



# Otezla (apremilast) Prior Authorization with Quantity Limit Program Summary

## POLICY REVIEW CYCLE

Effective Date  
06-01-2025

Date of Origin

## FDA LABELED INDICATIONS AND DOSAGE

| Agent(s)                                  | FDA Indication(s)                                                                                                                                                                                                                                                                                                                                                                                                                                              | Notes | Ref# |
|-------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------|------|
| Otezla®<br><br>(apremilast)<br><br>Tablet | Treatment of adult patients with active psoriatic arthritis<br><br>Treatment of adult patients with plaque psoriasis who are candidates for phototherapy or systemic therapy<br><br>Treatment of pediatric patients 6 years of age and older and weighing at least 20 kg with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy<br><br>Treatment of adult patients with oral ulcers associated with Behcet's disease |       | 1    |

See package insert for FDA prescribing information: <https://dailymed.nlm.nih.gov/dailymed/index.cfm>

## CLINICAL RATIONALE

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| Psoriasis (PS) | <p>Psoriasis (PS) is a chronic inflammatory skin and systemic disorder. It is a complex disease that affects the skin and joints and is associated with numerous comorbidities, including obesity and inflammatory bowel disease. Psoriasis vulgaris, or plaque psoriasis, is a cutaneous form that often presents with pink plaques with silvery scale on the scalp, elbows, knees, or presacral region, but any area of the skin may be involved.(4,5) Plaque psoriasis is the most common form (affecting 90% of adults with psoriasis), but others include guttate, erythrodermic, pustular, inverse, nail, and psoriatic arthritis (PsA). PS is clinically diagnosed based on the presence of cutaneous and systemic symptoms, and treatment is similar for most forms but is guided by the body surface area (BSA) involved.(2)</p> <p>The American Academy of Dermatology (AAD) and National Psoriasis Foundation (NPF) categorize psoriasis severity as mild (less than 3% of body BSA), moderate (3% to 10% of BSA), or severe (greater than 10% of BSA). The AAD/NPF guidelines also note that psoriasis can be considered severe irrespective of BSA when it causes serious emotional consequences, occurs in select locations (e.g., hands, feet, scalp, face, or genital area), or when it causes intractable pruritus.(4)</p> <p>Topical therapies are most commonly used to treat mild to moderate PS, but they may be used in combination with phototherapy, systemic, or biologic therapies for the treatment of moderate to severe PS.(9) Topical therapies alone can be sufficient for managing limited disease and also have fewer significant adverse effects compared to systemic treatment options. However, topical therapies may be inadequate to obtain and maintain skin clearance, and systemic therapies may be warranted. Conventional systemic agents are widely used as monotherapy or in combination with biologics for moderate to severe disease, and they are beneficial for widespread disease and ease of administration.(5) Biologics are routinely used when one or more conventional</p> |
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agents fail to produce an adequate response, but are considered first line in patients with severe PS or patients with concomitant severe PsA.(7)

The NPF medical board recommends a treat-to-target approach to therapy for psoriasis that includes the following: (6)

- The preferred assessment instrument for determining treatment response is BSA
- The preferred time to perform initial evaluation of treatment response is after 3 months
- Target response after treatment initiation should be BSA less than or equal to 1% after 3 months
- Acceptable response is either a BSA less than or equal to 3% or a BSA improvement greater than or equal to 75% from baseline at 3 months after treatment initiation

Selection of treatment is based on several factors including benefit-risk assessment, clinical presentation, disease severity, and comorbidities.(6) The AAD/NPF psoriasis treatment guidelines support the following treatment options:

- Topical therapies: (9)
  - Topical corticosteroids (TCS)
  - Topical calcineurin inhibitors (TCIs), such as tacrolimus and pimecrolimus
  - Vitamin D analogues (e.g., calcipotriene and calcitriol)
  - Tazarotene (topical retinoid)
  - Coal tar preparations
  - Topical anthralin
- Psoralen plus ultraviolet light (PUVA) phototherapy(3)
- Systemic non-biologic therapies: (5)
  - Methotrexate
  - Cyclosporine
  - Acitretin
  - Apremilast
- Biologic therapies: (4)
  - Tumor necrosis factor (TNF)- $\alpha$  inhibitors (e.g., adalimumab, certolizumab, etanercept, infliximab)
  - Interleukin (IL)-17 inhibitors (e.g., brodalumab, ixekizumab, secukinumab)
  - IL-23 inhibitors (e.g., guselkumab, risankizumab, tildrakizumab)
  - IL-12/IL-23 Inhibitors (e.g., ustekinumab)
  - \*Note: Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics was published in 2019. No specific biologic drug/class is recommended as first-line for all patients with psoriasis, and instead choice of therapy should be individualized based on patient specific factors. Additional biologic drugs have since received FDA approval for psoriasis that are not discussed.

Primary failure for biologics is defined as initial nonresponse to treatment. Primary failure to a tumor necrosis factor (TNF)- $\alpha$  inhibitor does not preclude successful response to a different TNF- $\alpha$  inhibitor, and failure of another biologic therapy does not preclude successful response to ustekinumab. All biologics may lose efficacy in a patient who initially responds favorably to the medication (secondary failure), and loss of efficacy may be attributed to the presence of antidrug antibodies. The concomitant use of MTX with a biologic may increase drug survival by limiting antibody formation.(4)

For the treatment of PS in the pediatric patient population, topical corticosteroids are the mainstay option based on extensive clinical experience that supports efficacy. Topical calcineurin inhibitors are also a treatment option and may be preferred for psoriasis of the face, genitalia, and body folds. Vitamin D analogues are recommended as a treatment option for childhood plaque psoriasis and are considered safe, effective,

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|                           | <p>and generally well tolerated. Other topical therapies that may be used for the treatment of pediatric psoriasis include tazarotene, anthralin, and coal tar. Phototherapy may be efficacious and well tolerated for pediatric patients with generalized psoriasis or localized psoriasis refractory to topical agents. Systemic non-biologic therapies, such as methotrexate, cyclosporine, and acitretin, are options for moderate to severe psoriasis. Biologic therapies (e.g., adalimumab, etanercept, infliximab, ustekinumab) have also shown efficacy in moderate to severe plaque psoriasis in this patient population.(10)</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| Psoriatic Arthritis (PsA) | <p>Psoriatic arthritis (PsA) is a chronic inflammatory musculoskeletal disease associated with psoriasis (PS), most commonly presenting with peripheral arthritis, dactylitis, enthesitis, and spondylitis. Active PsA is defined as symptoms at an unacceptably bothersome level as reported by the patient due to one of the following: actively inflamed joints, dactylitis, enthesitis, axial disease, active skin and/or nail involvement, and/or extraarticular manifestations such as uveitis or inflammatory bowel disease (IBD).(7)</p> <p>Disease severity is based on the assessment of the level of disease activity at a given point in time, and the presence/absence of poor prognostic factors and long-term damage. Severe PsA is defined in the American College of Rheumatology (ACR) and the National Psoriasis Foundation (NPF) guidelines for PsA and includes the presence of one or more of the following: (7)</p> <ul style="list-style-type: none"> <li>• Erosive disease</li> <li>• Elevated markers of inflammation (e.g., erythrocyte sedimentation rate [ESR], C-reactive protein [CRP]) attributable to PsA</li> <li>• Long-term damage that interferes with function (e.g., joint deformities, vision loss)</li> <li>• Highly active disease that causes a major impairment in quality of life, such as: <ul style="list-style-type: none"> <li>◦ Active PsA at many sites including dactylitis and enthesitis</li> <li>◦ Function-limiting PsA at a few sites</li> </ul> </li> <li>• Rapidly progressive disease</li> </ul> <p>Treatment involves the use of a variety of interventions, including many agents used for the treatment of other inflammatory arthritis disorders, particularly spondyloarthritis and rheumatoid arthritis, and other management strategies of the cutaneous manifestations of psoriasis. Symptomatic treatments include nonsteroidal anti-inflammatory drugs (NSAIDs), glucocorticoids, and local glucocorticoid injections.(7) Only patients with very mild peripheral disease may sufficiently benefit from NSAIDs as monotherapy, and instead patients are typically treated with disease-modifying antirheumatic drugs (DMARDs) and/or biologics. Efficacy of DMARD and biologic therapies should be assessed 3 months after initiation, and if adequate improvement is not seen then the treatment regimen should be updated or changed.(11)</p> <p>The ACR-NPF guidelines for PsA recommend a treat-to-target approach in therapy, regardless of disease activity, and treatment recommendations for active disease are as follows: (7)</p> <ul style="list-style-type: none"> <li>• <b>Treatment naïve patients:</b> <ul style="list-style-type: none"> <li>• First line options include oral small molecules (OSM), tumor necrosis factor (TNF) inhibitors, interleukin (IL)-17 inhibitors, and IL-12/23 inhibitors <ul style="list-style-type: none"> <li>▪ OSM (i.e., methotrexate [MTX], sulfasalazine, cyclosporine, leflunomide, apremilast) should be considered if the patient does not have severe PsA, does not have severe PS, prefers oral therapy, has concern over starting a biologic, or has contraindications to TNF inhibitors</li> </ul> </li> </ul> </li> </ul> |

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|                       | <ul style="list-style-type: none"> <li>▪ Biologics (e.g., TNF inhibitor, IL-17 inhibitor, IL-12/23 inhibitor) are recommended as a first line option in patients with severe PsA and/or severe PS</li> <li>• Previous treatment with OSM and continued active disease: <ul style="list-style-type: none"> <li>• Switch to a biologic (i.e., TNF inhibitor, IL-17 inhibitor, IL-12/23 inhibitor); recommended over switching to a different OSM <ul style="list-style-type: none"> <li>▪ Biologic monotherapy is conditionally recommended over biologic plus MTX combination therapy</li> </ul> </li> <li>• Switch to a different OSM (except apremilast) OR add on apremilast to current OSM therapy; recommended over adding another OSM</li> <li>• Add another OSM (except apremilast) to current OSM therapy; may consider for patients that have exhibited partial response to current OSM</li> <li>• Switch to apremilast monotherapy; may be considered instead of adding apremilast to current OSM therapy if the patient has intolerable side effects with the current OSM</li> </ul> </li> <li>• Previous treatment with a biologic and continued active disease: <ul style="list-style-type: none"> <li>• Switch to another biologic (e.g., TNF inhibitor, IL-17 inhibitor, IL-12/23 inhibitor, abatacept, or tofacitinib) as monotherapy</li> <li>• Add MTX to the current biologic; may consider adding MTX in patients with a partial response to current biologic therapy</li> </ul> </li> </ul> <p>The European Alliance of Associations for Rheumatology (EULAR) guidelines for PsA (2023 update) also recommend a treat-to-target approach in therapy. MTX (preferred) or another conventional synthetic disease-modifying antirheumatic drug (csDMARD) (e.g., sulfasalazine, leflunomide) should be used for initial therapy. If the treatment target is not achieved with a csDMARD, a biologic should be initiated with preference of product being based on patient specific disease characteristics. Biologics include TNF inhibitors, IL-12/23 inhibitors, IL-17A inhibitors, IL-17A/F inhibitors, IL-23 inhibitors, and cytotoxic T-lymphocyte-associated antigen 4 (CTLA4) analogs. No order of preference of biologics is provided since none have demonstrated superiority for joint involvement, however, CTLA4 analogs are least preferred due to limited efficacy in clinical trials. The use of a Janus kinase (JAK) inhibitor (e.g., tofacitinib, upadacitinib) may be used after failure of a biologic or if biologics are not clinically appropriate for the patient. However, careful consideration should be applied prior to using a JAK inhibitor due to the increased risk of cardiovascular and malignancy events in older patients with RA and cardiovascular risk factors. A phosphodiesterase-4 (PDE4) inhibitor (i.e., apremilast) may be considered in patients with mild disease and an inadequate response to at least one csDMARD, in whom neither a biologic nor a JAK inhibitor is appropriate. Patients with an inadequate response to a biologic or JAK inhibitor may switch to a different drug within the same class or switch to a different mode of action. Adding MTX to a biologic may increase drug survival by limiting the development of antidrug antibodies, especially for TNF inhibitors.(11)</p> |
| Behcet's Disease (BD) | <p>Behcet's disease (BD) is a chronic systemic inflammatory disease, defined as a variable vessel vasculitis, characterized by mucocutaneous lesions and involves numerous organ systems (e.g., mucocutaneous, musculoskeletal, ocular, vascular, neurologic, and gastrointestinal). BD has a relapsing-remitting course of disease and usually begins in the second or third decade of life. Recurring oral ulcers are seen in over 95% of patients and are typically the first clinical manifestation of the disease, usually preceding the diagnosis by an average of 6 to 7 years. No disease specific laboratory, histopathologic, or genetic findings exist to diagnose a patient with BD, and instead the diagnosis is mainly based on clinical presentation and findings.(12) The International Study Group (ISG) criteria for the diagnosis of Behcet's disease should be considered when diagnosing people with suspected BD.(13). It is the most widely used diagnosis criteria and has been shown to have 95% sensitivity and 98% specificity. In order to meet ISG criteria, a patient must have recurrent oral ulceration, with at least three occurrences during a 12-month period.(12)</p> <p>The goal of treatment in patients with BD is to suppress inflammatory exacerbations and recurrences to prevent irreversible organ damage. Disease manifestations may</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |

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|          | <p>improve over time in many patients. Ocular, vascular, neurological, and gastrointestinal involvement may be associated with a poor prognosis. Treatment needs to be individualized based on the type and severity of organ involvement, and a multidisciplinary approach is necessary for optimal care. Skin, mucosa, and joint involvement can impair a patient's quality of life but typically does not cause permanent damage. However, if scarring occurs due to chronic oral ulceration, vigorous treatment is needed to prevent oropharyngeal narrowing.(8)</p> <p>For the treatment of an acute exacerbation of oral ulcers, a topical corticosteroid (i.e., triamcinolone acetonide oral paste) should be used as it may help with the rapid healing of the lesions.(8) A topical corticosteroid may also be used as adjunctive therapy with a systemic immunosuppressant in patients with more severe disease. If topical corticosteroid therapy alone is inadequate to control the disease, colchicine should be used to treat mucocutaneous lesions.(13) Colchicine should be tried first for the prevention of recurrent mucocutaneous lesions due to its safety and tolerability.(8) If lesions continue to recur despite colchicine, immunomodulatory or immunosuppressive agents, such as azathioprine or apremilast, can be used.(8,13)</p> |
| Efficacy | <p><b>Behçet's Disease:</b></p> <p>The efficacy of Otezla for the treatment of oral ulcers associated with Behçet's disease (BD) was established in a multicenter, randomized, placebo-controlled trial (NCT02307513).(1) Patients were required to have a diagnosis of BD according to International Study Group criteria and have active oral ulcers at the time of enrollment and randomization. Patients had to have at least 3 occurrences of oral ulcers within the previous 12 months despite previous treatment with at least one non-biologic therapy (e.g., topical corticosteroids, colchicine, immunosuppressants).(14) All subjects had a history of recurrent oral ulcers that were currently active. Otezla had a greater reduction in the number of oral ulcers and patient reported ulcer pain when compared to placebo.(1)</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| Safety   | <p>Otezla is contraindicated in patients with a known hypersensitivity to apremilast or to any of the excipients in the formulation.(1)</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |

## REFERENCES

| Number | Reference                                                                                                                                                                                                                                                                                                        |
|--------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1      | Otezla prescribing information. Amgen Inc. May 2024.                                                                                                                                                                                                                                                             |
| 2      | Garner KK, Hoy KDS, Carpenter AM. Psoriasis: Recognition and Management Strategies. <i>Am Fam Physician</i> . 2023;108(6):562-573.                                                                                                                                                                               |
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| 4      | Menter A, Strober BE, Kaplan DH, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. <i>Journal of the American Academy of Dermatology</i> . 2019;80(4):1029-1072. doi: 10.1016/j.jaad.2018.11.057                                                             |
| 5      | Menter A, Gelfand JM, Connor C, et al. Joint American Academy of Dermatology–National Psoriasis Foundation guidelines of care for the management of psoriasis with systemic nonbiologic therapies. <i>Journal of the American Academy of Dermatology</i> . 2020;82(6):1445-1486. doi: 10.1016/j.jaad.2020.02.044 |
| 6      | Armstrong AW, Siegel MP, Bagel J, et al. From the medical board of the National Psoriasis Foundation: treatment targets for plaque psoriasis. <i>Journal of the American Academy of Dermatology</i> . 2017;76(2):290-298. doi: 10.1016/j.jaad.2016.10.017.                                                       |
| 7      | Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis. <i>Arthritis Care &amp; Research</i> . 2018;71(1):2-29. doi: 10.1002/acr.23789                                                                       |
| 8      | Hatemi G, Christensen R, Bang D, et al. 2018 update of the EULAR recommendations for the management of Behçet's syndrome. <i>Annals of the Rheumatic Diseases</i> . 2018;77:808-818. doi: 10.1136/annrheumdis-2018-213225                                                                                        |

| Number | Reference                                                                                                                                                                                                                                                                                                                      |
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| 9      | Elmets CA, Korman NJ, Prater EF, et al. Joint AAD–NPF Guidelines of care for the management and treatment of psoriasis with topical therapy and alternative medicine modalities for psoriasis severity measures. <i>Journal of the American Academy of Dermatology</i> . 2021; 84(2): 432-470. doi: 10.1016/j.jaad.2020.07.087 |
| 10     | Menter A, Cordoro KM, Davis DMR, et al. Joint American Academy of Dermatology–National Psoriasis Foundation guidelines of care for the management and treatment of psoriasis in pediatric patients. <i>Journal of the American Academy of Dermatology</i> . 2020; 82(1): 161-201. doi: 10.1016/j.jaad.2019.08.049              |
| 11     | Gossec L, Kerschbaumer A, Ferreira RJO, et al. EULAR recommendations for the management of psoriatic arthritis with pharmacological therapies: 2023 update. <i>Annals of the Rheumatic Diseases</i> . 2024; 83(6): 706-719. doi: 10.1136/ard-2024-225531                                                                       |
| 12     | Alibaz-Oner F, Direskeneli H. Update on the diagnosis of Behçet’s disease. <i>Diagnostics</i> . 2022; 13(1): 41. doi: 10.3390/diagnostics13010041                                                                                                                                                                              |
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| 14     | Hatemi G, Mahr A, Ishigatsubo Y, et al. Trial of apremilast for oral ulcers in Behçet’s syndrome. <i>New England Journal of Medicine</i> . 2019; 381(20): 1918-1928. doi: 10.1056/nejmoa1816594                                                                                                                                |

## POLICY AGENT SUMMARY PRIOR AUTHORIZATION

| Target Brand Agent(s) | Target Generic Agent(s)                                 | Strength                                             | Targeted MSC  | Available MSC | Final Age Limit | Preferred Status |
|-----------------------|---------------------------------------------------------|------------------------------------------------------|---------------|---------------|-----------------|------------------|
| Otezla                | apremilast tab ;<br>apremilast tab starter therapy pack | 10 & 20 & 30 MG ; 20 MG ; 30 MG ; 4 x 10 & 51 x20 MG | M ; N ; O ; Y | N             |                 |                  |

## POLICY AGENT SUMMARY QUANTITY LIMIT

| Target Brand Agent Name(s) | Target Generic Agent Name(s)                              | Strength           | QL Amount | Dose Form | Day Supply | Duration | Addtl QL Info | Allowed Exceptions | Targeted NDCs When Exclusions Exist |
|----------------------------|-----------------------------------------------------------|--------------------|-----------|-----------|------------|----------|---------------|--------------------|-------------------------------------|
| Otezla                     | apremilast tab                                            | 20 MG              | 60        | Tablets   | 30         | DAYS     |               |                    |                                     |
| Otezla                     | Apremilast Tab 30 MG                                      | 30 MG              | 60        | Tablets   | 30         | DAYS     |               |                    |                                     |
| Otezla                     | apremilast tab starter therapy pack                       | 4 x 10 & 51 x20 MG | 1         | Pack      | 180        | DAYS     |               |                    |                                     |
| Otezla                     | Apremilast Tab Starter Therapy Pack 10 MG & 20 MG & 30 MG | 10 & 20 & 30 MG    | 1         | Pack      | 180        | DAYS     |               |                    |                                     |

## CLIENT SUMMARY – PRIOR AUTHORIZATION

| Target Brand Agent Name(s) | Target Generic Agent Name(s)                         | Strength                                             | Client Formulary             |
|----------------------------|------------------------------------------------------|------------------------------------------------------|------------------------------|
| Otezla                     | apremilast tab ; apremilast tab starter therapy pack | 10 & 20 & 30 MG ; 20 MG ; 30 MG ; 4 x 10 & 51 x20 MG | Commercial ; HIM ; ResultsRx |

## CLIENT SUMMARY – QUANTITY LIMITS

| Target Brand Agent Name(s) | Target Generic Agent Name(s)                              | Strength           | Client Formulary             |
|----------------------------|-----------------------------------------------------------|--------------------|------------------------------|
| Otezla                     | apremilast tab                                            | 20 MG              | Commercial ; HIM ; ResultsRx |
| Otezla                     | Apremilast Tab 30 MG                                      | 30 MG              | Commercial ; HIM ; ResultsRx |
| Otezla                     | apremilast tab starter therapy pack                       | 4 x 10 & 51 x20 MG | Commercial ; HIM ; ResultsRx |
| Otezla                     | Apremilast Tab Starter Therapy Pack 10 MG & 20 MG & 30 MG | 10 & 20 & 30 MG    | Commercial ; HIM ; ResultsRx |

## PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

| Module                                                     | Clinical Criteria for Approval                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                                    |                                                            |
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| PA                                                         | <p><b>Initial Evaluation</b></p> <p><b>Target Agent(s)</b> will be approved when the ALL of the following are met:</p> <p>1. ONE of the following:</p> <p>A. The requested agent is eligible for continuation of therapy AND ONE of the following:</p> <table border="1"><tr><td><b>Agents Eligible for Continuation of Therapy</b></td></tr><tr><td>All target agents are eligible for continuation of therapy</td></tr></table> <p>1. The patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days <b>OR</b></p> <p>2. The prescriber states the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days AND is at risk if therapy is changed <b>OR</b></p> <p>B. BOTH of the following:</p> <p>1. ONE of the following:</p> <p>A. The patient has a diagnosis of active psoriatic arthritis (PsA) AND ONE of the following:</p> <p>1. The patient has ONE of the following:</p> <p>A. Has tried and had an inadequate response to ONE conventional agent (i.e., cyclosporine, leflunomide, methotrexate, sulfasalazine) used in the treatment of PsA after at least a 3-month duration of therapy <b>OR</b></p> <p>B. Has an intolerance or hypersensitivity to ONE conventional agent used in the treatment of PsA <b>OR</b></p> <p>2. The patient has an FDA labeled contraindication to ALL conventional agents used in the treatment of PsA <b>OR</b></p> <p>3. The patient's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of PsA <b>OR</b></p> <p>B. The patient has a diagnosis of plaque psoriasis (PS) AND BOTH of the following:</p> <p>1. ONE of the following:</p> | <b>Agents Eligible for Continuation of Therapy</b> | All target agents are eligible for continuation of therapy |
| <b>Agents Eligible for Continuation of Therapy</b>         |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                                    |                                                            |
| All target agents are eligible for continuation of therapy |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                                    |                                                            |

| Module | Clinical Criteria for Approval                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
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|        | <ul style="list-style-type: none"> <li>A. The patient is an adult with mild to severe plaque psoriasis <b>OR</b></li> <li>B. The patient is a pediatric patient 6 years of age or older AND BOTH of the following: <ul style="list-style-type: none"> <li>1. The patient has moderate to severe plaque psoriasis <b>AND</b></li> <li>2. The patient weighs at least 20 kg <b>AND</b></li> </ul> </li> <li>2. ONE of the following: <ul style="list-style-type: none"> <li>A. The patient has ONE of the following: <ul style="list-style-type: none"> <li>1. Has tried and had an inadequate response to ONE conventional agent (i.e., acitretin, anthralin, calcipotriene, calcitriol, coal tar products, cyclosporine, methotrexate, pimecrolimus, PUVA [phototherapy], tacrolimus, tazarotene, topical corticosteroids) used in the treatment of PS after at least a 3-month duration of therapy <b>OR</b></li> <li>2. Has an intolerance or hypersensitivity to ONE conventional agent used in the treatment of PS <b>OR</b></li> </ul> </li> <li>B. The patient has an FDA labeled contraindication to ALL conventional agents used in the treatment of PS <b>OR</b></li> <li>C. The patient's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of PS <b>OR</b></li> </ul> </li> <li>C. The patient has a diagnosis of Behcet's disease (BD) AND ALL of the following: <ul style="list-style-type: none"> <li>1. The patient has active oral ulcers associated with BD <b>AND</b></li> <li>2. The patient has had at least 3 occurrences of oral ulcers in the last 12-months <b>AND</b></li> <li>3. ONE of the following: <ul style="list-style-type: none"> <li>A. The patient has ONE of the following: <ul style="list-style-type: none"> <li>1. Has tried and had an inadequate response to ONE conventional agent (i.e., topical oral corticosteroids [i.e., triamcinolone dental paste], colchicine, azathioprine) used in the treatment of BD <b>OR</b></li> <li>2. Has an intolerance or hypersensitivity to ONE conventional agent used in the treatment of BD <b>OR</b></li> </ul> </li> <li>B. The patient has an FDA labeled contraindication to ALL conventional agents used in the treatment of BD <b>OR</b></li> <li>C. The patient's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of BD <b>OR</b></li> </ul> </li> <li>D. The patient has another FDA labeled indication for the requested agent and route of administration <b>AND</b></li> </ul> </li> <li>2. If the patient has an FDA labeled indication, then ONE of the following: <ul style="list-style-type: none"> <li>A. The patient's age is within FDA labeling for the requested indication for the requested agent <b>OR</b></li> <li>B. There is support for using the requested agent for the patient's age for the requested indication <b>OR</b></li> <li>C. The patient has another indication that is supported in compendia for the requested agent and route of administration <b>AND</b></li> </ul> </li> <li>2. ONE of the following (Please refer to "Agents NOT to be used Concomitantly" table):</li> </ul> |



| Module | Clinical Criteria for Approval                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
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|        | <p>A. The patient will NOT be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors) <b>OR</b></p> <p>B. The patient will be using the requested agent in combination with another immunomodulatory agent AND BOTH of the following:</p> <ol style="list-style-type: none"> <li>1. The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agent <b>AND</b></li> <li>2. There is support for the use of combination therapy (submitted copy of clinical trials, phase III studies, or guidelines required) <b>AND</b></li> </ol> <p>3. ONE of the following:</p> <ol style="list-style-type: none"> <li>A. The patient has a diagnosis of mild severity plaque psoriasis <b>OR</b></li> <li>B. The prescriber is a specialist in the area of the patient's diagnosis (e.g., dermatologist, rheumatologist), or the prescriber has consulted with a specialist in the area of the patient's diagnosis <b>AND</b></li> </ol> <p>4. The patient does NOT have any FDA labeled contraindications to the requested agent</p> <p><b>Compendia Allowed:</b> AHFS, DrugDex 1 or 2a level of evidence, or NCCN 1 or 2a recommended use</p> <p><b>Length of Approval:</b> 12 months</p> <p>NOTE: Quantity Limit applies, please refer to Quantity Limit Criteria.</p> <p><b>Renewal Evaluation</b></p> <p><b>Target Agent(s)</b> will be approved when ALL of the following are met:</p> <ol style="list-style-type: none"> <li>1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process [Note: patients not previously approved for the requested agent will require initial evaluation review] <b>AND</b></li> <li>2. The patient has had clinical benefit with the requested agent <b>AND</b></li> <li>3. ONE of the following (Please refer to "Agents NOT to be used Concomitantly" table): <ol style="list-style-type: none"> <li>A. The patient will NOT be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors) <b>OR</b></li> <li>B. The patient will be using the requested agent in combination with another immunomodulatory agent AND BOTH of the following: <ol style="list-style-type: none"> <li>1. The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agent <b>AND</b></li> <li>2. There is support for the use of combination therapy (submitted copy of clinical trials, phase III studies, or guidelines required) <b>AND</b></li> </ol> </li> </ol> </li> <li>4. ONE of the following: <ol style="list-style-type: none"> <li>A. The patient has a diagnosis of mild severity plaque psoriasis <b>OR</b></li> <li>B. The prescriber is a specialist in the area of the patient's diagnosis (e.g., dermatologist, rheumatologist), or the prescriber has consulted with a specialist in the area of the patient's diagnosis <b>AND</b></li> </ol> </li> <li>5. The patient does NOT have any FDA labeled contraindications to the requested agent</li> </ol> <p><b>Length of Approval:</b> 12 months</p> <p>NOTE: Quantity Limit applies, please refer to Quantity Limit Criteria.</p> |

## QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

| Module     | Clinical Criteria for Approval                                                                                                                                                                                                                                                                                                                         |
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| QL with PA | <p><b>Quantity limit for the Target Agent(s)</b> will be approved when ONE of the following is met:</p> <ol style="list-style-type: none"> <li>1. The requested quantity (dose) does NOT exceed the program quantity limit <b>OR</b></li> <li>2. The requested quantity (dose) exceeds the program quantity limit AND ONE of the following:</li> </ol> |

| Module | Clinical Criteria for Approval                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
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|        | <p>A. BOTH of the following:</p> <ol style="list-style-type: none"> <li>1. The requested agent does NOT have a maximum FDA labeled dose for the requested indication <b>AND</b></li> <li>2. There is support for therapy with a higher dose for the requested indication (submitted copy of clinical trials, phase III studies, or guidelines required) <b>OR</b></li> </ol> <p>B. BOTH of the following:</p> <ol style="list-style-type: none"> <li>1. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication <b>AND</b></li> <li>2. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit <b>OR</b></li> </ol> <p>C. BOTH of the following:</p> <ol style="list-style-type: none"> <li>1. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication <b>AND</b></li> <li>2. There is support of therapy with a higher dose for the requested indication (submitted copy of clinical trials, phase III studies, or guidelines required)</li> </ol> <p><b>Length of Approval:</b> up to 12 months</p> |

## CONTRAINDICATION AGENTS

| Contraindicated as Concomitant Therapy                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
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| <p><b>Agents NOT to be used Concomitantly</b></p> <p>Abrilada (adalimumab-afzb)<br/> Actemra (tocilizumab)<br/> Adalimumab<br/> Adbry (tralokinumab-ldrm)<br/> Amjevita (adalimumab-atto)<br/> Arcalyst (rilonacept)<br/> Avsola (infliximab-axxq)<br/> Benlysta (belimumab)<br/> Bimzelx (bimekizumab-bkzx)<br/> Cibinqo (abrocitinib)<br/> Cimzia (certolizumab)<br/> <b>Cinqair (reslizumab)</b><br/> Cosentyx (secukinumab)<br/> Cyltezo (adalimumab-adbm)<br/> <b>Dupixent (dupilumab)</b><br/> Ebglyss (lebrikizumab-lbkz)<br/> Enbrel (etanercept)<br/> Entyvio (vedolizumab)<br/> Fasenra (benralizumab)<br/> Hadlima (adalimumab-bwwd)<br/> Hulio (adalimumab-fkjp)<br/> Humira (adalimumab)<br/> Hyrimoz (adalimumab-adaz)<br/> Idacio (adalimumab-aacf)<br/> Ilaris (canakinumab)<br/> Ilumya (tildrakizumab-asmn)<br/> Imuldosa (ustekinumab-srlf)<br/> Inflectra (infliximab-dyyb)<br/> Infliximab<br/> Kevzara (sarilumab)<br/> Kineret (anakinra)<br/> Leqselvi (deuruxolitinib)<br/> Litfulo (ritlecitinib)<br/> Nemluvio (nemolizumab-ilto)</p> |

**Contraindicated as Concomitant Therapy**

Nucala (mepolizumab)  
Olumiant (baricitinib)  
Omvo (mirikizumab-mrkz)  
Opzelura (ruxolitinib)  
Orencia (abatacept)  
Otezla (apremilast)  
Otulfi (ustekinumab-aauz)  
Pyzchiva (ustekinumab-ttwe)  
Remicade (infliximab)  
Renflexis (infliximab-abda)  
Riabni (rituximab-arrx)  
Rinvoq (upadacitinib)  
Rituxan (rituximab)  
Rituxan Hycela (rituximab/hyaluronidase human)  
Ruxience (rituximab-pvvr)  
Saphnelo (anifrolumab-fnia)  
Selarsdi (ustekinumab-aekn)  
Siliq (brodalumab)  
Simlandi (adalimumab-ryvk)  
Simponi (golimumab)  
Simponi ARIA (golimumab)  
Skyrizi (risankizumab-rzaa)  
**Sotyktu (deucravacitinib)**  
**Spevigo (spesolimab-sbzo) subcutaneous injection**  
Stelara (ustekinumab)  
Steqeyma (ustekinumab-stba)  
Taltz (ixekizumab)  
Tezspire (tezepelumab-ekko)  
Tofidence (tocilizumab-bavi)  
Tremfya (guselkumab)  
Truxima (rituximab-abbs)  
Tyenne (tocilizumab-aazg)  
Tysabri (natalizumab)  
Ustekinumab  
Velsipity (etrasimod)  
Wezlana (ustekinumab-auub)  
Xeljanz (tofacitinib)  
Xeljanz XR (tofacitinib extended release)  
**Xolair (omalizumab)**  
Yesintek (ustekinumab-kfce)  
Yuflyma (adalimumab-aaty)  
Yusimry (adalimumab-aqvh)  
Zeposia (ozanimod)  
Zymfentra (infliximab-dyyb)