OVERVIEW

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 with 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-coverage instruction for OPT with verteporfin for AMD patients with occult and no classic subfoveal CNV as determined by an FA.

GUIDELINES

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) or a FA to access treatment response. There are no requirements regarding visual acuity, lesion size, and number of re-treatments when treating predominately classic lesions.

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

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

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.

Note: See NCD 80.2 Photodynamic Therapy for complete coding and coverage guidelines.

PURPOSE
The Medicare Advantage Policy Guideline documents are generally used to support UnitedHealthcare Medicare Advantage claims processing activities and facilitate providers’ submission of accurate claims for the specified services. The document can be used as a guide to help determine applicable:
- Medicare coding or billing requirements, and/or
- Medical necessity coverage guidelines; including documentation requirements.

UnitedHealthcare follows Medicare guidelines such as LCDs, NCDs, and other Medicare manuals for the purposes of determining coverage. It is expected providers retain or have access to appropriate documentation when requested to support coverage. Please utilize the links in the References section below to view the Medicare source materials used to develop this resource document. This document is not a replacement for the Medicare source materials that outline Medicare coverage requirements. Where there is a conflict between this document and Medicare source materials, the Medicare source materials will apply.

REFERENCES
CMS National Coverage Determinations (NCDs)
NCD 80.2.1 Ocular Photodynamic Therapy (OPT)
Reference NCDs: NCD 80.2 Photodynamic Therapy, NCD 80.3 Photosensitive Drugs, NCD 80.3.1 Verteporfin

GUIDELINE HISTORY/REVISION INFORMATION
Revisions to this summary document do not in any way modify the requirement that services be provided and documented in accordance with the Medicare guidelines in effect on the date of service in question.

<table>
<thead>
<tr>
<th>Date</th>
<th>Action/Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>06/12/2019</td>
<td>Annual review; no changes</td>
</tr>
</tbody>
</table>

TERMS AND CONDITIONS
The Medicare Advantage Policy Guidelines are applicable to UnitedHealthcare Medicare Advantage Plans offered by UnitedHealthcare and its affiliates.

These Policy Guidelines are provided for informational purposes, and do not constitute medical advice. Treating physicians and healthcare providers are solely responsible for determining what care to provide to their patients. Members should always consult their physician before making any decisions about medical care.

Benefit coverage for health services is determined by the member specific benefit plan document* and applicable laws that may require coverage for a specific service. The member specific benefit plan document identifies which services are covered, which are excluded, and which are subject to limitations. In the event of a conflict, the member specific benefit plan document supersedes the Medicare Advantage Policy Guidelines.

Medicare Advantage Policy Guidelines are developed as needed, are regularly reviewed and updated, and are subject to change. They represent a portion of the resources used to support UnitedHealthcare coverage decision making.
UnitedHealthcare may modify these Policy Guidelines at any time by publishing a new version of the policy on this website. Medicare source materials used to develop these guidelines include, but are not limited to, CMS National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Medicare Benefit Policy Manual, Medicare Claims Processing Manual, Medicare Program Integrity Manual, Medicare Managed Care Manual, etc. The information presented in the Medicare Advantage Policy Guidelines is believed to be accurate and current as of the date of publication, and is provided on an "AS IS" basis. Where there is a conflict between this document and Medicare source materials, the Medicare source materials will apply.

You are responsible for submission of accurate claims. Medicare Advantage Policy Guidelines are intended to ensure that coverage decisions are made accurately based on the code or codes that correctly describe the health care services provided. UnitedHealthcare Medicare Advantage Policy Guidelines 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 or guarantee claims payment.

Medicare Advantage Policy Guidelines are the property of UnitedHealthcare. Unauthorized copying, use and distribution of this information are strictly prohibited.

*For more information on a specific member's benefit coverage, please call the customer service number on the back of the member ID card or refer to the Administrative Guide.