Reference number(s)
1987-D

Enhanced Specialty Guideline Management
Treatment of Rheumatoid Arthritis

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Abrilada	adalimumab-afzb
Actemra	tocilizumab
adalimumab (unbranded Humira)	adalimumab
adalimumab-aacf (unbranded Idacio)	adalimumab-aacf
adalimumab-aaty (unbranded Yuflyma)	adalimumab-aaty
adalimumab-adaz (unbranded Hyrimoz)	adalimumab-adaz
adalimumab-adbm (unbranded Cyltezo)	adalimumab-adbm
adalimumab-fkjp (unbranded Hulio)	adalimumab-fkjp
adalimumab-ryvk (unbranded Simlandi)	adalimumab-ryvk
Amjevita	adalimumab-atto
Avsola	infliximab-axxq
Avtozma	tocilizumab-anoh
Cimzia	certolizumab
Cyltezo	adalimumab-adbm
Enbrel	etanercept
Hadlima	adalimumab-bwwd
Hulio	adalimumab-fkjp
Humira	adalimumab
Hyrimoz	adalimumab-adaz
Idacio	adalimumab-aacf

Brand Name	Generic Name
Inflectra	infliximab
infliximab (unbranded Remicade)	infliximab
Kevzara	sarilumab
Kineret	anakinra
Orencia	abatacept
Remicade	infliximab
Renflexis	infliximab-abda
Simlandi	adalimumab-ryvk
Simponi	golimumab
Simponi Aria	golimumab
Tofidence	tocilizumab-bavi
Tyenne	tocilizumab-aazg
Yuflyma	adalimumab-aaty
Yusimry	adalimumab-aqvh

Program Rationale

The intent of the criteria is to provide coverage for biologic drugs for adult members who have maximized the use of conventional synthetic drugs for the treatment of rheumatoid arthritis. This program applies to the following products that are FDA-approved for the treatment of rheumatoid arthritis (Abrilada, Actemra, adalimumab, adalimumab-aacf, adalimumab-aaty, adalimumab-adaz, adalimumab-adbm, adalimumab-fkjp, adalimumab-ryvk, Amjevita, Avsola, Avtozma, Cimzia, Cyltezo, Enbrel, Hadlima, Hulio, Humira, Hyrimoz, Idacio, Inflectra, infliximab, Kevzara, Kineret, Orencia, Remicade, Renflexis, Simlandi, Simponi, Simponi Aria, Tofidence, Tyenne, Yuflyma, Yusimry). Coverage will be provided if all approval criteria are met and the member has no exclusions to the prescribed therapy.

Documentation

The following information must be submitted:

Initial requests

- Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy.

- Laboratory results, chart notes, or medical record documentation of biomarker testing (i.e., rheumatoid factor [RF], anti-cyclic citrullinated peptide [anti-CCP], and C-reactive protein [CRP] and/or erythrocyte sedimentation rate [ESR]) (if applicable).

Continuation requests

Chart notes or medical record documentation supporting positive clinical response.

Prescriber Specialties

This medication must be prescribed by or in consultation with a rheumatologist.

Coverage Criteria

Authorization of 12 months may be granted when the member has previously received a biologic or targeted synthetic drug indicated for moderately to severely active rheumatoid arthritis (RA) within the past 120 days.

Authorization of 12 months may be granted when the member has moderately to severely active RA when all of the following criteria are met:

- Member meets either of the following:
  - Member has been tested for either of the following biomarkers and the test was positive:
    - Rheumatoid factor (RF)
    - Anti-cyclic citrullinated peptide (anti-CCP)
  - Member has been tested for ALL of the following biomarkers:
    - RF
    - Anti-CCP
    - C-reactive protein (CRP) and/or erythrocyte sedimentation rate (ESR)
- Member meets ONE of the following:
  - Member has failed to achieve a low disease activity after a 3-month trial of methotrexate (MTX) monotherapy at a maximum titrated dose of at least 15 mg per week and meets any of the following conditions:
    - Member has had a documented inadequate response to MTX in combination with at least one other conventional synthetic drug (i.e., hydroxychloroquine and/or sulfasalazine) after a 3-month trial at a maximum tolerated dose(s).
    - Member has experienced a documented intolerable adverse event to hydroxychloroquine or sulfasalazine.
    - Member has a documented contraindication to hydroxychloroquine (see Appendix) and sulfasalazine (e.g., porphyria, intestinal or urinary obstruction).

        - Member has moderate to high disease activity.
    - Member was unable to tolerate a 3-month trial of MTX monotherapy at a maximum titrated dose of at least 15 mg per week and meets any of the following conditions:
        - Member has had a documented inadequate response to MTX in combination with at least one other conventional synthetic drug (i.e., hydroxychloroquine and/or sulfasalazine) after a 3-month trial at a maximum tolerated dose(s).
        - Member has stopped taking MTX and has had a documented inadequate response to another conventional synthetic drug (i.e., leflunomide, hydroxychloroquine, and/or sulfasalazine) alone or in combination after a 3-month trial at a maximum tolerated dose(s).
        - Member has experienced a documented intolerable adverse event to leflunomide, hydroxychloroquine, or sulfasalazine.
        - Member has a documented contraindication to leflunomide, hydroxychloroquine (see Appendix), and sulfasalazine (e.g., porphyria, intestinal or urinary obstruction).
        - Member has moderate to high disease activity.
    - Member has experienced a documented intolerable adverse event or has a documented contraindication to MTX (see Appendix), discontinues MTX, and meets any of the following conditions:
        - Member has had a documented inadequate response to another conventional synthetic drug (i.e., leflunomide, hydroxychloroquine, and/or sulfasalazine) alone or in combination after a 3-month trial at a maximum tolerated dose(s).
        - Member has experienced a documented intolerable adverse event to leflunomide, hydroxychloroquine, or sulfasalazine.
        - Member has a documented contraindication to leflunomide, hydroxychloroquine (see Appendix), and sulfasalazine (e.g., porphyria, intestinal or urinary obstruction).
        - Member has moderate to high disease activity.
    - The requested product is Actemra, Avtozma, Tofidence, or Tyenne.
- For Avsola, Inflectra, infliximab, Remicade, Renflexis, Simponi, and Simponi Aria requests, member is prescribed the requested medication in combination with methotrexate or leflunomide or has a clinical reason not to use methotrexate or leflunomide (see Appendix).
- For Kineret requests, member has experienced an inadequate response to at least a 3-month trial of a biologic or a targeted synthetic drug (e.g., Rinvoq, Xeljanz) or has an intolerance to a biologic or targeted synthetic drug.

Continuation of Therapy

Authorization of 12 months may be granted for all adult members (including new members) who are using the requested medication for moderately to severely active rheumatoid arthritis and who achieve or

maintain a positive clinical response as evidenced by disease activity improvement of at least 20% from baseline in tender joint count, swollen joint count, pain, or disability.

Other

Member has had a documented negative tuberculosis (TB) test (which can include a tuberculosis skin test [TST] or an interferon-release assay [IGRA]) within 12 months of initiating therapy for persons who are naïve to biologic drugs or targeted synthetic drugs associated with an increased risk of TB.

If the screening testing for TB is positive, there must be further testing to confirm there is no active disease (e.g., chest x-ray). Do not administer the requested medication to members with active TB infection. If there is latent disease, TB treatment must be started before initiation of the requested medication.

For Actemra, Avtozma, Kineret, Kevzara, Tofidence, and Tyenne, member cannot use the requested medication concomitantly with any other biologic drug or targeted synthetic drug. For all other drugs, member cannot use the requested medication concomitantly with any other biologic drug or targeted synthetic drug for the same indication.

Dosage and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Appendix

Examples of Clinical Reasons to Avoid Pharmacologic Treatment with Methotrexate, Hydroxychloroquine, or Leflunomide[47]

- Clinical diagnosis of alcohol use disorder, alcoholic liver disease, or other chronic liver disease
- Drug interaction
- Risk of treatment-related toxicity
- Pregnancy or currently planning pregnancy
- Breastfeeding
- Significant comorbidity prohibits use of systemic agents (e.g., liver or kidney disease, blood dyscrasias, uncontrolled hypertension)
- Hypersensitivity
- History of intolerance or adverse event

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