



## Fact Sheet: Step Therapy in Medicare Advantage Plans

In August 2018, the Centers for Medicare and Medicaid Services (“CMS”) announced a new policy that will restrict the ability of Medicare beneficiaries to access their prescribed medications in efforts to save the government money.<sup>1</sup> The policy allows health insurers that offer Medicare Advantage (“MA”) plans to impose step therapy protocols. To learn more about what this means for America’s seniors and what you can do, read on.

### *What is Original Medicare?*

Original Medicare is managed by the federal government and includes Medicare Parts A and B.<sup>2</sup> Medicare Part A covers inpatient care, such as treatment received in a hospital, nursing facility, and limited home health services.<sup>3</sup> Medicare Part B covers services and supplies that are provided in an outpatient setting.<sup>4</sup> It also covers prescription medications that are administered in a doctor’s office or hospital.<sup>5</sup> It does not cover prescription medications that are typically taken at home.

### *What is Medicare Advantage?*

Medicare Advantage, also referred to as “Part C,” is a Medicare health plan offered by private insurers, rather than the government. MA plans generally must offer coverage benefits equal to those provided by Original Medicare (*i.e.*, inpatient care and outpatient services, supplies, and prescriptions).<sup>6</sup>

### *What is Medicare Part D?*

Medicare Part D is managed by private insurers and provides prescription drug coverage. A Medicare beneficiary must have a Part A or Part B plan to qualify for Part D coverage. While most medications are covered under Medicare Part D, there are some drugs that are only covered by Medicare Part B (*e.g.*, antigens, hemophilia clotting factors).<sup>7</sup>

### *What is step therapy?*

Often referred to as “fail first,” step therapy is an insurance protocol that requires a plan beneficiary to try and fail on a less expensive, insurer-selected drug before the insurer will cover the drug prescribed by the beneficiary’s health care practitioner. Generally, the “steps” are based on efforts to save money rather than medical judgment.<sup>8</sup> Moreover, a step therapy protocol may require beneficiaries to fail on more than one “step” before covering the prescribed treatment.

### *How will CMS’s new policy affect MA plans?*

Under Medicare regulations, MA plans must provide enrollees with the same benefit coverage they would be entitled to under Original Medicare.<sup>9</sup> Given that the Original Medicare regulations do not explicitly allow step therapy for Part B drugs, CMS has traditionally interpreted the regulations to prohibit step therapy in MA plans as well.<sup>10</sup> However, in August 2018, CMS rescinded previous guidance and officially stated that insurers offering MA plans may apply step therapy protocols for physician-administered prescription drugs.<sup>11</sup>

The new policy means that a MA plan will not necessarily cover the medication prescribed by

the enrollee's treating physician. Instead, the MA insurer will mandate that a different, cheaper medication be tried first. Only if the beneficiary fails on the insurer-mandated medication (or a series of medications) first will the MA insurer cover the drug that the doctor prescribed. The policy also allows a MA insurer to mandate that a beneficiary fail on a Part D drug (one that is not administered by a physician) before the plan will cover the prescribed Part B drug.<sup>12</sup>

### **The Problem with Step Therapy for Medicare Beneficiaries**

Step therapy can cause a number of issues that may significantly affect patient health. The negative impacts of step therapy policies include:

- Adverse events from taking medications that are inappropriate for the beneficiary's individual needs
- Critical delays in access to care that can result in disease progression
- Interference with the physician-patient relationship
- Required treatments that may be inconsistent with clinical standards of care

### **Step Therapy Is the Wrong Approach for Medicare Advantage**

CMS's step therapy policy will endanger seniors with serious medical conditions. The government explicitly states in its policy change that its goal is to save on drug costs, not to improve patient care. Simply put, the quest for lower drug prices should not be prioritized over our seniors' health and wellbeing.

### **Step Therapy Won't Save Money**

It is not clear that enforcing step therapy policies will save money for MA plans or beneficiaries. When CMS announced its new policy, the agency admitted that differences in cost-sharing requirements between Part B and Part D plans may result in a MA beneficiary paying *more* for the insurer-mandated drugs rather than the prescribed medications.<sup>13</sup> Further, beneficiaries could experience adverse events from trying medications that may be less effective for their individual needs, which may necessitate additional medical services, including hospitalizations.<sup>14</sup> This would scuttle any supposed savings from step therapy policies and place a vulnerable patient population at risk of avoidable harm.

### **Step Therapy Will Be Costly for Practitioners**

Step therapy policies may put financial pressure on clinics and private practices that specialize in administering Part B drugs and force them to rely on program fees for administering Part B drugs to cover the cost of operations. Step therapy policies are intended to slash the reimbursement that clinics and physicians need to keep their doors open. This financial pressure could result in clinics and practices going under, and patients being forced to receive their treatment from hospitals at significantly higher costs. One study found that outpatient cancer care delivered in hospitals was 38 percent higher than physician offices, without measurable improvements in patient outcomes,<sup>15</sup> and another found lower hospitalizations from cancer outpatient care delivered in non-hospital settings.<sup>16</sup>

### **Step Therapy Is a Discriminatory Practice**

Step therapy may result in discrimination if it is applied in a way that requires beneficiaries to fail on Part D drugs before accessing their prescribed Part B medication. Part B drugs typically treat a limited number of specific chronic conditions, such as cancer, macular degeneration,

rheumatoid arthritis, hemophilia, HIV, and end stage renal disease.<sup>17</sup> Therefore, individuals with such conditions will be disproportionately impacted by these step therapy protocols. While the government stated that an appeals process would be available for MA beneficiaries negatively affected by step therapy, such appeals are denied in roughly 90 percent of cases.<sup>18</sup> Seniors suffering from these conditions should not also have to grapple with their prescribed treatment being denied, increased out-of-pocket costs, or navigating complex and often fruitless insurance appeals processes.

### **Scrap Step Therapy for Medicare Advantage Enrollees**

The inclusion of step therapy in MA plans is simply not the solution to the government's concerns about health care costs in the U.S. It will not save Medicare money, and it may increase costs for beneficiaries. Moreover, there is ample evidence that step therapy can lead to significant negative health outcomes for Medicare beneficiaries, and imperil the health care providers these beneficiaries depend on to provide cost-effective care. Therefore, CMS should rescind its new guidance allowing step therapy in MA plans and reinstate its prior interpretation of Medicare law prohibiting this discriminatory and unsupportable policy.

### **About Aimed Alliance**

Established in 2013 and based in Washington, DC, Aimed Alliance is a not-for-profit organization that seeks to improve access to quality health care. Aimed Alliance achieves this mission by conducting legal research and analysis; developing economically sound, patient-centered recommendations; and disseminating our findings to inform policymakers and increase public awareness.

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<sup>1</sup> <https://www.cms.gov/newsroom/fact-sheets/medicare-advantage-prior-authorization-and-step-therapy-part-b-drugs>

<sup>2</sup> <https://www.cms.gov/Medicare/Eligibility-and-Enrollment/OrigMedicarePartABEligEnrol/index.html>

<sup>3</sup> <https://www.cms.gov/Medicare/Medicare-General-Information/MedicareGenInfo/index.html>

<sup>4</sup> 42 U.S. Code § 1395k(a)(3)(B)

<sup>5</sup> 42 U.S. Code § 1395x(s)(2)(A) and 42 U.S. Code § 1395x(s)(2).

<sup>6</sup> <https://www.medicare.gov/sites/default/files/2018-07/11474.pdf>; 42 C.F.R. §§ 417.414(b) and 422.101(a) and (b).

<sup>7</sup> <https://www.medicareinteractive.org/wp-content/uploads/2015/08/B-vs-D-chart.pdf>

<sup>8</sup> <https://www.statnews.com/2016/08/22/step-therapy-patients-insurance-treatments/>

<sup>9</sup> 42 C.F.R. §§ 417.414(b) and 422.101(a) and (b)

<sup>10</sup> [https://www.asrs.org/content/documents/cms\\_step\\_therapy\\_memo\\_091712-2.pdf](https://www.asrs.org/content/documents/cms_step_therapy_memo_091712-2.pdf)

<sup>11</sup> [https://www.cms.gov/Medicare/Health-Plans/HealthPlansGenInfo/Downloads/MA\\_Step\\_Therapy\\_HPMS\\_Memo\\_8\\_7\\_2018.pdf](https://www.cms.gov/Medicare/Health-Plans/HealthPlansGenInfo/Downloads/MA_Step_Therapy_HPMS_Memo_8_7_2018.pdf)

<sup>12</sup> [https://www.cms.gov/Medicare/Health-Plans/HealthPlansGenInfo/Downloads/MA\\_Step\\_Therapy\\_HPMS\\_Memo\\_8\\_7\\_2018.pdf](https://www.cms.gov/Medicare/Health-Plans/HealthPlansGenInfo/Downloads/MA_Step_Therapy_HPMS_Memo_8_7_2018.pdf)

<sup>13</sup> [https://www.cms.gov/Medicare/Health-Plans/HealthPlansGenInfo/Downloads/MA\\_Step\\_Therapy\\_HPMS\\_Memo\\_8\\_7\\_2018.pdf](https://www.cms.gov/Medicare/Health-Plans/HealthPlansGenInfo/Downloads/MA_Step_Therapy_HPMS_Memo_8_7_2018.pdf)

<sup>14</sup> <http://www.modernhealthcare.com/article/20180809/NEWS/180809903/medicare-part-b-change-could-lead-to-increased-hospitalizations>

<sup>15</sup> <http://communityoncology.org/UserFiles/Cancer-Treatment-Costs.pdf>

<sup>16</sup> <https://www.ajmc.com/contributor/coa/2018/08/the-financial-impact-of-the-sequester-cut-to-medicare-part-b-drug-reimbursement-in-community-oncology>

<sup>17</sup> [http://www.medpac.gov/docs/default-source/payment-basics/medpac\\_payment\\_basics\\_17\\_partb\\_final.pdf?sfvrsn=0](http://www.medpac.gov/docs/default-source/payment-basics/medpac_payment_basics_17_partb_final.pdf?sfvrsn=0)

<sup>18</sup> <https://khn.org/news/new-medicare-advantage-tool-to-lower-drug-prices-puts-crimp-in-patients-choices/>