



DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

AUG - 2 2016

Administrator
Washington, DC 20201

The Honorable Tom Price
U.S. House of Representatives
Washington, DC 20515

Dear Representative Price:

Thank you for your letter and sharing your concerns about step therapy. The Centers for Medicare & Medicaid Services (CMS) remains committed to Medicare and Medicaid beneficiaries' continued access to needed prescribed medications – a commitment that is also shared among the states. The purpose of this letter is to explain the application of step therapy within the Medicare Part D program and to describe federal requirements related to state Medicaid prior authorization programs, including step therapy protocols.

A Part D plan sponsor's Pharmacy & Therapeutics (P&T) committee must review for clinical appropriateness the practices and policies for formulary management activities, including step therapies. Formulary management decisions must be based on scientific evidence and may also be based on pharmacoeconomic considerations that achieve appropriate, safe and cost effective drug therapy. CMS reviews each Part D plan's benefit annually, including step therapy protocols. In addition, step therapy protocols are reviewed throughout the plan year should any updates occur. These reviews validate that each plan offers robust access to medications across drug categories and classes. If necessary, an enrollee, an enrollee's prescriber or an enrollee's representative may request a formulary exception to obtain a Part D drug that is subject to a utilization management restriction, such as step therapy, that the enrollee or enrollee's prescriber believes should not apply.

Coverage of prescription drugs is an optional benefit in state Medicaid programs, though all fifty states and the District of Columbia currently provide this benefit. These states have entered into and have in effect rebate agreements; therefore, these states are required to comply with the requirements of section 1927(d) of the Social Security Act (the Act). While states have the discretion to establish certain limitations on the coverage of these drugs – such as preferred drug lists and use of prior authorization processes, including step therapy – such practices must be consistent with requirements of section 1927(d) of the Act to ensure appropriate utilization.

The CMS encourages states to exercise sound clinical judgment and utilize available resources to determine their prescription drug coverage policies. These resources include P&T committees, drug utilization review (DUR) boards and comparative analysis of the costs to treat patients in light of the efficacy. On an annual basis, states are also required to report on their state's prescribing habits, cost savings generated from their DUR programs and their program's operations, including adoption of new innovative DUR practices through the Medicaid Drug Utilization Review Annual Report Survey. To access the FFY 2014 Annual DUR report, please visit <https://www.medicaid.gov/medicaid-chip-program-information/by-topics/benefits/prescription-drugs/downloads/2014-dur-summary-report.pdf>.

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I hope you find the information and clarification provided within this letter useful in administering step therapy protocols. If you have any questions regarding this information, please contact the CMS Office of Legislation at 202-690-8220. I will also provide this response to the co-signers of your letter.

Sincerely,

A handwritten signature in black ink, appearing to read "Andrew M. Slavitt". The signature is fluid and cursive, with a long horizontal stroke at the end.

Andrew M. Slavitt
Acting Administrator

Congress of the United States
Washington, DC 20515

June 8, 2016

Mr. Andy Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health & Human Services
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, S.W. Washington, D.C. 20201

Dear Acting Administrator Slavitt:

The use of step therapy is common and growing among private and public payers. In 2013, 67 percent of employer sponsored health insurance plans reported that they had implemented step therapy policies, an increase from 27 percent in 2005. While we recognize that step therapy has at times been an effective practice that helps control costs throughout the healthcare sector, we want to ensure that the practice is not being used at the expense of patient health and well-being.

In some instances, step therapy protocols may provide appropriate and affordable drug treatments, however, in some cases it could have the opposite effect. Prolonging ineffective treatment and preventing patients from starting treatments recommended by their physician or health care provider in a timely manner can lead to poorer health outcomes and increased costs for patients and the health care system.

Too often, Federal policy focuses on short-term savings instead of long-term costs. The same is true of the healthcare system: early investments in preserving health can lower the long-term costs—especially for patients dealing with chronic diseases like rheumatoid arthritis, psoriatic arthritis, multiple sclerosis, diabetes, inflammatory bowel disease, cancer and mental health, among others. In a study comparing spending on schizophrenia medications in Georgia's Medicaid program, step therapy saved the state \$19.62 per member per month in pharmacy spending but these savings were accompanied by a \$31.59 per member per month increase in expenditures for outpatient costs.ⁱ When patients receive the right medicine at the right time, as determined by their physician, there are reduced complications, fewer follow up visits, and potentially greater savings to the healthcare system.

When implemented appropriately, step therapy can be an effective tool to ensure patients receive cost effective care. However, we should ensure that physicians have the ability to prescribe what they believe to be the most appropriate and effective medicine for each patient. Under your authority to oversee the Medicare program, we ask that you work to ensure that step therapy

protocols are open and transparent, do not create a barrier to access, and do not take prescribing power out of the hands of physicians.

Sincerely,



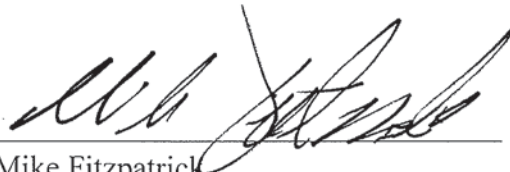
Leonard Lance
Member of Congress



Scott Peters
Member of Congress



Dan Benishek, M.D.
Member of Congress



Mike Fitzpatrick
Member of Congress



Mike Coffman
Member of Congress



Emanuel Cleaver
Member of Congress



H. Morgan Griffith
Member of Congress



Peter King
Member of Congress



Tom Price, M.D.
Member of Congress

¹Farley, J. et al., "Retrospective assessment of Medicaid step-therapy prior authorization policy for atypical antipsychotic medications," Clinical Therapeutics, 30: 1524-1539, 2008.