The Rheumatology Nurses Society (RNS) is a professional organization committed to the development and education of nurses and other advanced practice providers (APPs) to benefit patients, family and community. The RNS officially formed in January 2007 as a not-for-profit professional organization. We are dedicated to healthcare professionals who are passionate about and committed to rheumatology and the promotion of excellence in the delivery of patient care. We work to remain the gold standard of rheumatology nursing practice through nurse certification, the creation of rheumatology nursing standards and protocols, and by acting as a primary resource to healthcare professionals and the patients they serve.

We thank the agency for the opportunity to provide input on the ten medications selected to receive maximum fair prices (MFPs) beginning in 2026. We will limit our comments to Stelara® (ustekinumab), which is used to treat psoriasis and psoriatic arthritis, as well as several GI conditions.

Among the ten selected drugs, ustekinumab is in a unique position because it has both a provider-administered formulation and a self-administered formulation: thus, this medication may be covered via Part B or Part D. By statute, drugs that are "not usually self-administered by the patient" are covered via Part B. As a result, for drugs that have both self- and provider-administered options, determining the meaning of the phrase "not usually self-administered" becomes critical. Under its current approach, CMS has set a blunt threshold, which is to determine whether more than 50% of beneficiaries who use the drug use the self-administered version. When that is the case, the Medicare Administrative Contractors (MACs) can exclude the medication from Part B coverage by adding it to the Self-Administered Drug Exclusion List ("SAD List"). That means that it can only be covered through Part D.

The problems with the MACs' processes around the SAD List are longstanding and well-documented. For that reason, in the CY 2024 Medicare Physician Fee Schedule proposed rule, CMS issued a request for information related to coverage of drugs in this situation.

In many ways, Stelara® (ustekinumab) has been the "poster child" for problems with the SAD List. In part, this issue is exacerbated by the fact that it has indications affecting very different patient populations. For rheumatology patients, joint damage may make it physically impossible to self-administer. Yet the current system does not include a formalized, easily accessible, and prompt way for such beneficiaries to seek an exemption after their medication is moved to the SAD List. That leaves beneficiaries who need provider administration without any way to access their medication.

At this time, it is unclear how ustekinumab being subject to a maximum fair price (MFP) will affect this existing issue. On the one hand, beneficiary cost-sharing in Part D would be assessed against the MFP, which could help alleviate the financial barriers resulting from a drug being moved out of Part B, where most beneficiaries have supplemental coverage. On the other hand, when a dual-formulation drug gets an MFP in Part D, that may encourage the existing misbehavior by the MACs related to denying coverage in Part B, even for patients who have physical disabilities that prevent self-administration.

For now, on behalf of our rheumatology patients, we wanted to ensure that CMS keeps this dynamic in mind as the agency moves forward with implementation of the Medicare Drug Price Negotiation Program. We urge CMS to ensure that medications with both provider-administered and self-administered options remain fully accessible to patients under a comprehensive regulatory paradigm, taking into account all interactions and potential unintended consequences between the MFPs and the SAD List for these unique medications.