NATIONAL INFUSION CENTER ASSOCIATION

NICA Position on Step Therapy (Fail First) Policy

UPDATED 12/02/15

This position paper is the result of numerous reports from our partners around the country battling patient access issues resulting from health plan mandated Step Therapy policies. **NICA agrees with many other patient and disease advocacy organizations that the decision as to which biological therapy is best suited for a particular patient should be a collaborative determination by healthcare providers and patients on an individual patient basis, not a blanket requirement for all patients implemented by the health plan.**

Biologics are some of the most innovative and life changing medications developed in the last decade. They have years of proven benefits in many patients with Inflammatory Bowel Disease, Rheumatoid Arthritis, 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, we understand that one biologic may not work for all patients.

NICA understands that insurers have an ongoing need to control formularies and costs related to the growing specialty medication market. This class of medications brings unique challenges to manufacturers, providers, patients and insurers, including: escalating costs, complex clinical administration, and a difficult reimbursement environment. However, Step Therapy is not the responsible solution in many situations.

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 as outlined in Figure 1.

FIGURE 1: NICA CRITERIA FOR STEP THERAPY REQUIREMENTS

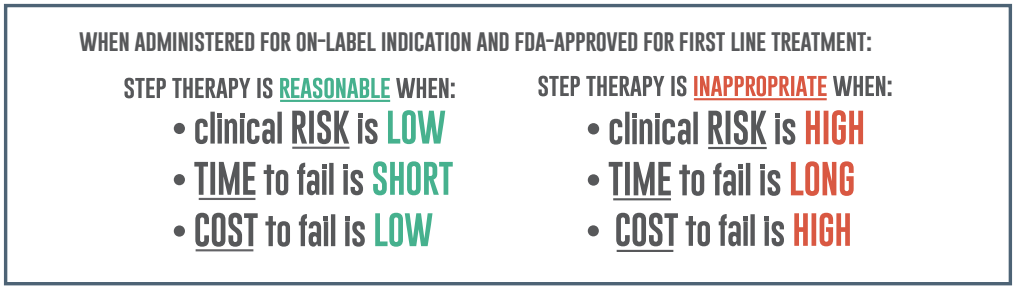

Figure 1 presents a common sense test for Step Therapy policies using NICA criteria for reasonable and inappropriate use of Step Therapy.

NICA STEP THERAPY POSITION SUMMARY

NICA supports responsible access to biologic therapies so providers and patients may safely and more cost-effectively find the best biologic therapy - the one that works. Imposing blanket requirements for all patients to try and fail health plan-prescribed drugs before pursuing provider-prescribed drugs may significantly delay therapeutic benefit (Time to fail is LONG), increase costs (Cost to fail is HIGH), and unnecessarily expose patients to additional clinical risk (Clinical Risk to Fail is HIGH).

In review of the varying criteria many health plans use to determine the appropriateness of Step Therapy policy, we identified a lack of consistency and a lack of applicability to biologics and high-cost intravenous and injectable therapies. Most of the existing criteria were developed around conventional oral medications (i.e., pills). However, biologics and many intravenous and injectable medications differ widely from conventional oral medications. As a result, conventional criteria for Step Therapy are inappropriate when applied to these non-oral, non-chemotherapeutic medications.

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STEP THERAPY IS INAPPROPRIATE WHEN THE TIME TO FAIL IS LONG

Biologics, and many intravenous and injectable medications, require a LONG time to be trialed and documented for failure. The time to failure can be up to a year of treatment or longer for "preferred biologics" listed by many health plans. For a patient with progressive chronic disease, this time equates to deteriorating health and significantly reduced quality of life. Each day of delayed treatment is often spent in debilitating pain and suffering. Requiring a patient to trial what might be an ineffective or second-choice biologic – as determined by the patient and physician – can allow further progression of disease to a state that requires further invasive intervention. **Therefore, when a physician and patient collectively decide that a drug is the best treatment option for their disease, they should be able to proceed with the physician-recommended therapy rather than delay treatment with one or more health plan mandated medications.**

STEP THERAPY IS INAPPROPRIATE WHEN THE CLINICAL RISK IS HIGH

All medications, including many health plan defined "preferred biologics", carry an inherent clinical risk that varies between patients. Many biologics carry FDA Black Box warnings and adverse event profiles that are far from benign (e.g., serious infections, malignancies, and injection site reactions).

We believe it is the primary responsibility of the provider and patient, not the health plan, to weigh these clinical risks and make a collaborative decision as to which medication is the most appropriate. It is inappropriate for a health plan to make this decision and subject the patient to the additional clinical risk of non-provider recommended medications. **Patients should not be required to expose themselves to these unnecessary clinical risks prior to receiving the treatment they need.**

STEP THERAPY IS INAPPROPRIATE WHEN THE COST TO FAIL IS HIGH

NICA, our partner advocacy groups, providers and health plans share a similar view – to decrease patient suffering, improve health outcomes and optimize quality of life as **safely** and **economically** responsible as possible. We understand that a primary driver of Step Therapy for health care plans is cost management. Many if not all intravenous and injectable specialty biologics have annual costs in the tens of thousands of dollars. At thousands of dollars per treatment, with an average treatment duration of up to a year to document failure, the cost of trying and failing the wrong drug is significant. Double Step Therapy requirements exponentially increase this cost. This cost is not only a burden on the health plan, but also a burden on the patients when typical patient cost-sharing on these meds ranging from the $100's to $1,000's per treatment. **A patient who receives thousands of dollars of a medication without therapeutic benefit is a Lose-Lose proposition for everyone.**

> "A PATIENT WHO RECEIVES THOUSANDS OF DOLLARS OF A MEDICATION WITHOUT THERAPEUTIC BENEFIT IS A LOSE-LOSE PROPOSITION FOR EVERYONE.

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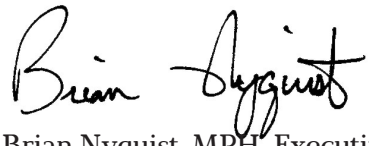
CONCLUSION

We believe health plans should consider alternative cost-management strategies for biologics and pursue Step Therapy for drugs only when reasonable – when the Cost of failure is LOW, the TIME to fail is SHORT, and the clinical RISK of failing preferred drugs is LOW. NICA agrees with many of our partner 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 healthcare providers and patients on an individual patient basis, not a blanket requirement for all patients implemented by the health plan. **Therefore, we find it impractical, wasteful, and possibly even harmful that accessing many physician-prescribed biologics would require failing one or more health plan-prescribed biologics. NICA supports responsible access to biologics so providers and patients can safely and more cost-effectively find the best biologic therapy – the one that works.**

Thank you for your support,



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ABOUT THE NICA

WHO WE ARE

Established in 2010, the National Infusion Center Association (NICA) is a 501(c)(3) non-profit organization formed with the purpose to improve patient access to office-administered intravenous and injectable medications and therapies. Our efforts are primarily focused on patient access to office-administered non-chemotherapeutic drugs in non-hospital sites of care (e.g., office-based Infusion Centers).

Discussions about how to improve access to care for these patients began in 2009 when a small group of entrepreneurs and infusion nurses engaged in conversations about access problems with insurers, infusion drug manufacturers, and other infusion service providers. From those conversations, it was clear that no organization was tackling this problem on a national scale.

WHAT WE DO

We link patients with the care they need by being the nation's voice for office-based Infusion Center patient access in three ways: Connect, Collaborate, and Advocate. We connect stakeholders to the resources they need to effectively educate, communicate and care for patients in office-based Infusion Centers. We collaborate with a network of stakeholders to develop all-win solutions to national patient access challenges. We advocate for the office-based Infusion Center as a more affordable, accessible and compassionate alternative to inpatient and outpatient hospital sites of care.

WHY WE ARE NEEDED

Healthcare providers, pharmaceutical manufacturers and insurers have historically looked at the access issue in silos - addressing only one particular drug and/or disease state at a time. However, all infusion and injectable medications face similar obstacles that restrict patient access. Restricted access to appropriate, office-based sites of care that safely and economically deliver infusion or injectable medications is a common problem facing many patients, prescribing providers, intravenous and injectable drug manufacturers, as well as payers. The nation needs a neutral advocacy voice to unite stakeholders in the interest of developing all-win solutions that improve patient access to the high-quality, cost-effective care they need.

WHERE CAN I FIND MORE INFORMATION ABOUT THE NICA?

Follow us and keep up with everything the NICA is doing for our partners, providers and patient access.

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