UnitedHealthcare®

Reimbursement Policy

Eylea (Aflibercept)

Policy Number	EYL03142012RP	**Approved By**	UnitedHealthcare Medicare Reimbursement Policy Committee	**Current Approval Date**	05/14/2014

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.

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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 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

Eylea (aflibercept ophthalmic solution), also known as VEGF Trap-Eye, is a fully human fusion protein, consisting of portions of VEGF receptors 1 and 2, that binds all forms of VEGF-A along with the related Placental Growth Factor (PlGF). Eylea is a specific and highly potent blocker of these growth factors. Eylea is specially purified and contains iso-osmotic buffer concentrations, allowing for injection into the eye.

Eylea was approved by the Food and Drug Administration (FDA) on November 18, 2011 for the treatment of patients with Neovascular (Wet) Age-Related Macular Degeneration (AMD). Eylea was approved by the Food and Drug Administration (FDA) on September 21, 2012 for the treatment of macular edema following central retinal vein occlusion (CRVO). The recommended dosage and frequency of treatment is 2 mg (0.05 mL) administered by intravitreal injection every 4 weeks (monthly) for the first 3 months, followed by 2 mg (0.05 mL) via intravitreal injection once every 8 weeks (2 months). Although Eylea may be dosed as frequently as 2 mg every 4 weeks (monthly), additional efficacy was not demonstrated when Eylea was dosed every 4 weeks compared to every 8 weeks.

Reimbursement Guidelines

This policy defines coding and coverage for Aflibercept including off-label indications. The administration for Aflibercept must be billed on the same claim as the drug, with CPT code 67028 (intravitreal injection of a pharmacologic agent). Effective for dates of service 11/18/2011 and after, the appropriate site modifier (RT, LT or 50) must be appended to CPT code 67028 to indicate if the service was performed unilaterally or bilaterally. Aflibercept is payable under Medicare Part B in places of service office (11) and independent clinic (49).

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 Medicare Program Integrity Manual Chapter 13 §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 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 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. 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. Self-administered drugs are not covered and should not be submitted to UHC unless requested to do so by the beneficiary. (See Self Administered Drug Policy SAD05152011SC)

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.

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

The payment allowance limits for drugs and biologicals that are not included in the ASP Medicare Part B Drug Pricing File or Not Otherwise Classified (NOC) Pricing File, other than new drugs that are produced or distributed under a new drug application (or other application) approved by the Food and Drug Administration, are based on the published Wholesale Acquisition Cost (WAC) or invoice pricing, except under OPPS where the payment allowance limit is 95 percent of the published AWP. An invoice may be requested if pricing is not available on the ASP pricing file. This file contains lists for NOC and true codes. This file can be located at the CMS website Medicare Part B Drug Average Sales Price.

Drug Wastage:

Medicare 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, the program 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:

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- 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)
J0178	Injection, aflibercept, 1 mg (effective 01/01/2013)
Q2046	Injection, aflibercept, 1 mg (expired 12/31/2012)

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

References Included (but not limited to):

CMS LCD(s)

Numerous LCDs

CMS Articles

Numerous Articles

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 2418, Change Request 7748, Dated 3/2/2012 (April 2012 Update of the Hospital Outpatient Prospective Payment System (OPPS))

Transmittal 2425, Change Request 7754, Dated 3/16/2012, (April 2012 Update of the Ambulatory Surgical Center (ASC) Payment System)

Transmittal 2611, Change Request 8141, Dated 12/14/2012, (January 2013 Update of the Hospital Outpatient Prospective Payment System (OPPS))

Transmittal 2598, Change Request 8082, Dated 11/26/2012, (Annual Type of Service (TOS) Update)

Transmittal 2616, Change Request 8137, Dated 12/21/2012, (January 2013 Integrated Outpatient Code Editor (I/OCE) Specifications Version 14.0)

Transmittal 2626, Change Request 8148, Dated 12/28/2012, (January Update of the Ambulatory Surgical Center (ASC) Payment System)

UnitedHealthcare Medicare Advantage Coverage Summaries

Age Related Macular Degeneration (AMD) Therapy

UnitedHealthcare Reimbursement Policies

Self Administered Drug(s)

Discarded Drugs and Biologicals

UnitedHealthcare Medical Policies

Ophthalmologic Policy: Vascular Endothelial Growth Factor (VEGF) Inhibitors

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MLN Matters

Article MM7748, April 2012 Update of the Hospital Outpatient Prospective Payment System (OPPS)
Article MM7754, April 2012 Update of the Ambulatory Surgical Center (ASC) Payment System
Article MM6950, Medicare Benefits Policy Manual Update-Determining Self-Administration of Drug or Biological

Others

FDA News Release
Medicare Program Integrity Manual Pub 100-08 Chapter 13 §13.5.1
Social Security Act §1861(t)(1)

History

Date	Revisions
05/14/2014	• Annual review • Administrative update
04/24/2013	Administrative update
12/18/2012	Administrative update
07/03/2012	Administrative update
07/01/2012	Administrative update
03/28/2012	Policy approved by committee
02/28/2012	Policy created

