L36962: Medicare Part A/B local coverage determination (LCD) comment summary

LCD Number

L36962

Contractor Name

First Coast Service Options, Inc.

Contractor Numbers

09101 – Florida
09201 – Puerto Rico/Virgin Islands
09102 – Florida
09202 – Puerto Rico
09302 – Virgin Islands

Contractor Type

MAC Part A/B

LCD Title

Vascular Endothelial Growth Factor Inhibitors for the Treatment of Ophthalmological Diseases

AMA CPT Copyright Statement

Start Date of Comment Period:

09/29/2016

End Date of Comment Period:

11/14/2016

Comments received:

Comment #1: Comment was received suggesting First Coast eliminate the language in the local coverage determination (LCD) that uses the labeling information from the manufacturer, as it is only a suggestion and is not meant to be a formal guideline. Long term results often suffer in some patients if the treatment interval is stretched out too far, and it sometimes is necessary to treat every four weeks. Allow it to be based on clinical evidence supported by optical coherence tomography (OCT) or angiogram.

Contractor response: Thank you for your comment and recommendation. The LCD will be revised to include additional US Food and Drug Administration (FDA) “Dosing and Administration” guidelines for Lucentis® (ranibizumab injection) and Eylea® (aflibercept) injection. In addition, as stated in the “Limitations” section of the LCD, frequency is considered excessive when services are performed more frequently than listed in the package insert or generally accepted by peers and the reason for additional services is not justified by documentation. Dose and frequency should be in accordance with the FDA label or recognized compendia (for off-label uses). Medical evidence that can be considered includes in order of preference, published authoritative evidence derived from definitive randomized clinical trials or other definitive studies, clinical guidelines, and general acceptance by the medical community (standard of practice), as supported by sound medical evidence based on: scientific data or research studies published in peer-reviewed medical journals; consensus of expert medical opinion (i.e., recognized authorities in the field); or medical opinion derived from consultations with medical associations or other health care experts. When services are performed in excess of established parameters, they may be subject to review for medical necessity.

Comment #2: A comment was received suggesting the potential for undertreating patients due to fear of non-reimbursement for Eylea. The recent American Society of Retina Specialists (ASRS) meeting and many journal articles show that real life patient vision gain/maintenance two to five years after diagnosis does NOT mirror clinical trials and the single consistent reason is under-treatment. Treat and-extend with close monitoring has the best success rate in maintaining vision.

The following language is concerning: “Frequency is considered excessive when services are performed more frequently than listed in the package insert or generally accepted by peers and the reason for additional services is not justified by documentation. Dose and frequency should be in accordance with the FDA label or recognized compendia (for off-label uses). When services are performed in excess of established parameters, they may be subject to review for medical necessity.”

The printed recommendation for Eylea does not work for every patient. There may be an upsurge in either unnecessary testing to justify more frequent dosing or a rise in denied claims with delay in payment to justify regimen. Regeneron has stated quite clearly that the labeling indications are a suggestion and NOT a treatment guideline.

A recommendation was received to amend the 4th and 5th indications for Eylea to include language explaining that these are only suggested dosing and individual patient dosing must be determined by outcome.

Contractor response: Thank you for your comment. See comment response #1.

Comment #3: Given the results of all studies to date that show no difference between Avastin and the others, Avastin should be the first line treatment and only allow the use of Lucentis or Eylea if Avastin fails or if there is evidence that Avastin did not work in the fellow eye. This is true for all diagnoses except diabetic macular edema with best corrected visual acuity worse than 20/50. In that case, Eylea has been found superior.

Contractor response: Thank you for your comment. The LCD addresses reasonable and necessary (R&N) criteria for the use of Vascular Endothelial Growth Factor (VEGF) inhibitors. As published in CMS IOM 100-08, Chapter 13, Section 13.5.1, in order to be covered under Medicare, a service shall be reasonable and necessary. One definition a contractor considers for a service to be reasonable and necessary is if the service is at least as beneficial as an existing and available medically appropriate alternative. Cost is not taken into account during the development of an LCD.

Comment #4: Once stability is reached and therapy is done for maintenance with wet macular degeneration, there is no need to bill for fundus photography, OCT and angiogram at every four week injection visit. Quarterly testing would be more appropriate in those cases. In the diabetic macular edema and vein occlusion patients, an end point is often reached and treatment should be discontinued. There is no proof that “prophylactic” treatment for these conditions has any benefit. In cases where macular degeneration has either geographic atrophy in addition to the wet form of the disease or the wet form did not respond or treatment was ineffective and the vision is poor (20/200 or worse, e.g.), there is no reason to continue the treatment so there should be cessation of treatment at that point.

Contractor response: Thank you for your comment. The contractor agrees that in cases where macular degeneration has either geographic atrophy in addition to the wet form of the disease or the wet form did not respond or treatment was ineffective and the vision is poor (20/200 or worse, e.g.), there is no reason to continue the treatment, so there should be cessation of treatment Continuing treatment in the aforementioned circumstances would not be reasonable and necessary since it would be exceeding the medical need.

The LCD addresses the limited indications of vascular endothelial growth factor inhibitors for the treatment of ophthalmological diseases. The treatment frequency should be consistent with the clinical assessment (symptoms, exam, testing when indicated (OCT, fluorescein angiogram, etc.) as documented in the medical record. The LCD does not address frequency limitations for fundus photography, OCT and angiogram. It is expected testing, when indicated, will be performed with accepted standards of practice and clearly supported in the medical record. First Coast has the following LCDs addressing these services: Scanning Computerized Ophthalmic Diagnostic Imaging (L33751), Fluorescein Angiography (L33997), and Fundus Photography (L33670).

Comment #5: Comment received requesting that the list of indications for Avastin (bevacizumab) in the new LCD include the conditions already listed in the existing Avastin (bevacizumab) LCD dated June 30, 2009, which are supported by the ASRS position paper on Avastin (bevacizumab) and are widely accepted within the retina community. Specifically, the new policy has not included retinal neovascularization, retinal edema, rubeosis iridis, branch retinal vein occlusion (BRVO) and central retinal vein occlusion (CRVO) with retinal neovascularization, or cystoid macular edema. Additionally, there are no restrictions on the use for proliferative diabetic retinopathy to only a single dose. A request was made to remove this limitation. Below is a list of revised/added indications.

Proliferative diabetic retinopathy ~~requiring treatment with retinal laser photocoagulation or vitrectomy as a single preoperative dose~~

Stage 3 retinopathy of prematurity (ROP)

Cystoid Macular Degeneration of Retina

Retina Edema

Rubeosis Iridis

Retinal Neovascularization

Glaucoma associated with vascular disorders of the eye

BRVO with retinal neovascularization

CRVO with retinal neovascularization

In addition, under “ICD-10 codes that support medical necessity” section on Avastin, a request was made to add the following codes to the current LCD.

H21.1 Vascular disorders of the iris and ciliary body

H34.8111 Central retinal vascular occlusion, right eye with retinal neovascularization

H34.8121 Central retinal vascular occlusion, left eye with retinal neovascularization

H34.8131 Central retinal vascular occlusion, bilateral with retinal neovascularization

H34.8311 Tributary (branch) retinal vein occlusion (BRVO), right eye with retinal neovascularization

H34.8321 Tributary (branch) retinal vein occlusion(BRVO), left eye, with retinal neovascularization,

H34.8331 Tributary (branch) retinal vein occlusion (BRVO). Bilateral, with retinal neovascularization

H35.351 Cystoid macular degeneration, right eye

H35.352 Cystoid macular degeneration, left eye

H35.353 Cystoid macular degeneration, bilateral

H35.81 Retina edema

H40.51 Glaucoma secondary to other eye disorders, right eye

H40.52 Glaucoma secondary to other eye disorders, left eye

H40.53 Glaucoma secondary to other eye disorders, bilateral

H35.059 Retina Neovascularization, unspecified, unspecified eye

Contractor response: Thank you for your comment and suggestions. The LCD will be revised to add some of the suggested indications and diagnosis codes. Diagnosis code H35.059 (Retina Neovascularization, unspecified, unspecified eye) and glaucoma associated with vascular disorders of the eye will not be added because the LCD already contains more specific coding and language related to these indications.

Comment #6: I would suggest the LCD be corrected to match the current FDA guidelines for Eylea® (aflibercept). The current FDA language for Eylea® (aflibercept) is as follows:

Eylea® (aflibercept) Injection is indicated for the treatment of patients with:

> Neovascular (Wet) Age-related Macular Degeneration (AMD): The recommended dose for Eylea is 2 mg administered by intravitreal injection every 4 weeks (monthly) for the 12 weeks (3 months), followed by 2 mg once every 8 weeks (2 months). Although Eylea may be dosed as frequently as 2 mg every 4 weeks (monthly), additional efficacy was not demonstrated in most patients when Eylea was dosed every 4 weeks compared to every 8 weeks. **Some patients may need every 4 week (monthly) dosing after the first 12 weeks (3 months).**
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> Macular Edema following Retinal Vein Occlusion (RVO): The recommended dose for Eylea is 2 mg administered by intravitreal injection every 4 weeks (monthly).
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> Diabetic Macular Edema (DME) and Diabetic Retinopathy (DR) in Patients with DME: The recommended dose is 2 mg administered by intravitreal injection every 4 weeks (monthly) for the first 5 injections, followed by 2 mg once every 8 weeks (2 months). Although Eylea may be dosed as frequently as 2 mg every 4 weeks (monthly), additional efficacy was not demonstrated in most patients when Eylea was dosed every 4 weeks compared to every 8 weeks. **Some patients may need every 4 week (monthly) dosing after the first 20 weeks (5 months).**

Contractor response: Thank you for your comment and recommendation. The LCD will be revised to add the current FDA language for Neovascular (Wet) Age-related Macular Degeneration (AMD) and Diabetic Macular Edema (DME) and Diabetic Retinopathy (DR) in patients with DME.

Comment #7: A comment was received suggesting eliminating the following contraindication in the "Limitations" section of the LCD: patients with active intraocular inflammation. There is not a contraindication to using anti-VEGF therapy in eyes with active inflammation, as it can be helpful in uveitis patients that develops rubeosis, neovascularization of the disc (NVD)/ neovascularization elsewhere (NVE), choroidal neovascularization (CNV) and in some cases cystoid macular edema (CME). This limitation (inflammation) should be eliminated, and if not for all the medications, at least for Avastin.

Contractor response: Thank you for your comment and suggestion. The LCD will be revised to remove this contraindication from the "Limitations" section of the LCD.

Comment #8: A comment was received requesting the following limitation be moved to indicate the acceptance of bilateral treatment, with different medication on the same date of service, as appropriate physician care.

> It is not typical to inject one anti-VEGF medication in one eye and another in the other eye. If different medications are injected into each eye during the same date of service, the rationale for this therapy must be documented in the medical record and the billing modifier (RT/LT) must be appended to the correct drug.

This guideline "allows" injecting two different medications on the same date of service. However, stating this "is not typical" is incorrect. This scenario is common in practice. Each eye is evaluated as a separate, independent organ. The diseases being treated with anti-VEGF mediations affect each eye differently, depending on the stage of the disease. Anti-VEGF medications have varying mechanisms of action. These differences can affect the eye differently. It is unusual to treat diabetic patients with different medication, but wet

macular degeneration is an entirely different disease. Treatment regiments last longer, and require adjustment of medications in many patients to produce the best therapeutic result.

Contractor response: Thank you for your comment and suggestion. The language in the LCD will be changed to: It is not expected to inject one anti-VEGF medication in one eye and another in the other eye.