. history of retinal detachment in either eye;
   j. prior vitrectomy in the affected eye;
   k. prior laser photocoagulation of the macula in the affected eye.
   l. prior treatment with ocular surgery, intravitreal injection or retinal laser photocoagulation in the previous 3 months;
   m. patients with uncontrolled glaucoma.

*Note: For treatment of bilateral VMA, a waiting period of at least seven (7) days is recommended before treatment of the contralateral eye.
Drugs and biologicals must be determined to meet the statutory definition. Under the statute §1861(t)(1), payment may be made for a drug or biological only where it is included, or approved for inclusion, in the latest official edition of the United States Pharmacopeia National Formulary (USP-NF), the United States Pharmacopeia-Drug Information (USD-DI), or the American Dental Association (ADA) Guide to Dental Therapeutics, except for those drugs and biologicals unfavorably evaluated in the ADA Guide to Dental Therapeutics. The inclusion of an item in the USP DI does not necessarily mean that the item is a drug or biological. The USP DI is a database of drug information developed by the U.S. Pharmacopoeia but maintained by Micromedex, which contains medically accepted uses for generic and brand name drug products. Inclusion in such reference (or approval by a hospital committee) is a necessary condition for a product to be considered a drug or biological under the Medicare program, however, it is not enough. Rather, the product must also meet all other program requirements to be determined to be a drug or biological. Combination drugs are also included in the definition of drugs if the combination itself or all of the therapeutic ingredients of the combination are included, or approved for inclusion, in any of the above drug compendia.

Drugs and biologicals are considered approved for inclusion in a compendium if approved under the established procedure by the professional organization responsible for revision of the compendium. Drugs that are usually self-administered by the patient, such as those in pill form, or are used for self-injection, are generally not covered by Part B. However, there are a limited number of self-administered drugs that are covered because the Medicare statute explicitly provides coverage. Examples of drugs that are usually self-administered by the patient and are covered include: blood clotting factors, drugs used in immunosuppressive therapy, erythropoietin for dialysis patients, and osteoporosis drugs for certain homebound patients.

Generally, when a physician gives a patient pills or other oral medication, these drugs are excluded from coverage since the form of the drug is self-administered. Similarly, if a physician gives a patient an injection that is usually self-injected this drug is excluded from coverage, unless administered to the patient in an emergency situation.

In order to meet all the general requirements for coverage under the incident-to provision, an FDA approved drug or biological must be of a form that cannot be self-administered and must be administered by a physician or by auxiliary personnel employed by him/her under his/her personal supervision. To be covered, drugs and biologicals must be an expense to the physician billing for the service. For example, if a patient purchases a drug and the physician administers it, the drug is not covered. However, the administration of the drug, regardless of the source, is a service that represents an expense to the physician. Therefore, administration of the drug is payable if the drug would have been covered if the physician purchased it.

Use of the drug or biological must be safe and effective and otherwise reasonable and necessary. Drugs or biologicals and cancer chemotherapeutic agents approved for marketing by the Food and Drug Administration (FDA) are considered safe and effective for purposes of this requirement when used for indications specified on the labeling.

An unlabeled use of a drug is a use that is not included as an indication on the drug's label as approved by the FDA. FDA approved drugs used for indications other than what is indicated on the official label may be covered under Medicare if the contractor determines the use to be medically accepted, taking into consideration the major drug compendia, authoritative medical literature and/or accepted standards of medical practice. The following guidelines identify three categories in which medications would not be reasonable and necessary according to accepted standards of medical practice.

- **Not for Particular Illness** – Medications given for a purpose other than the treatment of a particular condition, illness, or injury are not covered (except for certain immunizations).
- **Injection Method Not Indicated** – Medication given by injection (parenterally) is not covered if standard medical practice indicates that the administration of the medication by mouth (orally) is effective and is an accepted or preferred method of administration.
- **Excessive Medications** – Medications administered for treatment of a disease which exceed the frequency or duration of injections indicated by accepted standards of medical practice are not covered.

If a medication is determined not to be reasonable and necessary for diagnosis or treatment of an illness or injury according to these guidelines, the entire charge will be excluded (i.e., for both the drug and its administration). Also excluded from payment is any charge for other services (such as office visits) which are primarily for the purpose of administering a non-covered injection (i.e., an injection that is not reasonable and necessary for the diagnosis or treatment of an illness or injury).
A drug that is less than effective is not eligible for reimbursement, i.e., one that the Food and Drug Administration has determined to lack substantial evidence of effectiveness for all labeled indications. Any other drug product that is identical, similar, or related, will also be ineligible.

If a use is identified as not indicated by CMS or the FDA or if a use is specifically identified as not indicated (in one or more of the three compendia mentioned) or if it is determined (based on peer reviewed medical literature) that a particular use of a drug is not safe and effective, the off-label usage is not supported and, therefore, the drug is not covered. In this instance, the administration is also not covered.

### Discarded Drugs and Biologicals

In certain situations, physicians, hospitals and other providers may schedule patients in such a way that they can use drugs or biologicals most efficiently, in a clinically appropriate manner.

The following elements must be followed in order for the discarded amount to be covered.

1. The vial must be a single-use vial.
2. The units billed must correspond with the smallest dose (vial) available for purchase from the manufacturer(s) that could provide the appropriate dose for the patient.
3. The left-over amount must actually be discarded and may not be used for another patient regardless of whether or not that other patient has Medicare.

As a reminder, drug wastage cannot be billed if none of the drug was administered (such as a missed appointment by the patient).

**NOTE:** Multi-use vials are not subject to payment for discarded amounts of drug or biological.

Refer to national policy: Medicare Claims Processing Manual – Pub. 100-04, Chapter 17, Section 40.

Note: The JW modifier is not used on claims for drugs or biologicals provided under the Competitive Acquisition Program (CAP). Reference to national policy: Medicare Claims Processing Manual, Pub. 100-04, Chapter 17, Section 100.2.9.

### Documentation Requirements

Documentation is expected to be maintained in the patient’s medical record and to be available upon request.

Every page of the record is expected to be legible and include both the appropriate patient identification information (e.g., complete name dates of service(s)), and information identifying the physician or non-physician practitioner responsible for and providing the care of the patient.

The submitted medical record should support the use of the selected ICD-9-CM code(s). The submitted CPT/HCPCS code should describe the service performed.

When a portion of the drug or biological is discarded, the medical record must clearly document the amount administered and the amount wasted or discarded.

### CPT/HCPCS Codes

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<th>Description</th>
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<tr>
<td>J7316</td>
<td>Injection, ocriplasmin, 0.125 mg (effective 01/01/2014)</td>
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<tr>
<td>C9298</td>
<td>Injection, ocriplasmin, 0.125 mg (expired 12/31/2013 – See J7316)</td>
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<tr>
<td>67028</td>
<td>Intravitreal injection of a pharmacologic agent (separate procedure)</td>
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### Modifiers

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<tr>
<td>JW</td>
<td>Drug amount discarded/not administered to any patient</td>
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<tr>
<td>LT</td>
<td>Left side (used to identify procedures performed on the left side of the body)</td>
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<tr>
<td>RT</td>
<td>Right side (used to identify procedures performed on the right side of the body)</td>
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### References Included (but not limited to):

**CMS LCD(s)**
Numerous LCDs

**CMS Article(s)**
Numerous Articles
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**CMS Benefit Policy Manual**
Chapter 15; § 50 Drugs and Biologicals

**CMS Claims Processing Manual**
Chapter 17; § 40 Discarded Drugs and Biologicals, § 100.2.9 Submission of Claims With the Modifier JW, “Drug Amount Discarded/Not Administered to Any Patient”

**CMS Transmittals**
Transmittal 2664, Change Request 8228, Dated 03/01/2013 (April 2013 Update of the Hospital Outpatient Prospective Payment System (OPPS))
Transmittal 2662, Change Request 8237, Dated 03/01/2013 (April 2013 Update of the Ambulatory Surgical Center (ASC) Payment System)

**UnitedHealthcare Reimbursement Policies**
Discarded Drugs and Biologicals
Scanning Computerized Ophthalmic Diagnostic Imaging (SCODI)
Self Administered Drug(s)

**MLN Matters**
Article MM8228, April 2013 Update of the Hospital Outpatient Prospective Payment System (OPPS)

**Other**
Jetrea Highlights of Prescribing Information, Jetrea Website

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<tr>
<td>Date</td>
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<td>New policy</td>
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