



Indiana Enrollees Step-Therapy Exception (Effective 7/1/2016)

Step-Therapy Protocol

In order for some medications to be covered, Step-Therapy Protocol may be required. Step Therapy Protocol is an electronic Prior Authorization (PA) process that takes place at the time the pharmacist files the Claim. For medications that are considered “second-line” agents, the Claims system will look at the Enrollee’s BHP Claims history and if a Claim(s) for the required “first-line” medication(s) is found, the system will approve the Claim. If “first-line” medications are not found, the system will not approve the Claim and will send a message back to the pharmacy advising that the Step-Therapy Protocol has not been met. At that time, the pharmacy may contact Your Physician and request that they contact the Plan for PA and review for override or fail-first protocol.

Step-Therapy Exception Request

An Enrollee may submit a request for a Step-Therapy “protocol exception” by contacting the Plan’s Pharmacy Services Department by phone 877.205.6308 or by fax 859.335.3744. The protocol exception would allow the Enrollee to have coverage for a medication without the required first-line medication(s) described above in Step-Therapy Protocol or a “preceding prescription drug.” The term, “preceding prescription drug” means a Prescription Drug that according to Step-Therapy Protocol must be 1) first used to treat an enrollee's condition; and 2) as a result of the treatment, determined to be inappropriate to treat the Enrollee's condition.

Requests for protocol exceptions must be reviewed **PRIOR** to receiving the medication.

The Plan shall make a determination concerning the protocol exception or an appeal of an Adverse Benefit Determination of a protocol exception request not more than:

- A. One (1) business day after receiving the request or appeal, in an urgent care situation; or
- B. Three (3) business days after receiving the request or appeal in a non-urgent care situation.

An urgent care situation means:

- A. If medical care or treatment is not provided earlier than the time frame generally considered by the medical profession to be reasonable for a nonurgent situation, the injury or condition could seriously jeopardize the enrollee's life or health; or the ability to regain maximum function based on a Prudent Layperson's judgment; or
- B. If medical care or treatment is not provided earlier than the time frame generally considered by the medical profession to be reasonable for a nonurgent situation, the injury or condition could subject the Enrollee to severe pain that cannot be adequately managed, based on the Enrollee's treating health care Practitioner’s judgment.



A protocol exception will be granted if any of the following apply:

- A. A preceding prescription drug is contraindicated or will likely cause an adverse reaction or physical or mental harm to the insured.
- B. A preceding prescription drug is expected to be ineffective, based on both of the following:
 - 1. The known clinical characteristics of the insured; and
 - 2. Known characteristics of the preceding prescription drug, as found in sound clinical evidence.
- C. The insured has previously received:
 - 1. A preceding Prescription Drug; or
 - 2. Another Prescription Drug that is in the same pharmacologic class or has the same mechanism of action as a preceding prescription drug; and the Prescription Drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event.
- D. Based on clinical appropriateness, a preceding prescription drug is not in the best interest of the insured because the insured's use of the preceding prescription drug is expected to:
 - 1. Cause a significant barrier to the insured's adherence to or compliance with the insured's plan of care;
 - 2. Worsen a comorbid condition of the insured; or
 - 3. Decrease the insured's ability to achieve or maintain reasonable functional ability in performing daily activities.

If a protocol exception is granted, the Plan shall notify the insured and the insured's health care provider of the authorization for coverage of the Prescription Drug that is the subject of the protocol exception and will not require the Enrollee to use the first-line medication(s).

If a protocol exception request or an appeal of a denied protocol exception request result in a denial of the protocol exception, the Plan shall provide to the insured and the treating health care provider notice of the denial, including a detailed, written explanation of the reason for the denial and the clinical rationale that supports the denial. The Plan reserves the right to request a copy of relevant documentation from the insured's medical record in support of a protocol exception.