This policy has been developed through review of medical literature, consideration of medical necessity, generally accepted medical practice standards, and approved by the HPSJ Pharmacy and Therapeutic Advisory Committee.

OVERVIEW

Psoriatic arthritis (PsA) is an inflammatory condition that usually involves small joints and skin. Individuals with PsA exhibit both arthritis and psoriasis (PsO) symptoms (i.e. joint pain/stiffness, joint swelling, psoriatic plaque development, and/or nail disfiguration). This review will examine the treatment guidelines of PsA, the currently available PsA drug products, and their coverage criteria.

Severe Psoriatic Arthritis*  Severe Psoriasis*
Erosive disease Psoriasis area & Severity Index (PASI) ≥12
Elevated markers of inflammation (ESR, CRP) Body surface area (BSA) ≥ 10
Long-term damage that interferes with function and causing major impairment in quality of life Significant involvement in specific areas (e.g. face, hands or feet, nails intertriginous areas, scalp)
Many affected sites including dactylitis, enthesitis Burden of the disease causing significant disability
Function-limiting PsA at a few sites, rapidly progressive disease Impairment of physical or mental function and the designation of moderate-to-severe disease despite lower BSA

*The definition of severe PsA and psoriasis as the presence of 1 or more of the items listed. This is not a formal definition. Table adapted from the 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis.

Available Psoriatic Arthritis Agents (Current as of 01/2019)

<table>
<thead>
<tr>
<th>Therapeutic Class</th>
<th>Generic Name (Brand Name)</th>
<th>Available Strengths</th>
<th>Fml Limits</th>
<th>Cost/ Month*</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oral DMARDs</td>
<td>Azathioprine (Imuran)</td>
<td>50mg, 75mg, 100mg</td>
<td>-</td>
<td>$24.20</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Cyclosporine, micronized</td>
<td>25mg, 100mg Capsule</td>
<td>-</td>
<td>$256.86</td>
<td>Regular cyclosporine is non-formulary.</td>
</tr>
<tr>
<td></td>
<td>Leflunomide (Arava)</td>
<td>10mg Tablet</td>
<td>-</td>
<td>$148.78</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Methotrexate Tablet, Vial</td>
<td>2.5mg; 25mg/2ml</td>
<td>-</td>
<td>$61.38</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Sulfasalazine Tablet, DR Tablet</td>
<td>500mg</td>
<td>-</td>
<td>$40.91</td>
<td></td>
</tr>
<tr>
<td>PDE-4 Inhibitor</td>
<td>Apremilast (Otezla)</td>
<td>30mg</td>
<td>PA; PL; SP</td>
<td>$3,121.61</td>
<td>Reserved for treatment failure to one or more oral DMARD but unable to use biologics.</td>
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<tr>
<td>Biologics</td>
<td>Adalimumab (Humira, Humira CF)</td>
<td>20mg/0.4ml, 40mg/0.8ml, 40mg/0.4ml</td>
<td>PA; PL; SP</td>
<td>$4,944.39</td>
<td>Reserved for treatment failure to adequate trial of DMARD therapy.</td>
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<tr>
<td></td>
<td>Etanercept (Enbrel)</td>
<td>25mg/ml, 50mg/ml</td>
<td>PA; PL; SP</td>
<td>$4,997.94</td>
<td>Reserved for treatment failure to adequate trial of DMARD therapy.</td>
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<td></td>
<td>Infliximab-dyyb (Inflectra)</td>
<td>100mg IV vial</td>
<td>PA; PL; SP</td>
<td>--</td>
<td>Reserved for treatment failure to one oral DMARD for 3 months.</td>
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<tr>
<td></td>
<td>Infliximab (Remicade)</td>
<td>100mg IV vial</td>
<td>NF</td>
<td>$8,858.05</td>
<td>Non-Formulary</td>
</tr>
<tr>
<td></td>
<td>Abatacept (Oreicha)</td>
<td>125mg/ml; 250mg IV vial</td>
<td>PA; PL; SP</td>
<td>$3,842.27</td>
<td>Reserved for treatment failure to either Adalimumab, Etanercept, or Infliximab.</td>
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</tbody>
</table>
### EVALUATION CRITERIA FOR APPROVAL/EXCEPTION CONSIDERATION

Below are the coverage criteria and required information for each agent. These coverage criteria have been reviewed approved by the HPSJ Pharmacy & Therapeutics (P&T) Advisory Committee. For conditions not covered under this Coverage Policy, HPSJ will make the determination based on Medical Necessity as described in HPSJ Medical Review Guidelines (UM06).

<table>
<thead>
<tr>
<th>JAK-Inhibitor</th>
<th>Tofacitinib (Xeljanz, Xeljanz XR)</th>
<th>IR: 5mg, XR: 11mg</th>
<th>PA; PL;QL</th>
<th>$5,376.75</th>
<th>Reserved for treatment failure to two 1st line agents OR one 1st line agent and one 2nd line agent.</th>
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<tbody>
<tr>
<td>Golimumab (Simponi)</td>
<td>50mg/0.5ml, 100mg/ml</td>
<td>PA; PL; SP</td>
<td>$4,554.78</td>
<td>Reserved for treatment failure to Adalimumab, Etanercept, OR Infliximab.</td>
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<tr>
<td>Secukinumab (Cosentyx)</td>
<td>150mg/ml</td>
<td>PA; PL; SP</td>
<td>$5,445.48</td>
<td>Reserved for treatment failure to Adalimumab, Etanercept, OR Infliximab.</td>
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<tr>
<td>Ixekizumab (Taltz)</td>
<td>80mg/ml</td>
<td>PA; PL; SP</td>
<td>$7,246.89</td>
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<tr>
<td>Ustekinumab (Stelara)</td>
<td>45mg/0.5ml, 90mg/ml</td>
<td>PA; PL; SP</td>
<td>$10,497.99, $20,995.99</td>
<td>Reserved for treatment failure to two 1st line agents OR one 1st line agent and one 2nd line agent.</td>
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</table>

ST = Step Therapy; QL = Quantity Limit; PL = Prescriber Limit (Must be prescribed by Rheumatologist/Dermatologist); PA = Prior Authorization Required; NF = Non-Formulary; SP = Specialty; DMARDs = Disease Modifying Anti-Rheumatic Drugs; PDE-4 = Phosphodiesterase-4 Inhibitor

### Oral DMARDs

*Azathioprine, Cyclosporine (Modified), Leflunomide, Methotrexate 25mg/ml Vial, Methotrexate Tablets, Sulfasalazine IR/DR Tablets*

- **Coverage Criteria:** None.
- **Limits:** None.
- **Required Information for Approval:** None.
- **Non-Formulary:** Otrexup, Cyclosporine (Regular)

### Phosphodiesterase-4 Inhibitor (PDE-4 Inhibitor)

*Apremilast (Otezla)*

- **Coverage Criteria:** Apremilast is reserved for patients with PsA who have tried an adequate trial of oral DMARD but cannot use biologics (e.g. history of severe infection, etc). Must be prescribed by a rheumatologist or dermatologist.
- **Limits:** None
- **Required Information for Approval:** Clinic notes or prescription history indicating patient has tried at least 12 weeks of dose-optimized oral DMARD (Methotrexate, Cyclosporine, Leflunomide, etc.). If patient is unable to tolerate one oral DMARD, a second oral DMARD must be tried.
- **Other Notes:** Medication is to be dispensed by HPSJ’s designated specialty pharmacy.

### Biologics

*1st line—Adalimumab (Humira), Etanercept (Enbrel), Infliximab-dyyb (Inflectra), Infliximab-abda (Renflexis)*
Coverage Criteria: Reserved for treatment failure to 12 weeks of dose-optimized, oral DMARD therapy (Methotrexate 15-25mg/week, Cyclosporine, Acitretin, and Leflunomide). If patient is unable to tolerate one oral DMARD, a second oral DMARD must be tried. Must be prescribed by a rheumatologist or dermatologist.

Limits: None

Required Information for Approval: Clinic notes or prescription history indicating patient has tried at least 12 weeks of dose-optimized oral DMARD (Methotrexate, Cyclosporine, Leflunomide, etc).

Other Notes:
- Medication is to be dispensed by HPSJ’s designated specialty pharmacy.
- Biologics exceeding labeled standard maintenance doses may be approved 1 month at a time. Subsequent fills of the increased maintenance dose will require documentation of symptom improvement.
- Remicade is non-formulary.

2nd line—Cimzia (Certolizumab), Simponi (Golimumab), Abatacept (Orencia), Secukinumab (Cosentyx)

Coverage Criteria: Reserved for treatment failure documented intolerance to Adalimumab, Etanercept, or Infliximab. Must be prescribed by a rheumatologist or dermatologist.

Limits: None

Required Information for Approval: Prescription history of Adalimumab, Etanercept, or Infliximab.

Other Notes: Medication is to be dispensed by HPSJ’s designated specialty pharmacy. Biologics exceeding labeled standard maintenance doses may be approved 1 month at a time. Subsequent fills of the increased maintenance dose will require documentation of symptom improvement.

3rd line—Ustekinumab (Stelara), Ixekizumab (Taltz), Tofacitinib (Xeljanz, Xeljanz XR)

Coverage Criteria: Ustekinumab, Ixekizumab, Tofacitinib (IR/XR) are reserved for treatment failure documented intolerance to two 1st line agents (adalimumab, etanercept, infliximab) OR one 1st line agent (adalimumab, etanercept, infliximab) and one 2nd line agent (certolizumab, golimumab, secukinumab, abatacept). Must be prescribed by rheumatologist or dermatologist.

Limits: Xeljanz 5mg- 60 tablets per 30 days
Xeljanz XR 11mg- 30 tablets per 30 days

Required Information for Approval: Prescription history, medical authorization history, or clinic notes indicating fills of Adalimumab/Etanercept/Infliximab AND/OR Certolizumab/Golimumab/Secukinumab/Abatacept.

Other Notes: Medication is to be dispensed by HPSJ’s designated specialty pharmacy. Biologics exceeding labeled standard maintenance doses may be approved 1 month at a time. Subsequent fills of the increased maintenance dose will require documentation of symptom improvement.

Clinical Justification

Psoriatic Arthritis

2018 The American College of Rheumatology (ACR) and the National Psoriasis Foundation (NPF) Guideline for the Treatment of Psoriatic Arthritis

Highlights

- Most recommendations are conditional and applies to the majority of patients but may not be appropriate for all (shared decision-approach).
- Strong recommendations for patients with active PsA and concomitant active inflammatory bowel disease despite treatment with an oral small molecule (e.g. methotrexate)
  - Switch to a TNFi monoclonal antibody biologic over switching to a TNFi biologic soluble receptor biologic (i.e, etanercept).
  - Switch to a TNFi monoclonal antibody over switching to an interleukin (IL)-17 biologic
  - Switch to an IL-12/IL-23i biologic over switching to an IL-17i biologic.
• Other strong recommendations:
  o In adult patients with active PsA and frequent serious infections who are naïve to oral small molecule (OSM) and biologic drugs may start an oral small molecule over a TNFi biologic.
  o Smoking cessation over no smoking cessation.
• Conditional Recommendations
  o Treat-to-target approach for all patients with active PsA.
  o For treatment naïve, active PsA patients- use TNFi biologics as first-line therapy over OSM/DMARDs.
  o OSM drugs may be used instead of a TNFi biologic in patients without severe PsA and without severe psoriasis or in those who prefer an oral drug instead of parenteral therapy, or those with contraindications to TNFi treatment (congestive heart failure, previous serious infections, recurrent infections, or demyelinating disease).
  o For treatment-naïve patients with active PsA, the use of TNFi biologic or OSM is recommended over an interleukin-17.
  o An IL-17i or IL-12/23i may be used instead of TNFi biologics with severe psoriasis or contraindications to TNF biologics.
  o In patients with active PsA despite OSM therapy, switching to a TNFI, IL-17i, or an IL-12/23i biologic is recommended over switching to a different OSM. A different OSM may be used rather than a TNFi, IL17i, or IL-12/23i in patients who prefer an oral medication or those without evidence of severe PsA or severe psoriasis.
  o In patients with active PsA despite TNFi treatment, switching to a different TNFi biologic monotherapy is recommended over switching to IL-12/23i biologic, IL-17i biologic, abatacept, or tofacitinib monotherapy or adding methotrexate to the current TNFi biologic. An IL-12/23i biologic, IL-17i biologic, abatacept, or tofacitinib may be used instead of a different TNFi biologic in the case of a primary TNFi biologic failure or serious adverse event to a TNFi.
  o An IL-17i or IL-12/23i biologic may be used instead of a different TNFi biologic, particularly in the presence of severe psoriasis. Abatacept may be used instead of a TNFi biologic in patients with recurrent or serious infections in the absence of severe psoriasis.
  o In treatment-naïve PsA patients with predominant enthesitis, a TNFi biologic is recommended over an OSM as a first-line option.
• The recommendation to use biologics as first-line treatment diverges from recommendations by the European League for Rheumatism (EULAR) for PsA where oral small molecules are recommended as first-line agents for treatment-naïve patients. This was in part due to the lower cost of conventional oral small molecules agents. However, because the ACR/NPF guidelines note that this is a conditional recommendation due to low-to very-low quality evidence, HPSJ will continue to use oral small molecule drugs as first-line agents from a cost effective standpoint. HPSJ will take into consideration with the use of TNF-inhibitors as first line treatments in patients with predominant enthesitis or severe PsA.

The 2015 EULAR PsA Guidelines recommends the following:
Highlights

- Similar to the 2015 ACR Guidelines\(^2\), the 2015 EULAR Guidelines recommend a “treat-to-target” approach for PsA.
  - Patients with active disease should be monitored every 3 months and treatment should be adjusted when appropriate. The TICOPA trial demonstrated patients who had treatment escalation from DMARD therapy to biologics had better therapeutic outcomes when they were monitored and the treatment regimen was adjusted more vigorously.\(^3\)
  - MTX 15-25 mg/week is the preferred oral DMARD, especially for patients with skin involvement.\(^4\)
  - Patients with peripheral arthritis who have tried one or more oral DMARDs 3-6 months should consider therapy with a biologic (i.e. TNF inhibitor).
    - There were no significant differences in efficacy between TNF inhibitors. However, indirect comparison studies found Enbrel to be less efficacious or have a slower onset as compared to the rest of the TNF inhibitors.
  - Patients with peripheral arthritis who have tried one or more oral DMARDs for 3-6 months and cannot use TNF inhibitors, non-TNF biologics (i.e. IL 12/23, IL 17 inhibitors) should be considered.
    - Patients with peripheral arthritis who have tried one or more oral DMARDs for 3-6 months and cannot use biologics, PDE-4 inhibitor (i.e. Apremilast) should be considered.
      - Based on Apremilast’s relatively low efficacy and high cost (relative to the other oral agents), the Task Force concluded that Apremilast should, in most cases, be limited to patients who have tried an adequate trial of oral DMARD but cannot use biologics (e.g. history of severe infection, contraindications to biologics).
  - Patients with predominantly axial disease that is active and has insufficient response to NSAIDs, biologics should be considered (TNF inhibitors should be tried first unless inappropriate or contraindicated, in which non-TNF biologics are considered).
    - Patients who failed one TNF inhibitor should consider switching to another TNF inhibitor.

Treatment for PsA is similar to that of PsO. Skin lesion manifestations will be addressed with psoriatic therapies while joint disease is managed like rheumatoid arthritis. Please see the Psoriasis Medication Coverage Policy for PsO treatment with topical agents when a patient with active PsA has major skin involvement. Most cases of mild PsA (no evidence of bone or joint deformity and dysfunction) should not be automatically treated with biologics. In such cases, NSAIDs and intra-articular corticosteroid injections may be used for symptomatic relief for mild PsA or when only a few joints are involved. Sulfasalazine and leflunomide have shown modest benefit with conflicting data for methotrexate. The 2008 American Academy of Rheumatology guidelines also recommend keeping DMARDs in mind for PsA patients who have failed TNF inhibitors, as well as considering other biologics and small-molecule oral agents.

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**Coverage Policy - Rheumatology/Anti-inflammatory Disorders – Psoriatic Arthritis**
of Dermatology (AAD) and the 2012 British Society for Rheumatology (BSR)/British Health Professionals in Rheumatology (BHPR) PsA treatment guidelines agree that a 12-week trial of dose-optimized oral DMARDs (methotrexate, leflunomide, sulfasalazine, cyclosporine) should be tried prior to use of a biologic agent.\textsuperscript{5-6} The exception to this rule is when the patient has extensive joint involvement (at least 3 or more affected joints)—in which case, biologics may be used alone or in combination with an oral DMARD. Otherwise, patients that demonstrated treatment failure to dose-optimized oral DMARDs for 12 weeks should be given a trial of TNF-inhibitor. Partial responders to biologic therapy should be given a 12-week extension and the therapy continued if there continues to be a response measured during the extension period. The efficacy between biologics do not differ significantly but the cost may vary due to differences in administration frequency (twice monthly vs. weekly vs. monthly, and so forth). Therefore, HPSJ’s order of preference of the biologic therapies are based on the cost-benefit ratio where the first-line biologics are agents associated with the lowest cost-benefit ratio.

**Role of oral agents (DMARDs and immunosuppressants)**

Oral DMARDs are commonly used as first-line therapies in many mild-moderate inflammatory disorders with a few exceptions (e.g. Ankylosing Spondylitis). For most patients, treatment with oral agents may be sufficient for their condition. Generally, 12 weeks of continuous DMARD therapy is considered to be an adequate trial—assuming the drug is adequately dosed. In patients with liver and/or renal impairment, DMARDs are not necessarily excluded right away. In most cases, DMARDs can be safely used as long as there is regular monitoring of labs and side effects and the dosing is adjusted accordingly.

<table>
<thead>
<tr>
<th>Oral Agent</th>
<th>Joint</th>
<th>Skin</th>
<th>G.I.</th>
<th>liver damage</th>
<th>kidney damage</th>
<th>Pregnancy</th>
<th>Breastfeeding</th>
</tr>
</thead>
<tbody>
<tr>
<td>Azathioprine</td>
<td>X</td>
<td>X*</td>
<td>X</td>
<td>monitor</td>
<td>monitor &amp; dose adjust</td>
<td>Avoid use</td>
<td>Not recommended</td>
</tr>
<tr>
<td>Cyclosporine</td>
<td>X*</td>
<td>X</td>
<td>X*</td>
<td>monitor</td>
<td>monitor &amp; dose adjust</td>
<td>Avoid use</td>
<td>Not recommended</td>
</tr>
<tr>
<td>Leflunomide</td>
<td>X</td>
<td>X*</td>
<td>X</td>
<td>avoid use</td>
<td>avoid use</td>
<td>Contraindicated</td>
<td>Unknown</td>
</tr>
<tr>
<td>Mercaptopurine</td>
<td>X*</td>
<td>X</td>
<td>X*</td>
<td>monitor</td>
<td>monitor &amp; dose adjust</td>
<td>Avoid use</td>
<td>Unknown</td>
</tr>
<tr>
<td>Methotrexate</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>avoid use</td>
<td>monitor &amp; dose adjust</td>
<td>Contraindicated</td>
<td>Contraindicated</td>
</tr>
<tr>
<td>Sulfasalazine</td>
<td>X</td>
<td>X*</td>
<td>X</td>
<td>monitor</td>
<td>monitor</td>
<td>Generally safe</td>
<td>Generally safe</td>
</tr>
</tbody>
</table>

*limited evidence

**Special Populations**

**Pregnancy**

Guidelines for pregnancy, as stated by the Canadian guidelines and the American National Psoriasis Foundation, indicate that 1\textsuperscript{st} line therapy includes low- to moderate potency corticosteroids, 2\textsuperscript{nd} line therapy includes narrow band UVB, and 3\textsuperscript{rd} line therapy, only to be used if benefits outweigh risks, includes cyclosporine or TNF inhibitors.\textsuperscript{20-21} Other DMARDS deemed safe include sulfasalazine and azathioprine, and possibly leflunomide.\textsuperscript{22} Azathioprine has a risk for premature births and, although limited animal data contraindicates its use, leflunomide has an apparently low human teratogenicity risk. Cyclosporine and sulfasalazine seem to be the safest or most preferred DMARD agents.\textsuperscript{22}

**Elevated LFTs**

Specific guidelines for patients who have elevated LFTs are not available, but the American Academy of Dermatology guidelines do have suggestions for LFT monitoring and some recommendations on protocol if LFTs are elevated to a certain level. For methotrexate, if elevation exceeds 2x normal levels, LFT monitoring must be checked more frequently; if elevation exceeds 3x normal levels, consider dose reduction (administer 75% of dose); if elevation exceeds 5x normal, discontinuation of the medication is recommended. No other drugs have specific guidelines for LFT levels.\textsuperscript{23} The 2008 ACR guidelines state that leflunomide, methotrexate, and sulfasalazine should not be started nor resumed if liver transaminases were >2x the upper normal limit. Despite this, there are no recommendations on discontinuation.\textsuperscript{24} A paper regarding expert opinion on the treatment of psoriasis in special circumstances speaks to the use of biologics in the setting of
fatty liver disease. The panel considered etanercept and ustekinumab to be the best options for use in a patient with fatty liver disease.25

REFERENCES

32. Prescribing information: Taltz. Indianapolis, Indiana; Eli Lilly and Company
34. Prescribing information: Xeljanz and Xeljanz XR® NY, NY; Pfizer Labs.

**REVIEW & EDIT HISTORY**

<table>
<thead>
<tr>
<th>Document Changes</th>
<th>Reference</th>
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<th>P&amp;T Chairman</th>
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<tr>
<td>Creation of Policy</td>
<td>Psoriasis - biologicals 2-20-07.doc</td>
<td>2/2007</td>
<td>Allen Shek, PharmD</td>
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<td>Updated Policy</td>
<td>Biological Response Modifiers Review 2-19-08.doc</td>
<td>2/2008</td>
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<td>Updated Policy</td>
<td>HPA Suppression among Medium Potency Topical Corticosteroids.doc</td>
<td>6/2008</td>
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<td>Biologic Response Modifiers 2010 final.docx</td>
<td>5/2010</td>
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<td>2/2012</td>
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<td>10/2014</td>
<td>Jonathan Szkotak, PharmD</td>
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<td>Updated Policy</td>
<td>Class Review of Topical &amp; Systemic Agents Used for Skin Inflammation Disorders with an Emphasis on Psoriasis.docx</td>
<td>5/2015</td>
<td>Jonathan Szkotak, PharmD</td>
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<tr>
<td>Updated Policy</td>
<td>Class Review- Biologics, Apremilast, and Tofacitinib in Inflammatory Joint, Skin, and Bowel Diseases.docx</td>
<td>2/2016</td>
<td>Johnathan Yeh, PharmD</td>
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<td>Updated Policy</td>
<td>HPSJ Coverage Policy - Rheum &amp; Immuno - Psoriatic Arthritis 2017-02.docx</td>
<td>2/2017</td>
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<td>05/2019</td>
<td>Matthew Garrett, Pharm D</td>
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Note: All changes are approved by the HPSJ P&T Committee before incorporation into the utilization policy.