

42 C.F.R. § 422.136

Medicare Advantage (MA) and step therapy for Part B drugs.

- (a) *General.* If an MA plan implements a step therapy program to control the utilization of Part B-covered drugs, the MA organization must—
- (1) Apply step therapy only to new administrations of Part B drugs, using at least a 365 day lookback period;
 - (2) Establish policies and procedures to educate and inform health care providers and enrollees concerning its step therapy policies.
 - (3) Prior to implementation of a step therapy program, ensure that the step therapy program has been reviewed and approved by the MA organization's pharmacy and therapeutic (P&T) committee.
- (b) *Step therapy and pharmacy and therapeutic committee requirements.* An MA plan must establish a P&T committee prior to implementing any step therapy program. An MA plan must use a P&T committee to review and approve step therapy programs used in connection with Part B drugs. To meet this requirement, a MA–PD plan may utilize an existing Part D P&T committee established for purposes of administration of the Part D benefit under part 423 of this chapter and an MA plan may utilize an existing Part D P&T committee established by an MA–PD plan operated under the same contract as the MA plan. The P&T committee must—

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