



December 2, 2015

Naim Munir, MD
Senior Vice President & Chief Medical Officer
Health Alliance Plan of Michigan
2850 West Grand Boulevard
Detroit, MI 48202

RE: STEP THERAPY POLICY

Dr. Munir,

The National Infusion Center Association (NICA) was recently contacted by our concerned partners in Michigan regarding biologic medication claim rejection due to a Step Therapy policy under Health Alliance Plan of Michigan (HAP). It is our understanding that HAP has implemented Step Therapy or "Fail First" requirements for one or more biological injectable/infusible medications. In this particular case, patients and providers reported experiencing issues with Entyvio coverage.

We respectfully request the opportunity to review HAP Step Therapy guidelines for intravenous/injectable medications. We have been unable to locate any correspondence or formulary publication from HAP outlining Step Therapy policy guidelines. We wish to facilitate a conversation between our partners and HAP decision-makers to discuss the patient access impact of Step Therapy policies.

NICA understands that health care have an ongoing need to control formularies and costs related to the growing specialty medication market, particularly in the case of biologics. Biologics are some of the most innovative and life-changing medications developed in the last 15 years. Consequently, this class of medications brings unique challenges to manufacturers, providers, patients and insurers, including: escalating costs, complex clinical administration, and a difficult reimbursement environment.

It is with these challenges in mind that the NICA has formed criteria for Step Therapy/Fail First policies specific to intravenous and injectable medications and biologics, outlined below in Figure 1.

FIGURE 1: NICA CRITERIA FOR STEP THERAPY REQUIREMENTS

WHEN ADMINISTERED FOR ON-LABEL INDICATION AND FDA-APPROVED FOR FIRST LINE TREATMENT:
STEP THERAPY IS REASONABLE WHEN:
• clinical RISK is LOW
• TIME to fail is SHORT
• COST to fail is LOW
STEP THERAPY IS INAPPROPRIATE WHEN:
• clinical RISK is HIGH
• TIME to fail is LONG
• COST to fail is HIGH

Figure 1 presents a common sense test for Step Therapy policies using NICA criteria for reasonable and inappropriate use of Step Therapy.



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Biologic therapies have years of proven benefits in many patients with Inflammatory Bowel Disease (IBD), Rheumatoid Arthritis (RA), Psoriasis, and many other autoimmune disorders. These drugs have undoubtedly generated an incredible impact on the quality of life and health outcomes for many patients suffering from these conditions. However, one biologic does not fit all.

We understand that clinically sound and cost-effective treatment options should reasonably be tried before more expensive drugs are prescribed. We are concerned with a Step Therapy policy's impact upon health outcomes and quality of life if:

Patients currently undergoing therapies which have been effectively treating their condition, perhaps even inducing/maintaining remission, are being denied their medication due to a new prior authorization methodology.

AND/OR

Patients are being required to fail one or more anti-TNF therapies for which they are contraindicated before pursuing their physician-prescribed treatment.

Biologics are not pills, and the kind of failure required by the reported HAP Step Therapy policy means that the patient may be without therapeutic benefit while waiting 6 months or more to fail two anti-TNF drugs. This time is precious to the patient and the provider as it not only allows a chronic disease process to progress, but also costs the patient, and you the health plan, tens of thousands of dollars in medication and administration fees.

Using our current understanding of reported HAP Step Therapy guidelines, **we find it impractical, wasteful, and possibly even harmful that accessing physician-prescribed biologics would require failing one or more insurer-prescribed biologics.**

NICA agrees with many other patient and disease advocacy organizations and believes that the decision as to which biological therapy is best suited for a particular patient should be a collaborative determination by health care providers and patients on an individual patient basis, not a blanket requirement for all patients implemented by the health plan. **NICA supports responsible access to biologics so providers and patients can safely and more cost-efficiently find the best biologic therapy – the one that works.**

We place the utmost importance on improving health outcomes and optimizing quality of life with regards to both immediate-term and long-term cost-effectiveness in the use of high-cost intravenous/injectable treatment protocols. On behalf of patients and our provider partners, NICA respectfully requests the opportunity to review and discuss these Step Therapy policies with HAP decision-makers and our provider partners in the interest of identifying an all-win solution for HAP, providers and patients.

Thank you for your time and consideration,

A handwritten signature in black ink that reads "Brian Nyquist".

Brian Nyquist, MPH Executive Director
NATIONAL INFUSION CENTER ASSOCIATION

A handwritten signature in black ink that reads "Bryan Johnson".

Bryan Johnson | President of the Board
NATIONAL INFUSION CENTER ASSOCIATION

CC: Antonio Petitta – Vice President, Pharmacy Care Management



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