**Non-medical switching refers to changing a patient's medication for reasons unrelated to clinical efficacy, safety, or patient preferences often driven by payors, pharmacy benefit managers (PBMs), specialty pharmacies, or health systems.**

Non-medical switching is often seen within a therapeutic class of medications (e.g., TNF-inhibitors) and with biosimilar medications and is typically driven by cost-saving measures, as insurance companies and PBMs seek to reduce their drug expenditures.[1,2] In inflammatory bowel disease (IBD), substitution to a formulary-preferred biosimilar is a primary driver of non-medical switching, and it may occur with plan year changes or changes in PBM contracts.

## QUICK REFERENCE

**Key documentation to support appeals**

**Patient's current clinical status**
- Remission, partial response, or symptom control

**Treatment history**
- Prior medications tried and failed

**Effectiveness of current therapy**
- Objective improvement or stabilization

**Risks of switching**
- Potential for disease flare, loss of response, or adverse effects

**Patient preference**
- Concerns about change in therapy or past negative experience

**Supporting evidence**
- Labs, imaging, visit notes, and relevant clinical guidelines

## PATIENT IMPACT AND PROVIDER BURDEN

Non-medical switching may result in clinical and operational consequences. Patients who are stable and responding well to a therapy may experience disease flare, loss of response, or reduced adherence when switched to an alternative agent for non-clinical reasons. These disruptions can lead to avoidable complications, additional monitoring, and, in some cases, hospitalization. Switching biosimilars (e.g., infliximab) can also change the medication administration site, sometimes requiring patients to leave community-based infusion centers and instead receive care at hospital outpatient centers, which may carry higher out-of-pocket costs for patients and lower reimbursement for practices.

From the provider perspective, non-medical switching introduces substantial administrative burden, including preparation of appeals, coordination of peer-to-peer reviews, and additional follow-up visits. These added demands strain clinic workflows and may delay timely access to appropriate treatment. When responding to non-medical switch requests, providers are encouraged to document the patient's current treatment success and the potential risks associated with switching, including loss of disease control and disruption of continuity of care.

Often, the first notification of a change is a letter from the insurer informing the patient that their current therapy is no longer going to be covered. These letters trigger understandable patient concerns and fears that they can no longer obtain the therapy they have worked with their providers to establish. Appeals processes for non-medical switching are time-consuming, onerous, and include a different process for each insurer, burdening the health care team and introducing another potential for dangerous treatment delays.[3,4]

Following the below steps and examples can help your practice successfully appeal non-medical switching.

## STRATEGIES FOR APPEALING NON-MEDICAL SWITCHES

| | |
|---|---|
| Evaluate the patient's previous medications | ☐ Check if the patient has already tried and failed the medication. If so, note this in your appeal communication. |
| Document clinical circumstances supporting staying on the current medication | ☐ Document the patient's unique clinical situation that necessitates continuing the current medication.<br>○ Submit appeal letters that clearly document the patient's current clinical status, stability on therapy, and the risks associated with switching. Record the patient's current health status, any symptoms, and how they are being managed with the current medication.<br>○ Note the medication's effectiveness in controlling the patient's condition, any positive outcomes, and any adverse effects.<br>○ Explain why the current medication is necessary and why a switch would be detrimental to the patient's health (e.g., Patient is currently in clinical remission and stable on [current therapy]. A non-medical switch poses risk of disease flare and loss of response.) |
| Provide supporting documentation | ☐ Document supporting information.<br>○ Treatment history and prior response to other medications<br>○ Objective measures (e.g., lab results, imaging reports, functional assessments)<br>○ Notes from patient visits documenting disease status |
| Cite relevant guidelines and evidence | ☐ Review evidence supporting the exception:<br>○ FDA-approved product labeling<br>○ Nationally recognized compendia (e.g., American Hospital Formulary Service [AHFS] Drug Information, Micromedex drug database, and UpToDate Lexidrug)<br>○ Clinical practice guidelines<br>○ Peer-reviewed medical literature |
| Submit the exception request | ☐ Include:<br>○ Completed exception request form<br>○ Supporting clinical documentation |
| Prepare for potential follow-up | ☐ If the request is denied:<br>○ Review the denial letter to understand the reason<br>○ Consider appealing the decision, including new evidence or documentation<br>○ Request and prepare for a peer-to-peer discussion (timing may vary based on state regulations) |

## SITE OF CARE CHANGES

In many cases of non-medical switching, patients are not only required to change medications but also the location where they receive care. These site of care restrictions are often driven by payor or PBM cost-containment policies and may result in forced transitions from lower-cost, community-based infusion centers to hospital outpatient departments or third-party infusion vendors. In some cases, provider offices are not reimbursed for administering the payor's preferred biosimilar, effectively preventing on-site infusion and disrupting continuity of care.

**Common site of care issues:**

- Infusion denied unless performed at a contracted site
- Loss of access to in-office or community-based infusion centers
- Higher patient out-of-pocket costs at hospital-based sites
- Treatment delays due to scheduling or authorization at new locations
- When applicable, note that switching both drug and site of care concurrently may amplify the risk of disease flare or treatment disruption

**Sample appeal language:**

*"Patient is stable on current biologic therapy, administered in our in-office infusion suite. Changing both the therapy and site of care introduces unnecessary risk, disrupts care coordination, and increases cost burden to the patient. We respectfully request continuation of current treatment and site."*

**References**

1. Non-medical Switching. National Infusion Center Association. Accessed June 2025. https://infusioncenter.org/advocacy/explore-issues/non-medical-switching/
2. Fighting non-medical switching. Patients Rising. Accessed June 2025. https://www.patientsrising.org/fighting-nonmedical-switching/
3. Sofia MA, Feuerstein JD, Narramore L, Chachu KA, Streett S. White Paper: American Gastroenterological Association Position Statement: The Future of IBD Care in the United States-Removing Barriers and Embracing Opportunities. Clin Gastroenterol Hepatol. 2024;22(5):944-955. doi:10.1016/j.cgh.2024.01.050
4. Non-medical switching principles and guidelines. Biologics Prescribers Collaborative. Published March 16, 2018. Accessed June 2025. https://biologicsprescribers.org/non-medical-switching-principles-guidelines