Premier Health Plan

POLICY AND PROCEDURE

POLICY TITLE: ***Humira® (Adalimumab)***
DEPARTMENT: **Clinical Pharmacy Services – Utilization Management**
ORIGINAL DATE: ***October 2005 (as adopted from UPMC Health Plan)***

Last P & T Committee Approval Date: October 2018

Product Applicability: *mark all applicable products below:*

COMMERCIAL	[ ] HMO [ ] PPO *Products*: [ ] Small [ ] Indiv. [ ] Large *Exchange*: [ ] Shop [ ] Indiv. [x] All
OTHER	[x] Self-funded/ASO

PURPOSE

The purpose of this policy is to define the prior authorization process for Humira® (adalimumab).

Humira® (adalimumab) is indicated for:

- 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 rheumatoid arthritis. Humira® (adalimumab) can be used alone or in combination with methotrexate or other non-biologic disease-modifying anti-rheumatic drugs (DMARDs).
- Reducing signs and symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis in patients 2 years of age and older. Humira® (adalimumab) can be used alone or in combination with methotrexate.
- Reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in patients with active psoriatic arthritis. Humira® (adalimumab) can be used alone or in combination with non-biologic DMARDs.
- Reducing signs and symptoms in adult patients with active ankylosing spondylitis.
- Treatment of adult patients with moderate to severe chronic plaque psoriasis who

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are candidates for systemic therapy or phototherapy, and when other systemic therapies are medically less appropriate. Humira® (adalimumab) should only be administered to patients who are closely monitored and have regular follow-up visits with a physician.

- 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 AND for reducing signs and symptoms and inducing clinical remission in these patients if they have also lost response to or are intolerant to Remicade® (infliximab).
- Reducing signs and symptoms and inducing and maintaining clinical remission in patients 6 years of age and older with moderately to severely active Crohn's disease who have had an inadequate response to corticosteroids or immunomodulators such as azathioprine, 6-mercaptopurine, or methotrexate.
- Inducing and sustaining clinical remission in adult patients with moderately to severely active ulcerative colitis who have had an inadequate response to immunosuppressants such as corticosteroids, azathioprine, or 6-mercaptopurine (6-MP). The effectiveness of Humira® (adalimumab) has not been established in patients who have lost response to or were intolerant to Tumor Necrosis Factor (TNF) blockers.
- Treatment of moderate to severe Hidradenitis supperativa in patients 12 years of age and older

DEFINITIONS

Hurley Stage II – a staging system defining moderate dermatologic disease as being characterized by recurrent abscesses with tract formation

Hurley Stage III – a staging system defining severe dermatologic disease as being characterized by diffuse or near-diffuse involvement, or multiple interconnected tracts and abscesses across the entire area

POLICY

It is the policy of the Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications. This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity, as defined in CRM.015-Medical Necessity,

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and approval by the Pharmacy & Therapeutics Committee of the criteria for prior authorization, as described in RX.003-Prior Authorization Process.

The drug, Humira® (adalimumab), is subject to the prior authorization process.

PROCEDURE

Initial Authorization Criteria:

Must meet all of the criteria listed under the respective diagnosis:

For All Diagnoses:

- Must have a negative tuberculosis skin test [such as Tuberculin PPD (purified protein derivative) test] or Interferon-Gamma Release Assay (IGRA) whole-blood test [such as QuantiFERON®-TB Gold In-Tube test (QFT-GIT) or T-SPOT®.*TB* test (T-Spot)]
- Must currently not be using a tumor necrosis factor (TNF)-blocking agent or other biologic agents in combination with Humira

1. Rheumatoid Arthritis

- Must be prescribed by or in consultation with a rheumatologist
- Must be age 18 years or older
- Must have a diagnosis of moderate to severely active rheumatoid arthritis
- Must have an adequate trial of methotrexate with an inadequate response or significant side effects/toxicity or have a contraindication to this therapy

2. Juvenile Idiopathic Arthritis

- Must be prescribed by or in consultation with a rheumatologist
- Must be age 2 years or older
- Must have a diagnosis of moderately to severely active polyarticular juvenile idiopathic arthritis
- Must have an adequate trial of methotrexate with an inadequate response or significant side effects/toxicity or have a contraindication to this therapy

3. Psoriatic Arthritis

- Must be prescribed by or in consultation with a rheumatologist or dermatologist

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- Must be age 18 years or older
- Must have a diagnosis of moderately to severely active psoriatic arthritis

4. Ankylosing Spondylitis and Axial Spondyloarthritis

- Must be prescribed by or in consultation with a rheumatologist
- Must be age 18 years or older
- Must have a diagnosis of active ankylosing spondylitis or axial spondyloarthritis
- Must have an adequate trial with TWO non-steroidal anti-inflammatory drugs (NSAIDs), with an inadequate response, significant side effects/toxicity, or have a contraindication to these therapies

5. Plaque Psoriasis

- Must be prescribed by or in consultation with a dermatologist
- Must be age 18 years or older
- Must have a diagnosis of moderate to severe chronic plaque psoriasis
- Must have a minimum body surface area involvement of >5% (members with plaque psoriasis of palms, soles, head and neck, or genitalia are not required to have a minimum body surface area involvement)
- Must have an adequate trial of either phototherapy (e.g., UVB or PUVA) or pharmacologic treatment with methotrexate, cyclosporine, or acitretin with an inadequate response, intolerance/contraindication, or clinical reason not to use these therapies

6. Crohn's Disease

- Must be prescribed by or in consultation with a gastroenterologist
- Must be age 6 years or older
- Must have a diagnosis of moderately to severely active Crohn's disease
- Must have an adequate trial of conventional therapy including corticosteroids OR immunosuppressants (e.g., azathioprine, 6-mercaptopurine) with an inadequate response or significant side effects/toxicity or have a contraindication to these therapies

7. Ulcerative Colitis

- Must be prescribed by or in consultation with a gastroenterologist
- Must be age 18 years or older
- Must have a diagnosis of moderately to severely active Ulcerative Colitis

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- Must have an adequate trial of conventional therapy including corticosteroids, 5-ASA agents (e.g., sulfasalazine, mesalamine), **OR** immunosuppressants (e.g., azathioprine, 6-mercaptopurine) with an inadequate response or significant side effects/toxicity or have a contraindication to these therapies

8. Hidradenitis Supperativa

- Must be prescribed by or in consultation with a dermatologist
- Must be age 12 years or older
- Must have a diagnosis of moderate to severe Hidradenitits supperativa

9. Uveitis

- Must be prescribed by or in consultation with an ophthalmologist or rheumatologist
- Must be age 2 years or older
- Must have a diagnosis of non-infectious intermediate, posterior or panuveitis

Reauthorization Criteria:

1. Ulcerative Colitis

Authorization may be extended by 1 year based upon chart documentation showing that the member achieved clinical remission by treatment day 56 (week 8) and maintained positive clinical response with Humira thereafter as evidenced by low disease activity or improvement in signs and symptoms of ulcerative colitis.

2. All other indications

Authorization may be extended by 1 year based upon chart documentation showing that the member achieved or maintained positive clinical response after at least 3 months of therapy with Humira as evidenced by low disease activity or improvement in signs and symptoms of the condition.

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Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	• Hidradenitis supperativa: Up to 3 months • All other diagnoses: Up to 1 year
Reauthorization	Up to 1 year
Quantity Level Limit	
Starter Pack (all)	1 per lifetime
All (syringes)	2 syringes per month • For Psoriasis: a quantity of 4 syringes per month is covered for the first month of treatment • For Crohn's disease and Ulcerative Colitis: a quantity of 6 syringes per month is covered for the first month of treatment • For Hidradenitis supperativa: a quantity of 6 syringes per month is covered for the first month of treatment and a quantity of 4 syringes per month are covered for ongoing treatment • For non-infectious intermediate, posterior and panuveitis diagnosis only: a quantity of 4 syringes per month is covered for the first month of treatment

If the established criteria are not met, the request is referred to a Medical Director for review.

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RECORD RETENTION

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REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
Annual Review	*02/16, 02/17, 02/18*
Criteria update	*12/16. 6/18*
Age Indication Update (uveitis and HS)	*10/18*

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