



Alabama Medicaid Preferred Drug and Prior Authorization Program

DMARD/Biological Injectable Agents Prior Authorization (PA) Criteria Instructions

This document contains detailed instructions on completing the Medicaid Prior Authorization Form, Form 373. When a Disease-Modifying Antirheumatic Drug (DMARD)/biological injectable is prescribed, the practitioner will be required to obtain prior authorization (PA). If approval is given to dispense the DMARD/biological injectable, an authorization number will be given. Some DMARD/biological agents will be considered “preferred with clinical criteria”. Those agents will still require prior authorization.

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Overview

DMARD/Biological Injectable PA Form: General Information

DMARDs/Biological Injectable Diagnoses Requiring PA

DMARD/Biological injectable agents indicated for the diagnoses listed below will require PA:

- | | |
|--|---|
| A. Ankylosing Spondylitis | G. Psoriatic Arthritis |
| B. Crohn's Disease | H. Rheumatoid Arthritis |
| C. Generalized Lipodystrophy | I. Severe Asthma |
| D. Hidradenitis Suppurativa | J. Ulcerative Colitis |
| E. Juvenile Idiopathic Arthritis | K. Uveitis |
| F. Plaque Psoriasis | |

Definitions

Approval Timeframe

- The approval timeframe is the maximum period of time for which a PA can be approved. Refills within the approved timeframe will not require a new PA request.

Appropriate Diagnosis

- Requests for DMARD/biological injectable agents require an appropriate diagnosis(es) that justifies the drug requested. Diagnosis(es) **or** ICD-9 or ICD-10 code(s) may be used. Use of ICD-9 or ICD-10 codes provides specificity and legibility and will usually expedite review.

Medical Justification

- Medical justification is documentation to support the physician's choice for the requested course of treatment and may include documentation from the patient record or peer-reviewed literature. Documentation from the patient record (history and physical, tests, past or current medication/treatments, patient's response to treatment, etc) should illustrate and support the physician's request for the drug specified. For example, if a recommended therapy trial is contraindicated by the patient's condition or the patient has a history of allergy to a first-line drug, and the physician wants to prescribe a drug that requires prior authorization, documentation from the patient record would support that decision. Medical justification may be provided under the Clinical Information Section on the request form or included as an attachment.

Preferred with Clinical Criteria

- DMARDs/biological injectable agents that are "preferred with clinical criteria" will require a prior authorization request be submitted. Clinical criteria must be met in order to be approved. Non-preferred products will continue to require prior authorization; for a non-preferred product to be approved, failure with a designated number of preferred agents and clinical criteria must be met.

Prior Treatment Trials

- Prior authorization for DMARDs/biological injectables requires that a designated number of prescribed, preferred, generic, OTC or brand name drugs be utilized unsuccessfully relative to efficacy and/or safety within a specified timeframe prior to requesting the PA. **For prior therapy requirements, refer to the specific diagnosis section of the booklet.**
- The PA request must indicate that the prescribed, preferred, generic, OTC or brand drugs have been utilized for a specified period of time **unless** there is an adverse/allergic response or contraindication.
- If the prescribing practitioner feels there is a medical reason for which the patient should not be on a required previous drug therapy, medical justification may be submitted in lieu of previous therapy.

Stable Therapy

- Stable therapy does not apply to the DMARDs/biological injectables.

Prior Authorization Request Submittal

Electronic Prior Authorization (PA)

Electronic Prior Authorization does not apply to DMARDs/biological injectables.

Paper Requests

DMARD/biological injectable prior authorization requests should be submitted on PA Form 373. Once the form is completed, the paper request can be submitted via fax or mail.

Verbal PA Requests

Verbal PA requests cannot be submitted for the DMARD/biological injectable agents.

Section One
DMARD/Biological Injectable PA Form: Patient Information

Below are fields to be completed on the PA Form.

Form States	Your Response
Patient Name	Record the patient's name as it appears on their Medicaid card.
Patient Medicaid #	Record patient's Medicaid number.
Patient DOB	Record patient's date of birth.
Patient Phone # With Area Code	Record the patient's phone number including area code.

Section Two

DMARD/Biological Injectable PA Form: Prescriber Information

Below are fields to be completed on the PA Form.

Form States	Your Response
Prescriber Name	Record the prescribing practitioner's name.
NPI #	Record the prescribing practitioner's NPI number.
License #	Record the prescribing practitioner's license number.
Phone # With Area Code	Record the prescribing practitioner's phone number with area code.
Fax # With Area Code	Record prescribing practitioner's fax number with area code.
Address (optional)	Prescribing practitioner's mailing address is optional.
Prescribing Practitioner Signature/Date	The prescriber should sign and date in this section on the prescribing practitioner signature line.*

**By signing in the designated space, the practitioner verifies that the request complies with Medicaid's guidelines and that he/she will be supervising the patient during treatment with the requested product. The practitioner further certifies that documentation is available in the patient record to justify the requested treatment.*

Section Three

DMARD/Biological Injectable PA Form: Clinical Information

Below are fields to be completed on the PA Form.

Form States	Your Response
Drug Requested	Check the box of the drug being requested.
NDC/J Code	Enter the NDC. If the drug requested is to be administered using office medications, enter the J Code.
Strength	Record the strength of the drug.
Qty.	Enter the quantity of the drug being requested.
Day Supply	Enter the days supply for the quantity requested.
Current Weight	Record the current weight of the patient.
ICD-9 or ICD-10 Code	Record diagnosis(es) that justifies the requested drug. Diagnosis(es) <u>or</u> ICD-9 or ICD-10 code(s) may be used. Use of ICD-9 or ICD-10 codes provides specificity and legibility and will usually expedite review.
Number of Refills	Indicate the number of refills requested.
Diagnosis Specific Questions	Check the appropriate diagnosis and answer the diagnosis specific questions provided on the PA Form. More information on diagnosis specific information is included below.
Medical Justification	Explain the reason this drug is required, and attach any additional medical justification necessary.* Failed therapies can be listed in this section.

**Medical justification is documentation to support the physician's choice of the requested course of treatment and may include documentation from the patient record or peer-reviewed literature. Documentation from the patient record (history and physical, tests, past or current medication/treatments, patient's response to treatment, etc) illustrates and supports the physician's request for the drug specified. For example, if a recommended therapy trial is contraindicated by the patient's condition or a history of allergy to a first-line drug, and the physician wants to order a non-preferred drug, documentation from the patient record would support that decision.*

DMARD/Biological Injectables Diagnosis Specific Information

A. Ankylosing Spondylitis

Appropriate Diagnosis

- For prior authorization, the patient must have a diagnosis of active ankylosing spondylitis confirmed by a board certified rheumatologist.

Prior Treatment Trials

- The patient must have failed a 3-month treatment trial with at least two nonsteroidal anti-inflammatory drugs (NSAIDs) at maximum recommended doses, unless there is a documented adverse response or contraindication to NSAID use. Patients who have axial disease only do not require any additional treatment failures. Patients with symptoms of peripheral arthritis must also have failed a 30-day treatment trial with at least one nonbiological disease modifying antirheumatic drug (DMARD), and 2 preferred DMARDs (if applicable), unless there is a documented adverse response or contraindication to DMARD use. Nonbiological DMARDs include the following: hydroxychloroquine, sulfasalazine, methotrexate, leflunomide, d-penicillamine, azathioprine, oral gold, intramuscular gold.
- If there are preferred agents indicated for the above diagnosis, the preferred agent(s) must be tried prior to approval of a non-preferred agent.

Medical Justification

- Medical justification must include peer-reviewed literature and medical record documentation, including failure of NSAIDs and nonbiological DMARDs.

PA Approval Timeframes

- Approval may be given for up to 12 months.

DMARD/Biological Injectables
Diagnosis Specific Information
(continued)

B. Crohn's Disease

Appropriate Diagnosis

- For prior authorization, the patient must have a diagnosis of moderately to severely active Crohn's disease confirmed by a board certified gastroenterologist.

Prior Treatment Trials

- The patient must have had an inadequate response to one or more conventional therapies and two preferred DMARDs (if applicable), unless there is a documented adverse response or contraindication to the use of these agents. Conventional therapies include the following: aminosalicylates, corticosteroids, azathioprine/6-mercaptopurine, metronidazole, methotrexate or ciprofloxacin.
- If there are preferred agents indicated for the above diagnosis, the preferred agent(s) must be tried prior to approval of a non-preferred agent.
- For Entyvio® the patient must have had an inadequate response to one or more of the following therapies, a tumor necrosis factor blocker, immunomodulator, or corticosteroid, unless there is a documented adverse response or contraindication to the use of these agents.

Medical Justification

- Medical justification must include peer-reviewed literature and medical record documentation, including failure of conventional therapies.

PA Approval Timeframes

- Approval may be given for up to 12 months.

DMARD/Biological Injectables
Diagnosis Specific Information
(continued)

C. Generalized Lipodystrophy

Appropriate Diagnosis

- For prior authorization, the patient must have a diagnosis of congenital or acquired generalized lipodystrophy.

Medical Justification

- Medical justification must include peer-reviewed literature and medical record documentation, including failure of conventional therapies.
- If there are preferred agents indicated for the above diagnosis, the preferred agent(s) must be tried prior to approval of a non-preferred agent.

PA Approval Timeframes

- Approval may be given for up to 12 months.

DMARD/Biological Injectables
Diagnosis Specific Information
(continued)

D. Hidradenitis Suppurativa

Appropriate Diagnosis

- For prior authorization, the patient must have a diagnosis of moderate to severe hidradenitis suppurativa.

Medical Justification

- The patient must have had an inadequate response to at least one systemic antibiotic treatment within the past 12 months, unless there is a documented allergy or contraindication to antibiotic treatment
- If there are preferred agents indicated for the above diagnosis, the preferred agent(s) must be tried prior to approval of a non-preferred agent.

PA Approval Timeframes

- Approval may be given for up to 12 months.

DMARD/Biological Injectables
Diagnosis Specific Information
(continued)

E. Juvenile Idiopathic Arthritis

Appropriate Diagnosis

- For prior authorization, the patient must have a diagnosis of moderately to severely active polyarticular juvenile idiopathic arthritis confirmed by a board certified rheumatologist.

Prior Treatment Trials

- The patient must also have failed a 30-day treatment trial with at least one nonbiological disease modifying antirheumatic drug (DMARD) and two preferred DMARDs (if applicable), unless there is a documented adverse response or contraindication to DMARD use. Nonbiological DMARDs include the following: hydroxychloroquine, sulfasalazine, methotrexate, leflunomide, d-penicillamine, azathioprine, oral gold, intramuscular gold.
- If there are preferred agents indicated for the above diagnosis, the preferred agent(s) must be tried prior to approval of a non-preferred agent.

Medical Justification

- Medical justification must include peer-reviewed literature and medical record documentation, including failure of nonbiological DMARDs.

PA Approval Timeframes

- Approval may be given for up to 12 months.

DMARD/Biological Injectables
Diagnosis Specific Information
(continued)

F. Plaque Psoriasis

Appropriate Diagnosis

- For prior authorization, the patient must be ≥18 years of age and have a diagnosis of moderate to severe plaque psoriasis confirmed by a board certified dermatologist.

Prior Treatment Trials

- The patient must also have failed a 6-month treatment trial with topical treatment(s), either generic, OTC, or brand, within the last year, unless there is a documented adverse response or contraindication to topical treatments. The patient must also have had an inadequate response to phototherapy, systemic retinoids (oral isotretinoin), methotrexate or cyclosporine, unless there is a documented adverse response or contraindication to the use of these agents.
- If there are preferred agents indicated for the above diagnosis, the preferred agent(s) must be tried prior to approval of a non-preferred agent.

Medical Justification

- Medical justification must include peer-reviewed literature and medical record documentation, including failure of topical treatments, phototherapy, systemic retinoids (oral isotretinoin), methotrexate and cyclosporine.

PA Approval Timeframes

- Approval may be given for up to 12 months.

DMARD/Biological Injectables
Diagnosis Specific Information
(continued)

G. Psoriatic Arthritis

Appropriate Diagnosis

- For prior authorization, the patient must have a diagnosis of psoriatic arthritis confirmed by a board certified dermatologist or rheumatologist.

Prior Treatment Trials

- The patient must also have failed a 30-day treatment trial with at least one nonbiological disease modifying antirheumatic drug (DMARD) and two preferred DMARDs (if applicable), unless there is a documented adverse response or contraindication to DMARD use. Nonbiological DMARDs include the following: hydroxychloroquine, sulfasalazine, methotrexate, leflunomide, d-penicillamine, azathioprine, oral gold, intramuscular gold.
- If there are preferred agents indicated for the above diagnosis, the preferred agent(s) must be tried prior to approval of a non-preferred agent.

Medical Justification

- Medical justification must include peer-reviewed literature and medical record documentation, including failure of nonbiological DMARDs.

PA Approval Timeframes

- Approval may be given for up to 12 months.

DMARD/Biological Injectables
Diagnosis Specific Information
(continued)

H. Rheumatoid Arthritis

Appropriate Diagnosis

- For prior authorization, the patient must have a diagnosis of moderately to severely active rheumatoid arthritis confirmed by a board certified rheumatologist.

Prior Treatment Trials

- The patient must also have failed a 30-day treatment trial with at least one nonbiological disease modifying antirheumatic drug (DMARD) and two preferred DMARDs (if applicable), unless there is a documented adverse response or contraindication to DMARD use. Nonbiological DMARDs include the following: hydroxychloroquine, sulfasalazine, methotrexate, leflunomide, d-penicillamine, azathioprine, oral gold, intramuscular gold.
- If there are preferred agents indicated for the above diagnosis, the preferred agent(s) must be tried prior to approval of a non-preferred agent.
- For patients with rheumatoid arthritis that is newly diagnosed (<6 months) with high disease activity and features of a poor prognosis, therapy can be initiated with or without methotrexate and Actemra[®], Cimzia[®], Enbrel[®], Humira[®], Orencia[®], Remicade[®], or Simponi[®].
- For Remicade[®] and Simponi[®], the patient will need to continue on methotrexate in conjunction with Remicade[®] and Simponi[®] therapy, unless there is a contraindication to its use. Any contraindications or intolerance to methotrexate use will need to be identified with appropriate supportive documentation included.
- For Xeljanz[®], the patient must have moderately to severely active rheumatoid arthritis and have had an inadequate response or intolerance to methotrexate. It may be used as monotherapy or in combination with methotrexate or other nonbiological DMARDs.

Medical Justification

- Medical justification must include peer-reviewed literature and medical record documentation, including failure of nonbiological DMARDs.

PA Approval Timeframes

- Approval may be given for up to 12 months.

DMARD/Biological Injectables
Diagnosis Specific Information
(continued)

I. Severe Asthma

Appropriate Diagnosis

- For prior authorization, the patient must have a diagnosis of moderate to severe asthma with an eosinophilic phenotype.

Medical Justification

- The patient must be the indicated age or older and have a history of two or more exacerbations in the previous year despite regular use of high-dose inhaled corticosteroids plus an additional controller(s) with or without oral corticosteroids.

- If there are preferred agents indicated for the above diagnosis, the preferred agent(s) must be tried prior to approval of a non-preferred agent.

PA Approval Timeframes

- Approval may be given for up to 12 months.

DMARD/Biological Injectables
Diagnosis Specific Information
(continued)

J. Ulcerative Colitis

Appropriate Diagnosis

- For prior authorization, the patient must have a diagnosis of moderately to severely active ulcerative colitis confirmed by a board certified gastroenterologist.

Prior Treatment Trials

- The patient must have had an inadequate response to one or more conventional therapies and two preferred DMARDs (if applicable), unless there is a documented adverse response or contraindication to the use of these agents. Conventional therapies include the following: aminosalicylates, corticosteroids, azathioprine/6-mercaptopurine, metronidazole, methotrexate, ciprofloxacin, or cyclosporine.
- If there are preferred agents indicated for the above diagnosis, the preferred agent(s) must be tried prior to approval of a non-preferred agent.
- For Entyvio® the patient must have had an inadequate response to one or more of the following therapies, a tumor necrosis factor blocker, immunomodulator, or corticosteroid, unless there is a documented adverse response or contraindication to the use of these agents.

Medical Justification

- Medical justification must include peer-reviewed literature and medical record documentation, including failure of conventional therapies. The documentation must indicate that this treatment is the last resort before surgical intervention indicating therapies and timeframes of failure.

PA Approval Timeframes

- Approval may be given for up to 12 months.

DMARD/Biological Injectables
Diagnosis Specific Information
(continued)

K. Uveitis

Appropriate Diagnosis

- For prior authorization, the patient must have a diagnosis of non-infectious intermediate, posterior, and panuveitis, excluding patients with isolated anterior uveitis.

Medical Justification

- The patient must have had an inadequate response to at least one topical glucocorticoid treatment within the past 12 months, unless there is a documented allergy or contraindication to glucocorticoid treatment.
- If there are preferred agents indicated for the above diagnosis, the preferred agent(s) must be tried prior to approval of a non-preferred agent.

PA Approval Timeframes

- Approval may be given for up to 12 months.

Section Four
DMARD/Biological Injectable PA Form: Dispensing Pharmacy
Information

(Information in this area may be completed by the pharmacy).

Below are fields to be completed on the PA Form.

Form States	Your Response
Dispensing Pharmacy	Enter the pharmacy name.
NPI #	Enter the pharmacy NPI number.
NDC #	Record the NDC number of the drug requested.
Phone # With Area Code	Enter the pharmacy phone number with area code.
Fax # With Area Code	Enter the pharmacy fax number with area code.