



Horizon BCBSNJ  
Medical Necessity Guideline

**Section** Drugs  
**Policy Number**  
**Effective Date** 12/8/09  
**Review Date**

## SPECIALTY GUIDELINE MANAGEMENT

### Horizon: Humira® (adalimumab)

#### **IMPORTANT NOTE:**

*The purpose of this policy is to provide general information applicable to the administration of outpatient prescription drug benefits that Horizon Blue Cross Blue Shield of New Jersey and Horizon Healthcare of New Jersey, Inc. (collectively "Horizon BCBSNJ") insures or administers. **Outpatient prescription drugs are not covered under all Horizon benefit plans.** If the member's contract benefits differ from the pharmacy guideline, the contract prevails. Although a service, supply drug or procedure may be medically necessary, it may be subject to limitations and/or exclusions under a member's benefit plan. If a service, supply drug or procedure is not covered and the member proceeds to obtain the service, supply drug or procedure, the member may be responsible for the cost. Decisions regarding treatment and treatment plans are the responsibility of the physician. This policy is not intended to direct the course of clinical care a physician provides to a member, and it does not replace a physician's or pharmacist's independent professional clinical judgment or duty to exercise special knowledge and skill in the treatment of Horizon BCBSNJ members. Horizon BCBSNJ is not responsible for, does not provide, and does not hold itself out as a provider of medical care. The physician remains responsible for the quality and type of health care services provided to a Horizon BCBSNJ member.*

*Horizon BCBSNJ pharmacy guidelines do not constitute medical advice, authorization, certification, approval, explanation of benefits, offer of coverage, contract or guarantee of payment.*

#### **PROGRAM RATIONALE**

The intent of the criteria is to ensure that patients follow selection elements established by Horizon medical policy.

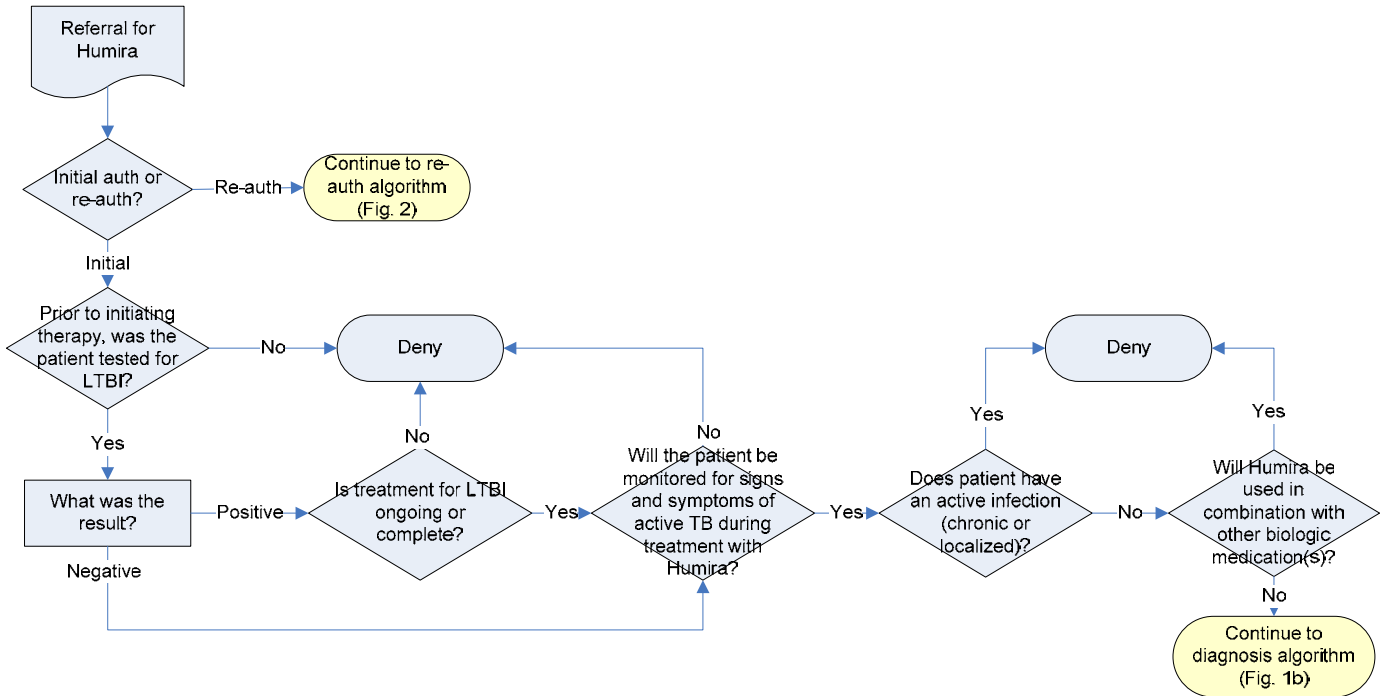
#### **FDA-APPROVED INDICATIONS**

Humira is approved for the following indications:<sup>1</sup>

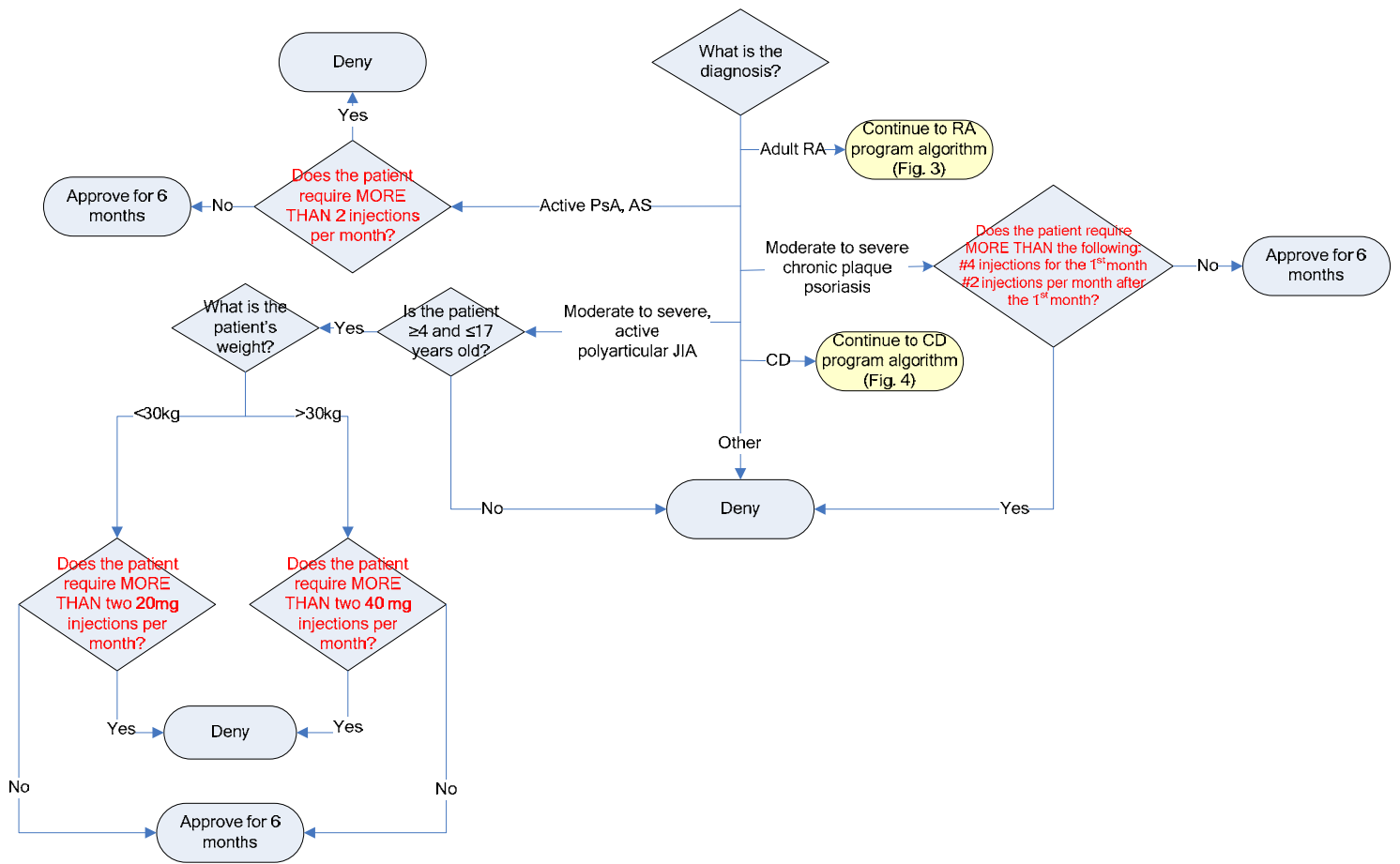
- **Rheumatoid arthritis (RA):** Reducing signs and symptoms, inducing major clinical response, inhibiting the progression of structural damage, and improving physical function in adult patients with moderately to severely active disease.
- **Juvenile idiopathic arthritis (JIA):** Reducing signs and symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis in patients 4 years of age and older.
- **Psoriatic arthritis:** Reducing signs and symptoms of active arthritis, inhibiting the progression of structural damage, and improving physical function.
- **Ankylosing spondylitis:** Reducing signs and symptoms in patients with active disease.
- **Plaque psoriasis:** The treatment of adult patients with moderate to severe chronic plaque psoriasis who are candidates for systemic therapy or phototherapy, and when other systemic therapies are medically less appropriate.
- **Crohn's Disease:** Reducing signs and symptoms and inducing and maintaining clinical remission in adult patients with moderately to severely active Crohn's disease who have had an inadequate response to conventional therapy. Reducing signs and symptoms and inducing clinical remission in these patients if they have also lost response to or are intolerant to infliximab.

## ALGORITHMS<sup>2</sup>

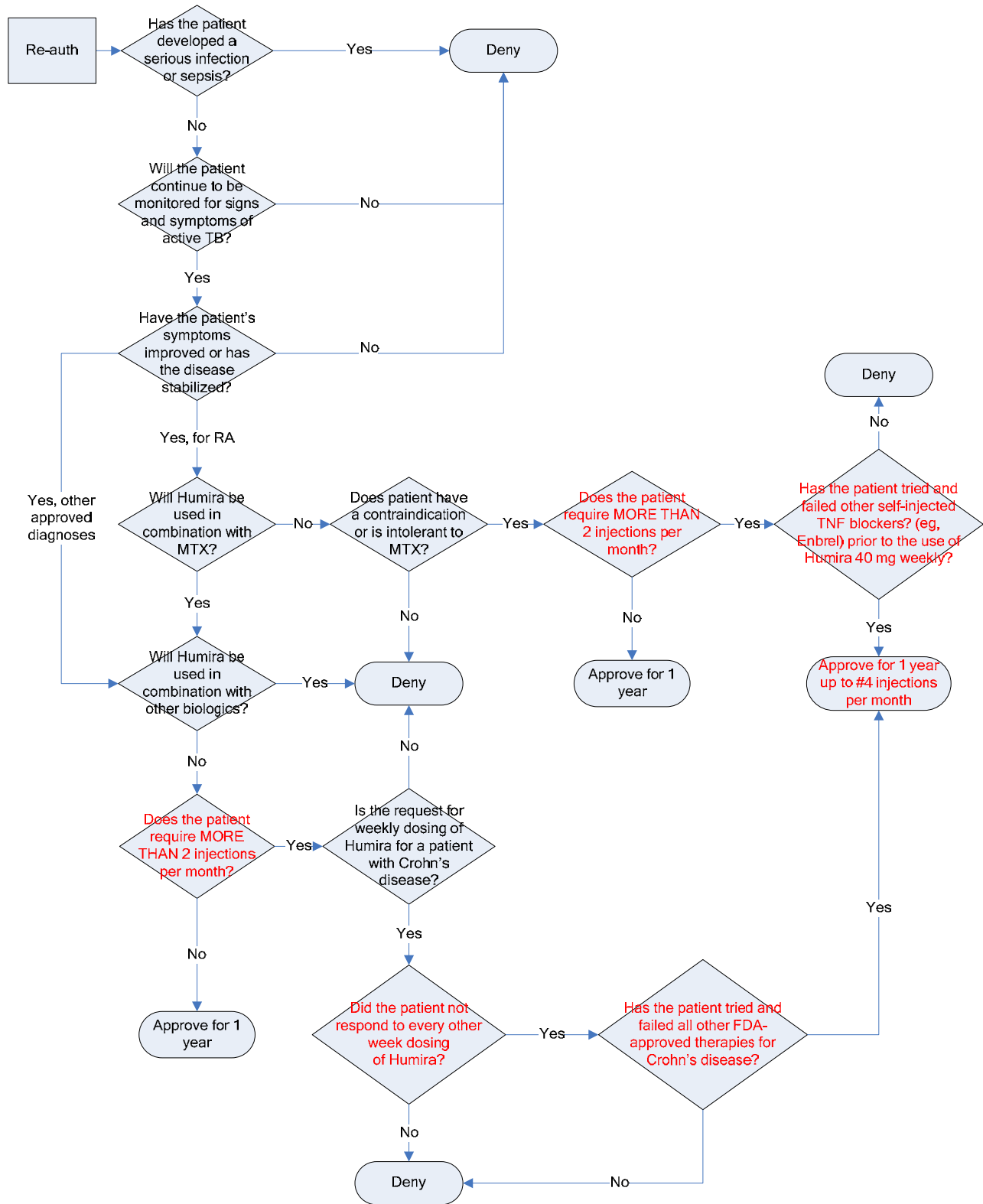
Figure 1a. Initial Authorization Safety Algorithm



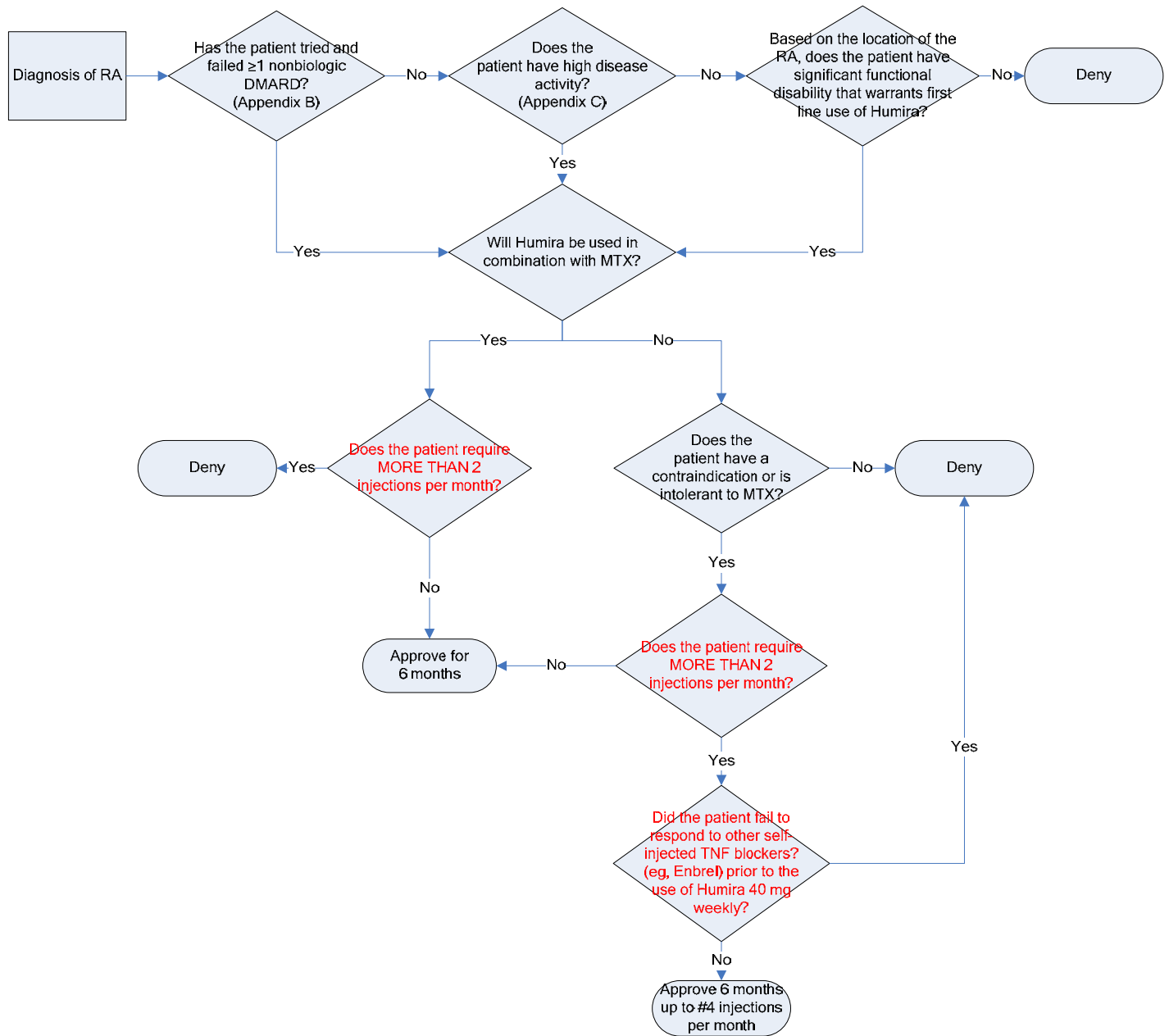
**Figure 1b. Initial Authorization Diagnosis Algorithm**



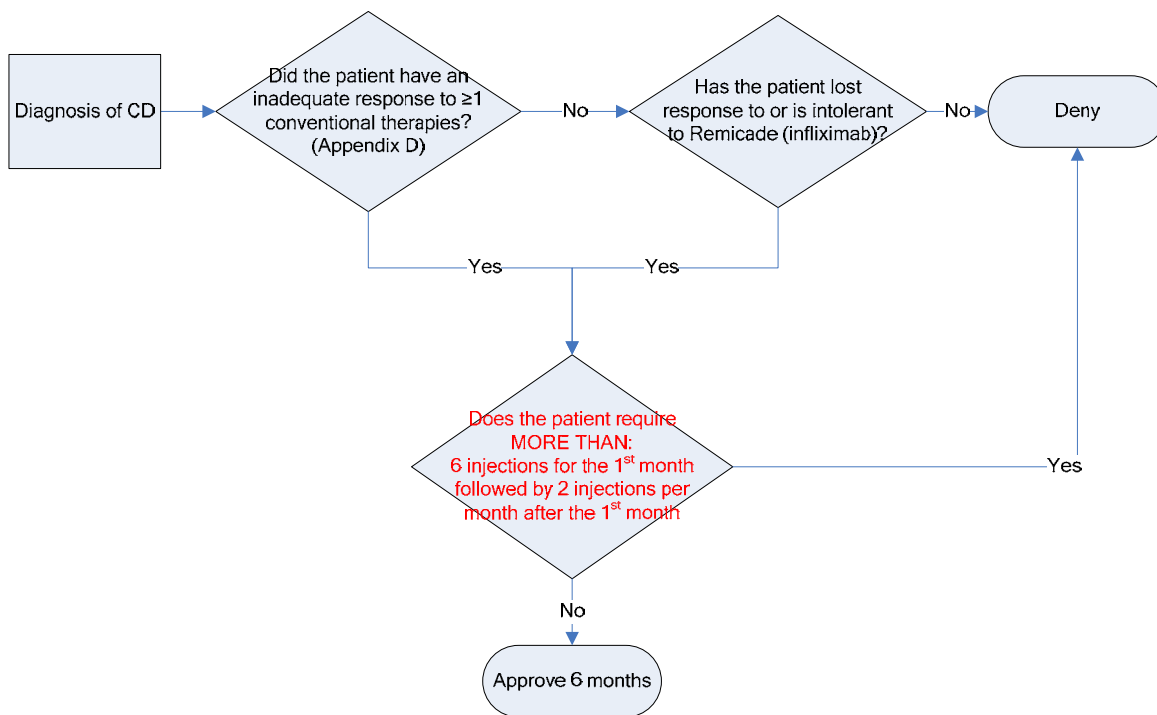
**Figure 2. Re-authorization Algorithm (All Diagnoses)**



**Figure 3. Rheumatoid Arthritis Algorithm**



**Figure 4. Crohn's Disease Algorithm**



**Horizon BCBSNJ Pharmacy Guideline Development Process:** This Horizon BCBSNJ Pharmacy Guideline (the “Pharmacy Guideline”) has been developed by Horizon BCBSNJ’s Pharmacy Drug Policy Subcommittee, Clinical Issues Subcommittee, and Quality Improvement Committee which include practicing physicians and pharmacists. This guideline is consistent with generally accepted standards of medical and pharmacy practice, and reflects Horizon BCBSNJ’s view of the subject health care services, supplies drugs or procedures, and in what circumstances they are deemed to be medically necessary or experimental/ investigational in nature. This Pharmacy Guideline also considers whether and to what degree the subject health care services, supplies or procedures are clinically appropriate, in terms of type, frequency, extent, site and duration and if they are considered effective for the illnesses, injuries or diseases discussed. Where relevant, this Pharmacy Guideline considers whether the subject prescription drugs are being requested primarily for the convenience of the covered person or the health care provider. It may also consider whether the prescription drugs are more costly than alternative prescription drugs that are at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the relevant illness, injury or disease. In reaching its conclusion regarding what it considers to be the generally accepted standards of medical and pharmacy practice, Horizon BCBSNJ reviews and considers the following: all credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, physician and health care provider specialty society recommendations, the views of physicians and health care providers practicing in relevant clinical areas (including, but not limited to, the prevailing opinion within the appropriate specialty), the findings and directives of the Food and Drug Administration and any other relevant factor as determined by applicable State and Federal laws and regulations.

**APPENDICES**

**Appendix A. Abbreviation Key**

- AS = ankylosing spondylitis
- CD = Crohn’s disease
- DMARD = disease modifying anti-rheumatic drug
- LTBI = latent tuberculosis infection
- MTX = methotrexate
- PsA = psoriatic arthritis
- RA = rheumatoid arthritis
- TB = tuberculosis
- TNF = tumor necrosis factor

## **Appendix B. Examples of Nonbiologic Disease Modifying Antirheumatic Drugs (DMARDs)**

- Methotrexate
- Sulfasalazine (Azulfidine, Azulfidine EN-tabs)
- Leflunomide (Arava)
- Hydroxychloroquine (Plaquenil)
- Azathioprine (Imuran)
- Gold compounds (Ridaura [auranofin], Myochrysine [gold sodium thiomalate])

## **Appendix C. Instruments Used to Measure Rheumatoid Arthritis Disease Activity<sup>2,3</sup>**

| Instrument                                  | Score Range | Thresholds of Disease Activity |               |       |
|---|-------------|--------------------------------|---------------|-------|
|   |             | Low                            | Moderate      | High  |
| Disease Activity Score in 28 joints         | 0-9.4       | ≤3.2                           | >3.2 and ≤5.1 | >5.1  |
| Simplified Disease Activity Index           | 0.1-86.0    | ≤11                            | >11 and ≤26   | >26   |
| Clinical Disease Activity Index             | 0-76.0      | ≤10                            | >10 and ≤22   | >22   |
| Rheumatoid Arthritis Disease Activity Index | 0-10        | <2.2                           | ≥2.2 and ≤4.9 | >4.9* |
| PAS or PASII                                | 0-10        | <1.9                           | ≥1.9 and ≤5.3 | >5.3  |
| Routine Assessment Patient Index Data       | 0-30        | <6                             | ≥6 and ≤12    | >12   |

\* Median; Abbreviation: PAS = Patient Activity Scale.

## **Appendix D. Examples of Conventional Therapies for Crohn's Disease**

- 5-Aminosalicylates (sulfasalazine [Azulfidine, Azulfidine EN-tabs], mesalamine [Asacol, Pentasa, Lialda, Apriso])
- Corticosteroids (budesonide [Entocort EC], prednisone)
- Azathioprine
- 6-Mercaptopurine
- Methotrexate

## **REFERENCES**

1. Humira [package insert]. North Chicago, IL: Abbott Laboratories; March 2009.
2. Horizon Medical Policy for Humira. <https://services3.horizon-bcbsnj.com/hcm/MedPol2.nsf>.
3. Saag KG, Teng GG, Patkar NM, et al. American College of Rheumatology 2008 recommendations for the use of nonbiologic and biologic disease-modifying antirheumatic drugs in rheumatoid arthritis. *Arthritis Rheum.* 2008;59(6):762-784.

*Pharmacy Guidelines can be highly technical and are designed for use by the Horizon BCBSNJ professional staff in making coverage determinations. Members referring to this policy should discuss it with their treating physician or pharmacist, and should refer to their specific benefit plan for the terms, conditions, limitations and exclusions of their coverage.*

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