DRUGS AND BIOLOGICAL SERVICES Documentation Checklist Tool

Required for all Drugs or Biological Services	Yes	No
Is an order or intent to order for the drug by the approved specialty present?	☐	☐
If order or intent to order is present, does it contain a valid signature?	☐	☐
Is a purchase order present with name of drug and information regarding vials?	☐	☐
Are ALL the following present in the documentation for the Drug Administration?	☐	☐
Patients weight if applicable for drug dosage	☐	☐
Name of the drug	☐	☐
Date of Service	☐	☐
Patient consent present	☐	☐
Drug was administered to the correct beneficiary	☐	☐
Does documentation state the amount of the drug administered per the order	☐	☐
Does the documentation support the route of drug administered	☐	☐
Does documentation contain the location the drug was administered	☐	☐
Does the documentation contain the amount of the drug wasted and signed by person wasting and claim billed with JW modifier for wasted amount if applicable?	☐	☐
Is the JZ modifier appended to the claim for single-dose containers where there are no discarded amounts?	☐	☐

Abatacept/Orencia J0129	Yes	No
Is the provider specialty 66 Rheumatology or 07 Dermatology?	☐	☐
Does the documentation support an approved diagnosis of Adult Rheumatoid Arthritis, Adult Psoriatic Arthritis, or Juvenile Idiopathic Arthritis?	☐	☐
Does the documentation support a 3-month trial of oral agent or IV agent that failed, or other indication?	☐	☐
Does the dosage and administration meet FDA approved guidelines?	☐	☐
Is one of the follow stated as medically necessary reason not to give SQ, such as:	☐	☐
• Age related (17 years and younger IV only)	☐	☐
• Patient/PCG mentally or medically impaired to self-inject (crippled hands), to learn self-injections (dementia), no available caregivers	☐	☐
• Patient may have condition flare and requires IV does(s) to obtain remission	☐	☐
• Patient may have skin condition more susceptible for infection	☐	☐
Physician documentation specifying rationale	☐	☐

Aflibercept/Eylea J0178	Yes	No
Is the provider specialty 18 Ophthalmology or (KY) 41 Optometrist?	☐	☐
Does the documentation support one of the following diagnoses are present?	☐	☐
• Neovascular (Wet) Aged-related Macular Degeneration (AMD)	☐	☐
• Macular Edema following Retinal Vein Occlusion (RVO)	☐	☐
• Diabetic Macular Edema (DME)	☐	☐
• Diabetic Retinopathy (DR)	☐	☐

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CMS CENTERS FOR MEDICARE & MEDICAID SERVICES

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Aflibercept/Eylea J0178	Yes	No
Does the dosage and administration meet FDA approved guidelines of each 2mg injection?	☐	☐
Is the frequency every 28 days(supported by documentation of last dose administered) or documentation to support a change in frequency?	☐	☐

Pegloticase/Krystexxa J2507	Yes	No
Does the adult patient have chronic gout refractory to conventional therapy proven by having ALL the following present in the documentation?	☐	☐
• Baseline serum uric acid of at least 8mg/dl	☐	☐
• Has symptomatic gout with at least 3 gout flares in the previous 18 months, at least 1 gout tophus (sodium urate monohydrate, or uric acid, builds up around your joints) or gouty arthritis	☐	☐
• Patient is currently on NSAIDS or Colchicine or both within last 30 days **OR** Documented intolerance, FDA labeled contraindication or hypersensitivity to both	☐	☐
• Patient has had insufficient response uric acid levels > 6mg/dl at least 3 months of therapy with both allopurinol and febuxostat at maximum tolerated does	☐	☐
Does the dosage and administration meet FDA approved guidelines of 8 mg intravenous (IV) infusion every 2 weeks?	☐	☐

Botox J0585	Yes	No
Does the documentation support one of the following diagnoses are present?	☐	☐
• Overactive bladder (OAB) with symptoms of urge urinary incontinence, urgency, and frequency, in adults who have an inadequate response to or are intolerant of an anticholinergic medication	☐	☐
• Urinary incontinence due to detrusor overactivity associated with a neurologic condition [e.g., spinal cord injury (SCI), multiple sclerosis (MS)] in adults who have an inadequate response to or are intolerant of an anticholinergic medication	☐	☐
• Prophylaxis of headaches in adult patients with chronic migraine (≥15 days per month with headache lasting 4 hours a day or longer)	☐	☐
• Spasticity in adult patients	☐	☐
• Cervical dystonia in adult patients, to reduce the severity of abnormal head position and neck pain	☐	☐
• Severe axillary hyperhidrosis that is inadequately managed by topical agents in adult patients	☐	☐
• Blepharospasm associated with dystonia in patients ≥12 years of age	☐	☐
• Strabismus in patients ≥12 years of age	☐	☐
• Prophylaxis of episodic migraine (14 headache days or fewer per month)	☐	☐
• Upper or lower limb spasticity in pediatric patients	☐	☐
• Hyperhidrosis in body areas other than axillary	☐	☐
Is the appropriate anatomic modifier(LT for Left or RT for Right), or modifier 59 (distinct procedural services) reported as applicable?	☐	☐
Does the dosage and administration meet FDA approved guidelines?	☐	☐

Lucentis J2778	Yes	No
Does the documentation support one of the following diagnoses are present?	☐	☐
• Neovascular (Wet) Age-Related Macular Degeneration (AMD)	☐	☐
• Macular Edema Following Retinal Vein Occlusion (RVO)	☐	☐
• Diabetic Macular Edema (DME) and Diabetic Retinopathy (DR)	☐	☐
• Myopic Choroidal Neovascularization (mCNV)	☐	☐

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Lucentis J2778	Yes	No
Is the appropriate anatomic modifier(LT for Left or RT for Right), or modifier 59 (distinct procedural services) reported as applicable?	☐	☐
Does documentation support relevant history to support medical necessity of administration and amount of drug used in administration, including:	☐	☐
• Treatments tried without success	☐	☐
• Plan of care establishing frequency and dosing schedule	☐	☐
• Medical notes supporting medical necessity and current medications	☐	☐
Does the dosage and administration meet FDA approved guidelines?	☐	☐

Resources

- Electronic Code of Federal Regulations, 482.23 Condition of participation: Nursing services: https://www.ecfr.gov/cgi-bin/text-idx?SID=128bcd4f248d0ac2c8ae0f4c672c3a24&mc=true&node=se42.5.482_123&rgn=div8
- State Operations Manual, Appendix A – Survey Protocol, Regulations & Interpretive Guidelines for Hospitals: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_a_hospitals.pdf
- Medicare Program Integrity Manual, Chapter 3 Verifying Potential Errors & Taking Corrective Actions: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/pim83c03.pdf
- ORENCIA package insert: https://packageinserts.bms.com/pi/pi_orencia.pdf
- EYLEA package insert: https://www.regeneron.com/sites/default/files/EYLEA_FPI.pdf
- FDA Label: https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/213736s000lbl.pdf
- Med Library.org, Krystexxa: https://medlibrary.org/lib/rx/meds/krystexxa-2/
- Krystexxa (pegloticase) Document #: IC-0158: https://specialtydrug.magellanprovider.com/media/41060/hne_mrxm_krystexxa_10_20.pdf