July 23, 2019

The Honorable Chuck Grassley
Chairman
Committee on Finance
United States Senate
219 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Ron Wyden
Ranking Member
Committee on Finance
United States Senate
219 Dirksen Senate Office Building
Washington, DC 20510

Dear Senator Grassley and Senator Wyden:

As physicians who routinely prescribe biologic medicines, patient advocates whose members rely on biologic medicines, and on behalf of professional organizations with numerous biologics prescribers as members, we write to thank you for your focus on drug costs, particularly the cost that patients bear.

As you consider the many proposals around this important issue, we want to express our support for the current Centers for Medicare and Medicaid Services (CMS) policy of unique Healthcare Common Procedure Coding System (HCPCS) billing codes (J-codes) for each biologic medicine, including innovator and biosimilar products.

We do so based on principles arising from our commitment to patient centered care and a clinically sound prescribing process for biologics, including biosimilars. The CMS policy supports the following principles:

Principle 1 - Science: Biosimilars are not generic drugs. They can only be similar to their reference product, not identical like a small-molecule generic drug. Biosimilars, like all biologics, are large molecules grown in living systems. A single code would in essence treat biosimilars like generics, which is contrary to the biosimilars pathway established in the Biologics Price Competition and Innovation Act (BPCIA).

Principle 2 - Choice: Unique J-codes increase the incentive for manufacturers to compete by bringing biosimilars to market. Access to a choice of biosimilars is important for our patients, especially where an individual patient's immune reaction may differ between drugs. Competition will also help drive prices down once there are a sufficient number of products on the market.

Principle 3 - Safety: Like any biologic, a biosimilar can trigger immune and other reactions due to differences in patients' antibody profiles. In addition, each biologic medicine possesses unique properties and sensitivities in manufacturing and handling, making quick and accurate identification of accountable manufacturers imperative. To enable effective traceability, each biosimilar should be fully distinguishable in all its names and tracking codes, including HCPCS billing codes.

The FDA's guidance on nonproprietary naming of biological products proposes distinguishable names, calling for biological products to bear a nonproprietary name that includes an FDA-designated suffix. The agency explained, "There is a need to clearly identify biological products to improve pharmacovigilance, and, for the purposes of safe use, to clearly differentiate among biological products that have not been determined to be interchangeable."

In addition, physicians and others in the U.S. primarily rely on a non-biologic's brand or nonproprietary generic name in reporting adverse events to the FDA.[i] On the other hand, the FDA's Sentinel Initiative uses claims data, including HCPCS billing codes.[ii] [iii]

Principle 4 - Consistency: Patients and physicians who contend with a highly complex healthcare system, we value consistency. As noted above, the FDA is assigning distinguishable names for all biologics, an approach that is consistent with unique HCPCS billing codes.

Principle 5 - Research: Many patients contend with particularly challenging conditions, sending physicians and patients to research literature to evaluate alternative treatment paths. Separate billing codes for biosimilars can facilitate claims-based research encompassing the differences between biologics, including biosimilars. By not differentiating between biosimilars, the CMS proposal would preclude important inquiries and significantly diminish the utility of the data that is collected.

Based on these factors, the Committee should reject consideration of requiring CMS to change current policy to a policy of shared J-codes or even bundled J codes or other policies that consider treatments equivalent through coding and payment.

We believe a robust, competitive market based on differentiated benefits, including price, will deliver the promise of biosimilars to our patients. For that market to thrive, each biosimilar needs a separate HCPCS billing code, thereby recognizing biosimilars as a new category of medicine. More options will help bring down the cost of these life-changing medicines and allow more patients to access optimal treatment.

Thank you for this opportunity to share our views and commitment to patient centered care and sound biologics prescribing based on our principles of science, choice, safety, consistency and research.

Respectfully,

Alliance for Patient Access

American Autoimmune Related Diseases Association

Biologics Prescribers Collaborative[iv]

Global Liver Institute

International Cancer Advocacy Network

Lupus and Allied Diseases Association, Inc.

National Infusion Center Association

National Psoriasis Foundation

The Alliance for Safe Biologic Medicines

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[i] Lietzan, E. F., et al., Biosimilar Naming: How Do Adverse Event Reporting Data Support the Need for Distinct Nonproprietary Names for Biosimilars, The Food and Drug Law Institute, Vol. 3, Issue 6, March 27, 2013. Accessed August 18, 2015.

[ii] Gnadinger, Tracy, New Health Policy Brief: The FDA's Sentinel Initiative, Health Affairs Blog, June 8, 2015, Accessed on August 18, 2015.

[iii] Mini-Sentinel, Distributed Database and Common Data Model, Accessed August 18, 2015.

[iv] Biologics Prescribers Collaborative members include: Alliance for Patient Access; American Association of Clinical Endocrinologists; American College of Allergy, Asthma & Immunology; American College of Rheumatology; The American Gastroenterological Association; Coalition of State Rheumatology Organizations; Endocrine Society