Pharmacy Management Drug Policy

SUBJECT: Adalimumab (Humira® [adalimumab], Amjevita™ [adalimumab-atto], Cyltezo® [adalimumab-adbm], Hadlima™ [adalimumab-bwwd], Hulio®/adalimumab-fkjp [adalimumab-fkjp], Hyrimoz®/adalimumab-adaz [adalimumab-adaz], Idacio® [adalimumab-aacf], Yuflyma® [adalimumab-aaty], Yusimry™ [adalimumab-aqvh]
POLICY NUMBER: PHARMACY-22
EFFECTIVE DATE: 05/2009
LAST REVIEW DATE: 09/01/2023

If the member's subscriber contract excludes coverage for a specific service or prescription drug, it is not covered under that contract. In such cases, medical or drug policy criteria are not applied. This drug policy applies to the following line/s of business:

Policy Application

Category:	☒ Commercial Group (e.g., EPO, HMO, POS, PPO)	☒ Medicare Advantage
	☒ On Exchange Qualified Health Plans (QHP)	☐ Medicare Part D
	☒ Off Exchange Direct Pay	☒ Essential Plan (EP)
	☒ Medicaid & Health and Recovery Plans (MMC/HARP)	☒ Child Health Plus (CHP)
	☐ Federal Employee Program (FEP)	☐ Ancillary Services
	☒ Dual Eligible Special Needs Plan (D-SNP)	

DESCRIPTION:

Adalimumab binds specifically to tumor necrosis factor (TNF)–alpha and blocks its interaction with the p55 and p75 cell surface TNF receptors. Adalimumab also lyses surface TNF-expressing cells in vitro in the presence of a complement. Adalimumab does not bind or inactivate lymphotoxin (TNF-beta). TNF is a naturally occurring cytokine that is involved in normal inflammatory and immune responses.

Adalimumab is indicated for:

- reducing signs and symptoms in adult patients with active ankylosing spondylitis
- the treatment of moderately to severely active Crohn's disease in adults and pediatric patients 6 years of age and older
- reducing signs and symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis in patients 2 years of age and older
- 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
- reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in adult patients with active psoriatic arthritis
- 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
- the treatment of moderately to severely active ulcerative colitis in adults and pediatric patients 5 years of age and older. The effectiveness of adalimumab has not been established in patients who have lost response to or were intolerant to TNF blockers.
- the treatment of moderate to severe hidradenitis suppurativa in patients 12 years of age and older
- the treatment of non-infectious intermediate, posterior, and panuveitis in adults and pediatric patients 2 years of age and older

POLICY:

Based upon our assessment and review of the peer-reviewed literature adalimumab (Humira® [adalimumab], Amjevita™ [adalimumab-atto], Cyltezo® [adalimumab-adbm], Hadlima™ [adalimumab-bwwd], Hulio®/adalimumab-fkjp [adalimumab-fkjp], Hyrimoz®/adalimumab-adaz [adalimumab-adaz], Idacio® [adalimumab-aacf], Yuflyma® [adalimumab-aaty], Yusimry™ [adalimumab-aqvh]) has been medically proven to be effective and therefore, **medically necessary** for the treatment of the following FDA-approved diagnoses if specific criteria are met:

A. Plaque Psoriasis

1. Member must be followed by a dermatologist or rheumatologist **AND**
2. Member must be at least 18 years of age **AND**
3. Member must have moderate to severe chronic plaque psoriasis that involves at least 10% of their body surface area. Consideration will be given to those who have less than 10% body surface area involvement but have severe disease of sensitive areas or areas causing significant disruption in normal activities (such as the hands, feet, face, genitalia) **AND**
4. Member must be a candidate for systemic therapy (i.e., acitretin, methotrexate, or cyclosporine) with a trial period of at least 3 months that resulted in an inadequate response (failure). A 3-month trial will not be required if the member experienced serious side effects during a trial of one of the above-mentioned agents **OR**
5. If systemic therapy is contraindicated, then one of the following must be attempted for a reasonable period of time (at least 3 months):
    a. UVB in combination with a topical therapy such as coal tar, steroids or tazarotene **OR**
    b. PUVA in combination with topical corticosteroids **OR**
    c. Medium/High potency topical steroids in combination with anthralin, calcipotriene, or tazarotene
6. Coverage of adalimumab in psoriasis patients will be limited to an initial dose of adalimumab 80mg at week 0, and 40mg one week after initial dosing and every other week thereafter.
    a. #4 injections/28 days for first fill
    b. #2 injections/28 days thereafter
7. Dose escalation to 40mg weekly may be considered for patients who have had an inadequate response to 40mg every other week after 24 weeks of therapy.
8. Step Therapy Applies to Amjevita, Hulio/adalimumab-fkjp, Hyrimoz/adalimumab-adaz, Idacio, Yuflyma, Yusimry
    a. Based on comparable indications, efficacy, safety profile, and equivalent strengths of Humira, Hadlima, and Cyltezo, the member will be required to use Humira, Hadlima, and Cyltezo unless there is adequate justification as to why they cannot be used

B. Rheumatoid Arthritis

1. Member must be actively followed by, and the drug prescribed by a Rheumatologist **AND**
2. Member must have active moderate to severe rheumatoid arthritis **AND**
3. Member must have failed to respond to and/or is intolerant to approved disease-modifying antirheumatic drug (DMARD) agents, such as methotrexate, azathioprine, sulfasalazine, or hydroxychloroquine, either alone or in combination for a 3-month period **AND**
4. Initial dosing is limited to 1-40 mg subcutaneous injection every two weeks (2-40 mg injections/28 days)
    a. Requests for increasing the dosage of adalimumab to 40 mg weekly or 80 mg every other week will require a trial of methotrexate, or an alternative DMARD if methotrexate is contraindicated, used in combination with adalimumab prior to authorization of the requested dose increase

5. Low disease activity or remission should be considered treatment targets for members receiving adalimumab. Members with moderate or high disease activity >3 months due to lack of or loss of benefit should discontinue adalimumab and switch to another biologic agent.
6. Members with high disease activity who fail adalimumab therapy due to a serious adverse effect should switch to a non-TNF biologic. Member with moderate or high disease activity who fail adalimumab therapy due to non-serious adverse effects should switch to another TNF-blocker or a non-TNF biologic agent.
7. Step Therapy Applies to Amjevita, Hulio/adalimumab-fkjp, Hyrimoz/adalimumab-adaz, Idacio, Yuflyma, Yusimry
    a. Based on comparable indications, efficacy, safety profile, and equivalent strengths of Humira, Hadlima, and Cyltezo, the member will be required to use Humira, Hadlima, and Cyltezo unless there is adequate justification as to why they cannot be used

C. Juvenile Idiopathic Arthritis

1. Member must be actively followed by a Rheumatologist **AND**
2. Member must be at least 2 years old **AND**
3. Member must have moderately to severely active polyarticular juvenile idiopathic arthritis **AND**
4. Member must have failed to respond to and/or is intolerant to approved disease-modifying antirheumatic drugs (DMARDs) agents, such as methotrexate, NSAIDs, analgesics or corticosteroids either alone or in combination **AND**
5. The recommended dose for pediatric patients ages 2 to 17 years of age is 10 mg every other week for patients 10kg to < 15kg, 20 mg every other week for patients 15kg to < 30kg, and 40 mg every other week for patients weighing ≥ 30kg
6. Step Therapy Applies to Amjevita, Hulio/adalimumab-fkjp, Hyrimoz/adalimumab-adaz, Idacio, Yuflyma, Yusimry
    a. Based on comparable indications, efficacy, safety profile, and equivalent strengths of Humira, Hadlima, and Cyltezo, the member will be required to use Humira, Hadlima, and Cyltezo unless there is adequate justification as to why they cannot be used

D. Psoriatic Arthritis

1. A diagnosis of definitive psoriatic arthritis established by a Rheumatologist or Dermatologist **AND**
2. Member must have some clinical features of psoriatic arthritis such as: involvement of the DIP joints, an asymmetric distribution of joint disease, spondyloarthritis, sausage digits, new bone formation on radiographs, cutaneous findings, and the characteristic nail manifestations of psoriatic arthritis (nail pitting, onycholysis & other lesions, which include leukonychia, red spots in the lunula, and nail plate crumbling) all may be present.
3. Member must be actively followed by, and the drug prescribed by a Rheumatologist or Dermatologist **AND**
4. Approved dosing is 40 mg subcutaneously every other week only
5. Step Therapy Applies to Amjevita, Hulio/adalimumab-fkjp, Hyrimoz/adalimumab-adaz, Idacio, Yuflyma, Yusimry
    a. Based on comparable indications, efficacy, safety profile, and equivalent strengths of Humira, Hadlima, and Cyltezo, the member will be required to use Humira, Hadlima, and Cyltezo unless there is adequate justification as to why they cannot be used

E. Ankylosing Spondylitis

1. Member must be actively followed by, and the drug prescribed by a Rheumatologist **AND**
2. Member must have ankylosed spondylitis **AND**
3. Presence of refractory disease defined by failure of or intolerance to at least two NSAIDS at maximum strength for at least 1 month each

4. Approved dosing is 40 mg subcutaneously every other week only
5. Step Therapy Applies to Amjevita, Hulio/adalimumab-fkjp, Hyrimoz/adalimumab-adaz, Idacio, Yuflyma, Yusimry
    a. Based on comparable indications, efficacy, safety profile, and equivalent strengths of Humira, Hadlima, and Cyltezo, the member will be required to use Humira, Hadlima, and Cyltezo unless there is adequate justification as to why they cannot be used

F. Crohn's Disease

1. The patient must be actively followed by, and the drug prescribed by a gastroenterologist **AND**
2. The patient must have a diagnosis of moderately to severely active Crohn's disease
    a. Moderate to severe disease - Crohn's Disease Activity Index (CDAI) score of 220-450, typically described as having more prominent symptoms of fever, significant weight loss, abdominal pain or tenderness, intermittent nausea or vomiting or significant anemia **AND**
3. There must be documentation that azathioprine, 6-mercaptopurine, or methotrexate is ineffective, contraindicated or not tolerated
    a. Treatment with a biologic medication as first-line therapy will be assessed on a case-by-case basis through a letter of medical necessity and clinical progress notes based on severity of the disease
4. Authorization period and dosing limitations:
    a. Adult dosing:
        i. Induction dose - At week 0, 160mg (dose can be administered as four 40mg injections in one day or two 40mg injections per day on two consecutive days), followed by 80mg at week 2
        ii. Maintenance dose – Starting at week 4, adalimumab 40 mg every other week in patients who respond to the initial induction doses prolongs response and remission.
        iii. Dose escalation to 40 mg weekly may be necessary to maintain responses in some patients. 40mg once weekly will only be allowed for people who responded to induction and maintenance therapy but have now lost response
            a) Response to therapy is generally classified as an increase in CDAI of ≥ 70 points
    b. Pediatric dosing (17kg to <40 kg) *:
        i. Induction dose – At week 0, 80mg in one day; second dose at week 2 (day 15): 40mg
        ii. Maintenance dose – starting at week 4 (day 29), adalimumab 20mg every other week. * If pediatric patient is equal to or greater than 40kg, please follow adult dosing.
5. Step Therapy Applies to Amjevita, Hulio/adalimumab-fkjp, Hyrimoz/adalimumab-adaz, Idacio, Yuflyma, Yusimry
    a. Based on comparable indications, efficacy, safety profile, and equivalent strengths of Humira, Hadlima, and Cyltezo, the member will be required to use Humira, Hadlima, and Cyltezo unless there is adequate justification as to why they cannot be used

G. Ulcerative Colitis

1. The patient must be actively followed by, and the drug prescribed by a gastroenterologist
2. The patient must have a diagnosis of moderate to severe active Ulcerative Colitis **AND**
3. Tried and failed or has documented intolerance to at least ONE of the following conventional therapies for at least 3 months:
    a. Thiopurines: Azathioprine/6-mercaptopurine (6-MP)
    b. 5-Aminosalicylates: Sulfasalazine, Mesalamine, Olsalazine
    c. Cyclosporine
    d. IV or oral steroids - note, a 3-month trial of systemic steroid therapy will not be required

4. Authorization period and dosing limitations:
    a. Adults Patients:
        i. At week 0, 160mg (dose can be administered as four 40mg injections in one day or two 40mg injections per day on two consecutive days), followed by 80mg at week 2, followed by a maintenance dose of 40mg every other week beginning at week 4.
        ii. Dose escalation to 40mg once weekly may be approvable for patients who initially responded to adalimumab therapy but have lost response after week 12
    b. Pediatric Patients (5 years of age and older):
        i. Weighing 20 kg to less than 40 kg: 80 mg on day 1, 40 mg on day 8, and 40 mg on day 15 followed by a maintenance dose of 40 mg every other week or 20 mg every week starting on day 29
        ii. Weighing 40 kg or more: 160 mg on day 1, 80 mg on day 8, and 80 mg on day 15 followed by a maintenance dose of 80 mg every other week or 40 mg every week starting on day 29
        iii. Continue the recommended pediatric dosage in patients who become 18 years old and are well-controlled
5. Step Therapy Applies to Amjevita, Hulio/adalimumab-fkjp, Hyrimoz/adalimumab-adaz, Idacio, Yuflyma, Yusimry
    a. Based on comparable indications, efficacy, safety profile, and equivalent strengths of Humira, Hadlima, and Cyltezo, the member will be required to use Humira, Hadlima, and Cyltezo unless there is adequate justification as to why they cannot be used

H. Hidradenitis Suppurativa

1. Member must be at least 12 years old and actively followed by and drug prescribed by a Dermatologist **AND**
2. Must have a diagnosis of stage II, stage III, or severe refractory hidradenitis suppurativa with recurrent abscesses
3. Must have had a minimum of a three-month trial of systemic antibiotics (such as minocycline, doxycycline, clindamycin, or rifampin) which failed to provide clinical improvement.
    a. A 3-month trial will not be required if the member experienced serious side effects during a trial of one of the above-mentioned agents
4. Approval will be for 160mg week 0, then 80mg week 2 and then 40mg every week thereafter starting at week 4.
5. Step Therapy Applies to Amjevita, Hulio/adalimumab-fkjp, Hyrimoz/adalimumab-adaz, Idacio, Yuflyma, Yusimry
    a. Based on comparable indications, efficacy, safety profile, and equivalent strengths of Humira, Hadlima, and Cyltezo, the member will be required to use Humira, Hadlima, and Cyltezo unless there is adequate justification as to why they cannot be used

I. Non-Infectious Panuveitis

1. Member must be actively followed by, and drug prescribed by a Rheumatologist or Ophthalmologist **AND**
2. Member must be at least 2 years old and have a diagnosis of non-infectious intermediate-, posterior- or Pan-uveitis
3. Must have had a previous trial of **ALL** the following:
    a. A topical or injected ophthalmologic steroid (unless contraindications are present)
    b. An oral systemic steroid
    c. An adequate trial of an immunosuppressive agent, such as but not limited to, azathioprine, mycophenolate, or methotrexate

4. Coverage of adalimumab for Panuveitis patients will be limited to an initial dose of adalimumab 80mg at week 0, and 40mg one week after initial dosing and every other week thereafter.
   a. #4 injections / 30 days for first month
   b. #2 injections / 30 days thereafter
5. Step Therapy Applies to Amjevita, Hulio/adalimumab-fkjp, Hyrimoz/adalimumab-adaz, Idacio, Yuflyma, Yusimry
   a. Based on comparable indications, efficacy, safety profile, and equivalent strengths of Humira, Hadlima, and Cyltezo, the member will be required to use Humira, Hadlima, and Cyltezo unless there is adequate justification as to why they cannot be used

APPROVAL TIME PERIODS:

Line of Business	Rx Initial approval	Rx recertification
Essential Plan (EP)/Child Health Plus (CHP)	1 year	1 year
Commercial/Exchange	1 year	1 year

POLICY GUIDELINES:

1. Unless otherwise stated above within the criteria, approval time-period will be for 1 year.
   - Continued approval at time of recertification will require documentation that the drug is providing ongoing benefit to the patient in terms of improvement or stability in disease state or condition. Such documentation may include progress notes, imaging or laboratory findings, and other objective or subjective measures of benefit which support that continued use of the requested product is medically necessary. Also, ongoing use of the requested product must continue to reflect the current policy's preferred formulary. Recertification reviews may result in the requirement to try more cost-effective treatment alternatives as they become available (i.e., generics, biosimilars, or other guideline supported treatment options). Requested dosing must continue to be consistent with FDA-approved or off-label/guideline-supported dosing recommendations
2. Prior authorization is contract dependent.
3. This policy does not apply to Medicare Part D. The drugs in this policy may apply to the following formularies: Commercial, Exchange, Child Health Plus, and Essential Plan. If a drug referenced in this policy is non-formulary, please reference Non-Formulary Medication Exception Review Policy for all Lines of Business policy (Pharmacy-69)
4. Adalimumab is self-administered and therefore fall under the pharmacy benefit.
5. Consideration should be given to initiating therapy with a DMARD such as methotrexate, NSAID, or steroid depending on diagnosis.
6. Involvement of the DIP joints, an asymmetric distribution of joint disease, spondyloarthritis, sausage digits, new bone formation on radiographs, cutaneous findings, and the characteristic nail manifestations of psoriatic arthritis all help to distinguish psoriatic arthritis from other inflammatory arthritis, including RA.
7. A diagnosis of Irritable Bowel Disease associated arthritis will be evaluated using criteria for Ankylosing Spondylitis.
8. Adalimumab is **not to be used in immunocompromised patients** due to the possible risk of serious infection
9. In clinical trials of all TNF inhibitors, a higher rate of lymphoma was seen compared to the general population; however, the risk of lymphoma may be up to several-fold higher in RA and psoriasis patients. Post-marketing cases of aggressive and fatal hepatosplenic T-cell lymphoma (HSTCL) have occurred in adolescents and young adults receiving Adalimumab for inflammatory bowel disease.

10. Per the adalimumab prescribing information: In the treatment of Rheumatoid Arthritis (RA), some patients not taking concomitant methotrexate (MTX) may derive additional benefit from increasing the dosage of adalimumab to 40 mg every week or 80 mg every other week. A study completed by Heiberg MS, Rødevand E, Mikkelsen K, et al. concluded that adalimumab using in combination with methotrexate (MTX) is superior to adalimumab monotherapy for the treatment for Rheumatoid Arthritis. Based on the prescribing information and supporting literature, a trial of concomitant MTX/DMARD is required prior to dose escalation of adalimumab. Dose escalation for patients with RA is reserved for those who are unable to tolerate MTX/DMARD concomitant use or for those who have failed MTX/DMARD concomitant use.
11. Tuberculosis (frequently disseminated or extrapulmonary at clinical presentation), invasive fungal infections, and other opportunistic infections have been observed in patients receiving adalimumab. All patients being considered for biologic therapy should be screened for latent tuberculosis infection, regardless of the presence of risk factors. Annual testing is recommended for patients who live, travel, or work in situations where tuberculosis exposure is likely.
12. Use of TNF inhibitors has been associated with reactivation of hepatitis B virus (HBV) in patients who are chronic carriers of this virus. Patients at risk for HBV infection should be evaluated for prior evidence of HBV infection before initiating TNF inhibitor therapy. Patients with plaque psoriasis who are seropositive for hepatitis B surface antigen with inactive disease should undergo a course of antiviral therapy 2 – 4 weeks prior to initiation of anti-TNF therapy.
13. Use of TNF inhibitors has been associated with rare cases of new onset or worsening of neurologic conditions, such as multiple sclerosis (MS), optic neuritis, and Geillain-Barré syndrome. Exercise caution when using adalimumab in patients with preexisting or recent-onset central or peripheral nervous system demyelinating disorders. Consider the discontinuation of adalimumab if any of these disorders develop.
14. Cases of worsening congestive heart failure (CHF) and new onset CHF have been reported with TNF blockers. Exercise caution when using adalimumab in patients who have heart failure and monitor them carefully. Use of anti-TNF agents is not recommended in patients with New York Heart Association class III or IV heart failure that have an ejection fraction of 50% or less.
15. Patients should not receive live attenuated herpes zoster vaccine while receiving anti-TNF therapy.
16. **Concurrent use of Inflammatory Agents**
    a. Adalimumab as well as other immunomodulating therapies or Targeted Synthetic Disease-Modifying Antirheumatic Drugs (DMARDs) (Enbrel, Stelara, Cimzia, Remicade, biosimilars, etc.) should not be administered in combination with another biologic or targeted synthetic DMARD used for an inflammatory condition. Combination therapy is generally not recommended due to the added risk of immunosuppression, potential for a higher rate of adverse effects, and lack of evidence for additive therapy. NOTE: This does NOT exclude the use of conventional synthetic DMARDs (e.g., MTX, leflunomide, hydroxychloroquine, and sulfasalazine) in combination with biologics and targeted synthetic DMARDs.
    b. Requests for the concurrent use of inflammatory agents will be evaluated for safety and efficacy and subject to off-label review.
    c. Otezla in combination with biologic DMARD therapy (such as adalimumab, Enbrel, Cosentyx, etc.) is not FDA approved or supported with a high level of clinically valid medical evidence for the treatment of plaque psoriasis or psoriatic arthritis. Therefore, these requests are considered combination therapy and are considered not medically necessary.

UPDATES:

Date	Revision
09/01/2023	Revised
08/24/2023	P&T Committee Approval
07/19/2023	Revised
04/01/2023	Revised
03/15/2023	Revised
01/01/2023	Revised
9/22/2022	P&T Committee Approval
05/2022	Revised
03/2022	Revised
02/2022	Revised
09/2021	Reviewed / P & T Committee Approval
09/2020	P & T Committee Approval
08/2020	Reviewed
04/2020	Reviewed
02/2020	Revised
05/2019	Revised
01/2019	Revised
05/2018	Reviewed
06/2017	Revised
05/2017	P & T Committee Approval
04/2017	Revised
09/2015	Revised
05/2015	Revised
12/2014	Revised
10/2014	Revised
12/2013	Revised

REFERENCES:

In addition to the full prescribing information for each individual drug, the following references have been utilized in creating drug specific criteria:

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