NATIONAL INFUSION CENTER ASSOCIATION

November 2, 2016

Jami S. Earnest, Pharm.D.
United States Pharmacopeia
12601 Twinbrook Parkway
Rockville, Maryland 20852-1790

BY ELECTRONIC DELIVERY

RE: Draft USP Medicare Model Guidelines v7.0; Healthcare Quality Expert Committee Exclusion of Biologics from Updated Model Guidelines; Methodologies for Classifying New Medications; Vedolizumab Exclusion from USP Model Guidelines v7.0.

Dear Dr. Earnest:

The National Infusion Center Association (NICA) is pleased to submit its comments to U.S. Pharmcopeial Convention's Healthcare Quality Expert Committee regarding the draft USP Medicare Model Guidelines (USP MMG v7.0).

NICA is a nonprofit advocacy organization, established in 2010, to provide a national voice to patients relying upon office-based Infusion Centers to access high-quality, cost-effective care. Our efforts are focused on improving patient access to non-chemotherapeutic provider-administered intravenous and injectable medications in non-hospital, office-based Infusion Centers. NICA and its infusion provider partners are committed to maintaining the viability of office-based Infusion Centers as a more accessible, more patient-friendly, and more economical alternative to the hospital care setting.

NICA supports Medicare patients and their healthcare providers having access to a wide range of therapies so that they can find the right medication. This is particularly important in the case of biologic therapies for patients with immune-mediated inflammatory conditions, like rheumatoid arthritis, Crohn's disease, and ulcerative colitis. We are concerned that the draft Medicare Model Guidelines may restrict patient access to the high-quality care they need.

NICA offers its comments on the draft USP Medicare Model Guidelines (USP MMG v7.0.) to:

- Direct USP's attention to aspects of the draft Medicare Model Guidelines that may restrict patient access to safe and effective medications.
    - By including only some medical benefit biologics in the Medicare Model Guidelines, USP is providing health plans with an incomplete picture of available treatment options.
    - Limited specificity among current classifications may group biologics too broadly and restrict access to therapies with varying mechanisms of action.

Exclusion of biologics from the USP Medicare Model Guidelines will produce suboptimal guidance upon which drug formularies are developed.

The goal of the original Model Guidelines Expert Committee (2004) was "to strike a balance of assuring beneficiary access to the safe and effective drugs that they need…" The Healthcare Quality Expert Committee is expected to retain this goal and assure beneficiary access to the care they need. NICA is concerned that the draft USP MMG v7.0 may jeopardize the fulfillment of this goal by excluding a wide selection of provider-administered IV/injectable biologic therapy options.

We understand that the Medicare Model Guidelines are intended to inform pharmacy benefit drug formularies, and that office-administered IV/injectable biologics are covered under the medical benefit. However, there are several of these biologics covered under the medical benefit included in the previous version of the Medicare Model Guidelines (USP MMG v6.0). By including some medical benefit biologics in the draft guidelines, but not others, USP is providing a misleading and limited picture of the medication landscape.

We are concerned that if health plans use the Medicare Model Guidelines to influence their medical benefit drug formularies, as well as their pharmacy benefit formularies, patients may not have access to a wide array of treatment options. The resulting infusion landscape would contradict one in which the Healthcare Quality Expert Committee's goal of assuring beneficiary access to the safe and effective drugs that they need would otherwise be fulfilled. To ensure that patients have access to the safe and effective care they need, it is imperative that USP guidance captures the entire landscape of currently available therapeutic options.

U.S. Pharmacopeia is a reputable agency upon which health plans rely for accurate and comprehensive guidance to develop drug formularies that provide their beneficiaries with access to safe and effective therapies. As such, plans that utilize incomplete guidance in the development of their drug formularies will produce restrictive drug formularies that may not cover the medications that patients desperately need.

Classification structure may group medications too broadly and restrict access to available treatment options.

The current classification structure within the "Immunological Agents" category does not support the wide array of varying mechanisms of action among currently available biologics as well as those in the pipeline. Under the current structure, two medical benefit biologics are grouped into the "Immune Suppressants" class, and two are grouped into the "Immunomodulators" class, as illustrated below in Figure 1.

NICA is concerned that grouping biologics with a high diversity in mechanisms of action into a single class would restrict patient access to most of the medications in that class, including different mechanisms of action, since Medicare plans are only required to cover two drugs in the same class. This classification methodology does not appear to align with the Committee's goal.

As new medications with novel mechanisms of action become available, it is important to allow patients to access these therapies. For example, vedolizumab came to market in 2014 as the first, and only, gut-selective biologic. However, with the current classification methodology, this medication may be grouped with a handful of biologics as "Immune Suppressants", several of which are anti-TNF medications with systemic mechanisms of action. Alternatively, vedolizumab may be grouped with biologics currently listed as "Immunomodulators", including natalizumab, which has a similar mechanism of action but different target.

This difference attributes to vedolizumab's gut-selectivity instead of also targeting central nervous system inflammatory processes, like natalizumab.

Vedolizumab was FDA-approved for first-line indication in "adult patients with moderately to severely active ulcerative colitis who have had an inadequate response to, lost response to, or were intolerant to a tumor necrosis factor (TNF) blocker or immunomodulator; or had an inadequate response with, were intolerant to, or demonstrated dependence on corticosteroids [an immune suppressant]" and in "adult patients with moderately to severely active Crohn's disease who have had an inadequate response with, lost response to, or were intolerant to a TNF blocker or immunomodulator; or had an inadequate response with, were intolerant to, or demonstrated dependence on corticosteroids [an immune suppressant] As such, grouping this medication with immunomodulators or immune suppressants may not provide access to this particular therapy and instead require a patient to take an immunomodulator or immune suppressant that has already proven to be ineffective.

To maintain patient access to a wide array of safe and effective therapies — both current as well as novel therapies in the pipeline — it is essential to classify medications more specifically based on mechanism of action to maintain a low diversity in mechanism of action within each class. As such, we respectfully request that the U.S. Pharmacopeial Convention consider revising its classification methodology accordingly.

FIGURE 1: BIOLOGICS BY USP CLASSIFICATION

MEDICATION	USP CLASSIFICATION	TARGET	INDICATION	BENEFIT
Adalimumab	Immune Suppressants	TNF α	RA; JIA; PsA; AS; CD; PsO; UC	Pharmacy
Certolizumab pegol	Immune Suppressants	TNF α	CD; RA	Medical & Pharmacy
Etanercept	Immune Suppressants	TNF α	RA; JIA; PsA; AS; PsO	Pharmacy
Golimumab	Immune Suppressants	TNF α	RA; PsA; AS	Pharmacy
Infliximab	Immune Suppressants	TNF α	CD; UC; RA; AS; PsA; PsO	Medical
Natalizumab	Immunomodulators	α4 integrin	MS; CD	Medical
Tocilizumab	Immunomodulators	Interleukin-6 (IL-6)	RA	Medical
Vedolizumab	Reviewed, but not included in v7.0	α4β7 integrin	CD; UC	Medical

Ankylosing Spondylitis (AS); Crohn's Disease (CD); Juvenile Idiopathic Arthritis (JIA); Multiple Sclerosis (MS); Psoriatic Arthritis (PsA); Rheumatoid Arthritis (RA); Plaque Psoriasis (PsO); Ulcerative Colitis (UC)

Figure 1: Illustrates the different biologics included in USP MMG v6.0, and vedolizumab which was reviewed for inclusion in v7.0 but ultimately not included.

Patients on IV/injectable biologics suffer from serious, chronic disease with significant quality of life implications. Due to the complexity of these disease states, and the complexity of the biologic therapies themselves, patients typically need to try several different treatment options before finding the medication

that effectively manages their condition. As such, patients must have access to the entire gamut of treatment options and mechanisms of action to find the "safe and effective drug they need".

The draft Medicare Model Guidelines (USP MMG v7.0) provide an incomplete picture of therapeutic options and, therefore, suboptimal guidance for the development of drug formularies. Additionally, the lack of specificity in the classification structure will group too many biologics with unrelated mechanisms of action into a single class. This could further detract from the usefulness of these guidelines. If health plans utilize incomplete guidance based on a small number of high density classifications, patients may not have access to the safe and effective medication they need.

NICA and its infusion provider partners are committed to delivering high-quality care that is both cost-effective and patient-centered. This commitment requires access to the *right* medication for each patient. Guiding the development of drug formularies that support access to only a narrow array of available therapy options goes against the intentions of the USP Medicare Model Guidelines. We implore the Healthcare Quality Expert Committee to reconsider inclusion of additional bioloigcs, like vedolizumab, in the draft Medicare Model Guidelines. NICA welcomes the opportunity to work with the U.S. Pharmacopeial Convention and the Healthcare Quality Expert Committee toward a comprehensive set of guidelines that reflects the entire array of safe and effective therapy options that are currently available.

Conclusion

NICA appreciates the opportunity to submit its comments on behalf of office-based Infusion Centers serving some of our nation's most vulnerable Medicare patients. We are eager to work with USP and the Committee toward addressing the concerns expressed in this letter.

Respectfully,

BRIAN NYQUIST, MPH | EXECUTIVE DIRECTOR
NATIONAL INFUSION CENTER ASSOCIATION