# J2778

RANIBIZUMAB/LUCENTIS

# FACT SHEET

## Decscription

**CPT Code J2778 (Injection, ranibizumab, 0.n1 mg)**

Ranibizumab is indicated for the treatment of patients with:

- Exudative senile macular degeneration
- Macular edema following retinal vein occlusion
- Diabetic macular edema
- Neovascular age-related macular degeneration in patients without ocular or periocular infections

## Accepted Dosage and Administration

For ophthalmic intravitreal injection only

| Condition | Dosage |
|---|---|
| Neovascular (Wet) Age-Related Macular Degeneration (AMD) (2.2) | Administer 0.5 mg (0.05 mL) by intravitreal injection once a month (approximately 28 days) |
| Macular Edema Following Retinal Vein Occlusion (RVO) (2.3) | Administer 0.5 mg (0.05 mL) by intravitreal injection once a month (approximately 28 days), for 6 months |
| Diabetic Macular Edema (DME) and Diabetic Retinopathy (DR) (2.4) | Administer 0.3 mg (0.05 mL) by intravitreal injection once a month (approximately 28 days) |
| Myopic Choroidal Neovascularization (mCNV) (2.5) | Administer 0.5 mg (0.05 mL) by intravitreal injection once a month (approximately 28 days) for up to three months<br>Patients may be retreated if needed |

## Medical Necessity

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.

Medical records should support one of the above listed conditions.

Are the correct modifiers present? Note: Bilateral services must be reported on separate lines using an RT and LT modifier (bilateral modifier (50) should not be used.

- Medicare requires the JZ modifier on all claims for single-dose containers where there are no discarded amounts.

Relevant history if needed to support medical necessity of administration and amount of drug used in administration, including:

- Statement of Medical Necessity
- List of treatments tried without success

## Supporting Documentation

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.

## 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 route drug was administered
- Amount of the drug wasted, signature of person wasting, and appropriate modifier (JW) if applicable







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- Plan of care establishing frequency and dosing schedule.
- Health care provider's chart notes
- Hospital admission/emergency department notes
- List of current medications, with dose and frequency
- Test and lab results

## 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 Biologicals 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
- Lucentis Prescribing Information https://www.gene.com/download/pdf/lucentis_prescribing.pdf
- Federal Drug Administration Medication Guide https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/125156s105lbl.pdf