**Allowing Step Therapy in Medicare Advantage can Hinder Beneficiary Access to the Most Appropriate Therapy and Increase Overall Costs**

Step therapy is a form of utilization management that requires patients to “fail first” on a drug before the insurer will cover another treatment. In an effort to control overall drug spend, payors are increasingly implementing step therapy protocols. Of great concern is the recently announced policy to allow step therapy for Part B drugs in Medicare Advantage.[[1]](#footnote-1) Drugs covered under the Medicare Part B benefit often treat vulnerable populations suffering from severe diseases such as cancer, hemophilia, and autoimmune disorders.

**Step therapy inappropriately places the insurance company between the patient and his/her provider.**

* Step therapy policies can delay patient access to the treatment that his/her provider has deemed most appropriate for the associated condition, with the highest likelihood of delivering the best outcome.
* Delaying access to the prescribed therapy can have severe implications for the complex patients who rely on drugs covered by Medicare Part B.
* Step therapy policies must provide for an adequate and timely exceptions and appeals process—as well as a comprehensive review of the patient’s history—in order to protect the patient-provider decision-making process and avoid subjecting the patient to harmful adverse side effects.

**Step therapy requirements lack transparency and are often not guided by evidence or appropriate clinical criteria.**

* If used by a health plan, step therapy requirements should be evidence-based and clinically appropriate. However, a recent study on health plan strategies for restricting coverage of specialty drugs (primarily through use of step therapy) found this is not the case. Specifically, the researchers did not find a strong association between restricted coverage decisions (i.e., step therapy) and the evidence cited by payers to justify such a decision.[[2]](#footnote-2)
* One study that looked at coverage policies for rheumatoid arthritis drugs found that almost 70% of coverage determinations were more restrictive than the corresponding FDA label.[[3]](#footnote-3)
  + There is wide variation in how the largest payers cover these drugs as well as a large variation in the evidence reviewed to justify their coverage restrictions. Step edits often lack uniformity questioning the clinical basis for the lack of coverage for particular therapies.
  + The variety and uncertainty in how plans are applying step edits highlights the importance for there to be sufficient oversight on MA plans who intend to require Medicare beneficiaries to adhere to these “fail first” policies.
* It is critical that step therapy requirements are implemented appropriately to protect beneficiary access to the most appropriate therapy for his/her given condition and to avoid unnecessary complications.

**Step therapy can lead to higher overall utilization costs and diminished outcomes due to adverse events and harmful side effects.**

* While there is some evidence that appropriate step therapy requirements can effectively control costs, other studies have found that inappropriately implementing step therapy can lead to increases in overall utilization through increased inpatient admissions and emergency department visits.
* One study that sought to determine the effects of antihypertensive step therapy on prescription drug and medical care utilization and spending found that after an initial decline in spending, patients who were in step-therapy plans incurred $99 more per user in quarterly expenditures due to the increase in inpatient admissions and emergency room visits.[[4]](#footnote-4)
* Further, it is well documented that delays in treatment can lead to disease progression, increased symptom severity, and diminished treatment outcomes.
  + One study found that in breast cancer patients, delays in treatment of 3-6 months were associated with a 12 percent lower five-year survival rate.[[5]](#footnote-5)
  + Additionally, patients with rheumatoid arthritis who delayed treatment to disease-modifying agents for approximately 4 months experience significantly more radiologic joint damage after two years when compared with patients who began treatment within 2 weeks.[[6]](#footnote-6)
  + Similarly, early detection and treatment for Alzheimer’s can delay progression of disease by at least 2.8 years in some cases.[[7]](#footnote-7)
* Step therapy requirements unduly delay patient access to the most appropriate treatment, leading to negative patient outcomes, increased side effects, and higher overall utilization costs. It is vital for there to be oversight and transparency into the step edits placed on treatments covered by Medicare Part B.

1. CMS Memo to Medicare Advantage Organizations. 7 August 2018. [↑](#footnote-ref-1)
2. Chambers J, Panzer A, Neumann P. Variation in the Use of Step Therapy Protocols Across US Health Plans. Health Affairs. 14 September 2018. Available at: https://www.healthaffairs.org/do/10.1377/hblog20180912.391231/full/?utm\_term=Variation%20In%20The%20Use%20Of%20Step%20Therapy%20Protocols%20Across%20US%20Health%20Plans&utm\_campaign=HAT&utm\_content=email&utm\_source=act-on%209%2F14%2F18&utm\_medium=email&cm\_mmc=Act-On%20Software-\_-email-\_-Step%20Therapy%20Protocols%3B%20Medicaid%20Work%20Demonstration%20Legal%20Developments%3B%20Effects%20Of%20Climate%20Change%20On%20Health%20In%20California-\_-Variation%20In%20The%20Use%20Of%20Step%20Therapy%20Protocols%20Across%20US%20Health%20Plans [↑](#footnote-ref-2)
3. Chambers, et al. Variation in Private Payer Coverage of Rheumatoid Arthritis Drugs. J Manag Care Spec Pharm, 2016 Oct;22(10):1176-1181. Available at: https://www.ncbi.nlm.nih.gov/pubmed/27668566. [↑](#footnote-ref-3)
4. Mark TL, Gibson TB, McGuigan KA. The effects of antihypertensive steptherapy protocols on pharmaceutical and medical utilization and expenditures. Am J Mang Care. 2009;15(2):123-31. Available at: https://www.ncbi.nlm.nih.gov/pubmed/19284809. [↑](#footnote-ref-4)
5. Richards, et al. Influence of Delay on Survival in Patients with Breast Cancer: a systematic review. The Lancet, Volume 353, Issue 9159. 3 April 1999. Available at: https://www.ncbi.nlm.nih.gov/pubmed/10209974. [↑](#footnote-ref-5)
6. Land, et al. Early versus delayed treatment in patients with recent-onset rheumatoid arthritis: comparison of two cohorts who received different treatment strategies. The American Journal of Medicine. Volume 111, Issue 6. 15 October 2001. Available at: https://www.ncbi.nlm.nih.gov/pubmed/11690569. [↑](#footnote-ref-6)
7. [Geldmacher, D S](https://search.proquest.com/indexinglinkhandler/sng/au/Geldmacher,+D+S/$N;jsessionid=566564BB36129D3586C8776F86E8E73E.i-0eda121e6e344fcb9); [Frolich, L](https://search.proquest.com/indexinglinkhandler/sng/au/Frolich,+L/$N;jsessionid=566564BB36129D3586C8776F86E8E73E.i-0eda121e6e344fcb9); [Doody, R S](https://search.proquest.com/indexinglinkhandler/sng/au/Doody,+R+S/$N;jsessionid=566564BB36129D3586C8776F86E8E73E.i-0eda121e6e344fcb9); [Erkinjuntti, T](https://search.proquest.com/indexinglinkhandler/sng/au/Erkinjuntti,+T/$N;jsessionid=566564BB36129D3586C8776F86E8E73E.i-0eda121e6e344fcb9); [et al](https://search.proquest.com/indexinglinkhandler/sng/au/et+al/$N;jsessionid=566564BB36129D3586C8776F86E8E73E.i-0eda121e6e344fcb9). Realistic Expectations for Treatment Success in Alzheimer’s Disease. [**The Journal of Nutrition, Health & Aging**](https://search.proquest.com/pubidlinkhandler/sng/pubtitle/The+Journal+of+Nutrition,+Health+$26+Aging/$N/28850/OpenView/222312142/$B/FF9F4DC2BD904951PQ/1;jsessionid=566564BB36129D3586C8776F86E8E73E.i-0eda121e6e344fcb9)**; Volume 10, Issue 5** (Sep/Oct 2006): 417-29. Available at: https://www.ncbi.nlm.nih.gov/pubmed/17066215. [↑](#footnote-ref-7)