Part B Prior Authorization Guidelines

Humira (adalimumab) J0135

Prior Authorization Request
Medicare Part B Form

*Instructions: * Indicates required information – Form may be returned if required information is not provided. Please fax this request to the appropriate fax number listed at the bottom of the page.*

☐	**Standard Request– (72 Hours)**	☐	**Urgent Request** (standard time frame could place the member's life, health or ability in serious jeopardy)
	Date Requested _____		
	Requestor _____ Clinic name: _____ Phone / Fax		

MEMBER INFORMATION

*Name:_____ *ID#:_____ *DOB:_____

PRESCRIBER INFORMATION

*Name:_____ ☐MD ☐FNP ☐DO ☐NP ☐PA *Phone:_____

*Address:_____ *Fax:_____

DISPENSING PROVIDER / ADMINISTRATION INFORMATION

*Name:_____ Phone:_____

*Address:_____ Fax:_____

PROCEDURE / PRODUCT INFORMATION

HCPC Code	Name of Drug	Dose (Wt: _____ kg Ht:_____)	Frequency	End Date if known

☐ **Self-administered** ☐ **Provider-administered** ☐ **Home Infusion**

☐Chart notes attached. **Other important information:**_____

Diagnosis: ICD10: _____ **Description**: _____

☐ Provider attests the diagnosis provided is an FDA-Approved indication for this drug

CLINICAL INFORMATION

☐ **New Start or Initial Request: (Clinical documentation required for all requests)**

☐ Patient has tried / failed Humira under Medicare Part D - Billing Date: _____

If not, please provide clinical rationale why member cannot Self-Administer

_____

☐ Crohn's disease (CD) when each of the following criteria are met:

- ☐ Patient is 6 years of age or older with moderate to severe CD; AND
- ☐ Patient has had an inadequate response to, is intolerant of, or has a contraindication to conventional therapy (such as systemic corticosteroids or immunosuppressants [thiopurines or methotrexate]);

☐ Ulcerative colitis (UC) when each of the following criteria are met:

- ☐ Patient is 5 years of age or older with moderate to severe UC; AND
- ☐ Patient has had an inadequate response to, is intolerant of, or has a contraindication to contraindication to conventional therapy (such as 5-Aminosalicylic acid products, systemic corticosteroids, or immunosuppressants [such as thiopurines]);

CLINICAL/CMS ONLY

☐ Rheumatoid arthritis (RA) when each of the following criteria are met:
- ☐ Patient is 18 years of age or older with moderate to severe RA; AND
- ☐ Patient has had an inadequate response to methotrexate titrated to maximally tolerated dose OR
- ☐ If methotrexate is not tolerated or contraindicated, Patient has had an inadequate response to, is intolerant of, or has a contraindication to other conventional therapy (sulfasalazine, leflunomide, or hydroxychloroquine);

☐ Ankylosing spondylitis (AS) when each of the following criteria are met:
- ☐ Patient is 18 years of age or older with moderate to severe AS; AND
- ☐ Patient has had an inadequate response to, is intolerant of, or has a contraindication to conventional therapy [such as NSAIDs or nonbiologic DMARDs (such as sulfasalazine)];

☐ Polyarticular juvenile idiopathic arthritis (PJIA) when each of the following criteria are met:
- ☐ Patient is 2 years of age or older with moderate to severe PJIA; AND
- ☐ Patient has had an inadequate response to, is intolerant of, or has a contraindication to conventional therapy [nonbiologic DMARDs (such as methotrexate)] (ACR 2019);

☐ Psoriatic arthritis (PsA) when each of the following criteria are met:
- ☐ Patient is 18 years of age or older with moderate to severe PsA; AND
- ☐ Patient has had an inadequate response to, is intolerant of, or has a contraindication to conventional therapy [nonbiologic DMARDs (such as methotrexate, sulfasalazine, cyclosporine, or leflunomide)];

☐ Plaque psoriasis (Ps) when each of the following criteria are met:
- ☐ Patient is 18 years of age or older with chronic moderate to severe (that is, extensive or disabling) plaque Ps with either of the following (AAD 2019):
  - ☐ Plaque Ps involving greater than three percent (3%) body surface area (BSA); OR
  - ☐ Plaque Ps involving less than or equal to three percent (3%) BSA involving sensitive areas or areas that significantly impact daily function (such as palms, soles of feet, head/neck, or genitalia); AND
- ☐ Patient has had an inadequate response to, is intolerant of, or has a contraindication to phototherapy or other systemic therapy (such as acitretin, cyclosporine, or methotrexate);

☐ Non-infectious uveitis (UV) when each of the following criteria are met:
- ☐ Patient has chronic, recurrent, treatment-refractory or vision-threatening disease; AND
- ☐ Patient has had an inadequate response to, is intolerant of, or has a contraindication to conventional therapy [such as corticosteroids or immunosuppressants (azathioprine, cyclosporine, or methotrexate)];

☐ Hidradenitis suppurativa (HS) when each of the following criteria are met:
- ☐ Patient is 12 years of age or older; AND
- ☐ Patient has moderate to severe HS (Hurley stage II or Hurley stage III disease); AND
- ☐ Patient has had an inadequate response to, is intolerant of, or has a contraindication to conventional therapy (such as oral antibiotics);

☐ Sarcoidosis when each of the following criteria are met (Sweiss 2014):
- ☐ Patient is 18 years of age or older; AND
- ☐ Patient has chronic, progressive, treatment-refractory disease; AND
- ☐ Patient has had an inadequate response to, is intolerant of, or has a contraindication to systemic corticosteroids; AND

CLINICAL / CMS ONLY

☐ Patient has had an inadequate response to, is intolerant of, or has a contraindication to non-biologic DMARDs (such as methotrexate or azathioprine).

☐ **Continuation Requests: (Clinical documentation required for all requests)**

☐ Patient had an adequate response or significant improvement while on this medication.

If not, please provide clinical rationale for continuing this medication: _____

_____

ACKNOWLEDGEMENT

Request By (Signature Required): _____Date:_____ /____ /____

Any person who knowingly files a request for authorization of coverage of a medical procedure or service with the intent to injure, defraud or deceive any insurance company by providing materially false information or conceals material information for the purpose of misleading, commits a fraudulent insurance act, which is a crime and subjects such person to criminal and civil penalties. **THIS AUTHORIZATION IS NOT A GUARANTEE OF PAYMENT.** PAYMENT IS BASED ON BENEFITS IN EFFECT AT THE TIME OF SERVICE, MEMBER ELIGIBILITY AND MEDICAL NECESSITY.

CLINICAL / CMS ONLY

Prior Authorization Group – Humira PA

Drug Name(s):
HUMIRA **ADALIMUMAB**

Criteria for approval of Prior Authorization Drug:

1. Prescribed for an approved FDA diagnosis (as listed below):
2. Member does not have any clinically relevant contraindications, or CMS/Plan exclusions, to the requested drug.

- If the member meets all these criteria, they may be approved by the Plan for the requested drug.
- Quantity limits and Tiering will be determined by the Plan.

Exclusion Criteria:
N/A

Prescriber Restrictions:
N/A

Coverage Duration:
Approvals will be for 6 months
NO PA REQUIRED FOR J3490

FDA Indications:
Humira

- Ankylosing spondylitis
- Crohn's disease (Moderate to Severe)
- Hidradenitis suppurativa (Moderate to Severe)
- Juvenile idiopathic arthritis
- Plaque psoriasis (Moderate to Severe)
- Psoriatic arthritis
- Rheumatoid arthritis (Moderate to Severe)
- Ulcerative colitis (Moderate to Severe)
- Uveitis

Off-Label Uses:
Humira

- Anterior uveitis
- Behcet's syndrome
- Non-radiographic axial spondyloarthritis
- Polyarteritis nodosa
- Psoriasis (Moderate to Severe)
- Psoriasis of nail (Moderate to Severe), Fingers
- Retinal vasculitis
- Sarcoidosis, Refractory to glucocorticosteroids and/or anti-metabolite therapy; Adjunct

Age Restrictions:
N/A

CLINICAL / CMS ONLY

Other Clinical Considerations:

N/A

Resources:

https://www.micromedexsolutions.com/micromedex2/librarian/CS/F9A228/ND_PR/evidencexpert/ND_P/evidencexpert/DUPLICATIONSHIELDSYNC/2BA7E5/ND_PG/evidencexpert/ND_B/evidencexpert/ND_AppProduct/evidencexpert/ND_T/evidencexpert/PFActionId/evidencexpert.GoToDashboard?docId=927665&contentSetId=100&title=Adalimumab&servicesTitle=Adalimumab&brandName=Humira&UserMdxSearchTerm=Humira&=null

CLINICAL / CMS ONLY