



Otezla (apremilast) Prior Authorization with Quantity Limit Program Summary

This program applies to Medicaid.

For Medicaid, the Non-Preferred Drug Supplement applies.

The BCBS MN Step Therapy Supplement also applies to this program for Medicaid.

POLICY REVIEW CYCLE

Effective Date
8/1/2023

Date of Origin
1/1/2018

FDA APPROVED INDICATIONS AND DOSAGE

Agent(s)	FDA Indication(s)	Notes	Ref#
Otezla® (apremilast) Tablets	Treatment of adult patients with active psoriatic arthritis Treatment of adult patients with plaque psoriasis who are candidates for phototherapy or systemic therapy 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

Psoriasis (PS)	<p>Psoriasis (PS) is a chronic inflammatory skin condition that is often associated with systemic manifestations, especially arthritis. Diagnosis is usually clinical, based on the presence of typical erythematous scaly patches, papules, and plaques that are often pruritic and sometimes painful. Treatment goals for psoriasis include improvement of skin, nail, and joint lesions plus enhanced quality of life.(2)</p> <p>The American Academy of Family Physicians (AAFP) categorizes psoriasis severity into mild to moderate (less than 5% of body surface area [BSA]) and moderate to severe (5% or more of BSA). The AAFP psoriasis treatment guidelines recommend basing treatment on disease severity:(2)</p> <ul style="list-style-type: none"> • Mild to moderate (less than 5% of BSA and sparing the genitals, hands, feet, and face): <ul style="list-style-type: none"> ○ Candidate for intermittent therapy: topical corticosteroids, vitamin D analogs (calcipotriene and calcitriol), or tazarotene (Tazorac) ○ Candidate for continuous therapy: calcineurin inhibitors (tacrolimus and pimecrolimus) • Severe (5% or more of BSA or involving the genitals, hands, feet, and face): <ul style="list-style-type: none"> ○ Less than 20% of BSA affected: vitamin D analogs (calcipotriene and calcitriol) with or without phototherapy. These agents have a slower onset of action but a longer disease-free interval than topical corticosteroids
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	<ul style="list-style-type: none"> ○ 20% or more of BSA affected: systemic therapy with MTX, cyclosporine, acitretin, or biologics. Biologics are recommended for those with concomitant PsA ● Less commonly used topical therapies include non-medicated moisturizers, salicylic acid, coal tar, and anthralin <p>The American Academy of Dermatology (AAD) and National Psoriasis Foundation (NPF) categorize psoriasis severity as limited or mild (less than 3% of 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 occurs in select locations (e.g., hands, feet, scalp, face, or genital area) or when it causes intractable pruritus.(5) The AAD psoriasis treatment guidelines recommend the following:(3,4)</p> <ul style="list-style-type: none"> ● Limited disease (less than 5% of BSA): <ul style="list-style-type: none"> ○ Topical corticosteroids are first line as either monotherapy or in conjunction with non-steroidal topical agents ○ Vitamin D analogs, calcipotriene, calcipotriol, and calcitriol, are other first line agents and are often used in combination with topical corticosteroids ○ Tazarotene is a corticosteroid sparing agent and can be used in combination with topical corticosteroids to produce a synergistic effect and longer durations of treatment benefit and remission ○ Phototherapy is another first line option for limited disease, and allows for selective targeting of localized lesions and resistant areas such as the scalp and skin folds, leaving surrounding, non-lesional skin unaffected ○ Calcineurin inhibitors (tacrolimus and pimecrolimus) may also be considered first line for intertriginous, inverse, face, and genital psoriasis ○ Systemic agents are considered second line and only for short term use ● Moderate to severe disease without PsA (more than 5% of BSA or psoriasis in vulnerable areas [e.g., face, genitals, hands, and feet] that adversely affects quality of life): <ul style="list-style-type: none"> ○ UV-therapy is considered first line as monotherapy or in combination with acitretin or MTX ○ If UV-therapy is unavailable first line therapies include MTX, cyclosporine, acitretin, and biologics ○ Second line systemic agents include leflunomide, sulfasalazine, and tacrolimus ● Biologics are routinely used when one or more traditional systemic agents fail to produce adequate response, but are considered first line in patients with moderate to severe psoriasis with concomitant severe PsA <p>The National Psoriasis Foundation (NPF) medical board recommend a treat-to-target approach to therapy for psoriasis that include the following:(6)</p> <ul style="list-style-type: none"> ● The preferred assessment instrument for determining disease severity is BSA ● 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
Psoriatic Arthritis (PsA)	Psoriatic arthritis (PsA) is a chronic inflammatory musculoskeletal disease associated with psoriasis, most commonly presenting with peripheral arthritis, dactylitis,

enthesitis, and spondylitis. Treatment involves the use of a variety of interventions, including many agents used for the treatment of other inflammatory arthritis, particularly spondyloarthritis and RA, and other management strategies of the cutaneous manifestations of psoriasis.(7)

The American Academy of Dermatology (AAD) recommends initiating MTX in most patients with moderate to severe PsA. After 12 to 16 weeks of MTX therapy with appropriate dose escalation, the AAD recommends adding or switching to a TNF inhibitor if there is minimal improvement on MTX monotherapy.(3)

The American College of Rheumatology (ACR) and the National Psoriasis Foundation (NPF) guidelines for PsA recommend a treat-to-target approach in therapy, regardless of disease activity, and the following:(7)

- Active PsA is defined as symptoms at an unacceptably bothersome level as reported by the patient and health care provider to be due to PsA based on the presence of one of the following:
 - Actively inflamed joints
 - Dactylitis
 - Enthesitis
 - Axial disease
 - Active skin and/or nail involvement
 - Extraarticular manifestations such as uveitis or inflammatory bowel disease
- Disease severity includes level of disease activity at a given time point and the presence/absence of poor prognostic factors and long-term damage
- Severe PsA disease includes the presence of 1 or more of the following:
 - Erosive disease
 - Elevated markers of inflammation (ESR, CRP) attributable to PsA
 - Long-term damage that interferes with function (i.e., joint deformities)
 - Highly active disease that causes a major impairment in quality of life
 - Active PsA at many sites including dactylitis, enthesitis
 - Function limiting PsA at a few sites
 - Rapidly progressive disease
- Symptomatic treatments include nonsteroidal anti-inflammatory drugs (NSAIDs), glucocorticoids, local glucocorticoid injections
- Treatment recommendations for active disease:
 - Treatment naïve patients first line options include oral small molecules (OSM), TNF biologics, IL-17 inhibitor, and IL-12/23 inhibitor
 - OSM (i.e., methotrexate [MTX], sulfasalazine, cyclosporine, leflunomide, apremilast) should be considered if the patient does not have severe PsA, does not have severe psoriasis, prefers oral therapy, has concern over starting a biologic, or has contraindications to TNF inhibitor
 - Biologics (i.e., TNF biologic, IL-17 inhibitor, IL-12/23 inhibitor) are recommended as a first line option in patients with severe PsA and/or severe psoriasis
 - Previous treatment with OSM and continued active disease:
 - Switch to a different OSM (except apremilast) in patients without severe PsA or severe PS, contraindications to TNF biologics, prefers oral therapy OR add on apremilast to current OSM therapy
 - May add another OSM (except apremilast) to current OSM therapy for patients that have exhibited partial response to current OSM in patients without severe PsA or severe PS, contraindications to TNF biologics, or prefers oral therapy

	<ul style="list-style-type: none"> ▪ Biologic (i.e., TNF biologic, IL-17 inhibitor, IL-12/23 inhibitor) monotherapy ○ Previous treatment with a biologic (i.e., TNF biologic, IL-17 inhibitor, IL-12/23 inhibitor) and continued active disease: <ul style="list-style-type: none"> ▪ Switch to another biologic (i.e., TNF biologic, IL-17 inhibitor, IL-12/23 inhibitor, abatacept, or tofacitinib) monotherapy or add MTX to the current TNF biologic
Behcet's Disease (BD)(8)	<p>Behcet's disease (BD) is a type of vasculitis that involves numerous organ systems, such as the skin, mucosa, joints, eyes, veins, arteries, nervous system, and gastrointestinal system. BD runs a relapsing and remitting course and a multidisciplinary approach is necessary for optimal care. The goal of treatment is to suppress inflammatory exacerbations and recurrences to prevent irreversible organ damage.</p> <p>Chronic oral ulceration can cause scarring requiring vigorous treatment to prevent oropharyngeal narrowing. The European League Against Rheumatism recommends topical measures, such as steroids, for the treatment of oral and genital ulcers. Colchicine is recommended for the prevention of recurrent mucocutaneous lesions. Patients with lesions that continue to recur despite colchicine may use immunomodulatory or immunosuppressive agents, such as azathioprine, tumor necrosis factor (TNF) inhibitors, or apremilast.</p>
Efficacy(1)	The efficacy of Otezla for the treatment of oral ulcers associated with BD was established in a multicenter, randomized, placebo-controlled trial. Patients were required to have active oral ulcers at the time of enrollment, have had at least 3 occurrences of oral ulcers within the previous 12 months, and have received treatment with at least one non-biologic therapy. 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.
Safety(1)	Otezla is contraindicated in patients with a known hypersensitivity to apremilast or to any of the excipients in the formulation.

REFERENCES

Number	Reference
1	Otezla Prescribing Information. Celgene Corporation. December 2021.
2	Weigle, Nancy, MD, et al. Psoriasis. American Academy of Family Physicians. May 2013. 87 (9): 626-633.
3	Menter A, Korman NJ, Elmets CA, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. J Am Acad Dermatol. 2011;65(1):137-174.
4	Menter A, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis: Section 1. Overview of psoriasis and guidelines of care for the treatment of psoriasis with biologics. Journal of the American Academy of Dermatology. 2008; 58:826-850. doi: 10.1016/j.jaad.2008.02.039.
5	Menter, Alan et al. (2019). Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. Journal of the American Academy of Dermatology. doi: https://doi.org/10.1016/j.jaad.2018.11.057 .
6	Armstrong AW, Siegel MP, Bagel J, et al. From the medical board of the National Psoriasis Foundation: treatment targets for plaque psoriasis. Journal of the American Academy of Dermatology. 2017;76(2):290-298. doi: 10.1016/j.jaad.2016.10.017.
7	Singh, J. A., et al. (2019). 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis. Arthritis Care Res, 71: 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. Ann Rheum Dis 2018; 77:808.

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 ; apremilast tab starter therapy pack	10 & 20 & 30 MG ; 30 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 ; apremilast tab starter therapy pack	10 & 20 & 30 MG ; 30 MG	60	Tablets	30	DAYS			
Otezla	Apremilast Tab 30 MG	30 MG	60	Tablets	30	DAYS			
Otezla	Apremilast Tab Starter Therapy Pack 10 MG & 20 MG & 30 MG	10 & 20 & 30 MG	1	Kit	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 ; 30 MG	Medicaid

CLIENT SUMMARY – QUANTITY LIMITS

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 ; 30 MG	Medicaid
Otezla	Apremilast Tab 30 MG	30 MG	Medicaid
Otezla	Apremilast Tab Starter Therapy Pack 10 MG & 20 MG & 30 MG	10 & 20 & 30 MG	Medicaid

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	<p>Initial Evaluation</p> <p>Target Agent(s) will be approved when the ALL of the following are met:</p> <ol style="list-style-type: none"> ONE of the following: <ol style="list-style-type: none"> The requested agent is eligible for continuation of therapy AND ONE of the following: <div style="text-align: center; border: 1px solid black; padding: 5px; margin-top: 10px;"> Agents Eligible for Continuation of Therapy </div>

Module	Clinical Criteria for Approval
	<p style="text-align: center; border: 1px solid black; padding: 5px;">All target agents are eligible for continuation of therapy</p> <ol style="list-style-type: none"> 1. Information has been provided that indicates the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days OR 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 OR <p>B. The patient has a diagnosis of active psoriatic arthritis (PsA) AND ONE of the following:</p> <ol style="list-style-type: none"> 1. The patient is currently being treated with the requested agent as indicated by ALL of the following: <ol style="list-style-type: none"> A. A statement by the prescriber that the patient is currently taking the requested agent AND B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent AND C. The prescriber states that a change in therapy is expected to be ineffective or cause harm OR 2. The patient's medication history includes ONE conventional agent (i.e., cyclosporine, leflunomide, methotrexate, sulfasalazine) used in the treatment of PsA AND ONE of the following: <ol style="list-style-type: none"> A. The patient has had an inadequate response to a conventional agent (i.e., cyclosporine, leflunomide, methotrexate, sulfasalazine) used in the treatment of PsA OR B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over a conventional agent (i.e., cyclosporine, leflunomide, methotrexate, sulfasalazine) used in the treatment of PsA OR 3. The patient has an intolerance or hypersensitivity to ONE of the conventional agents used in the treatment of PsA OR 4. The patient has an FDA labeled contraindication to ALL of the conventional agents used in the treatment of PsA OR 5. 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 OR 6. The prescriber has provided documentation that ALL conventional agents (i.e., cyclosporine, leflunomide, methotrexate, sulfasalazine) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm OR <p>C. The patient has a diagnosis of plaque psoriasis (PS) AND ONE of the following:</p> <ol style="list-style-type: none"> 1. The patient is currently being treated with the requested agent as indicated by ALL of the following: <ol style="list-style-type: none"> A. A statement by the prescriber that the patient is currently taking the requested agent AND B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent AND C. The prescriber states that a change in therapy is expected to be ineffective or cause harm OR 2. The patient's medication history includes use of 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 AND ONE of the following: <ol style="list-style-type: none"> A. The patient has had an inadequate response to a conventional agent (i.e., acitretin, anthralin, calcipotriene, calcitriol, coal tar products, cyclosporine, methotrexate, pimecrolimus, PUVA

Module	Clinical Criteria for Approval
	<p>[phototherapy], tacrolimus, tazarotene, topical corticosteroids) used in the treatment of PS OR</p> <p>B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over 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 OR</p> <p>3. The patient has an intolerance or hypersensitivity to ONE conventional agent used in the treatment of PS OR</p> <p>4. The patient has an FDA labeled contraindication to ALL conventional agents used in the treatment of PS OR</p> <p>5. 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 OR</p> <p>6. The prescriber has provided documentation that ALL conventional agents (i.e., acitretin, anthralin, calcipotriene, calcitriol, coal tar products, cyclosporine, methotrexate, pimecrolimus, PUVA [phototherapy], tacrolimus, tazarotene, topical corticosteroids) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm OR</p> <p>D. The patient has a diagnosis of Behcet’s disease (BD) AND ALL of the following:</p> <ol style="list-style-type: none"> 1. The patient has active oral ulcers associated with BD AND 2. The patient has had at least 3 occurrences of oral ulcers in the last 12-months AND 3. ONE of the following: <ol style="list-style-type: none"> A. The patient is currently being treated with the requested agent as indicated by ALL of the following: <ol style="list-style-type: none"> 1. A statement by the prescriber that the patient is currently taking the requested agent AND 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent AND 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm OR B. The patient’s medication history includes ONE conventional agent (i.e., topical oral corticosteroids [i.e., triamcinolone dental paste], colchicine, azathioprine) used in the treatment of BD AND ONE OF the following: <ol style="list-style-type: none"> 1. The patient has had an inadequate response to a conventional agent (i.e., topical oral corticosteroids [i.e., triamcinolone dental paste], colchicine, azathioprine) used in the treatment of BD OR 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over conventional agent (i.e., topical oral corticosteroids [i.e., triamcinolone dental paste], colchicine, azathioprine) used in the treatment of BD OR C. The patient has an intolerance or hypersensitivity to ONE conventional agent used in the treatment of BD OR D. The patient has an FDA labeled contraindication to ALL conventional agents used in the treatment of BD OR E. 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 OR F. The prescriber has provided documentation that ALL conventional agents (i.e., topical oral corticosteroids [i.e., triamcinolone dental

Module	Clinical Criteria for Approval
	<p style="text-align: center;">paste], colchicine, azathioprine) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm OR</p> <ul style="list-style-type: none"> E. The patient has another FDA labeled indication for the requested agent not mentioned previously OR F. The patient has another indication that is supported in compendia for the requested agent not mentioned previously AND <ul style="list-style-type: none"> 2. If the patient has an FDA approved indication, then ONE of the following: <ul style="list-style-type: none"> A. The patient's age is within FDA labeling for the requested indication for the requested agent OR B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication AND 3. ONE of the following (Please refer to "Agents NOT to be used Concomitantly" table): <ul style="list-style-type: none"> 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) OR B. The patient will be using the requested agent in combination with another immunomodulatory agent AND BOTH of the following: <ul style="list-style-type: none"> 1. The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agent AND 2. The prescriber has provided information in support of combination therapy (submitted copy required, e.g., clinical trials, phase III studies, guidelines required) AND 4. ONE of the following: <ul style="list-style-type: none"> A. The requested agent is a preferred agent in the Minnesota Medicaid Preferred Drug List (PDL) OR B. The request is for a non-preferred agent in the Minnesota Medicaid Preferred Drug List (PDL) and ONE of the following: <ul style="list-style-type: none"> 1. The patient is currently being treated with the requested agent as indicated by ALL of the following: <ul style="list-style-type: none"> A. A statement by the prescriber that the patient is currently taking the requested agent AND B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent AND C. The prescriber states that a change in therapy is expected to be ineffective or cause harm OR 2. The patient has tried and had an inadequate response to two preferred chemically unique agents within the same drug class in the Minnesota Medicaid Preferred Drug List (PDL) as indicated by BOTH of the following: <ul style="list-style-type: none"> A. ONE of the following: <ul style="list-style-type: none"> 1. Evidence of a paid claim(s) OR 2. The prescriber has stated that the patient has tried the required prerequisite/preferred agent(s) AND B. ONE of the following: <ul style="list-style-type: none"> 1. The required prerequisite/preferred agent(s) was discontinued due to lack of effectiveness or an adverse event OR 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over the prerequisite/preferred agent(s) OR 3. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to the preferred agents within the same drug class in the Minnesota Medicaid Preferred Drug List (PDL) that is not expected to occur with the requested agent OR 4. The prescriber has provided documentation that the required prerequisite/preferred agent(s) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm OR

Module	Clinical Criteria for Approval
	<p>5. The prescriber has submitted documentation supporting the use of the non-preferred agent over the preferred agent(s) AND</p> <p>5. 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 AND</p> <p>6. The patient does NOT have any FDA labeled contraindications to the requested agent</p> <p>Compendia Allowed: CMS approved compendia</p> <p>Length of approval: 12 months</p> <p>NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.</p> <p>Renewal Evaluation</p> <p>Target Agent(s) will be approved when ALL of the following are met:</p> <ol style="list-style-type: none"> 1. The patient has been previously approved for the requested agent through the plan’s Prior Authorization process AND 2. The patient has had clinical benefit with the requested agent AND 3. ONE of the following (Please refer to “Agents NOT to be used Concomitantly” table): <ol style="list-style-type: none"> 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) OR 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"> 1. The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agent AND 2. The prescriber has provided information in support of combination therapy (submitted copy required, e.g., clinical trials, phase III studies, guidelines required) AND 4. 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 AND 5. The patient does NOT have any FDA labeled contraindications to the requested agent <p>Length of approval: 12 months</p> <p>NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.</p>

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
QL with PA	<p>Quantity Limit for the Target Agent(s) will be approved when ONE of the following is met:</p> <ol style="list-style-type: none"> 1. The requested quantity (dose) does NOT exceed the program quantity limit OR 2. ALL of the following: <ol style="list-style-type: none"> A. The requested quantity (dose) is greater than the program quantity limit AND B. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication AND C. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit OR 3. ALL of the following: <ol style="list-style-type: none"> A. The requested quantity (dose) is greater than the program quantity limit AND B. The requested quantity (dose) is greater than the maximum FDA labeled dose for the requested indication AND

Module	Clinical Criteria for Approval
	<p data-bbox="354 180 1401 268">c. The prescriber has provided information in support of therapy with a higher dose for the requested indication (e.g., clinical trials, phase III studies, guidelines required)</p> <p data-bbox="232 304 638 333">Length of Approval: 12 months</p>

CONTRAINDICATION AGENTS

Contraindicated as Concomitant Therapy
<p data-bbox="99 527 646 556">Contraindicated as Concomitant Therapy</p> <p data-bbox="99 594 423 623">Adbry (tralokinumab-ldrm)</p> <p data-bbox="99 661 367 690">Actemra (tocilizumab)</p> <p data-bbox="99 728 342 758">Arcalyst (rilonacept)</p> <p data-bbox="99 795 391 825">Avsola (infliximab-axxq)</p> <p data-bbox="99 863 367 892">Benlysta (belimumab)</p> <p data-bbox="99 930 342 959">Cibinqo (abrocitinib)</p> <p data-bbox="99 997 367 1026">Cimzia (certolizumab)</p> <p data-bbox="99 1064 342 1094">Cinqair (reslizumab)</p> <p data-bbox="99 1131 399 1161">Cosentyx (secukinumab)</p> <p data-bbox="99 1199 367 1228">Dupixent (dupilumab)</p> <p data-bbox="99 1266 334 1295">Enbrel (etanercept)</p> <p data-bbox="99 1333 367 1362">Entyvio (vedolizumab)</p> <p data-bbox="99 1400 383 1430">Fasenra (benralizumab)</p> <p data-bbox="99 1467 367 1497">Humira (adalimumab)</p> <p data-bbox="99 1535 350 1564">Ilaris (canakinumab)</p> <p data-bbox="99 1602 448 1631">Ilumya (tildrakizumab-asmn)</p> <p data-bbox="99 1669 415 1698">Inflectra (infliximab-dyyb)</p> <p data-bbox="99 1736 220 1766">Infliximab</p> <p data-bbox="99 1803 342 1833">Kevzara (sarilumab)</p> <p data-bbox="99 1871 318 1900">Kineret (anakinra)</p> <p data-bbox="99 1938 367 1967">Nucala (mepolizumab)</p>

Contraindicated as Concomitant Therapy

Olumiant (baricitinib)
Opzelura (ruxolitinib)
Orencia (abatacept)
Otezla (apremilast)
Remicade (infliximab)
Renflexis (infliximab-abda)
Riabni (rituximab-arrx)
Rinvoq (upadacitinib)
Rituxan (rituximab)
Rituxan Hycela (rituximab/hyaluronidase human)
Ruxience (rituximab-pvvr)
Siliq (brodalumab)
Simponi (golimumab)
Simponi ARIA (golimumab)
Skyrizi (risankizumab-rzaa)
Sotyktu (deucravacitinib)
Stelara (ustekinumab)
Taltz (ixekizumab)
Tezspire (tezepelumab-ekko)
Tremfya (guselkumab)
Truxima (rituximab-abbs)
Tysabri (natalizumab)
Xeljanz (tofacitinib)
Xeljanz XR (tofacitinib extended release)
Xolair (omalizumab)
Zeposia (ozanimod)