Intraocular Radiotherapy for Age-Related Macular Degeneration

Policy Number: 9.03.20  Last Review: 9/2020

Policy
Blue Cross and Blue Shield of Kansas City (Blue KC) will not provide coverage for intraocular radiation therapy for age-related macular degeneration. This is considered investigational.

When Policy Topic is covered
Not Applicable

When Policy Topic is not covered
Intraocular placement of a radiation source (brachytherapy) for the treatment of choroidal neovascularization is considered investigational.

Proton beam therapy for the treatment of choroidal neovascularization is considered investigational.

Stereotactic radiation therapy for the treatment of choroidal neovascularization is considered investigational.

Description of Procedure or Service

<table>
<thead>
<tr>
<th>Populations</th>
<th>Interventions</th>
<th>Comparators</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Individuals:  ▪ With choroidal neovascularization associated with age-related macular degeneration</td>
<td>Interventions of interest are:  ▪ Brachytherapy</td>
<td>Comparators of interest are:  ▪ Intravitreal vascular endothelial growth factor  ▪ Photodynamic therapy</td>
<td>Relevant outcomes include:  ▪ Change in disease status  ▪ Morbid events  ▪ Functional outcomes  ▪ Quality of life  ▪ Medication use  ▪ Treatment-related morbidity</td>
</tr>
<tr>
<td>Individuals:  ▪ With choroidal neovascularization associated with age-related macular</td>
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<td>Comparators of interest are:  ▪ Intravitreal vascular endothelial growth factor  ▪ Photodynamic therapy</td>
<td>Relevant outcomes include:  ▪ Change in disease status  ▪ Morbid events  ▪ Functional outcomes</td>
</tr>
</tbody>
</table>
Individuals: ▪ With choroidal neovascularization associated with age-related macular degeneration

Interventions of interest are: ▪ Stereotactic radiotherapy

Comparators of interest are: ▪ Intravitreal vascular endothelial growth factor ▪ Photodynamic therapy

Relevant outcomes include: ▪ Change in disease status ▪ Morbid events ▪ Functional outcomes ▪ Quality of life ▪ Medication use ▪ Treatment-related morbidity

Intraocular radiation, including brachytherapy, proton beam therapy, and stereotactic radiotherapy, are being evaluated to treat choroidal neovascularization (CNV) associated with age-related macular degeneration (AMD).

For individuals who have CNV due to AMD who receive brachytherapy, the evidence includes 2 randomized controlled trials (RCTs) comparing brachytherapy plus vascular endothelial growth factor (VEGF) to VEGF monotherapy as well as phase 1/2 trials and case series on the use of brachytherapy. Relevant outcomes are change in disease status, morbid events, functional outcomes, quality of life, medication use, and treatment-related morbidity. Both RCTs showed that brachytherapy did not attain noninferiority for visual acuity outcomes and was associated with a higher proportion of adverse events. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have CNV due to AMD who receive proton beam therapy, the evidence includes a randomized, prospective, sham-controlled trial and a pilot study. Relevant outcomes are change in disease status, morbid events, functional outcomes, quality of life, medication use, and treatment-related morbidity. Recruitment into the RCT was halted for ethical concerns, and available results did not show statistically significant stabilization of visual acuity. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have CNV due to AMD who receive stereotactic radiotherapy, the evidence includes an RCT with sham control. Relevant outcomes are change in disease status, morbid events, functional outcomes, quality of life, medication use, and treatment-related morbidity. The RCT showed a reduction in the number of VEGF treatments at 12- and 24-month intervals, but no significant differences versus controls for changes in visual acuity. The evidence is insufficient to determine the effects of the technology on health outcomes.

**Background**

**Age-Related Macular Degeneration**

Age-related macular degeneration (AMD) is the leading cause of legal blindness in individuals older than age 60 in developed nations. AMD is characterized in its earliest stages by minimal visual impairment and the presence of large drusen and...
other pigmentary abnormalities on ophthalmoscopic examination. Two distinctive forms of degeneration may be observed. The first, called the atrophic or areolar or dry form, evolves slowly. Atrophic AMD is the most common form of degeneration and may be a precursor of the more visually impairing exudative neovascular form, also referred to as disciform or wet AMD. The wet form is distinguished from the atrophic form by the development of choroidal neovascularization (CNV) and serous or hemorrhagic detachment of the retinal pigment epithelium. Risk of developing severe irreversible loss of vision is greatly increased by the presence of CNV.

**Standard Clinical Management**

Usual care for neovascular AMD includes intravitreal agents that target vascular endothelial growth factor (VEGF), including pegaptanib, ranibizumab, bevacizumab, and aflibercept. Photodynamic therapy is an older method that has been largely replaced by anti-VEGF therapies. The intravitreal therapies may necessitate repeated intravitreal injections. Hence, alternative treatments, such as intraocular radiation, including brachytherapy, proton beam therapy (PBT), and stereotactic radiotherapy, are being investigated.

The NeoVista Epi-Rad90 Ophthalmic System, a brachytherapy device, treats CNV by delivering focal radiation to a subfoveal choroidal neovascular lesion. Using a standard vitrectomy procedure, the cannula tip of a handheld (pipette-like) surgical device is inserted into the vitreous cavity and positioned under visual guidance over the target lesion. The radiation source (strontium 90) is advanced down the cannula until it reaches the tip, which is then held in place over the lesion for a “prescribed” time to deliver focused radiation. The system is designed to deliver a 1-time peak dose of beta particle energy (24 gray) for a target area 3 mm in depth and up to 5.4 mm in diameter. This dose is believed to be below that toxic to the retina and optic nerve. Radiation exposure outside of the target area is expected to be minimal.

PBT is a type of external radiation that uses charged atomic particles (protons or helium ions) to target a given area. PBT differs from conventional electromagnetic (photon) radiotherapy in that, with PBT, there is less scatter as the particle beams pass through tissue to deposit ionizing energy at precise depths (Bragg peak). The theoretical advantage of PBT over photon therapy is the ability to deliver higher radiation doses to the target without harm to adjacent normal tissue.

Stereotactic radiotherapy is a nonsurgical procedure performed in an office setting. It uses a robotically controlled device to deliver radiation beams through the inferior sclera to overlap at the macula.

**Other Treatments**

Other available therapeutic options for AMD not addressed in this evidence review include photodynamic therapy (see separate policy) and VEGF antagonists or angiostatics (evidence review in separate policy).
For those whose visual loss impairs their ability to perform daily tasks, low-vision rehabilitative services offer resources to compensate for deficits.

**Regulatory Status**

No devices are specifically approved by the U.S. Food and Drug Administration (FDA) for intraocular radiation. An investigational device exemption was granted by FDA for a phase 3 multicenter trial of the EPI-RAD90™ (now known as Vidion Anti-Neovascular Epimacular Brachytherapy [EMBT] System; NeoVista) to provide data for a device application to FDA. This is a category B procedure.

**Rationale**

This evidence review was created in July 2008 and has been updated regularly with searches of the MEDLINE database. The most recent literature update was performed through January 13, 2020.

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function—including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice. The following is a summary of the key literature to date.

**Brachytherapy**

**Clinical Context and Therapy Purpose**

The purpose of brachytherapy for patients who have choroidal neovascularization associated with age-related macular degeneration is to provide a treatment option that is an alternative to or an improvement on existing therapies.
The question addressed in this evidence review is: Does the use of brachytherapy for patients who have choroidal neovascularization associated with age-related macular degeneration improve net health outcomes?

The following PICO was used to select literature to inform this review.

**Patients**
The relevant population of interest is patients with choroidal neovascularization associated with age-related macular degeneration.

**Interventions**
The treatment being considered is brachytherapy. Brachytherapy treats choroidal neovascularization by delivering focal radiation to a subfoveal choroidal neovascular lesion.

Brachytherapy is performed by ophthalmologists and radiation oncologists in a surgical setting. After surgery, patients are hospitalized for 2-4 days during the brachytherapy. Once the brachytherapy is complete, the patient undergoes another operation to remove the protective gold plaque that was placed on the eye during the first operation. At this point the patient may go home.

**Comparators**
The following practices are currently being used to treat choroidal neovascularization associated with age-related macular degeneration: intravitreal vascular endothelial growth factor and photodynamic therapy. These treatments are generally administered by an ophthalmologist or other eye specialist in an outpatient clinical setting.

**Outcomes**
The general outcomes of interest are change in disease status, morbid events, functional outcomes, quality of life, medication use, and treatment-related morbidity.

Follow-up of 1-2 years is desirable to assess outcomes.

**Study Selection Criteria**
Methodologically credible studies were selected using the following principles:

1. To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs.
2. In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
3. To assess longer-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.

Jackson et al. (2016) reported on the results of a phase 3 RCT, Epimacular Brachytherapy for Previously Treated Neovascular Age-Related Macular Degeneration (Macular Epiretinal Brachytherapy versus Ranibizumab (Lucentis)
Only Treatment - MERLOT), comparing epimacular brachytherapy plus as-needed ranibizumab (n=224) with as-needed ranibizumab alone (n=119) in patients with neovascular age-related macular degeneration, already receiving ranibizumab.\(^1\) It was not feasible to mask patients to their surgical group (epimacular brachytherapy), but visual acuity testing and macular imaging results were evaluated by masked assessors. The trial was powered to test the hypothesis that epimacular brachytherapy would reduce the number of antivascular endothelial growth factor treatments, with a noninferior visual outcome (a margin of 5 letters of visual acuity). Over 12 months of follow-up, the mean number of as-needed ranibizumab injections did not differ significantly between the epimacular brachytherapy arm (4.8 treatments) and the ranibizumab monotherapy arm (4.1 treatments; p=0.068). From baseline to month 12, the mean change in best-corrected visual acuity was -4.8 letters in the epimacular brachytherapy arm compared with -0.9 letters in the ranibizumab monotherapy arm (between-group difference 95% confidence interval [CI], -6.6 to -1.8, which did not demonstrate inferiority at the prespecified 5-letter margin). In contrast to the null hypothesis, ranibizumab monotherapy patients had superior outcomes for visual acuity. Adverse events were more common in the epimacular brachytherapy arm. Overall, these results did not support the use of epimacular brachytherapy over ranibizumab monotherapy for neovascular age-related macular degeneration.

A phase 3 multicenter RCT, A Study of Strontium90 Beta Radiation With Lucentis to Treat Age-Related Macular Degeneration (CABERNET; NCT00454389), enrolled 494 subjects with age-related macular degeneration related wet choroidal neovascularization from 42 sites.\(^2,3\) The safety and efficacy of epimacular brachytherapy combined with 2 loading injections of ranibizumab (Lucentis) were compared with ranibizumab monotherapy (2 loading doses and then quarterly). Patients in both arms of the trial could receive monthly treatment with ranibizumab as needed. At 24 months, 77% of the patients in the epimacular brachytherapy group lost fewer than 15 letters compared with 90% in the control group. This result did not meet the prespecified noninferiority margin. Epimacular brachytherapy treatment also did not meet the superiority end point, which was the proportion of participants gaining more than 15 letters (16% vs. 26% for the ranibizumab group). The most common serious adverse event was cataract surgery (known to be associated with vitrectomy), which occurred in 40% of the epimacular brachytherapy group compared with 11% of the ranibizumab monotherapy group. Mild radiation retinopathy occurred in 3% of the patients who received epimacular brachytherapy treatment. This trial did not support the use of epiretinal radiotherapy.

Twelve- and 24-month results from the multicenter study, A Study of the NeoVista Ophthalmic System for the Treatment of Subfoveal choroidal neovascularization Associated With Wet age-related macular degeneration in Patients That Require Persistent Antivascular Endothelial Growth Factor Therapy (MERITAGE; NCT00809419) were reported between 2012 and 2014.\(^4,5,6\) MERITAGE was a phase 1/2 study of epimacular brachytherapy for the treatment of subfoveal choroidal neovascularization associated with wet age-related macular degeneration in patients requiring continued antivascular endothelial growth factor therapy to
maintain an adequate response. Following a single 24-gray dose, the 53 patients in the study received retreatment with ranibizumab administered monthly (as needed). In the 12 months before the study, participants received 0.45 injections per month. At the 12-month follow-up, 81% (43/53) of patients maintained stable vision (loss of <15 letters), with a mean of 3.49 antivascular endothelial growth factor injections (0.29 per month). Over 24 months, the durability of the application diminished, with 68% (32/47) of patients maintaining stable vision at a mean of 8.7 antivascular endothelial growth factor injections (0.72 per month).

Three publications from 2 studies have been reported by Avila et al on epimacular brachytherapy using the EPI-RAD90 System.\textsuperscript{7,8,9} One report (2009) described 12-month safety and visual acuity results of a feasibility study in 34 treatment-naive patients from Turkey, Mexico, and Brazil who were recruited between 2005 and 2006.\textsuperscript{7} The second report (2009) described 12-month safety and visual acuity results for 24-gray (Gy) epimacular brachytherapy combined with bevacizumab in 34 treatment-naive patients enrolled between 2006 and 2007.\textsuperscript{8} Adverse events related to the device or procedure included subretinal hemorrhage (n=1), retinal tear (n=1), subretinal fibrosis (n=2), epiretinal membrane (n=1), and cataract (n=6/24; 24 patients were phakic at baseline). All occurrences of cataracts were deemed to be related to the vitrectomy procedure. Two- and 3-year results from this trial were published in 2012.\textsuperscript{9} All 34 subjects were followed for 24 months; 1 site that enrolled 19 patients agreed to re-consent and follow patients for 3 years. On average, the cohort followed for 36 months received 3.0 bevacizumab injections. Twelve (50%) of the 24 phakic patients developed cataracts, and 4 had phacoemulsification with intraocular lens implantation. Mean change in visual acuity at 36 months was +3.9 letters. Seven (54%) of 13 phakic patients developed cataracts, and 4 had phacoemulsification with intraocular lens implantation. One case of nonproliferative radiation retinopathy was observed at 36 months.

**Section Summary: Brachytherapy**

At least 2 RCTs, which have been supported by additional non-randomized studies, have found that epimacular brachytherapy is inferior to local treatment with ranibizumab for the treatment of wet age-related macular degeneration.

**Proton Beam Therapy**

**Clinical Context and Therapy Purpose**

The purpose of proton beam therapy for patients who have choroidal neovascularization associated with age-related macular degeneration is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The question addressed in this evidence review is: Does the use of proton beam therapy for patients who have choroidal neovascularization associated with age-related macular degeneration improve net health outcomes?

The following PICO was used to select literature to inform this review.
**Patients**
The relevant population of interest is patients with choroidal neovascularization associated with age-related macular degeneration.

**Interventions**
The treatment being considered is proton beam therapy. Proton beam therapy is external therapy that uses charged atomic particles to target a given area with less scatter of particle beams than conventional electromagnetic (photon) radiotherapy. Multiple treatments are required.

Proton beam therapy is performed by ophthalmologists and radiation oncologists in an outpatient setting.

**Comparators**
The following practices are currently being used to treat choroidal neovascularization associated with age-related macular degeneration: intravitreal vascular endothelial growth factor and photodynamic therapy. These treatments are generally administered by an ophthalmologist or other eye specialist in an outpatient clinical setting.

**Outcomes**
The general outcomes of interest are change in disease status, morbid events, functional outcomes, quality of life, medication use, and treatment-related morbidity.

Follow-up of 1-3 years is desirable to assess outcomes.

**Study Selection Criteria**
Methodologically credible studies were selected using the principles described in the first indication.

Park et al. (2012) reported on 12- to 36-month follow-up for a pilot study of ranibizumab combined with proton beam therapy for age-related macular degeneration. Six eyes (6 patients) were treated with 4 monthly ranibizumab plus 24-Gy proton beam treatments, followed by ranibizumab if needed. No radiation retinopathy was observed at follow-up.

Ciulla et al. (2002) reported on results from a randomized, prospective, sham-controlled, double-masked treatment trial that examined the effect of proton beam therapy on subfoveal choroidal neovascular membranes associated with age-related macular degeneration. Thirty-seven subjects were randomized to 16-Gy proton irradiation delivered in 2 fractions 24 hours apart or to sham control treatment. Recruitment was halted at 37 subjects for ethical reasons related to randomization to sham treatment when U.S. Food and Drug Administration approval of verteporfin (Visudyne; a light-activated drug used with photodynamic therapy) was anticipated. Proton beam therapy was associated with a trend
toward stabilization of visual acuity, but this association was not statistically significant.

**Section Summary: Proton Beam Therapy**
There is currently no available clinical trial evidence suggesting that proton beam therapy is noninferior to available treatment alternatives for age-related macular degeneration.

**Stereotactic Radiotherapy**

**Clinical Context and Therapy Purpose**
The purpose of stereotactic radiotherapy for patients who have choroidal neovascularization associated with age-related macular degeneration is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The question addressed in this evidence review is: Does the use of stereotactic radiotherapy for patients who have choroidal neovascularization associated with age-related macular degeneration improve net health outcomes?

The following PICO was used to select literature to inform this review.

**Patients**
The relevant population of interest is patients with choroidal neovascularization associated with age-related macular degeneration (described under Rationale).

**Interventions**
The treatment being considered is stereotactic radiotherapy. Stereotactic radiotherapy is a nonsurgical procedure using a robotically controlled device to deliver radiation beams through the inferior sclera to overlap at the macula.

Stereotactic radiotherapy is performed by ophthalmologists in a clinical setting.

**Comparators**
The following practices are currently being used to treat choroidal neovascularization associated with age-related macular degeneration: intravitreal vascular endothelial growth factor and photodynamic therapy. These treatments are generally administered by an ophthalmologist or other eye specialist in an outpatient clinical setting.

**Outcomes**
The general outcomes of interest are change in disease status, morbid events, functional outcomes, quality of life, medication use, and treatment-related morbidity.

Follow-up of 1-2 years is desirable to assess outcomes.
Study Selection Criteria
Methodologically credible studies were selected using the principles described in the first indication.

The study reported by Jackson et al (2013), IRay in Conjunction with antivascular endothelial growth factor (Anti-VEGF) Treatment for Patients with Wet Age-related Macular Degeneration (INTREPID), was a randomized, sham-controlled, double-masked trial with 230 patients that assessed the efficacy and safety of stereotactic radiotherapy to treat neovascular age-related macular degeneration. The primary outcome measure was the number of ranibizumab injections needed over 52 weeks. Both stereotactic radiotherapy and sham control patients received ranibizumab as needed. After 1 year, treatment with 16- or 24-Gy stereotactic radiotherapy reduced the number of ranibizumab treatments (median, 2 vs. 3.5 for sham controls) with no significant differences from controls in changes in visual acuity over the 1-year follow-up. No safety concerns were identified in the first 12 months.

In 2015, year 2 safety and efficacy results from the INTREPID trial were published. Participants received 16- or 24-Gy stereotactic radiotherapy plus ranibizumab or sham stereotactic radiotherapy plus ranibizumab for 12 months, with bevacizumab or ranibizumab thereafter as needed. At year 2, the 16- and 24-Gy arms received fewer as-needed bevacizumab (mean, 4.5; p=0.008) or ranibizumab (mean, 5.4; p=0.09) treatments compared with sham (mean, 6.6). Changes in mean best-corrected visual acuity were -10.0, -7.5, and -6.7 letters, respectively, with 68%, 75%, and 79% losing fewer than 15 letters, respectively. Differences for visual acuity were not statistically significant. Microvascular abnormalities were detected in 6 control eyes and 29 stereotactic radiotherapy eyes, of which 18 were attributed to radiotherapy, with only 2 possibly affecting vision. The authors concluded that a single dose of stereotactic radiotherapy significantly reduced intravitreal injections over 2 years and that, although radiotherapy can induce microvascular changes, only in 1% of eyes did this seem to affect vision.

Ranjbar et al. (2016) reported on results from an observational study of 32 patients (32 eyes) with neovascular age-related macular degeneration who met criteria for best responders in the INTREPID trial and were treated with stereotactic radiotherapy (16 Gy) along with aflibercept or ranibizumab. For the study’s primary outcome (the number of antivascular endothelial growth factor treatments in the 12 months after stereotactic radiotherapy), significantly fewer intravitreal injections were given (3.47) compared with the year preceding stereotactic radiotherapy (6.81; p<0.001). No ocular or systemic adverse events occurred.

Section Summary: Stereotactic Radiotherapy
Evidence from a double-blind, randomized trial comparing stereotactic radiotherapy with ranibizumab for neovascular age-related macular degeneration has suggested that stereotactic radiotherapy can reduce the number or
ranibizumab injections, but was associated with radiation retinopathy leading to microvascular changes.

**Summary of Evidence**
For individuals who have choroidal neovascularization due to age-related macular degeneration who receive brachytherapy, the evidence includes 2 randomized controlled trials (RCTs) comparing brachytherapy plus vascular endothelial growth factor with vascular endothelial growth factor monotherapy as well as phase 1/2 trials and case series on the use of brachytherapy. Relevant outcomes are change in disease status, morbid events, functional outcomes, quality of life, medication use, and treatment-related morbidity. Both RCTs showed that brachytherapy did not attain noninferiority for visual acuity outcomes and was associated with a higher proportion of adverse events. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have choroidal neovascularization due to age-related macular degeneration who receive proton beam therapy, the evidence includes a randomized, prospective, sham-controlled trial and a pilot study. Relevant outcomes are change in disease status, morbid events, functional outcomes, quality of life, medication use, and treatment-related morbidity. Recruitment into the RCT was halted for ethical concerns, and available results did not show statistically significant stabilization of visual acuity. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have choroidal neovascularization due to age-related macular degeneration who receive stereotactic radiotherapy, the evidence includes an RCT with sham control. Relevant outcomes are change in disease status, morbid events, functional outcomes, quality of life, medication use, and treatment-related morbidity. The RCT showed a reduction in the number of vascular endothelial growth factor treatments at 12- and 24-month intervals, but no significant differences vs controls for changes in visual acuity. The evidence is insufficient to determine the effects of the technology on health outcomes.

**SUPPLEMENTAL INFORMATION**

**Practice Guidelines and Position Statements**

**American Academy of Ophthalmology**
In 2015, the American Academy of Ophthalmology updated its evidence-based preferred practice pattern on age-related macular degeneration. For extrafoveal choroidal neovascularization, radiotherapy was not recommended (SIGN grade: III; GRADE assessment: moderate level of evidence, strong recommendation).

In their 2019 Preferred Practice Pattern for age-related macular degeneration, they state that current data is insufficient “to demonstrate clinical efficacy” for extrafoveal choroidal neovascularization.
**National Institute for Health and Care Excellence**
The 2011 guidance from the National Institute for Health and Care Excellence stated that current evidence on the efficacy of epiretinal brachytherapy for wet age-related macular degeneration is “inadequate and limited to small numbers of patients.”\(^1\) For safety, “vitrectomy has well-recognized complications and there is a possibility of subsequent radiation retinopathy.” The Institute concluded that wet age-related macular degeneration should only be used for “research.”

**U.S. Preventive Services Task Force Recommendations**
Not applicable.

**Medicare National Coverage**
There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

**Ongoing and Unpublished Clinical Trials**
Some currently ongoing trials that might influence this review are listed in Table 1.

**Table 1. Summary of Key Trials**

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
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<tr>
<td>Ongoing</td>
<td>A Prospective Study of Episceral Brachytherapy for the Treatment of Neovascular Age-related Macular Degeneration (NEAMES)</td>
<td>20</td>
<td>Dec 2022</td>
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<tr>
<td>NCT02988895</td>
<td>Stereo Tactic Radiotherapy for Wet Age-Related Macular Degeneration (STAR): A Randomised, Double-masked, Sham-controlled, Clinical Trial Comparing Low-voltage Irradiation With as Needed Ranibizumab, to as Needed Ranibizumab Monotherapy</td>
<td>411</td>
<td>Mar 2024</td>
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NCT: national clinical trial.

**REFERENCES**


**Billing Coding/Physician Documentation Information**

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<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tr>
<td>0190T</td>
<td>Placement of intraocular radiation source applicator (List separately in addition to primary procedure) (Code Deleted 01/01/2019)</td>
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<tr>
<td>67036</td>
<td>Vitrectomy, mechanical, pars plana approach;</td>
</tr>
<tr>
<td>67299</td>
<td>Unlisted procedure, posterior segment</td>
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**ICD-10 Codes**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tr>
<td>H35.30</td>
<td>Unspecified macular degeneration (age-related)</td>
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<tr>
<td>H35.3110-3194</td>
<td>Nonexudative age-related macular degeneration code range</td>
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<tr>
<td>H35.3210-3293</td>
<td>Exudative age-related macular degeneration code range</td>
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**Additional Policy Key Words**

N/A

**Policy Implementation/Update Information**

9/1/08 New policy; considered investigational.
9/1/09  No policy statement changes.
9/1/10  No policy statement changes.
9/1/11  No policy statement changes.
9/1/12  No policy statement changes.
9/1/13  Investigational statement added on proton beam therapy and title changed from “Epiretinal Radiation Therapy...” to “Intraocular Radiation Therapy...”
9/1/14  Investigational statement added regarding stereotactic radiation therapy.
9/1/15  Title revised to say Radiotherapy. No policy statement changes.
9/1/16  Policy statements clarified as to type of radiation therapy used, but intent unchanged.
9/1/17  No policy statement changes.
9/1/18  No policy statement changes.
9/1/19  No policy statement changes.
9/1/20  No policy statement changes.

State and Federal mandates and health plan contract language, including specific provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage. The medical policies contained herein are for informational purposes. The medical policies do not constitute medical advice or medical care. Treating health care providers are independent contractors and are neither employees nor agents Blue KC and are solely responsible for diagnosis, treatment and medical advice. No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any form or by any means, electronic, photocopying, or otherwise, without permission from Blue KC.