CMS Manual System

Pub. 100-03 Medicare National Coverage Determinations

Department of Health & Human Services (DHHS)
Centers for Medicare & Medicaid Services (CMS)

Transmittal 9 **Date: APRIL 1, 2004**

CHANGE REQUEST 3191

I. SUMMARY OF CHANGES: Upon reconsideration of a previous noncoverage determination, OPT with verteporfin will be covered for: 1) subfoveal occult with no classic CNV associated with AMD; and 2) subfoveal minimally classic CNV (where the area of classic CNV occupies <50% of the area of the entire lesion) associated with AMD, provided certain criteria are met.

NEW/REVISED MATERIAL - EFFECTIVE DATE: April 1, 2004
***IMPLEMENTATION DATE: April 1, 2004**

(These revisions to §§80.2 and 80.3 of Pub. 100-03 are national coverage determinations (NCDs). The NCDs are binding on all carriers, fiscal intermediaries, quality improvement organizations, health maintenance organizations, competitive medical plans, and health care prepayment plans. Under 42 CFR 422.256(b), an NCD that expands coverage is also binding on a Medicare+Choice Organizations. In addition, an administrative law judge may not review an NCD. See §1869(f)(1)(A)(i) of the Social Security Act.)

Disclaimer for manual changes only: The revision date and transmittal number apply to the red italicized material only. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS:
(R = REVISED, N = NEW, D = DELETED)

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
R	1/Table of Contents
N	1/80.2.1/Ocular Photodynamic Therapy (OPT)
N	1/80.3.1/Verteporfin

***III. FUNDING:**

These instructions shall be implemented within your current operating budget.

IV. ATTACHMENTS:

X	**Business Requirements**

X	**Manual Instruction**
	Confidential Requirements
	One-Time Notification
	Recurring Update Notification

***Medicare contractors only**

Attachment - Business Requirements

Pub. 100-03	Transmittal: 9	Date: April 1, 2004	Change Request 3191

SUBJECT: NCD - Ocular Photodynamic Therapy (OPT) With Verteporfin for Age-Related Macular Degeneration (AMD)

I. GENERAL INFORMATION

A. Background: These revisions to §§80.2 and 80.3 of Pub. 100-03 are NCDs. The NCDs are binding on all Medicare carriers, fiscal intermediaries, quality improvement organizations, health maintenance organizations, competitive medical plans, and health care prepayment plans. Under 42 CFR 422.256(b), an NCD that expands coverage is also binding on a Medicare+Choice Organizations. In addition, an administrative law judge may not review an NCD. (See §1869(f)(1)(A)(i) of the Social Security Act.)

B. Policy: Upon reconsideration of a previous noncoverage determination, OPT with verteporfin will be covered for: 1) subfoveal occult with no classic choroidal neovascularization (CNV) associated with AMD; and 2) subfoveal minimally classic CNV (where the area of classic CNV occupies <50% of the area of the entire lesion) associated with AMD, provided certain criteria are met.

C. Provider Education: A provider education article related to this instruction will be available at www.cms.hhs.gov/medlearn/matters shortly after the CR is released. You will receive notification of the article release via the established "medlearn matters" listserv. Contractors shall post this article, or a direct link to this article, on their Web site and include information about it in a listserv message within 1 week of the availability of the provider education article. In addition, the provider education article must be included in your next regularly scheduled bulletin.

II. BUSINESS REQUIREMENTS

"Shall" denotes a mandatory requirement
"Should" denotes an optional requirement

Requirement #	Requirements	Responsibility
3191.1	Effective April 1, 2004, contractors shall note that, based on a reconsideration of current Medicare policy for OPT with verteporfin, CMS expands coverage to include the following 2 indications: 1) subfoveal occult with no classic CNV associated with AMD; and 2) subfoveal minimally classic CNV (where the area of classic CNV occupies <50% of the area of the entire lesion) associated with AMD.	Carriers/FIs

3191.2	Effective April 1, 2004, contractors shall note that, based on a reconsideration of current Medicare policy for OPT with verteporfin, CMS expands coverage to include 2 new indications indicated in 3191.1 above, only when the following 2 criteria are met: 1) the lesions are small (4 disk areas or less in size) at the time of initial treatment or within the 3 months prior to initial treatment; and 2) the lesions have shown evidence of progression within the 3 months prior to initial treatment. Evidence of progression must be documented by deterioration of visual acuity (at least 5 letters on a standard eye examination chart), lesion growth (an increase in at least 1 disk area), or the appearance of blood associated with the lesion.	Carriers/FIs
3191.3	Effective April 1, 2004, contractors shall note that, OPT with verteporfin continues to be covered for a diagnosis of neovascular AMD with predominantly classic CNV lesions (where the area of classic CNV occupies $\geq$50% of the area of the entire lesion) at the initial visit as determined by a fluorescein angiogram. (CNV lesions are comprised of classic and/or occult components.) Subsequent follow-up visits require a fluorescein angiogram prior to treatment. There are no requirements regarding visual acuity, lesion size, and number of re-treatments when treating predominantly classic lesions.	Carriers/FIs
3191.4	Effective April 1, 2004, contractors shall note that, other uses of OPT with verteporfin to treat AMD not already addressed by CMS, continue to be noncovered. These include, but are not limited to: 1) juxtafoveal or extrafoveal CNV lesions (lesions outside the fovea); 2) inability to obtain a fluorescein angiogram; and 3) atrophic or "dry" AMD.	Carriers/FIs
3191.5	Effective April 1, 2004, contractors shall note that, OPT with verteporfin for other ocular indications, such as pathologic myopia or presumed ocular histoplasmosis syndrome, continue to be eligible for local coverage determinations through individual contractor discretion.	Carriers/FIs

III. SUPPORTING INFORMATION AND POSSIBLE DESIGN CONSIDERATIONS

A. Other Instructions: N/A

X-Ref Requirement #	Instructions

B. Design Considerations: N/A

X-Ref Requirement #	Recommendation for Medicare System Requirements

C. Interfaces: N/A

D. Contractor Financial Reporting /Workload Impact: N/A

E. Dependencies: N/A

F. Testing Considerations: N/A

IV. SCHEDULE, CONTACTS, AND FUNDING

Effective Date: April 1, 2004 **Implementation Date: April 1, 2004** **Pre-Implementation Contact(s): Stuart Caplan, 410-786-8564, Pat Brocato-Simons, 410-786-0261** **Post-Implementation Contact(s): Stuart Caplan, 410-786-8564, Pat Brocato-Simons, 410-786-0261**	**These instructions shall be implemented within your current operating budget.**

Medicare National Coverage Determinations Manual

Chapter 1 - Coverage Determinations

Table of Contents

(Rev.9, 04-01-04)

80.2.1 Ocular Photodynamic Therapy (OPT) - Effective April 1, 2004 (see also 80.3 Photosensitive Drugs)

(Rev 9, 04-01-04)

General

The OPT is used in the treatment of ophthalmologic diseases; specifically, for age-related macular degeneration (AMD), a common eye disease among the elderly. OPT involves the infusion of an intravenous photosensitizing drug called verteporfin followed by exposure to a laser. OPT is only covered when used in conjunction with verteporfin.

Effective July 1, 2001, OPT with verteporfin was approved for a diagnosis of neovascular AMD with predominately classic subfoveal choroidal neovascularization (CNV) lesions (where the area of classic CNV occupies ≥ 50% of the area of the entire lesion) at the initial visit as determined by a fluorescein angiogram.

On October 17, 2001, CMS announced its "intent to cover" OPT with verteporfin for AMD patients with occult and no classic subfoveal CNV as determined by a fluorescein angiogram. The October 17, 2001, decision was never implemented.

On March 28, 2002, after thorough review and reconsideration of the October 17, 2001, intent to cover policy, CMS determined that the current noncoverage policy for OPT for verteporfin for AMD patients with occult and no classic subfoveal CNV as determined by a fluorescein angiogram should remain in effect.

Effective August 20, 2002, CMS issued a noncovered instruction for OPT with verteporfin for AMD patients with occult and no classic subfoveal CNV as determined by a fluorescein angiogram.

Covered Indications

Effective April 1, 2004, OPT with verteporfin continues to be approved for a diagnosis of neovascular AMD with predominately classic subfoveal CNV lesions (where the area of classic CNV occupies ≥ 50% of the area of the entire lesion) at the initial visit as determined by a fluorescein angiogram. (CNV lesions are comprised of classic and/or occult components.) Subsequent follow-up visits require a fluorescein angiogram prior to treatment. There are no requirements regarding visual acuity, lesion size, and number of re-treatments when treating predominantly classic lesions.

In addition, after thorough review and reconsideration of the August 20, 2002, noncoverage policy, CMS determines that the evidence is adequate to conclude that OPT with verteporfin is reasonable and necessary for treating:

1. *Subfoveal occult with no classic CNV associated with AMD; and,*

2. *Subfoveal minimally classic CNV (where the area of classic CNV occupies <50% of the area of the entire lesion) associated with AMD.*

The above 2 indications are considered reasonable and necessary only when:

1. The lesions are small (4 disk areas or less in size) at the time of initial treatment or within the 3 months prior to initial treatment; and,

2. The lesions have shown evidence of progression within the 3 months prior to initial treatment. Evidence of progression must be documented by deterioration of visual acuity (at least 5 letters on a standard eye examination chart), lesion growth (an increase in at least 1 disk area), or the appearance of blood associated with the lesion.

Noncovered Indications

Other uses of OPT with verteporfin to treat AMD not already addressed by CMS will continue to be noncovered. These include, but are not limited to, the following AMD indications:

- *Juxtafoveal or extrafoveal CNV lesions (lesions outside the fovea),*
- *Inability to obtain a fluorescein angiogram,*
- *Atrophic or "dry" AMD.*

Other

OPT with verteporfin for other ocular indications, such as pathologic myopia or presumed ocular histoplasmosis syndrome, continue to be eligible for local coverage determinations through individual contractor discretion.

(This NCD last reviewed March 2004.)

80.3.1 Verteporfin - Effective April 1, 2004 (see also 80.2.1 Ocular Photodynamic Therapy (OPT))

(Rev 9, 04-01-04)

General

Verteporfin, a benzoporphyrin derivative, is an intravenous lipophilic photosensitive drug with an absorption peak of 690 nm. Verteporfin was first approved by the Food and Drug Administration on April 12, 2000, and subsequently approved for inclusion in the United States Pharmacopoeia on July 18, 2000, meeting Medicare's definition of a drug as defined under §1861(t)(1) of the Social Security Act. Verteporfin is only covered when used in conjunction with ocular photodynamic therapy OPT) when furnished intravenously incident to a physician's service.

Covered Indications

Effective April 1, 2004, OPT with verteporfin is covered for patients with a diagnosis of neovascular age-related macular degeneration (AMD) with:

- *Predominately classic subfoveal choroidal neovascularization (CNV) lesions (where the area of classic CNV occupies ≥ 50% of the area of the entire lesion) at the initial visit as determined by a fluorescein angiogram. (CNV lesions are comprised of classic and/or occult components.) Subsequent follow-up visits require a fluorescein angiogram prior to treatment. There are no requirements regarding visual acuity, lesion size, and number of retreatments when treating predominantly classic lesions.*

- *Subfoveal occult with no classic associated with AMD.*

- *Subfoveal minimally classic CNV CNV (where the area of classic CNV occupies <50% of the area of the entire lesion) associated with AMD.*

The above 2 indications are considered reasonable and necessary only when:

1. The lesions are small (4 disk areas or less in size) at the time of initial treatment or within the 3 months prior to initial treatment; and,

2. The lesions have shown evidence of progression within the 3 months prior to initial treatment. Evidence of progression must be documented by deterioration of visual acuity (at least 5 letters on a standard eye examination chart), lesion growth (an increase in at least 1 disk area), or the appearance of blood associated with the lesion.

Noncovered Indications

Other uses of OPT with verteporfin to treat AMD not already addressed by CMS will continue to be noncovered. These include, but are not limited to, the following AMD indications: juxtafoveal or extrafoveal CNV lesions (lesions outside the fovea), inability to obtain a fluorescein angiogram, or atrophic or "dry" AMD.

Other

OPT with verteporfin for other ocular indications, such as pathologic myopia or presumed ocular histoplasmosis syndrome, continue to be eligible for local coverage determinations through individual contractor discretion.

(This NCD last reviewed March 2004.)