NATIONAL INFUSION CENTER ASSOCIATION

December 2, 2015

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Director, Pharmacy Services–Clinical
BCBS of Michigan
600 E. Lafayette Blvd., Mail Code 512A
Detroit, Michigan 48226

## RE: REVISING THE PRIOR AUTHORIZATION MEDICAL COVERAGE DRUG LIST GUIDELINES

Dear Ms. Wesolowicz:

The National Infusion Center Association (NICA) has been contacted by several of our concerned partners in Michigan regarding the updated Medical Prior Authorization policy by Blue Cross Blue Shield of Michigan (BCBSM). We sent letters to Dr. Simmer and Mr. Loepp in July 2015 voicing our concerns and requesting the opportunity to discuss this policy. While our letters have been acknowledged, our requests for a meeting or discussion have gone unanswered. We are reaching out again in hopes of opening an important dialogue concerning prior authorization methodologies that include Step Therapy or "Fail First" requirements for certain injectable/infusible biologic medications.

We wish to facilitate a conversation between our provider and advocacy partners and BCBSM decision-makers to discuss the patient access impact of these specific Step Therapy policies.

NICA has reviewed and discussed these policies with our provider partners in Michigan. As set forth in this letter, NICA believes that the Step Therapy policies in place for these medications (e.g., Actemra, Entyvio, Cimzia and Simponi ARIA) should be reconsidered by the health plan.

NICA understands that health care plans have an ongoing need to control formularies and costs related to the growing specialty medication market. Biologics are some of the most innovative and life-changing medications developed in the last 15 years. This class of medications brings unique challenges to manufacturers, providers, patients and insurers, including: escalating costs, complex clinical administration, site of care cost considerations, access challenges, 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.

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## FIGURE 1: NICA CRITERIA FOR STEP THERAPY REQUIREMENTS

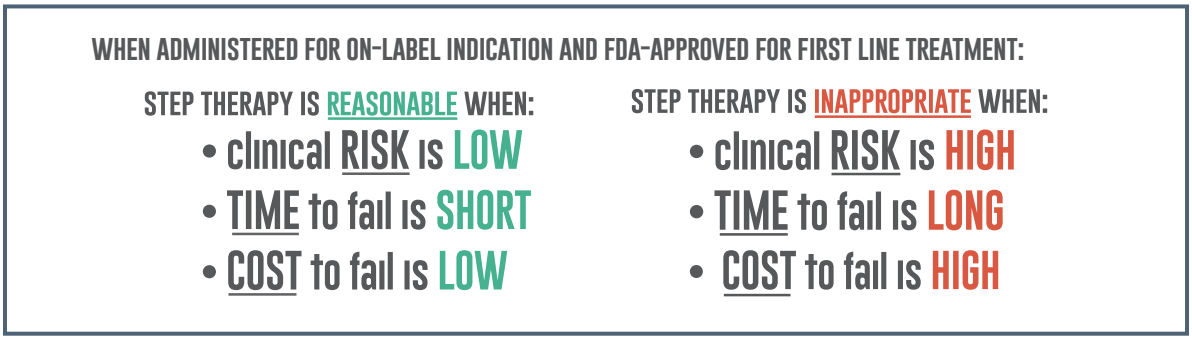


Figure 1 presents a common sense test for Step Therapy policies using NICA criteria for reasonable and inappropriate use of Step Therapy.

**NICA 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.** According to the criteria outlined above in Figure 1, NICA believes that Step Therapy is reasonable in certain circumstances: when the clinical RISK is LOW, the TIME to fail is SHORT, and the COST to fail is LOW.

### BCBSM–CURRENT STEP THERAPY REQUIREMENTS

In referencing the published "Prior Authorization Medical Coverage Drug List" available on the BCBSM website, we noticed 4 biologics that had Step Therapy requirements. We researched these medications and found that all of them have FDA approval as first-line biologic treatments for their primary indications. However, according to the BCBSM Prior Authorization document, they each have at least 1 or 2 failure requirements of a "preferred biologic" which are listed as: Enbrel, Humira, and/or Remicade. The specific language used in the BCBSM Prior Authorization Drug List is outlined below in Table 1.

## TABLE 1: STEP THERAPY REQUIREMENTS FOR CERTAIN BIOLOGICS

| MEDICATION | STEP THERAPY LANGUAGE |
|---|---|
| ACTEMRA | "...TRIAL AND FAILURE OF ONE OF THE FOLLOWING AGENTS: ENBREL, HUMIRA, OR REMICADE." |
| ENTYVIO | "...INADEQUATE RESPONSE TO AT LEAST TWO PREFERRED BIOLOGICS." [HUMIRA, REMICADE] |
| CIMZIA | "...TREATMENT WITH TWO BIOLOGIC AGENTS (SUCH AS HUMIRA AND REMICADE) IS CONTRAINDICATED OR WAS NOT EFFECTIVE AFTER AN ADEQUATE TRIAL PERIOD." |
| SIMPONI ARIA | "...TRIED AND FAILED...TWO OR MORE OF THE FOLLOWING: ENBREL, HUMIRA, OR REMICADE." |

SOURCE: *BCBS OF MICHIGAN PRIOR AUTHORIZATION MEDICAL COVERAGE DRUG LIST* (ACCESSED 10/21/2015)

Table 1 outlines the specific Step Therapy language for Actemra, Entyvio, Cimzia and Simponi ARIA included in the Prior Authorization Medical Coverage Drug List.

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We also reviewed the BCBSM "Prior Approval and Step Therapy Guidelines" available on the BCBSM website and agree that health plans may reasonably require *"...that safe, high-quality cost-effective drugs are prescribed prior to the use of more expensive agents that may not have proven value over current preferred medications."*[1]

## INCONGRUENT WITH NICA CRITERIA FOR REASONABLE STEP THERAPY

When considering both the NICA Criteria for Step Therapy and BCBSM's own Step Therapy Guidelines, we conclude that the current Step Therapy requirements for these 4 drugs are unreasonable. The current guidelines fall short in all 3 of our test criteria for reasonable Step Therapy requirements.

## TIME TO FAIL IS LONG

All of the listed preferred biologics, for both primary and secondary mandated failures, require a long time to be considered and documented for failure. The time to failure is 6 months of treatment or longer for Enbrel, Humira, and Remicade. For a patient with progressive chronic disease, time is a precious commodity. Requiring a patient to try what might be an ineffective or second-choice biologic—as determined by the patient and physician —can allow progression of disease to a state that requires more invasive intervention.[5,7,9] Therefore, when time to fail is long, and a provider 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-recommended therapies.

## CLINICAL RISK IS HIGH

All medications, including the preferred biologics, carry an inherent clinical risk that varies between patients. *ALL* of the preferred biologics outlined in the BCBSM Prior Authorization Medical Coverage Drug List carry FDA Black Box warnings and adverse event profiles that are far from benign (e.g., serious infections, malignancies, and adverse reactions).

We could not locate any head-to-head peer reviewed evidence where either safety or clinical efficacy for the 4 biologics (Actemra, Entyvio, Cimzia or Simponi ARIA) was demonstrated to be less than that of the "preferred biologics" when used for their FDA-approved indications. We did find evidence which at least suggests that failure of 1 anti-TNF treatment was associated with an increased rate of second anti-TNF discontinuation for the same reason (i.e. primary failure, secondary failure, or intolerance).[8] According to a 2010 study, approximately one in three patients with Crohn's disease that failed standard treatment did not respond to anti-TNF drugs and at least half of those that did respond experienced secondary failure within a year.[6] This makes the failure requirement of 2 anti-TNF's via Step Therapy seem less reasonable, wasteful and possibly more harmful.[4,7,8] These Step Therapy requirements force health care providers and patients to try and fail medications which they have already decided are not the best primary pathway to treat the disease.

It is appropriate for the provider and patient to be responsible for weighing these risks and making a collaborative decision as to which primary treatment protocol to use. **Patients should not be required to expose themselves to these unnecessary clinical risks prior to receiving the treatment they need.**

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## COST TO FAIL IS HIGH

We understand that a primary driver of Step Therapy for health care plans is cost management. All of the medications listed in this letter have annual costs in the tens of thousands of dollars. With an average treatment duration of at least 6 months to document failure, the cost of trying and failing the wrong drug is very high—especially when a double Step Therapy requirement is in place. In our research we found evidence indicating that the high cost of failing biologic therapy in patients with autoimmune diseases can easily negate any short-term cost savings realized through Step Therapy as a cost management strategy.[2-4,7,8,10] Typical cost-sharing on these medications range from the $100's to $1,000's per treatment. A patient who receives thousands of dollars of medication without therapeutic benefit is a **Lose-Lose** proposition for everyone. This cost is not only a burden on the health plan, but also a burden on the patient.

## CONCLUSION

Biologics are not pills and the kind of failure required by this Step Therapy policy means that the patient may be without therapeutic benefit while waiting months to a year in order to initiate their original treatment plan. This time is precious to the patient and the provider as it not only allows a chronic disease to progress, but may place the patient at higher risk while also costing the patient and the payer tens of thousands of dollars in medication and administration fees over the short-run and potentially tens of thousands of dollars in more invasive interventions in the long-run.

Using our current understanding of BCBSM's Step Therapy guidelines and existing literature, we conclude that imposing blanket requirements for all patients to try and fail health plan-prescribed biologic before pursuing provider-prescribed biologics may significantly delay therapeutic benefit (time to FAIL is LONG), increase costs (cost to FAIL is HIGH), restrict patient access to needed therapies, while unnecessarily exposing patients to additional risk (clinical RISK is HIGH). **Therefore, we find it impractical, wasteful, and possibly even harmful that accessing these physician-prescribed biologics would require failing one or more heath plan-prescribed biologics.**

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 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, quickly, and more cost-effectively find the best biologic therapy—the one that works.**

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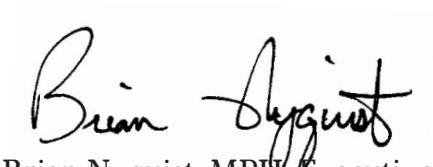
The purpose of this letter is to create an open dialogue, seeking solutions beneficial to all parties involved, including BCBSM, patients and health care providers. We would like to set up a meeting to discuss the NICA criteria for reasonable Step Therapy and ask that BCBSM reconsider these policies. We look forward to hearing from you soon.

Thank you for your time and consideration,



Brian Nyquist, MPH Executive Director
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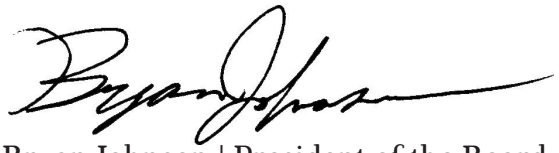

Bryan Johnson | President of the Board
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CC: Daniel Loepp – President and CEO
Thomas Simmer, MD – Senior Vice President and Chief Medical Officer

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