Medlearn Matters
Information for Medicare Providers

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Implementation Date: April 1, 2004

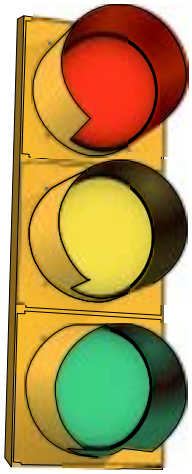
Medlearn Matters Number: MM3191

Ocular Photodynamic Therapy (OPT) with Verteporfin for Age-Related Macular Degeneration (AMD)

Provider Types Affected

All Medicare providers.

Provider Action Needed



STOP – Impact to You

This National Coverage Determination (NCD) provides for a change in the Medicare coverage policy for the use of Ocular Photodynamic Therapy (OPT) with verteporfin for age-related macular degeneration (AMD). Under certain conditions (described below), OPT with verteporfin for AMD will now be covered for additional clinical indications.

CAUTION – What You Need to Know

CMS has determined that, provided certain criteria are met, OPT with verteporfin (CPT codes 67221 and 67225, as well as HCPCS code J3395) will now be covered for AMD in two additional clinical instances:

1) subfovial occult lesions with no classic choroidal neovascularization (CNV); and

2) subfoveal minimally classic CNV associated with AMD.

GO – What You Need to Do

Make sure that your billing staffs are aware of these coverage changes.

Background

This NCD is documented in revisions to Chapters 80.2 and 80.3 of Pub. 100-03. Remember that NCDs are binding on all Medicare carriers, fiscal intermediaries, quality improvement organizations, health maintenance organizations, competitive medical plans, and health care prepayment plans. An NCD is also binding on Medicare + Choice Organizations. Administrative Law Judges may not review NCDs.

This NCD addresses coverage for the use of OPT with verteporfin in additional clinical instances. OPT with verteporfin continues to be approved for patients with 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).

> Note: Remember that this diagnosis must be determined by a fluorescein angiogram at the initial visit. Also, there are no requirements regarding visual acuity, lesion size, and number of re-treatments when treating predominantly classic lesion patients; however, they do require a fluorescein angiogram in subsequent, follow-up visits prior to treatment.

In addition to this diagnosis, after thorough review and reconsideration of the August 20, 2002 noncoverage policy, CMS has determined that there is enough evidence to conclude that OPT with verteporfin, in certain instances, may be reasonable and necessary for treating subfoveal occult lesions with no classic CNV and subfoveal minimally-classic CNV lesions (where the area of classic CNV occupies <50% of the area of the entire lesion).

These two new covered 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
- They have shown evidence of progression within the 3 months prior to initial treatmentYou must confirm this evidence of progression by documenting the 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.

Be aware that the other AMD-related uses of OPT with verteporfin, not already addressed by CMS, will continue to be noncovered. These include, but are not limited to: juxtafoveal or extrafoveal CNV lesions (lesions outside the fovea); inability to obtain a fluorescein angiogram; or atrophic or “dry” AMD. On the other hand, the use of 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 Medicare contractor discretion.

The following is a short history leading up to the current NCD.

1. Effective July 1, 2001, CMS approved the use of OPT with verteporfin in neovascular AMD patients having predominately classic subfoveal CNV lesions.
2. On October 17, 2001, CMS announced its “intent to cover” OPT with verteporfin for AMD patients with occult subfoveal CNV lesions; however, this decision was never implemented.
3. On March 28, 2002, CMS reviewed the October 17, 2001 intent to cover policy, and determined that the (then) current noncoverage policy for OPT for verteporfin for AMD patients with occult subfoveal CNV should remain in effect.
4. Effective August 20, 2002, CMS issued a noncovered instruction for OPT with verteporfin for AMD patients with occult subfoveal CNV lesions.

5. Now CMS, after through review and reconsideration of the August 2002 decision, has determined that there is enough evidence to conclude that OPT with verteporfin is also reasonable and necessary in these additional clinical instances. Therefore, this NCD, effective April 1, 2004, provides for covering the use of OPT with verteporfin in patients with subfoveal occult lesions with no classic CNV, and subfoveal minimally classic CNV lesions as described above.

Additional Information

You can find additional background information in Pub. 100-03, Chapters 80.2 and 80.3, which are included in the actual instruction issued to Medicare carriers and fiscal intermediaries on this NCD. This instruction can be found in CR3191 at:

http://www.cms.hhs.gov/manuals/transmittals/comm_date_dsc.asp

Once at that site, scroll down to find 3191 in the CR NUM column on the right and then click on the file for that number.