Society for Women's Health Research

October 5, 2018

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue SW
Washington, DC 20201

Re: CMS August 7, 2018 Memorandum Regarding Use of Step Therapy for Part B Physician-Administered Drugs in Medicare Advantage

Dear Administrator Verma:

I am writing on behalf of the Society for Women's Health Research (SWHR) to express our serious concerns with the recent memorandum from the Centers for Medicare & Medicaid Services (CMS) that changes long-standing policy by allowing Medicare Advantage (MA) plans to implement step therapy protocols to manage Part B-covered medications. CMS announced the new policy on August 7, 2018, without any statutory change or opportunity for public comment, and stated it would take effect January 1, 2019.

This policy reversal will be harmful and disruptive to women, who constitute more than half of the individuals in the Medicare program.[1] Older women have more chronic conditions and live longer than men, on average, making them especially reliant on the health care services Medicare funds.[2]

SWHR is deeply concerned that the August 7, 2018, memorandum lacks basic beneficiary protections and agency oversight that should be fundamental to any utilization

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management policy. Of particular concern to SWHR are:

- lack of CMS oversight of the policy and transparency to beneficiaries,
- lack of protections to prevent interference with patients' continuity of care,
- an insufficient appeals process for patients to seek step therapy exceptions, and
- increased possibility of higher cost-sharing exposure.

As such, I urge CMS to issue oversight and safeguard requirements to this new policy to ensure women continue to have timely access to the most appropriate health care services and medications in Medicare.

SWHR is a nonprofit organization that is widely recognized as a national thought leader in promoting research on biological differences in disease and eliminating imbalances in care for women through science, policy, and education. From our work studying a range of acute and chronic diseases that exclusively or disproportionately affect women, we know that requiring patients to try and fail certain treatments before allowing access to provider-recommended treatments of choice can have devastating consequences on patient health outcomes, functional status, pain, and even survival.

A woman's course of treatment for serious, life-threatening diseases such as cancer as well as chronic, debilitating conditions such as autoimmune disorders and multiple sclerosis routinely involve physician-administered medications. When developing the most appropriate care plan for a given medical condition, a woman's physician must consider her individual health needs. Understanding a woman's unique clinical situation entails assessing multiple factors including the presence of co-morbidities, potential drug interactions, and other intolerances. Step therapy protocols frequently do not allow for consideration of such factors, resulting in delays in women getting the most appropriate course of treatment and increasing the possibility of adverse events.

Below we discuss our specific concerns and suggestions for how CMS can address policy safeguards for use of step therapy for Part B medications in Medicare Advantage.

<u>Lack of CMS Oversight of the Policy and Transparency to Beneficiaries</u>

CMS states that health plans:

1) *are not required* to submit their step therapy protocols to the agency for review and
2) *do not have to specify* whether step therapy will be required and for which medications.

CMS and beneficiaries must have transparency as to which plans are implementing step therapy and in what manner to ensure that any step therapy protocol is clinically appropriate and evidence-based. CMS can collect information on a plan's step therapy activities, similar to the collection of formulary information in Part D, through updates to the Health Plan Management System (HPMS).

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Interference with Continuity of Care

Question 4 of CMS' August 29, 2018, Step Therapy Q's & A's states that "CMS expects plans will follow a look-back period of at least 108 days to determine whether the enrollee is eligible for a new start prescription."[3] This look-back period is not sufficient to ensure continuity of care for patients undergoing treatment. For example, it is not uncommon for patients undergoing treatment for cancer and rheumatoid arthritis to have treatment-free intervals that can last for many months.

CMS should institute protections to ensure that patients who were previously receiving a therapy are not subject to step requirements to continue care.

Insufficient Exceptions and Appeals Process

CMS states that the standard (14 calendar days) and expedited (72 hours) timeframes for Part C organization determinations apply to a request for a Part B drug.[4] CMS "strongly encourages" but stops short of requiring plans to expedite requests consistent with timelines under Part D.

To avoid the possibility of access delays to Part B therapies, CMS should require plans to follow the same timelines under Part D.

Increased Cost-Sharing Exposure

Also noticeably absent from the new policy are needed protections against higher out-of-pocket cost exposure. Female seniors forced to try a Part D drug before a Part B therapy that was their provider's first choice will be subject to potential increases in cost sharing.

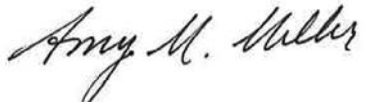
CMS policy must clearly address:

1) cost sharing differences between the Part B and Part D programs, and
2) a patient's out-of-pocket cost burden associated with step edit requirements.

While we appreciate CMS' attention to examining key factors that influence spending on medicines and identifying areas where improvements are needed, the new policy as issued is a step in the wrong direction for Medicare and female seniors. **Therefore, we urge CMS to issue oversight and safeguard requirements to this new policy to ensure women continue to have timely access to the most appropriate health care services and medications in Medicare.**

If you have questions, please contact Sarah Wells Kocsis, Vice President, Public Policy, at 202.496.5003 or swellskocsis@swhr.org. Thank you for your prompt attention on this important matter.

Sincerely,



Amy M. Miller, PhD
President and Chief Executive Officer
Society for Women's Health Research

cc: Dan Best, Senior Advisor to Secretary for Drug Pricing Reform, Department of Health and Human Services (HHS)

John O'Brien, Advisor to the Secretary and Deputy Assistant Secretary for Health Policy, HHS

Demetrios Kouzoukas, Principal Deputy Administrator for Medicare and Director of the Center for Medicare, CMS

Shari Ling, MD, Deputy Chief Medical Officer, CMS

[1] Kaiser Family Foundation. *Distribution of Medicare Beneficiaries by Gender*, available at: https://www.kff.org/medicare/state-indicator/medicare-beneficiaries-by-gender/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D

[2] Kaiser Family Foundation. *Medicare's Roll for Women (June 2009)* available at: https://www.kff.org/medicare/fact-sheet/medicares-role-for-women/

[3] Centers for Medicare & Medicaid Services. *CY 2019 Step Therapy Q's & A's, Question 4 (August 29, 2018).*

[4] Centers for Medicare & Medicaid Services. *CY 2019 Step Therapy Q's & A's, Question 11 (August 29, 2018).*