CSRO

COALITION OF STATE RHEUMATOLOGY ORGANIZATIONS

Regulatory Update

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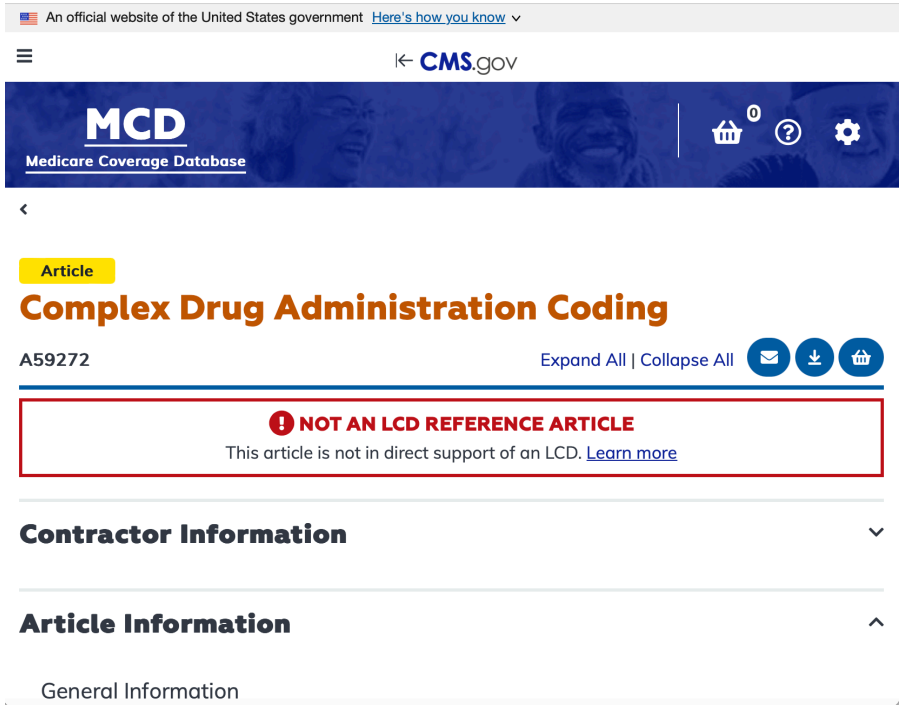
Hot Topics

"Down Coding"

- MACs previously issued "billing and coding" articles that directed practices to use "therapeutic" admin codes when infusing/injecting several rheumatology drugs rather than "complex" admin codes
- CSRO argued this was inconsistent with:
  - Statute: *Medicare Prescription Drug and Modernization Act of 2003*
  - CMS' long-established payment policies
  - AMA coding guidance

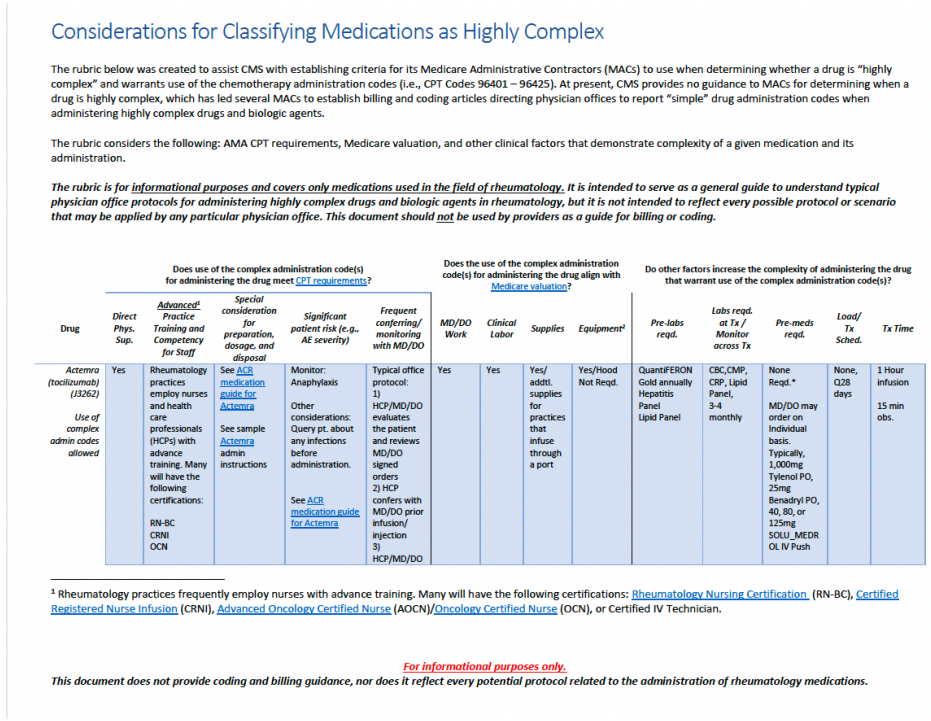


SEC. 304. EXTENSION OF APPLICATION OF PAYMENT REFORM FOR COVERED OUTPATIENT DRUGS AND BIOLOGICALS TO OTHER PHYSICIAN SPECIALTIES.

Notwithstanding section 303(j), the amendments made by section 303 shall also apply to payments for drugs or biologicals and drug administration services furnished by physicians in specialties other than the specialties of hematology, hematology/oncology, and medical oncology.

"Down Coding"

- CSRO led advocacy efforts on this topic, which resulted in:
  - CMS direction to the MACs requiring them to pay claims with the complex drug administration code for rheumatology drugs by way of a "technical director letter" (TDL)
  - Retirement of all "down coding" articles with each MAC
  - CMS issuing:
    - A Request for Information (RFI) in the CY 2024 PFS rule on this topics, and
    - Proposals in the CY 2025 PFS proposed rule to update its program manual to clarify that *"the administration of infusion for particular kinds of drugs and biologics can be considered complex and may be appropriately reported using the chemotherapy administration CPT codes 96401-96549, noting that these services do involve serious patient risk which requires frequent consults with a physician or other qualified healthcare professional."*
- CY 2025 PFS final rule slated for November 1
- MAC's may establish new policies based on these updated criteria



Considerations for Classifying Medications as Highly Complex

The rubric below was created to assist CMS with establishing criteria for its Medicare Administrative Contractors (MACs) to use when determining whether a drug is "highly complex" and warrants use of the chemotherapy administration codes (i.e., CPT Codes 96401 – 96425). At present, CMS provides no guidance to MACs for determining when a drug is highly complex, which has led several MACs to establish billing and coding articles directing physician offices to report "simple" drug administration codes when administering highly complex drugs and biologic agents.

The rubric considers the following: AMA CPT requirements, Medicare valuation, and other clinical factors that demonstrate complexity of a given medication and its administration.

The rubric is for informational purposes and covers only medications used in the field of rheumatology. It is intended to serve as a general guide to understand typical physician office protocols for administering highly complex drugs and biologic agents in rheumatology, but it is not intended to reflect every possible protocol or scenario that may be applied by any particular physician office. This document should not be used by providers as a guide for billing or coding.

	Does use of the complex administration code(s) for administering the drug meet CPT requirements?					Does the use of the complex administration code(s) for administering the drug align with Medicare valuation?				Do other factors increase the complexity of administering the drug that warrant use of the complex administration code(s)?				
Drug	***Direct Phys. Sup.***	***Advanced[1] Practice Training and Competency for Staff***	***Special consideration for preparation, dosage, and disposal***	***Significant patient risk (e.g., AE severity)***	***Frequent conferring/ monitoring with MD/DO***	***MD/DO Work***	***Clinical Labor***	***Supplies***	***Equipment[1]***	***Pre-labs reqd.***	***Labs reqd. at Tx / Monitor across Tx***	***Pre-meds reqd.***	***Load/ Tx Sched.***	***Tx Time***
Actemra (tocilizumab) (J3262) *Use of complex admin codes allowed*	Yes	Rheumatology practices employ nurses and health care professionals (HCPs) with advance training. Many will have the following certifications: RN-BC CRNI OCN	See ACR medication guide for Actemra See sample Actemra admin instructions	Monitor: Anaphylaxis Other considerations: Query pt. about any infections before administration. See ACR medication guide for Actemra	Typical office protocol: 1) HCP/MD/DO evaluates the patient and reviews MD/DO signed orders 2) HCP confers with MD/DO prior infusion/ injection 3) HCP/MD/DO	Yes	Yes	Yes/ addtl. supplies for practices that infuse through a port	Yes/Hood Not Reqd.	QuantiFERON Gold annually Hepatitis Panel Lipid Panel	CBC,CMP, CRP, Lipid Panel, 3-4 monthly	None Reqd.* MD/DO may order on individual basis. Typically, 1,000mg Tylenol PO, 25mg Benadryl PO, 40, 80, or 125mg SOLU_MEDROL IV Push	None, Q28 days	1 Hour infusion 15 min obs.

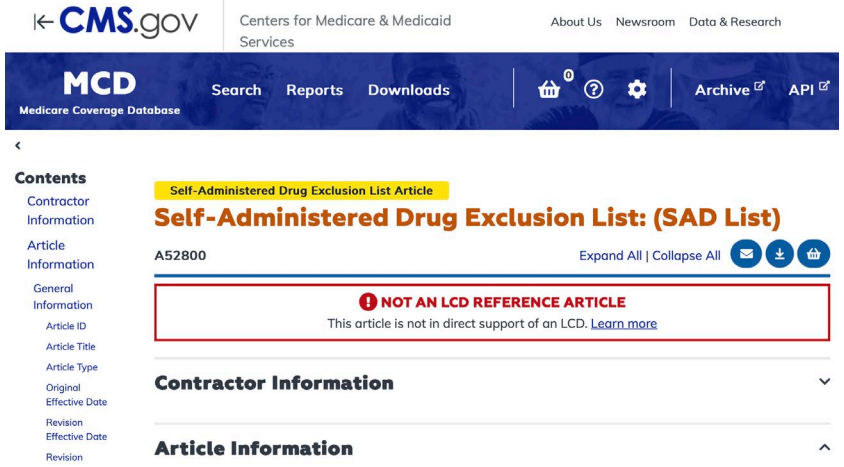
[1] Rheumatology practices frequently employ nurses with advance training. Many will have the following certifications: Rheumatology Nursing Certification (RN-BC), Certified Registered Nurse Infusion (CRNI), Advanced Oncology Certified Nurse (AOCN)/Oncology Certified Nurse (OCN), or Certified IV Technician.

For informational purposes only.

This document does not provide coding and billing guidance, nor does it reflect every potential protocol related to the administration of rheumatology medications.

Self-Administered Drug (SAD) Exclusion List

- By law, drugs that are "*not usually self-administered by the patient*" are paid under Part B
- Using CMS' criteria in subregulatory guidance (i.e., program manual), MACs determine which drugs are self-administered and place them on the "SAD List"
- Drugs on the SAD List are *excluded* from Medicare Part B; beneficiary is liable for full cost of these drugs, regardless of disability, etc.
- HHS' nondiscrimination regulations conflict with the SAD List policy, and result in discrimination against beneficiaries with disabilities
- CSRO advocacy led CMS to issue a RFI in the CY 2024 PFS proposed rule and a plan for future rulemaking
- CSRO is leading a multistakeholder effort to secure changes to this policy through the HHS Secretary's office



SAD Exclusion List

- Direct the MACs to:
  - Remove dual formulation drugs from the SAD Exclusion List, and
  - Postpone adding dual formulation drugs to the SAD Exclusion List.
- Reinterpret “not usually self-administered by the patient” and revise the Manual to:
  - Include all Medicare beneficiaries (original Medicare and Medicare Advantage) in the denominator for making SAD Exclusion List determinations,
- Appropriately account for beneficiaries that receive assistance administering their medication from another individual, such as a family member, caregiver, or a health professional. and
  - For medications included on the SAD Exclusion List, establish exclusion criteria based on clinical, social and economic factors that allow physicians, based on their clinical expertise and judgement, to provide the Part B formulation of those drugs.
  - Publish data sources and all analysis used to make SAD Exclusion List determinations to improve transparency.

Biosimilars

- CSRO has been working to address challenges facing rheumatology practices with "underwater" biosimilars
- Multi-pronged approach:
  - Reimbursement: Comments to CMS in response to CY 2025 PFS proposals
  - Utilization management: Template letter to insurers urging "by-pass" of prior auth, step therapy, Discussions with UHC, OptumRx
- CSRO is a leading voice in the Underwater Biosimilars Coalition:
  - Joined coalition letter to CMS
  - Meeting with Medicare Payment Advisory Commission (MedPAC)
  - Meeting with CMS' Deputy Administrator

CY 2025 Medicare PFS Proposals

Conversion Factor

- The CY 2025 Medicare PFS proposed rule reflects a **$32.36** conversion factor (CF), representing -2.8% reduction over the CY 2024 CF. This is due to the following:
  - 0.0% statutory update as required under MACRA
  - Expiration of 2.93% update in the CAA, 2024
  - A positive 0.5% budget neutrality adjustment
- Other key challenges
  - Medicare sequester: 2% (in effect)
  - PAYGO sequester: 4% (begins January 1, 2025)
- *Congressional action needed!*
  - Address budget neutrality requirements including raising the threshold
  - Provide positive payment updates based on inflation as measured by the Medicare Economic Index (MEI)
  - Require CMS to make routine updates to practice expense inputs used to set payments for physician fee schedule services

Practice Expense

- Practice expense accounts for direct (*i.e.*, *clinical labor*, *supplies*, *equipment*) and indirect (e.g., *rent*, *administrative staff*) costs.
- In the CY 2022 PFS, CMS finalized a policy to update clinical labor pricing over a 4-year period, infusing current data on clinical labor wages into the PFS - an exercise that hasn't occurred in 20 years!
  - Note that we are in the last year of the 4-year transition, meaning CY 2025 is the final phase-in of the new prices
- In contrast to expectations and due to budget-neutrality, payments for some services – including drug administration - suffered steep reductions, despite the increased costs to deliver them.
- In this CY 2025 PFS, CMS highlights a contract with RAND to address the practice expense methodology broadly, including how it could better update direct PE costs (e.g., every 4 years).

Telehealth

REMINDER: Congress must act to extend (or make permanent) remaining flexibilities, such as site of service and geographic requirements, or they will expire at the end of CY 2024

"Audio-Only": CMS proposes to allow audio-only communication technology to meet the definition of "telecommunications system" for the purposes of furnishing telehealth to beneficiaries in their homes, when certain conditions are met. However, with the expiration of PHE-related telehealth flexibilities on December 31, 2024, a patient's home would not be a permissible originating site except in *limited cases* (e.g., behavioral health).

Reporting of Distant Site Address: CMS proposes that, through 2025, it will continue to permit practitioners to use their currently enrolled practice location instead of their home address when providing telehealth services from their home.

Telehealth

Direct Supervision via "Virtual Presence" : CMS proposes to allow for direct supervision via virtual presence using audio/video real-time communications technology on a permanent basis, but only for a subset of incident to services when:

- the service is provided by auxiliary personnel employed by the billing practitioner and working under their direct supervision, and for which the underlying HCPCS code has been assigned a PC/TC indicator of '5'; or
- the service is an office or other outpatient E/M visit for an established patient that may not require the presence of a physician or other qualified healthcare practitioner.

For all other services, CMS proposes to continue to allow for direct supervision via virtual presence using real-time audio and visual interactive telecommunications technology through 2025.

Quality Payment Program

MIPS

Cost measurement has been a challenge for some rheumatology practices, with many practices that performed well in prior years seeing penalties for the first time

Despite opposition, CMS proposes to implement the flawed Rheumatoid Arthritis (RA) cost measure in CY 2025

Advancing Rheumatology Care MVP

In CY 2024, CSRO secured inclusion of key improvement activities (IA) that reflect the work rheumatologists do to help patients access their medicines

- IA_BE_ 24: Financial Navigation Program
- IA_BE_25: Drug Cost Transparency

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Questions?

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