514F.7 Use of step therapy protocols.

1. *Definitions.* For the purposes of this section:

a. *"Authorized representative"* means the same as defined in section 514J.102.

b. *"Clinical practice guidelines"* means a systematically developed statement to assist health care professionals and covered persons in making decisions about appropriate health care for specific clinical circumstances and conditions.

c. *"Clinical review criteria"* means the same as defined in section 514J.102.

d. *"Covered person"* means the same as defined in section 514J.102.

e. *"Health benefit plan"* means the same as defined in section 514J.102.

f. *"Health care professional"* means the same as defined in section 514J.102.

g. *"Health care services"* means the same as defined in section 514J.102.

h. *"Health carrier"* means an entity subject to the insurance laws and regulations of this state, or subject to the jurisdiction of the commissioner, including an insurance company offering sickness and accident plans, a health maintenance organization, a nonprofit health service corporation, a plan established pursuant to chapter 509A for public employees, or any other entity providing a plan of health insurance, health care benefits, or health care services. *"Health carrier"* does not include a managed care organization as defined in 441 IAC 73.1 when the managed care organization is acting pursuant to a contract with the department of health and human services to provide services to Medicaid recipients.

i. *"Pharmaceutical sample"* means a unit of a prescription drug that is not intended to be sold and is intended to promote the sale of the drug.

j. *"Step therapy override exception"* means a step therapy protocol should be overridden in favor of coverage of the prescription drug selected by a health care professional within the applicable time frames and in compliance with the requirements specified in section 505.26, subsection 7, for a request for prior authorization of prescription drug benefits. This determination is based on a review of the covered person's or health care professional's request for an override, along with supporting rationale and documentation.

k. *"Step therapy protocol"* means a protocol or program that establishes a specific sequence in which prescription drugs for a specified medical condition and medically appropriate for a particular covered person are covered under a pharmacy or medical benefit by a health carrier, a health benefit plan, or a utilization review organization, including self-administered drugs and drugs administered by a health care professional.

l. *"Utilization review"* means a program or process by which an evaluation is made of the necessity, appropriateness, and efficiency of the use of health care services, procedures, or facilities given or proposed to be given to an individual. Such evaluation does not apply to requests by an individual or provider for a clarification, guarantee, or statement of an individual's health insurance coverage or benefits provided under a health benefit plan, nor to claims adjudication. Unless it is specifically stated, verification of benefits, preauthorization, or a prospective or concurrent utilization review program or process shall not be construed as a guarantee or statement of insurance coverage or benefits for any individual under a health benefit plan.

m. *"Utilization review organization"* means an entity that performs utilization review, other than a health carrier performing utilization review for its own health benefit plans.

2. *Establishment of step therapy protocols.* A health carrier, health benefit plan, or utilization review organization shall consider available recognized evidence-based and peer-reviewed clinical practice guidelines when establishing a step therapy protocol. Upon written request of a covered person, a health carrier, health benefit plan, or utilization review organization shall provide any clinical review criteria applicable to a specific prescription drug covered by the health carrier, health benefit plan, or utilization review organization.

3. *Step therapy override exceptions process transparency.*

a. When coverage of a prescription drug for the treatment of any medical condition is restricted for use by a health carrier, health benefit plan, or utilization review organization through the use of a step therapy protocol, the covered person and the prescribing health care professional shall have access to a clear, readily accessible, and convenient process to request a step therapy override exception. A health carrier, health benefit plan, or utilization review

organization may use its existing medical exceptions process to satisfy this requirement. The process used shall be easily accessible on the internet site of the health carrier, health benefit plan, or utilization review organization.

b. A step therapy override exception shall be approved by a health carrier, health benefit plan, or utilization review organization if any of the following circumstances apply:

(1) The prescription drug required under the step therapy protocol is contraindicated pursuant to the drug manufacturer's prescribing information for the drug or, due to a documented adverse event with a previous use or a documented medical condition, including a comorbid condition, is likely to do any of the following:

(a) Cause an adverse reaction to a covered person.

(b) Decrease the ability of a covered person to achieve or maintain reasonable functional ability in performing daily activities.

(c) Cause physical or mental harm to a covered person.

(2) The prescription drug required under the step therapy protocol is expected to be ineffective based on the known clinical characteristics of the covered person, such as the covered person's adherence to or compliance with the covered person's individual plan of care, and any of the following:

(a) The known characteristics of the prescription drug regimen as described in peer-reviewed literature or in the manufacturer's prescribing information for the drug.

(b) The health care professional's medical judgment based on clinical practice guidelines or peer-reviewed journals.

(c) The covered person's documented experience with the prescription drug regimen.

(3) The covered person has had a trial of a therapeutically equivalent dose of the prescription drug under the step therapy protocol while under the covered person's current or previous health benefit plan for a period of time to allow for a positive treatment outcome, and such prescription drug was discontinued by the covered person's health care professional due to lack of effectiveness.

(4) The covered person is currently receiving a positive therapeutic outcome on a prescription drug selected by the covered person's health care professional for the medical condition under consideration while under the covered person's current or previous health benefit plan. This subparagraph shall not be construed to encourage the use of a pharmaceutical sample for the sole purpose of meeting the requirements for a step therapy override exception.

c. Upon approval of a step therapy override exception, the health carrier, health benefit plan, or utilization review organization shall authorize coverage for the prescription drug selected by the covered person's prescribing health care professional if the prescription drug is a covered prescription drug under the covered person's health benefit plan.

d. A health carrier, health benefit plan, or utilization review organization shall make a determination to approve or deny a request for a step therapy override exception within the applicable time frames and in compliance with the requirements specified in section 505.26, subsection 7, for a request for prior authorization of prescription drug benefits.

e. If a request for a step therapy override exception is denied, the health carrier, health benefit plan, or utilization review organization shall provide the covered person or the covered person's authorized representative and the patient's prescribing health care professional with the reason for the denial and information regarding the procedure to request external review of the denial pursuant to chapter 514J. Any denial of a request for a step therapy override exception that is upheld on appeal shall be considered a final adverse determination for purposes of chapter 514J and is eligible for a request for external review by a covered person or the covered person's authorized representative pursuant to chapter 514J.

4. *Limitations.* This section shall not be construed to do either of the following:

a. Prevent a health carrier, health benefit plan, or utilization review organization from requiring a covered person to try a prescription drug with the same generic name and demonstrated bioavailability or a biological product that is an interchangeable biological product, as defined in section 155A.3, prior to providing coverage for the equivalent branded prescription drug.

b. Prevent a health care professional from prescribing a prescription drug that is determined to be medically appropriate.

2017 Acts, ch 124, §1, 2; 2017 Acts, ch 148, §103; 2023 Acts, ch 19, §1203; 2024 Acts, ch 1056, §26

Referred to in §514F.9

Subsection 4, paragraph a amended