UnitedHealthcare®

**Reimbursement Policy**

# Lucentis(Ranibizumab)

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| **Policy Number** | LUC01112012RP | **Approved By** | UnitedHealthcare Medicare Reimbursement Policy Committee | **Current Approval Date** | 06/11/2014 |

**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.



**Table of Contents**

# Lucentis(Ranibizumab)

## 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 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.  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. 

## Summary

### Overview

Ranibizumab (Lucentis ®), is a recombinant humanized immunoglobulin G1 kappa (IgG1 kappa) monoclonal antibody fragment designed for intraocular use, is a vascular endothelial growth factor A (VEGF-A) antagonist. Ranibizumab binds to active forms of human VEGF-A, including the cleaved form (VEGF 110), and inhibits their biologic activity.

VEGF-A induces neovascularization (angiogenesis) and increases vascular permeability, which appears to play a role in the pathogenesis and progression of the neovascular (wet) form of age-related macular degeneration (AMD), a leading cause of blindness in adults older than 60 years of age in developed countries. Binding of ranibizumab to VEGF-A prevents VEGF-A from binding to VEGF receptors (i.e., VEGFR-1, VEGFR-2) on the surface of endothelial cells, reducing endothelial cell proliferation, angiogenesis, and vascular permeability. Ranibizumab was approved by the Food and Drug Administration (FDA) on June 30, 2006 for the treatment of patients with exudative senile macular degeneration. Effective June 22, 2010, the Food and Drug Administration (FDA) approved ranibizumab for macular edema following retinal vein occlusion (RVO). Effective August 10, 2012, the Food and Drug Administration (FDA) approved ranibizumab for diabetic macular edema.

### Reimbursement Guidelines

This policy defines coding and coverage for Ranibizumab including off-label indications. The recommended dosage and frequency of treatment is 0.3mg/0.3 ml or 0.5 mg/0.05 mL (10mg/mL) administered by intravitreal injection once a month(approximately 28 days). Treatment may be continued monthly or reduced to one injection every three months after the first four injections, if monthly treatments are not feasible. Compared to monthly dosing, however, it is expected that quarterly dosing may be less effective, and as such, patients should be evaluated at regular regimens. The administration for ranibizumab must be billed on the same claim as the drug, with CPT code 67028 (intravitreal injection of a pharmacologic agent).

**Notice:** This reimbursement policy imposes diagnosis limitations that support diagnosis to procedure code automated denials. However, services performed for any given diagnosis must meet all of the indications and limitations stated in this policy, the general requirements for medical necessity as stated in CMS payment policy manuals, any and all existing CMS national coverage determinations, and all Medicare payment rules. As published in CMS Medicare Program Integrity Manual 100-08, Section 13.5.1, in order to be covered under Medicare, a service shall be reasonable and necessary. UHC shall consider a service to be reasonable and necessary if we determine that the service is:

- Safe and effective.
- Not experimental or investigational (exception: routine costs of qualifying clinical trial services with dates

of service on or after September 19, 2000, that meet the requirements of the Clinical Trials NCD are considered reasonable and necessary).

- Appropriate, including the 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 needs.
  - At least as beneficial as an existing and available medically appropriate alternative.

Drugs and biologicals must be determined to meet the statutory definition. Under the Title XVIII of the Social Security Act (SSA): §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 Pharmacopoeia National Formulary (USP-NF), the United States Pharmacopoeia-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.

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 by UHC if we determine 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.

Medicare Benefit Policy Manual - Pub. 100-02, Chapter 15, Section 50, describes national policy regarding Medicare guidelines for coverage of drugs and biologicals.

Coverage for medication is based on the patient's condition, the appropriateness of the dose and route of administration, based on the clinical condition and the standard of medical practice regarding the effectiveness

 

of the drug for the diagnosis and condition. The drug must be used according to the indication and protocol listed in the accepted compendia ratings listed below.

- National Comprehensive Cancer Network (NCCN) Drugs and Biologies Compendium
- Thomson Micromedex DrugDex
- American Hospital Formulary Service-Drug Information (AHFS-DI)
- Clinical Pharmacology

**Drug Wastage**

UHC provides payment for the discarded drug/biological remaining in a single-use drug product after administering what is reasonable and necessary for the patient's condition. If the physician has made good faith efforts to minimize the unused portion of the drug/biological in how patients are scheduled and how he ordered, accepted, stored and used the drug, and made good faith efforts to minimize the unused portion of the drug in how it is supplied, UHC will cover the amount of drug discarded along with the amount administered. Documentation requirements are given below. 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 to UHC 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 patient's medical record must contain documentation that fully supports the medical necessity for services. This documentation includes, but is not limited to, relevant medical history, physical examination, and results of pertinent diagnostic tests or procedures.

The medical record must include the following information:

- A physician's order
- The name of the drug or biological administered;
- The route of administration;
- The dosage (e.g., mgs, mcgs, cc's or IU's);

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**

| Code | Description |
|---|---|
| 67028 | Intravitreal Injection of a Pharmacologic Agent (Separate Procedure) |
| J2778 | Injection, Ranibizumab, 0.1 mg |

**Modifiers**

| Code | Description |
|---|---|
| LT | Left side (used to identify procedures performed on the left side of the body) |
| RT | Right side (used to identify procedures performed on the right side of the body) |
| 50 | Bilateral Procedure |
| JW | Drug amount discarded/not administered to any patient |
| EJ | Subsequent doses in a series |

**References Included (but not limited to):**

**CMS LCD(s)**

Numerous LCDs

**CMS Articles**

Numerous Articles

# Lucentis(Ranibizumab)

**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 1419, Change Request 5865, Dated 01/18/2008

**UnitedHealthcare Medicare Advantage Coverage Summaries**

Age Related Macular Degeneration (AMD) Therapy

Vision Services, Therapy and Rehabilitation

**UnitedHealthcare Medicare & Retirement Reimbursement Policies**

Self Administered Drugs Reimbursement Policy

**UnitedHealth Group Medical Policies**

Macular Degeneration and Ocular Tumor Treatment

Proton Beam Radiation Therapy

Ophthalmologic Policy: Vascular Endothelial Growth Factor (VEGF) Inhibitors

**Others**

CMS Medicare Program Integrity Manual 100-08, § 13.5.1

XVIII of the Social Security Act (SSA): §1861(t)(1), payment

FDA News Release

**History**

| Date | Revisions |
|---|---|
| 06/11/2014 | • Annual review<br>• Removed *"The drug must be reported on a separate claim line for each eye treated, using the appropriate site modifier, RT or LT."* from the Riembursement Guidelines section as it was removed from some sourcing and remains in others<br>• Administrative updates |
| 04/10/2013 | Policy re-reviewed presented to committee/approved |
| 02/08/2012 | Policy approved by committee |
| 12/28/2011 | Policy created |

 