Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	July 16, 2018 July 23, 2018, May 17, 2019, July 9, 2019, September 4, 2019, October 3, 2019, October 11, 2019, February 17, 2020, July 7, 2020, October 28, 2020, January 11, 2021, January 28, 2021, August 26, 2021, March 9, 2022, April 5, 2022, July 7, 2022, October 14, 2022

CYTOKINES AND CELL ADHESION MOLECULE (CAM) ANTAGONISTS:

Preferred agents: Enbrel®, Humira®, Xeljanz® (automation with diagnosis on file)

Non-preferred agents: Actemra®, Arcalyst®, Avsola®, Cimzia®, Cosentyx®, Entyvio, Hyrimoz®, Ilaris®, Ilumya™, Inflectra®, Kevzara®, Kineret®, Olumiant®, Orencia, Otezla®, Remicade, Renflexis, Rinvoq™, Rinvoq ER™, Siliq®, Simponi, Simponi Aria, Skyrizi®, Stelara®, Taltz®, Tremfya®, Yusimry and Xeljanz XR®.

LENGTH OF AUTHORIZATION: SIX MONTHS

INITIAL REVIEW CRITERIA:

- A negative tuberculin test prior to initiating therapy and results have been provided.
- Medication requested must have the FDA approved indication and the patient must be within the FDA approved age limits.
- Quantity and age limits are located on the Summary of Drug Limitations at the following website: http://www.ahca.myflorida.com/medicaid/Prescribed_Drug/preferred_drug.shtml

Acute Graft Versus Host Disease (aGVHD)

- Medication is being used for the prophylaxis of **aGVHD**.
- Must be used in combination with a calcineurin inhibitor and methotrexate.
- Patient must be undergoing hematopoietic stem cell transplantation (HSCT).

Alopecia Areata

- Patient has a documented diagnosis of severe alopecia areata.
- Patient has had an inadequate response, intolerance, or contraindication (clinical documentation must be submitted demonstrating response to previous therapies) with the following:
  - a 3-month minimum trial of ≥ 1 preferred systemic agent (e.g., cyclosporine, corticosteroids, methotrexate) **OR**
  - Topical corticosteroids
- Patient does not have hair loss due to androgenetic alopecia, chemotherapy-induced hair loss, or causes of hair loss other than alopecia areata.

Ankylosing Spondylitis:

- Patient has a documented diagnosis of ankylosing spondylitis.
- Patient has had an inadequate response, intolerance, or contraindication (clinical documentation must be submitted demonstrating response to previous therapies) with the following:
  - One or more non-steroidal anti-inflammatory drugs –NSAIDs (trial at maximum dose for at least 2-3 weeks before considering them as failures); **OR**
  - Analgesic agents (e.g. acetaminophen or codeine) if NSAIDs do not completely control the pain; **OR**
  - Sulfasalazine (if peripheral joint involvement is present); **AND**

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- Patient has had a trial of at least one of the preferred alternatives with the FDA approved indication, and experienced inadequate response or intolerance. If the request is for Xeljanz XR, a trial of Xeljanz (immediate-release) is required. If a preferred agent(s) is contraindicated, trial of an alternative preferred agent is required, if appropriate.

Atopic Dermatitis:

- Patient must have a diagnosis of refractory moderate-to-severe atopic dermatitis (AD).
- Patient has had a trial of at least
  - one preferred medium to very-high potency topical corticosteroid and experienced inadequate response or intolerance; **AND**
  - one preferred topical calcineurin inhibitor (Elidel, Protopic) and experienced inadequate response or intolerance; **AND**
  - documentation of trial and failure of Eucrisa.
- Patient did NOT respond adequately (or is not a candidate) to
  - a 3-month minimum trial of phototherapy; **AND**
  - a 3-month minimum trial of ≥ 1 preferred systemic agent (e.g., cyclosporine, azathioprine, methotrexate, mycophenolate mofetil, dupilumab).
- Patient individual risks and benefits have been considered prior to initiating or continuing therapy in those at higher risk for malignancy and/or major adverse cardiovascular events (MACE).
- Patient is NOT considered to be at high risk for thrombosis and does NOT have an active infection, including clinically important localized infections.

Axial Spondyloarthritis, non-radiographic

- Patient has a documented diagnosis of axial spondyloarthritis, non-radiographic with objective signs of inflammation.
- Patient has had an inadequate response, intolerance, or contraindication (clinical documentation must be submitted demonstrating response to previous therapies) with the following:
  - One or more non-steroidal anti-inflammatory drugs -NSAIDs (trial at maximum dose for at least 2-3 weeks before considering them as failures); **OR**
  - Analgesic agents (e.g. acetaminophen or codeine) if NSAIDs do not completely control the pain.

Crohn's Disease:

- Patient has a documented diagnosis of Crohn's disease (moderate to severe); **AND**
- Patient has inadequate responses, intolerance, or has contraindications to conventional therapy (clinical documentation must be submitted demonstrating response previous therapies):
  - Budesonide, mesalamine, or corticosteroids (e.g. prednisone or methylprednisolone); **OR**
  - Non-biologic DMARDs (e.g. azathioprine, methotrexate, or mercaptopurine); **AND**
- Patient has had a trial of at least one of the preferred alternatives with the FDA approved indication, and experienced inadequate response or intolerance. If a preferred agent(s) is contraindicated, trial of an alternative preferred agent is required, if appropriate.

Cytokine Release Syndrome (CRS):

- Patient has a documented diagnosis of CRS.

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Deficiency of Interleukin-1 Receptor Antagonist (DIRA)

- Patient has a documented diagnosis of DIRA confirmed by genetic testing.

Enthesitis-Related Arthritis (ERA)

- Patient has a documented diagnosis of ERA.
- Patient has had an inadequate response, intolerance, or contraindication (clinical documentation must be submitted demonstrating response to previous therapies) with the following:
    - One or more non-steroidal anti-inflammatory-NSAIDS; **AND**
    - One or more non-biologic- DMARDs (e.g. methotrexate, or sulfasalazine [in patients six and older]).

Hidradenitis Suppurativa

- Patient has a documented diagnosis of Hidradenitis Suppurativa.
- Patient has had a trial and failure on the preferred alternative with the FDA approved indication, and experienced inadequate response or intolerance.

Giant Cell Arteritis (GCA):

- Patient has a documented diagnosis of GCA.
- Patient has had an inadequate response (clinical documentation must be submitted demonstrating response to previous therapies) or failed to tolerate oral corticosteroids (e.g., prednisone, dexamethasone, or methylprednisolone).

Oral Ulcers associated with Behcet's Disease

- Patient has a documented diagnosis of Behcet's Disease.
- Patient has had an inadequate response, intolerance, or contraindication (clinical documentation must be submitted demonstrating response to previous therapies) with the following:
    - Triamcinolone oral paste AND
    - Immunosuppressive agents (e.g. azathioprine, hydroxychloroquine, colchicine)

Periodic Fever Syndromes:

- Patient has a documented diagnosis of Cryopyrin-Associated Periodic Syndromes (CAPS):
    - Muckle-Wells Syndrome
    - Familial Cold Autoinflammatory Syndrome
    - Neonatal-Onset Multisystem Inflammatory Disease/Chronic Infantile Neurological, Cutaneous, Articular Syndrome; OR
- Tumor Necrosis Factor Receptor Associated Periodic Syndrome; OR
- Hyperimmunoglobulin D Syndrome/ Mevalonate Kinase Deficiency; OR
- Familial Mediterranean Fever.

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Plaque Psoriasis:

- Patient has a documented diagnosis of moderate to severe plaque psoriasis for at least 6 months with at least one of the following:
  - Incapacitation due to plaque location (e.g., head and neck, palms, soles, or genitalia); **OR**
  - Involvement of at least 10 percent of body surface area (BSA); **OR**
  - Psoriasis Area and Severity Index (PASI) score of 12 or greater; **AND**
- Patient is free of any clinically important active infections; **AND**
- Patient did not respond adequately (or is not a candidate) to a 3-month minimum trial of at least 1 systemic agent (e.g. immunosuppressives, retinoic acid derivatives, and/or methotrexate); **AND**
- Patient did not respond adequately (or is not a candidate) to a 3 month minimum trial of phototherapy (e.g. Psoralens with UVA light (PUVA), UVB with coal tar or dithranol); **AND**
- Patient has had a trial of at least one of the preferred alternatives with the FDA approved indication, and experienced inadequate response or intolerance. If a preferred agent(s) is contraindicated, trial of an alternative preferred agent is required, if appropriate.

Polyarticular Juvenile Idiopathic Arthritis (PJIA):

- Patient has a documented diagnosis of polyarticular juvenile idiopathic arthritis.
- Patient has had an inadequate response, intolerance, or contraindication (clinical documentation must be submitted demonstrating response to previous therapies) with the following:
  - One or more non-steroidal anti-inflammatory-NSAIDS; **AND**
  - One or more non-biologic- DMARDs (e.g. methotrexate, or sulfasalazine [in patients six and older]); **AND**
- Patient has had a trial of at least one of the preferred alternatives with the FDA approved indication, and experienced inadequate response or intolerance. If the request is for Xeljanz XR, a trial of Xeljanz (immediate-release) is required. If a preferred agent(s) is contraindicated, trial of an alternative preferred agent is required, if appropriate.

Psoriatic Arthritis:

- Patient has a documented diagnosis of psoriatic arthritis; **AND**
- Patient has active psoriatic arthritis for at least 6 months defined as:
  - $\geq$ 3 swollen joints, **AND**
  - $\geq$ 3 tender joints, **AND**
- Patient has had an inadequate response, intolerance, or contraindication (clinical documentation must be submitted demonstrating response previous therapies) with the following:
  - One or more non-steroidal anti-inflammatory drugs –NSAIDs (trial at maximum dose for at least 2-3 weeks before considering them as failures); **AND**
  - One or more non-biologic disease modifying anti-rheumatic drugs DMARDs (e.g. methotrexate, sulfasalazine, leflunomide, or cyclosporine); **AND**
- Patient has had a trial of at least one of the preferred alternatives with the FDA approved indication, and experienced inadequate response or intolerance. If the request is for Xeljanz XR, a trial of Xeljanz (immediate-release) is required. If a preferred agent(s) is contraindicated, trial of an alternative preferred agent is required, if appropriate.

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Recurrent Pericarditis (RP):

- Patient has a documented diagnosis of pericarditis.
- Patient has had an inadequate response, intolerance, or contraindication (clinical documentation must be submitted demonstrating response to previous therapies) with the following:
    - Colchicine **AND**
    - One or more non-steroidal anti-inflammatory drugs (NSAIDS) **AND/OR**
    - Systemic corticosteroids (e.g. prednisone, dexamethasone)

Rheumatoid Arthritis:

- Patient has a documented diagnosis of moderate to severe rheumatoid arthritis.
- Patient has had an inadequate response, intolerance, or contraindication (clinical documentation must be submitted demonstrating response to previous therapies) to one or more non-biologic- DMARDs (e.g. methotrexate, leflunomide, sulfasalazine, or hydroxychloroquine) for at least 3 consecutive months; **AND**
- Patient has had a trial of at least one of the preferred alternatives with the FDA approved indication, and experienced inadequate response or intolerance. If the request is for Xeljanz XR, a trial of Xeljanz (immediate-release) is required. If a preferred agent(s) is contraindicated, trial of an alternative preferred agent is required, if appropriate.

Still's Disease, adult onset:

- Patient has a documented diagnosis of adult onset Still's disease.
- Patient has had an inadequate response, intolerance, or contraindication (clinical documentation must be submitted demonstrating response to previous therapies) with the following:
    - One or more non-steroidal anti-inflammatory-NSAIDS; **AND**
    - One or more non-biologic- DMARDs (e.g. methotrexate or sulfasalazine); **AND**

Systemic Juvenile Idiopathic Arthritis:

- Patient has a documented diagnosis of systemic juvenile idiopathic arthritis.
- Patient has had an inadequate response, intolerance, or contraindication (clinical documentation must be submitted demonstrating response to previous therapies) with the following:
    - One or more non-steroidal anti-inflammatory-NSAIDS; **AND**
    - One or more non-biologic- DMARDs (e.g. methotrexate or sulfasalazine); **AND**

Systemic Sclerosis-Associated Interstitial Lung Disease (SSc-ILD):

- Patient has a documented diagnosis of SSc-ILD.
- Patient has confirmation of diagnosis via high resolution computed tomography.
- Patient must have a baseline Forced Vital Capacity (FVC) test prior to starting treatment.

Ulcerative Colitis:

- Patient has a documented diagnosis of moderately to severely active ulcerative colitis.
- Patient has demonstrated corticosteroid dependence; **OR**

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- Patient has had an inadequate response (clinical documentation must be submitted demonstrating response to previous therapies) or failed to tolerate oral mesalamine, oral corticosteroids (e.g. prednisone, dexamethasone, or methylprednisolone), cyclosporine, azathioprine or 6-mecaptopurine (6-MTP); **AND**
- Patient has had a trial of at least one of the preferred alternatives with the FDA approved indication, and experienced inadequate response or intolerance. If the request is for Xeljanz XR, a trial of Xeljanz (immediate-release) is required. If a preferred agent(s) is contraindicated, trial of an alternative preferred agent is required, if appropriate.

Uveitis:

- Patient has a documented diagnosis of non-infectious intermediate, posterior, and panuveitis.
- Patient has had a trial and failure on the preferred alternative with the FDA approved indication, and experienced inadequate response or intolerance.

CONTINUATION OF THERAPY:

- Patient met initial review requirements.
- Clinical response to therapy submitted (supporting documentation required).
- Dosage and administration do not exceed FDA approved maximum for the patient's indication.
- Supporting documentation required if dose requested exceeds FDA approved maximum.

DOSING AND ADMINISTRATION:

- Refer to product labeling at https://www.accessdata.fda.gov/scripts/cder/daf/