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| 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 |

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, Ilaris, Ilumya, Inflectra, Kevzara, Kineret, Olumiant, Orencia, Otezla, Remicade, Renflexis, Rinvoq ER, Siliq, Simponi, Simponi Aria, Skyrizi, Stelara, Taltz, Tremfya and Xeljanz XR.

LENGTH OF AUTHORIZATION: SIX MONTHS

INITIAL REVIEW CRITERIA:

Ankylosing Spondylitis:

- Patient is ≥ 18 years of age; **AND**
- The prescribing physician is in consultation with or a related clinical specialist.
- Patient has a documented diagnosis of ankylosing spondylitis.
- A negative tuberculin test prior to initiating therapy and results have been provided.
- 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**
- 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.

Axial Spondyloarthritis, non-radiographic

- Patient is ≥ 18 years of age; **AND**
- The prescribing physician is in consultation with or a related clinical specialist.
- Patient has a documented diagnosis of axial spondyloarthritis, non-radiographic with objective signs of inflammation.
- A negative tuberculin test prior to initiating therapy and results have been provided.
- 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.
- Medication(s) with the FDA approved indication for axial spondyloarthritis, non-radiographic will be approved.



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Crohn's Disease:

- The prescribing physician is in consultation with or a related clinical specialist.
- Patient has a documented diagnosis of Crohn's disease (moderate to severe); **AND**
- A negative tuberculin test prior to initiating therapy and results have been provided; **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.

Oral Ulcers associated with Behcet's Disease

- Patient is ≥ 18 years of age; **AND**
- 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)
- Medication(s) with the FDA approved indication for oral ulcers associated with Behcet's disease will be approved.

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.
- Medication(s) with the FDA approved indication for periodic fever syndromes will be approved.

Plaque Psoriasis:

- The prescribing physician is in consultation with or a related clinical specialist.
- Patient has 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 has a negative tuberculin test prior to initiating therapy and results have been provided; **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**



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- 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):

- The prescribing physician is in consultation with or a related clinical specialist.
- 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 a preferred agent(s) is contraindicated, trial of an alternative preferred agent is required, if appropriate.

Psoriatic Arthritis:

- The prescribing physician is in consultation with or a related clinical specialist.
- Patient is ≥ 18 years of age.
- Patient has a documented diagnosis of psoriatic arthritis; **AND**
- A negative tuberculin test prior to initiating therapy and results have been provided; **AND**
- Patient has active psoriatic arthritis for at least 6 months defined as:
 - ≥ 3 swollen joints, **AND**
 - ≥ 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 a preferred agent(s) is contraindicated, trial of an alternative preferred agent is required, if appropriate.

Rheumatoid Arthritis:

- Patient is ≥ 18 years of age.
- The prescribing physician is in consultation with or a related clinical specialist.
- Patient has a documented diagnosis of moderate to severe rheumatoid arthritis.
- A negative tuberculin test prior to initiating therapy and results have been provided.
- 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



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(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 a preferred agent(s) is contraindicated, trial of an alternative preferred agent is required, if appropriate.

Still's Disease, adult onset:

- Patient is ≥ 18 years of age.
- The prescribing physician is in consultation with or a related clinical specialist.
- 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**
- Medication(s) with the FDA approved indication for adult onset Still's disease will be approved.

Systemic Juvenile Idiopathic Arthritis:

- Patient is 2 years of age or older; **AND**
- The prescribing physician is in consultation with or a related clinical specialist.
- 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**
- Medication(s) with the FDA approved indication for systemic juvenile idiopathic arthritis will be approved.

Ulcerative Colitis:

- The prescribing physician is in consultation with or a related clinical specialist.
- Patient has a documented diagnosis of moderately to severely active ulcerative colitis.
- A negative tuberculin test prior to initiating therapy and results have been provided
- Patient has demonstrated corticosteroid dependence; **OR**
- 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-mercaptopurine (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 a preferred agent(s) is contraindicated, trial of an alternative preferred agent is required, if appropriate.



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CONTINUATION OF THERAPY:

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

***** 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