CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-03 Medicare National Coverage Determinations	Centers for Medicare & Medicaid Services (CMS)
Transmittal 155	**Date: June 14, 2013**
	Change Request 8292

SUBJECT: Ocular Photodynamic Therapy (OPT) with Verteporfin for Macular Degeneration

I. SUMMARY OF CHANGES: Effective for claims with dates of service on and after April 3, 2013, CMS will expand coverage of OPT with verteporfin for "wet" AMD. CMS is revising the requirements for testing to permit either optical coherence tomography (OCT) or FA to assess treatment response.

This revision to the Medicare National Coverage Determinations Manual is a national coverage determination (NCD). NCDs are binding on all carriers, fiscal intermediaries,contractors with the Federal government that review and/or adjudicate claims, determinations, and/or decisions], quality improvement organizations, qualified independent contractors, the Medicare appeals council, and administrative law judges (ALJs) (see 42 CFR section 405.1060(a)(4) (2005)). An NCD that expands coverage is also binding on a Medicare advantage organization. In addition, an ALJ may not review an NCD. (See section 1869(f)(1)(A)(i) of the Social Security Act.)

EFFECTIVE DATE: April 3, 2013
IMPLEMENTATION DATE: July 16, 2013

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. 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: (N/A if manual is not updated)
R=REVISED, N=NEW, D=DELETED-*Only One Per Row.*

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	1/80.2/Photodynamic Therapy
R	1/80.2.1/Ocular Photodynamic Therapy (OPT)
R	1/80.3/Photosensitive Drugs
R	1/80.3.1/Verteporfin

III. FUNDING:
For Fiscal Intermediaries (FIs), Regional Home Health Intermediaries (RHHIs) and/or Carriers:
No additional funding will be provided by CMS; Contractors activities are to be carried out with their operating budgets

For Medicare Administrative Contractors (MACs):
The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC statement of Work. The contractor is not obliged to incur costs in excess of the amounts allotted in your contract unless and until specifically

authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

IV. ATTACHMENTS:

Business Requirements
Manual Instruction

**Unless otherwise specified, the effective date is the date of service.*

Attachment - Business Requirements

Pub. 100-03	Transmittal: 155	Date: June 14, 2013	Change Request: 8292

SUBJECT: Ocular Photodynamic Therapy (OPT) with Verteporfin for Macular Degeneration

EFFECTIVE DATE: April 3, 2013

IMPLEMENTATION DATE: July 16, 2013

I. GENERAL INFORMATION

A. Background: The Centers for Medicare & Medicaid Services (CMS) received a formal written request from the American Academy of Ophthalmology (AAO) to review and update National Coverage Determination (NCD) 80.3.1 (Ocular Photodynamic Therapy (OPT) with Verteporfin) since this coverage decision was from 2004, prior to the emergence of targeted anti-VEGF intravitreal treatments. These newer therapies have largely supplanted OPT as initial management of age-related macular edema (AMD) and OPT is largely relegated to patients in whom the newer therapies have failed. When the policy was first written, an initial fluorescein angiography (FA) was ordered to determine if the lesions were considered classic choroidal neovascular (CNV) lesions. Then the patients were followed monthly with additional FA to determine the need for retreatment. The NCD requirement for monthly follow-up FA for OPT with verteporfin is no longer supportable for these "end-stage" patients. (Note: The request specifies NCD 80.3.1 of the NCD Manual but corresponding changes also appear in NCDs 80.2, 80.2.1, and 80.3.)

B. Policy: Effective for claims with dates of service on and after April 3, 2013, CMS will expand coverage of OPT with verteporfin for "wet" AMD. CMS is revising the requirements for testing to permit either optical coherence tomography (OCT) or FA to assess treatment response.

For complete guidelines on claims processing please refer to the Claims Processing Manual, Chapter 32, Section 300. All other coverage and claims processing criteria continue to apply. Please also refer to the NCD manual, Chapter 1, section 80.3.1, 80.2, 80.2.1, and 80.3 for coverage criteria.

II. BUSINESS REQUIREMENTS TABLE

"Shall" denotes a mandatory requirement, and "should" denotes an optional requirement.

Number	Requirement	Responsibility											
		A/B MAC			DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				Other
		A	B	HHH					FISS	MCS	VMS	CWF	
8292-03.1	Effective for claims with dates of service on or after April 3, 2013, CMS will expand coverage of OPT with verteporfin for "wet" AMD. Contractors shall accept and process claims for subsequent follow-up visits with either a fluorescein angiogram (FA), or optical coherence tomography (OCT) prior to treatment. Please refer to the Pub. 100-03 NCD Manual, Chapter 1, Sections 80.3.1, 80.2, 80.2.1, and 80.3 for coverage policy. For claims		X				X						

Number	Requirement	Responsibility											
		A/B MAC			DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				Other
		A	B	HHH					FISS	MCS	VMS	CWF	
	processing instructions please refer to Pub. 100-04, Claims Processing Manual, Chapter 32, Section 300.												

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility							
		A/B MAC			DME MAC	FI	CARRIER	RHHI	Other
		A	B	HHH					
8292-03.2	MLN Article : A provider education article related to this instruction will be available at http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/ shortly after the CR is released. You will receive notification of the article release via the established "MLN Matters" listserv. Contractors shall post this article, or a direct link to this article, on their Web sites and include information about it in a listserv message within one week of the availability of the provider education article. In addition, the provider education article shall be included in the contractor's next regularly scheduled bulletin. Contractors are free to supplement MLN Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly.	X	X			X	X		

IV. SUPPORTING INFORMATION

Section A: Recommendations and supporting information associated with listed requirements: N/A

"Should" denotes a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:

Section B: All other recommendations and supporting information: N/A

V. CONTACTS

Pre-Implementation Contact(s): Patricia Brocato-Simons, 410-786-0261 or Patricia.Brocatosimons@cms.hhs.gov (Coverage) , Brian Reitz, 410-786-5001 or Brian.Reitz@cms.hhs.gov (Part B Claims Processing) , Kimberly Long, 410-786-5702 or Kimberly.Long@cms.hhs.gov (Coverage) , Chuck Shih, 410-786-6671 or chuck.shih@cms.hhs.gov (Coverage) , Cami DiGiacomo, 410-786-5888 or cami.digiacomo@cms.hhs.gov (Part A Claims Processing) , Cynthia Thomas, 410-786-8169 or cynthia.thomas@cms.hhs.gov (Practitioner Part B) , Wanda Belle, 410-786-7491 or wanda.belle@cms.hhs.gov (Coverage)

Post-Implementation Contact(s): Contact your Contracting Officer's Representative (COR) or Contractor Manager, as applicable.

VI. FUNDING

Section A: For Fiscal Intermediaries (FIs), Regional Home Health Intermediaries (RHHIs), and/or Carriers:
No additional funding will be provided by CMS; Contractors activities are to be carried out with their operating budgets

Section B: For Medicare Administrative Contractors (MACs):
The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS do not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

80.2 - Photodynamic Therapy – *Effective April 3, 2013*
(*Rev.*155, Issued: 06-14-13, Effective: 04- 03-13, Implementation: 07-16-13)

Photodynamic therapy is a medical procedure which involves the infusion of a photosensitive (light-activated) drug with a very specific absorption peak. This drug is chemically designed to have a unique affinity for the diseased tissue intended for treatment. Once introduced to the body, the drug accumulates and is retained in diseased tissue to a greater degree than in normal tissue. Infusion is followed by the targeted irradiation of this tissue with a non-thermal laser, calibrated to emit light at a wavelength that corresponds to the drug's absorption peak. The drug then becomes active and locally treats the diseased tissue.

Ocular Photodynamic Therapy (OPT)

Ocular Photodynamic Therapy (OPT) is used in the treatment of ophthalmologic diseases. OPT is only covered when used in conjunction with verteporfin (see section 80.3, "Photosensitive Drugs").

• Classic Subfoveal Choroidal Neovascular (CNV) Lesions - OPT is covered with a diagnosis of neovascular age-related macular degeneration (AMD) with predominately classic subfoveal choroidal neovascular (CNV) lesions (where the area of classic CNV occupies ≥ 50 percent of the area of the entire lesion) at the initial visit as determined by a fluorescein angiogram. Subsequent follow-up visits will require *either* a*n optical coherence tomography (OCT) or a* fluorescein angiogram *(FA)* to *access* treatment *response*. There are no requirements regarding visual acuity, lesion size, and number of re-treatments.

• Occult Subfoveal Choroidal Neovascular (CNV) Lesions - OPT is noncovered for patients with a diagnosis of age-related macular degeneration (AMD) with occult and no classic CNV lesions.

• Other Conditions - Use of OPT with verteporfin for other types of AMD (e.g., patients with minimally classic CNV lesions, atrophic, or dry AMD) is noncovered. OPT with verteporfin for other ocular indications such as pathologic myopia or presumed ocular histoplasmosis syndrome, is eligible for coverage through individual contractor discretion.

80.2.1 - Ocular Photodynamic Therapy (OPT) - Effective April *3*, 20*13*
***Rev.*155, Issued: 06-14-13, Effective: 04- 03-13, Implementation: 07-16-13)**

A. General

*Ocular Photodynamic Therapy (*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 *(FA).*

On October 17, 2001, *the Centers for Medicare & Medicaid Services (*CMS*)* announced its "intent to cover" OPT with verteporfin for AMD patients with occult and no classic subfoveal CNV as determined by *an FA.* 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 non-coverage policy for OPT for verteporfin for AMD patients with occult and no classic subfoveal CNV as determined by *an FA* should remain in effect.

Effective August 20, 2002, CMS issued a non-covered instruction for OPT with verteporfin for AMD patients with occult and no classic subfoveal CNV as determined by *an FA.*

B. *Nationally* 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 *an FA.* (CNV lesions are comprised of classic and/or occult components.) Subsequent follow-up visits require *either an optical coherence tomography (OCT) (effective April 3. 2013) or* an *FA (effective April 1, 2004)* to *access* treatment *response*. 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, non-coverage 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:

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.

C. *Nationally* Non-Covered Indications

Other uses of OPT with verteporfin to treat AMD not already addressed by CMS will continue to be non-covered. 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.

D. Other

The 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.

80.3 - Photosensitive Drugs – *Effective April 3, 2013*

***Rev.*155, Issued: 06-14-13, Effective: 04- 03-13, Implementation: 07-16-13)**

Photosensitive drugs are the light-sensitive agents used in photodynamic therapy. Once introduced into the body, these drugs selectively identify and adhere to diseased tissue. The drugs remain inactive until they are exposed to a specific wavelength of light, by means of a laser, that corresponds to their absorption peak. The activation of a photosensitive drug results in a photochemical reaction which treats the diseased tissue without affecting surrounding normal tissue.

Verteporfin

Verteporfin, a benzoporphyrin derivative, is an intravenous lipophilic photosensitive drug with an absorption peak of 690 nm. This drug was first approved by the Food and Drug Administration (FDA) 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 when used in conjunction with ocular photodynamic therapy *(OPT)* (see *section* 80.2, "Photodynamic Therapy") when furnished intravenously incident to a physician's service. For patients with age-related macular degeneration *(AMD),* Verteporfin is only covered with a diagnosis of neovascular age-related macular degeneration with predominately classic subfoveal choroidal neovascular (CNV) lesions (where the area of classic CNV occupies ≥ 50 percent of the area of the entire lesion) at the initial visit as determined by a fluorescein angiogram *(FA).* Subsequent follow-up visits will require *either an optical coherence tomography (OCT) or an* FA to *access* treatment *response*. OPT with verteporfin is covered for the above indication and will remain non-covered for all other indications related to AMD (see *section* 80.2). OPT with Verteporfin for use in non-AMD conditions is eligible for coverage through individual contractor discretion.

80.3.1- Verteporfin - Effective April *3*, 20*13*

***Rev.*155, Issued: 06-14-13, Effective: 04- 03-13, Implementation: 07-16-13)**

A. 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.

B. *Nationally* 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 *either an optical coherence tomography (OCT) (effective April 3, 2013) or a* fluorescein angiogram (FA) *(effective April 1, 2004)* to access treatment response.

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.

C. *Nationally* Non-*C*overed Indications

Other uses of OPT with verteporfin to treat AMD not already addressed by *the Centers for Medicare & Medicaid Services* will continue to be non-covered. These include, but are not limited to, the following AMD indications: juxtafoveal or extrafoveal CNV lesions (lesions outside the fovea), inability to obtain an FA, or atrophic or "dry" AMD.

D. Other

The 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.