J0178
AFLIBERCEPT/EYLEA

FACT SHEET

Description

HCPCS J0178 (Injection, aflibercept, mg)

Aflibercept (EYLEA®) is a vascular endothelial growth factor (VEGF) inhibitor approved by the Food and Drug Administration (FDA) for the treatment of patients with:

- Neovascular (Wet) Aged-related Macular Degeneration (AMD)
- Macular Edema following Retinal Vein Occlusion (RVO)
- Diabetic Macular Edema (DME)
- Diabetic Retinopathy (DR)

Accepted Dosage and Administration

Neovascular (Wet) Age-Related Macular Degeneration (AMD)

- The recommended dose for EYLEA is 2 mg (0.05 mL) administered by intravitreal injection every 4 weeks (approximately every 28 days, monthly) for the first 3 months, followed by 2 mg (0.05 mL) via intravitreal injection once every 8 weeks (2 months).
- Although EYLEA may be dosed as frequently as 2 mg every 4 weeks (approximately every 25 days, 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).
- Although not as effective as the recommended every 8-week dosing regimen, patients may also be treated with one dose every 12 weeks after one year of effective therapy. Patients should be assessed regularly.

Macular Edema Following Retinal Vein Occlusion (RVO)

The recommended dose for EYLEA is 2 mg (0.05 mL) administered by intravitreal injection once every 4 weeks (approximately every 25 days, monthly).

Diabetic Macular Edema (DME) and Diabetic Retinopathy (DR)

- The recommended dose for EYLEA is 2 mg (0.05 mL) administered by intravitreal injection every 4 weeks (approximately every 28 days, monthly) for the first 5 injections followed by 2 mg (0.05 mL) via intravitreal injection once every 8 weeks (2 months).
- Although EYLEA may be dosed as frequently as 2 mg every 4 weeks (approximately every 25 days, 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).

Medical Necessity

A/B MACs (A), (B), and (HHH) must continue to apply the policy that not only the drug is medically reasonable and necessary for any individual claim, but also that the route of administration is medically reasonable and necessary.

For certain injectable drugs, it will be apparent due to the nature of the condition(s) for which they are administered or the usual course of treatment for those conditions, they are, or are not, usually self-administered.

Medicare Billing

To bill aflibercept services, submit the following claim information on CMS Form 1500:

- J0178 - Injection, aflibercept, 1 mg (each injection is 2mg = 2 units)
- 67028 - Intravitreal injection of a pharmacologic agent (separate procedure)
- **Note:** Quantity to be billed 67028 is 1 as this is a bilateral procedure.

The injection of more than one anti-vascular endothelial growth factor (VEGF) medication (bevacizumab, ranibizumab, aflibercept) in the same eye during the same treatment session is not reasonable and necessary. Rationale for using different medications in each eye on the same date of service must be documented in the medical record and the billing modifier (RT/LT) must be appended to the correct drug. This therapy method would be atypical and is expected to be a rare occurrence.

Regardless of which intravitreal drug is used for therapy, the beneficiary may not receive more than one injection per eye more frequently than every 4 weeks. Drugs alternated every 2 weeks will not be covered.

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Documentation must support compliance with Medicare rules and regulations such as: diagnoses; appropriate orders and signatures; administration/frequency/deliverance of the service; as well as correct coding and billing of the drug, per medical necessity.

Documentation must support provider specialty of 18 Ophthalmology, (KY) 41 Optometrist.

Supporting Documentation

Diagnosis codes must support one of the above listed conditions.

Documentation of frequency, as noted above, must support accepted prescribing guidelines.

A signed order must be present for the drug by the approved specialty provider or intent to order within the progress note.

In addition, a purchase order with the name of the drug and information of the vial should be included.

If applicable, an Advance Beneficiary Notice (ABN) should be included in the record.

Appropriate Signatures

- Signature and credentials of person performing the service must meet CMS requirements
- Amendments/corrections/delayed entries are properly identified

For more information regarding signature requirements, please view the following resources:

- CGS Administrators, LLC, J15 Part B Medical Review https://www.cgsmedicare.com/partb/mr/signatures.html
- https://www.cgsmedicare.com/partb/cert/signatures.pdf
- CMS MLN Fact Sheet, Complying with Medicare Signature Requirements.
- https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/signature_requirements_fact_sheet_icn905364.pdf
- CMS IOM Pub. 100-08, Medicare Program Integrity Manual, Chapter 3, Section 3.3.2.4, Signature Requirements. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/pim83c03.pdf

References

- IOM 100-02, Chapter 15 – Covered Medical and Other Health Services: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf
- IOM 100-04, Chapter 17 – Drugs and Biological: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c17.pdf
- IOM 100-08, Chapter 3 – Verifying Potential Errors and Taking Corrective Actions: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/pim83c03.pdf
- Notice of Service Specific Post Payment Review for Drugs: https://www.cgsmedicare.com/partb/pubs/news/2020/08/cope18504b.html
- Eylea Prescribing Information: https://www.regeneron.com/sites/default/files/EYLEA_FPI.pdf

Documentation of Administration

The following administration details must be documented within the record

- Name of the drug
- Date of Service
- Patient consent
- Documentation to support drug was administered to the correct beneficiary
- Amount of the drug administered per the order
- Documentation to support drug was administered by intravitreal route
- Documentation containing location the intravitreal injection was administered
- Amount of the drug wasted, signature of person wasting, and appropriate modifier (JW) if applicable