



Part B Prior Authorization Guidelines

Humira (adalimumab) J0135 is non-preferred. The preferred products are Yuflyma (adalimumab-aaty) C9399 and Simlandi (adalimumab-ryvk) J0135. Prior Authorization Step Therapy 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.

Request type selection: Standard Request (72 Hours) or Urgent Request. Includes fields for Date Requested, Requestor, Clinic name, Phone, and 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

Table with 5 columns: HCPC Code, Name of Drug, Dose (Wt: ___ kg Ht: ___), Frequency, End Date if known.

Self-administered, Provider-administered, Home Infusion checkboxes.

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) criteria: 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...

Ulcerative colitis (UC) criteria: 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 conventional therapy...

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- 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

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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.

Prior Authorization Group – Humira PA

Drug Name(s):

HUMIRA	ADALIMUMAB
YUFLYMA	ADALIMUMAB-AATY
SIMLANDI	ADALIMUMAB-RYVK

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, Continuation may be approved for up to 12 months.

FDA Indications:

Humira, Yuflyma, Simlandi

- 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, Yuflyma, Simlandi

- 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

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

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