

Guiding Principles of Step Therapy for Kansas Medicaid Drug Use

Step Therapy Background

A step therapy approach to care requires the use of a clinically recognized first-line or previously available drug before approval of a more complex and often more expensive medication where the safety, effectiveness and value has not been well established. Step therapy requirements ensure that an established and cost-effective therapy is utilized prior to progressing to other therapies. If the required therapeutic benefit is not achieved by use of the first-line drug, the prescriber may request use of a second-line, then subsequent lines of medication.

Where criteria make possible and related factors allow, this prior authorization process will utilize an automated adjudication logic that reviews a patient's past prescription claims history to qualify a patient for coverage without requiring the prescriber to complete the administrative prior authorization review process. If patients have the required drug or drug class to be used first in their claim's history, they may automatically qualify for coverage the drug or line of therapy requested without triggering a review for coverage. Some exceptions to an automated adjudication logic: previous drug was tried while member was on a commercial insurance plan (drug not on file with Medicaid) or the claim is a manual claim, where this technology is not applicable.

**Note: CMS recognizes and encourages step therapy as a utilization management tool in its Part D formulary management.*

Inclusion of Step Therapy

Step therapy may be added based on ANY of the following criteria:

1. The drug is of the same specific therapeutic class (STC) without significant clinical outcome differences but priced at a higher cost when compared to other existing drug(s) within the same therapeutic class.
 - a. This could include different formulations, pack sizes or delivery devices of currently available drug(s).
2. The drug is placed as second, third, fourth (and subsequent) or last line of treatment based on treatment guideline and standard of care practice.
3. If a first or subsequent line of treatment has more than one drug class, the more cost-effective drug or drug class will be required before the other drug or drug class in that line of treatment level.
4. The drug is from a newer therapeutic class in which another existing therapeutic class has been established as standard of care.
5. The drug does not add incremental value to the therapeutic outcome and is less cost-effective compared to existing drug(s) treating the same disease state or medical condition.
6. The drug has safety concern compared to another existing drug(s) treating the same disease state or medical condition.
7. National Standard of Care Guidelines (Ex: ADA, AHA, NIH, ACG, NDEI, NCCN) will be used and referenced during the DUR Board meetings, for proposed step therapy criteria, when different lines of care are addressed.

Exclusion of Step Therapy

Step therapy should NOT be added based on ANY of the following criteria:

1. The drug efficacy data shows clinically significant superiority over existing agents to be stepped through.
2. The drug shows clinically significant improved safety profile over existing agents to be stepped through.
3. The drug is the recommended first line drug based on treatment guideline and standard of care practice.
4. The drug is more cost effective over existing agents to be stepped through.