

September 17, 2019

Administrator Seema Verma
Center for Medicare and Medicaid Services
U.S. Department of Health and Human Services
7500 Security Blvd.
Baltimore, MD 21244-1850

RE: Medicare Part D Compendia

Dear Administrator Verma,

On behalf of the millions of Americans living with chronic, disabling, and life-threatening medical conditions, the undersigned patient and provider organizations have joined together to express our concern regarding beneficiaries' barriers to accessing off-label treatments in Medicare Part D. Currently, the Centers for Medicare and Medicaid Services (CMS) relies on the American Hospital Formulary Service Drug Information (AHFS) and Drugdex compendia, which is restricting the ability of physicians to treat orphan, rare, and even common diseases (e.g., Hidradenitis suppurativa, sarcoidosis, autoimmune ILD) and preventing patients from accessing medically necessary treatments. We ask CMS to take immediate action to address this critical issue.

There appears to be a disconnect between Medicare coverage and inclusion of treatments in the compendia which CMS relies upon. We have observed that inaccurate information in these compendia can result in coverage denials for medically necessary, effective, and evidence-based treatments. It is particularly concerning that these compendia completely omit several important diseases impacting our patients. This results in an operational challenge where a patient cannot access treatment for a disease that is covered under the Medicare statute and regulations because the medication associated with that disease has been omitted from the compendia. Rare diseases, by nature, frequently have only a limited number of evidence-based treatments. If these fail, prior authorization determinations of treatments are difficult, or impossible if they are based on these compendia. This unfortunate circumstance has been recognized for oncology indications in the past and led to changes in policy.¹²³

A recent study demonstrates this disconnect. The enclosed study evaluated a list of 238 accepted treatments for 22 chronic, noninfectious, nonneoplastic dermatological conditions covered by Medicare for which each had at least four systemic therapies, including one considered first-line. Only 73/238 (30.7%) of these treatments were listed in either the AHFS or Drugdex compendia. In addition, there were frequent inconsistencies between the compendia, with 53/238 (22.3%) medications evaluated included in one compendium but not in the other. Additionally, the literature used was often based on decades-old sources. Qualitative assessment demonstrated that the level of evidence for inclusion of treatment and the

¹ Abernethy AP, Raman G, Balk EM, et al. Systematic review: reliability of compendia methods for off-label oncology indications. *Ann Intern Med.* 2009;150(5):336-343.

² The NCCN Compendium for Cancer Management: interview with Bill McGivney, PhD. *Am Health Drug Benefits.* 2008;1(5):40-44.

³ <https://www.cms.gov/medicare-coverage-database/details/technology-assessments-details.aspx?TAId=46&bc=AAAQAAAAAAAA&>

frequency of updates was arbitrary.⁴ Notably, many cost-effective therapies were excluded from these compendia, thus limiting access to their use. For example, antimalarial agents such as hydroxychloroquine are broadly effective, inexpensive, and safe medications for the treatment of connective tissue disease such as cutaneous lupus, yet both hydroxychloroquine and chloroquine were absent from DRUGDEX. Some diseases such as pemphigus have indications for medications that are no longer included in the compendia, resulting in Medicare beneficiaries unable to access necessary treatments. Additionally, several specialties have been impacted by this policy issue. For example:

- Rheumatology;
- Oncology;
- Gastroenterology; and
- In organ transplantation, several immunosuppressive medications are used off-label to prevent allograft rejection.⁵ Inside this specialty, lung transplant recipients are particularly vulnerable since no immunosuppressant medications are FDA-approved for use in lung transplantation, calcineurin inhibitors are the only medications mentioned by the compendia for off-label use, yet no lung transplant recipient patient can survive on calcineurin inhibitor monotherapy.

Frequently, patients and clinicians do not know when a coverage decision is denied based on a compendia determination. Physicians face challenges submitting treatments to be added to the compendia, with it often taking several years to submit just one treatment and indication. The American Society of Transplantation has submitted a formal request to Micromedex with specific recommendations in order to bring their compendia in line with current literature and practice; it has been over three months and they have yet to receive a response. More clarity is needed to help understand how and when the compendia would include the treatment and indication. Furthermore, it is difficult for patients and clinicians to access the compendia. These compendia are cost-prohibitive due to the high subscription fees. Finally, the compendia coverage determination process has a significant lack of transparency.

Given that these barriers are significant and complex, we suggest that CMS take the following steps to demystify drug coverage and to modernize the compendia:

- Require plans to notify the patient when the denial is based on the use of the compendia and explain how to access the compendia and accepted alternatives;
- Provide an affordable and easily accessible method for physicians and patients to use the AHFS and Drugdex compendias;
- Develop and make public a clear pathway and timeline for updating the compendia as new research becomes available; and
- For those indications with limited or inaccurate information in the compendia, require Part D plans to accept evidence from the literature citations presented by clinicians during the prior authorization process to support appeals of coverage determinations.

⁴ S. Barbieri, John & St Claire, Kayla & Mostaghimi, Arash & Albrecht, Joerg. (2019). Evaluation of Clinical Compendia Used for Medicare Part D Coverage Determinations for Off-label Prescribing in Dermatology. *JAMA Dermatology*. 155. 10.1001/jamadermatol.2018.5052.

⁵ Potter LM, Maldonado AQ, Lentine KL, et al. Transplant recipients are vulnerable to coverage denial under Medicare Part D. *Am J Transplant* 2018; 18(6): 1502-9.

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In conclusion, we respectfully request that CMS address these coverage issues as soon as possible so that patients can have access to these affordable and effective treatments. We welcome the opportunity to meet with you to discuss our recommendations further. Please contact Ashley John, Manager, Advocacy and Policy at (202) 609-4355 or ajohn@aad.org to arrange a mutually convenient meeting time. Thank you for your attention to our concerns.

Sincerely,

American Academy of Dermatology Association

American College of Rheumatology

American Gastroenterological Association

American Society for Mohs Surgery

American Society of Clinical Oncology

American Society of Transplantation

Cutaneous Lymphoma Foundation

Foundation for Ichthyosis & Related Skin Types

Haystack Project

International Pemphigus and Pemphigoid Foundation

MLD Foundation

National Alopecia Areata Foundation

National Eczema Association

CC:

Demetrios Kouzoukas, Principal Deputy Administrator for Medicare and Director