



Position Paper

Step Therapy/Fail First

Issue

Insurers recently adopted policies such as “step therapy,” also referred to as “step protocol” or “fail first,” requiring beneficiaries to use a certain category of medication(s) before they can seek to use a second category of medication. This blanket policy, where insurers substitute their judgment for that of the treating physicians, can lead to dangerous results for certain patients.

Step therapy creates barriers to care resulting in higher costs, and delays in effective treatment. Step Therapy may also lead individuals to receive less appropriate medications outside of the treating physician’s care.

Studies have shown that step therapy results in increased hospital admissions, emergency room visits, and overall health care costs when compared to those not subject to step therapy. (*The American Journal of Managed Care*, 2009.)

Type of Medications	Description of drugs
First Line	FDA approved generic
	Lowest copayment or cost
Second Line	Drugs recommended if first step drugs are not effective
	Brand names
	Higher copayment or cost

Legislative Overview

Legislation to prohibit or limit the use of step therapy has been confined to a small number of states including California, Florida, Louisiana, Missouri, and New Jersey.

Example: Louisiana

On July 2, 2010, Governor Bobby Jindal (R-Louisiana) signed a measure to protect patients from “fail first” restrictions by insurers. The law mandates that if insurers restrict the use of medication through step therapy and fail first protocols, the prescribing physician must be given access to a clear and convenient process to quickly override the restriction. Additionally, the law requires the insurer to expeditiously consider the override request when the physician can demonstrate that the preferred treatment required under the step therapy or “fail first” protocol has been, or is expected to be, ineffective. This new law became effective for all plans issued or renewed on or after January 1, 2011.

Example: Medicare

In 2010, the Centers for Medicare and Medicaid Services limited step therapy for Medicare patients to two failures before providing access to the prescribed medicine. Additionally, Medicare Part D drug plan sponsors must post online quantity limit restrictions and step therapy requirements. Health insurers are prohibited by federal regulations from requiring Medicare patients to try off-label drugs before providing a medication approved by the Food and Drug Administration.

There has not been federal legislation introduced to ban the use of step therapy or “fail first” protocols by insurance providers. Unfortunately there has been movement towards “Least Costly Alternative” therapies and “comparative effectiveness” among more insurance providers.

Alliance Policy

Step therapy and fail first protocols create barriers to care, lead to patients receiving inadequate medications, and can result in more costly medical care. The Alliance is particularly concerned about the move towards utilizing least costly alternatives where patients’ therapies are routinely switched to therapies that merely treat symptoms and not the underlying disease.

The Alliance supports policies that place patient care back in the hands of the health care providers through the banning of step therapy and “fail first” protocols. Medication allocation must be focused on patients first and based upon policies and actions that prioritize quality and efficient care.