

304.17A-163 Override of restrictions on medication sequence in step therapy or fail-first protocol.

- (1) As used in this section, unless the context requires otherwise:
 - (a) "Step therapy" means a protocol that establishes the specific sequence in which prescription drugs for a specified medical condition and medically appropriate for a particular patient are to be prescribed;
 - (b) "Fail-first protocol" has the same meaning as step therapy in paragraph (a) of this subsection;
 - (c) "Override of the restriction" means the permission to deviate from the required sequence by prescribing another drug that is medically necessary; and
 - (d) "Insurer" has the same meaning as in KRS 304.17A-005.
- (2) When medications for the treatment of any medical condition are restricted for use by an insurer or a pharmacy benefit manager by a step therapy or fail-first protocol, the prescribing practitioner shall have access to a clear and convenient process to request an override of the restriction from the insurer. An override of the restriction shall be granted by the insurer or the pharmacy benefit manager within forty-eight (48) hours, if all necessary information to perform the override review has been provided, under the following documented circumstances:
 - (a) The prescribing practitioner can demonstrate, based on sound clinical evidence, that the preferred treatment required under step therapy or fail-first protocol has been ineffective in the treatment of the insured's disease or medical condition; or
 - (b) Based on sound clinical evidence or medical and scientific evidence:
 1. The prescribing practitioner can demonstrate that the preferred treatment required under the step therapy or fail-first protocol is expected or likely to be ineffective based on the known relevant physical or mental characteristics of the insured and known characteristics of the drug regimen; or
 2. The prescribing practitioner can demonstrate that the preferred treatment required under the step therapy or fail-first protocol will cause or will likely cause an adverse reaction or other physical harm to the insured.
- (3) The duration of any step therapy or fail-first protocol shall not be longer than a period of thirty (30) days if the treatment is deemed and documented as clinically ineffective by the prescribing practitioner. When the prescribing practitioner can demonstrate, through sound clinical evidence, that the originally prescribed medication is likely to require more than thirty (30) days to provide any relief or an amelioration to the insured, the step therapy or fail-first protocol may be extended up to seven (7) additional days.

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