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Gateway Health Plan
Pharmacy Division
Phone 800-392-1147 Fax 888-245-2049

I. Requirements for Prior Authorization of Cytokine and CAM Antagonists

A. <u>Prescriptions That Require Prior Authorization</u>

All prescriptions for Cytokine and CAM Antagonists must be prior authorized.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a Cytokine and CAM Antagonist, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

- Is prescribed the Cytokine and CAM Antagonist for the treatment of a diagnosis that is indicated in the U.S. Food and Drug Administration (FDA)-approved package labeling OR a medically accepted indication; AND
- 2. Is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
- 3. Is prescribed the Cytokine and CAM Antagonist by or in consultation with an appropriate specialist (e.g., gastroenterologist, dermatologist, rheumatologist, ophthalmologist, immunologist, genetic specialist, pulmonologist, oncologist, etc.); **AND**
- 4. If currently using a different Cytokine and CAM Antagonist, **one** of the following:
 - Will discontinue use of that Cytokine and CAM Antagonist prior to starting the requested Cytokine and CAM Antagonist
 - b. **One** of the following:
 - i. Has a medical reason for concomitant use of both Cytokine and CAM Antagonists that is supported by peer-reviewed literature or national treatment guidelines,
 - ii. Is dependent on glucocorticoids in addition to a Cytokine and CAM Antagonist to prevent life-threatening complications,
 - iii. Has 2 or more autoimmune or autoinflammatory conditions for which a single Cytokine and CAM Antagonist is not sufficient;

AND

- 5. Does not have a contraindication to the prescribed Cytokine and CAM Antagonist; AND
- 6. Is prescribed a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
- 7. For a Cytokine and CAM Antagonist associated with an increased risk of infection according to the FDA-approved package labeling, was evaluated for **both** of the following:
 - a. Active or latent tuberculosis infection documented by results of a tuberculin skin test (purified protein derivative) or blood test (interferon-gamma release assay)
 - b. Hepatitis B virus infection documented by results of anti-HBs, HBsAg, and anti-HBc;

AND

8. For a Cytokine and CAM Antagonist associated with behavioral and/or mood changes as stated in the FDA-approved package labeling (e.g., Otezla, Siliq), was evaluated for a history of prior suicide attempt, bipolar disorder, or major depressive disorder; **AND**



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- 9. For treatment of Crohn's disease, **one** of the following:
 - a. For a diagnosis of moderate to severe Crohn's disease, one of the following:
 - i. Failed to achieve remission with or has a contraindication or an intolerance to an induction course of corticosteroids
 - ii. **One** of the following:
 - a) Failed to maintain remission with an immunomodulator in accordance with current consensus guidelines¹
 - b) Has a contraindication or an intolerance to immunomodulators in accordance with current consensus guidelines,
 - b. Has a diagnosis of Crohn's disease that is associated with one or more high-risk or poor prognostic feature(s),²
 - c. Both of the following:
 - i. Has achieved remission with the requested Cytokine and CAM Antagonist
 - Will be using the requested medication as maintenance therapy to maintain remission;

AND

- 10. For treatment of ulcerative colitis (UC), **one** of the following:
 - a. Both of the following:
 - i. Has **one** of the following diagnoses:
 - a) Mild UC that is associated with multiple poor prognostic factors³
 - b) Moderate to severe UC
 - ii. One of the following:
 - a) Failed to achieve remission with or has a contraindication or an intolerance to an induction course of corticosteroids
 - b) **One** of the following:
 - (i) Failed to maintain remission with an immunomodulator in accordance with current consensus guidelines⁴
 - (ii) Has a contraindication or an intolerance to immunomodulators in accordance with current consensus guidelines
 - b. **Both** of the following:
 - i. Has achieved remission with the requested Cytokine and CAM Antagonist
 - ii. Will be using the requested medication as maintenance therapy to maintain remission:

AND

¹ e.g., American College of Gastroenterology [ACG], American Gastroenterological Association [AGA], Canadian Association of Gastroenterology [CAG], European Crohn's and Colitis Organization [ECCO]

² Examples of high-risk or poor prognostic features in patients with Crohn's disease include initial diagnosis or clinical evidence supports the onset of symptoms at <30 years of age, extensive anatomic involvement, presence of fistula, perianal and/or severe rectal disease, large or deep mucosal lesions on endoscopy or imaging, prior surgical resection, stricturing and/or penetrating behavior, need for steroid therapy at initial diagnosis, extra-intestinal manifestations, laboratory markers such as low hemoglobin, low albumin, high C-reactive protein, high fecal calprotectin levels, severe growth delay (AGA 2014; ECCO 2017; CAG 2019; ECCO-ESPGHAN 2021; AGA 2021).

³ Poor prognostic factors include initial diagnosis or clinical evidence supports the onset of symptoms at <40 years of age, extensive colitis, severe endoscopic disease (presence of large and/or deep ulcers), hospitalization for colitis, elevated inflammatory markers, low serum albumin, extra-intestinal manifestations, early need for corticosteroids (ACG 2019; AGA 2019; AGA 2020).

⁴ e.g., American College of Gastroenterology [ACG], American Gastroenterological Association [AGA], Canadian Association of Gastroenterology [CAG], European Crohn's and Colitis Organization [ECCO]

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- 11. For treatment of moderately to severely active rheumatoid arthritis, has **one** of the following:
 - A history of therapeutic failure of a 3-month trial of a conventional non-biologic disease-modifying antirheumatic drug (DMARD) in accordance with current consensus guidelines⁵
 - b. A contraindication or an intolerance to conventional non-biologic DMARDs;

AND

- 12. For treatment of juvenile idiopathic arthritis (JIA), one of the following:
 - a. Has **one** of the following:
 - i. A history of therapeutic failure of a 3-month trial of a conventional non-biologic DMARD
 - ii. A contraindication or an intolerance to non-biologic DMARDs,
 - b. Has systemic JIA with active systemic features,⁶
 - c. Has a diagnosis of JIA that is associated with **both** of the following:
 - i. One or more risk factors⁷ for disease severity
 - ii. At least **one** of the following:
 - a) Involvement of high-risk joints (e.g., cervical spine, hip, wrist),
 - b) High disease activity,
 - c) Is at high risk of disabling joint damage as judged by the prescriber,
 - d. Has active sacroiliitis and/or enthesitis and **one** of the following:
 - A history of therapeutic failure of a 2-week trial of an oral non-steroidal antiinflammatory drug (NSAID)
 - ii. A contraindication or an intolerance to oral NSAIDs:

AND

- 13. For treatment of adult-onset Still's disease, **one** of the following:
 - a. Has predominantly systemic disease and **one** of the following:
 - Has a history of therapeutic failure of or a contraindication or an intolerance to systemic glucocorticoids
 - ii. **Both** of the following:
 - a) Has glucocorticoid-dependent Still's disease
 - b) Will be using the requested Cytokine and CAM Antagonist with the intent of discontinuing or decreasing the dose of the systemic glucocorticoid
 - b. Has predominantly joint disease and **one** of the following:
 - i. A history of therapeutic failure of a conventional non-biologic DMARD
 - ii. A contraindication or an intolerance to conventional non-biologic DMARDs:

AND

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⁵ e.g., American College of Rheumatology [ACR], European League Against Rheumatism [EULAR]

⁶ Active systemic features include the following: fever, evanescent rash, lymphadenopathy, hepatomegaly, splenomegaly, and serositis (ACR 2013).

⁷ Risk factors include positive anti-cyclic citrullinated peptide antibodies, positive rheumatoid factor, presence of joint damage (ACR-AF 2019).

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4. For treatment of ankylosing spondylitis or other axial spondyloarthritis, has **one** of the following:

- a. A history of therapeutic failure of a 2-week trial of continuous treatment with 2 different oral NSAIDs (i.e., an oral NSAID taken daily for 2 weeks and a different oral NSAID taken daily for 2 weeks)
- b. A contraindication or an intolerance to oral NSAIDs:

AND

- 15. For treatment of active⁸ psoriatic arthritis, **one** of the following:
 - a. Has axial disease and/or enthesitis,
 - b. Has peripheral disease and **one** of the following:
 - i. A history of therapeutic failure of an 8-week trial of a conventional non-biologic DMARD
 - ii. A contraindication or an intolerance to conventional non-biologic DMARDs,
 - c. Has severe disease as determined by the prescriber,9
 - d. Has concomitant moderate to severe nail disease:

AND

- 16. For treatment of moderate to severe chronic psoriasis, **all** of the following:
 - a. Has psoriasis associated with at least **one** of the following:
 - i. A body surface area (BSA) of 3% or more that is affected,
 - ii. A BSA of less than 3% that is affected with involvement of critical areas, 10
 - iii. Significant disability or impairment of physical or mental functioning,
 - b. Has **one** of the following:
 - i. A history of therapeutic failure of topical corticosteroids OR other topical pharmacologic therapy.¹¹
 - ii. A contraindication or an intolerance to topical corticosteroids AND other topical pharmacologic therapy.
 - iii. Moderate to severe nail disease,
 - c. Has a history of therapeutic failure of or a contraindication or an intolerance to at least **one** of the following:
 - i. A 3-month trial of oral systemic therapy 12
 - ii. Ultraviolet light therapy; 13

AND

⁸ Active disease is defined as disease causing symptoms at an unacceptable bothersome level as reported by the patient and judged by the examining clinician to be due to PsA based on 1 or more of the following: swollen joints, tender joints, dactylitis, enthesitis, axial disease, active skin and/or nail involvement, and extraarticular inflammatory manifestations such as uveitis or IBD (ACR-NPF 2018; EULAR 2015).

[§] Examples of severe disease include the presence of ≥1 of the following: a poor prognostic factor (erosive disease, elevated levels of inflammation markers such as C-reactive protein or erythrocyte sedimentation rate attributable to PsA), long-term damage that interferes with function (e.g., joint deformities, vision loss), highly active disease that causes major impairment in quality of life (i.e., active psoriatic inflammatory disease at many sites [including dactylitis, enthesitis] or function-limiting inflammatory disease at a few sites), and rapidly progressive disease (ACR-NPF 2018; EULAR 2015).

¹⁰ Critical areas include, but are not restricted to, hands, feet, scalp, face, genitals, nails, and intertriginous areas (AAD-NPF 2018).

¹¹ e.g., anthralin, calcineurin inhibitors, tar, tazarotene, vitamin D analogs

¹² e.g., methotrexate, cyclosporine, acitretin

¹³ e.g., NB-UVB, BB-UVB, PUVA, excimer laser

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- 17. For treatment of moderate to severe hidradenitis suppurativa (HS), one of the following:
 - a. Both of the following:
 - i. Has Hurley stage II or stage III disease
 - ii. Has a history of therapeutic failure of or a contraindication or an intolerance to **both** of the following:
 - a) A 3-month trial of topical clindamycin
 - b) An adequate trial of a systemic antibiotic 14
 - b. **Both** of the following:
 - i. Has Hurley stage III disease
 - Is a candidate for or has a history of surgical intervention for HS;

AND

- 18. For treatment of non-infectious uveitis, **one** of the following:
 - a. Has a diagnosis of uveitis associated with JIA or Behçet's syndrome,
 - Has a history of therapeutic failure of or a contraindication or an intolerance to one of the following:
 - i. A systemic, topical, intraocular, or periocular corticosteroid
 - ii. A conventional systemic immunosuppressive, 15
 - c. Both of the following:
 - i. Has corticosteroid-dependent uveitis 16
 - ii. Will be using the requested Cytokine and CAM Antagonist with the intent of discontinuing or decreasing the dose of the systemic corticosteroid;

AND

- 19. For treatment of giant cell arteritis, one of the following:
 - a. Has a history of therapeutic failure of or a contraindication or an intolerance to systemic glucocorticoids,
 - b. Is at high-risk for glucocorticoid-related complications,
 - c. Both of the following:
 - i. Has glucocorticoid-dependent disease
 - ii. Will be using the requested Cytokine and CAM Antagonist with the intent of discontinuing or decreasing the dose of the systemic glucocorticoid;

AND

- 20. For treatment of familial Mediterranean fever, has **one** of the following:
 - A history of therapeutic failure of at least a 3-month trial of colchicine at maximally tolerated doses
 - b. A contraindication or an intolerance to colchicine;

AND

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¹⁴ e.g., doxycycline, minocycline, or tetracycline; clindamycin; clindamycin + rifampin; rifampin + moxifloxacin + metronidazole; rifampin + levofloxacin + metronidazole; amoxicillin/clavulanate

¹⁵ e.g., azathioprine, cyclophosphamide, cyclosporine, methotrexate, mycophenolate, tacrolimus

¹⁶ Corticosteroid-dependent uveitis is defined as requiring a daily systemic corticosteroid dose equivalent to 7.5 mg or greater of prednisone in adults for six weeks or longer.



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- 21. For treatment of Behçet's syndrome, **all** of the following:
 - a. Has a diagnosis of Behçet's syndrome according to current consensus guidelines, ¹⁷
 - b. Has recurrent oral ulcers associated with Behçet's syndrome,
 - c. Has a history of therapeutic failure of or a contraindication or an intolerance to a topical corticosteroid (e.g., triamcinolone dental paste),
 - d. Has **one** of the following:
 - A history of therapeutic failure of an adequate trial of colchicine at maximally tolerated doses
 - ii. A contraindication or an intolerance to colchicine:

AND

- 22. For treatment of moderate to severe chronic atopic dermatitis, has a history of therapeutic failure of at least **two** of the following OR a contraindication or an intolerance to **all** of the following:
 - a. One of the following:
 - For treatment of the face, skin folds, or other critical areas, a low-potency topical corticosteroid
 - For treatment of other areas, a medium-potency or higher topical corticosteroid.
 - b. A topical calcineurin inhibitor,
 - c. Phototherapy in accordance with current consensus guidelines,
 - d. Systemic immunosuppressives in accordance with current consensus guidelines (e.g., cyclosporine, azathioprine, methotrexate, mycophenolate mofetil);

AND

- 23. For treatment of sarcoidosis, **both** of the following:
 - a. **One** of the following:
 - Has a history of therapeutic failure of or a contraindication or an intolerance to systemic glucocorticoids
 - ii. Has glucocorticoid-dependent sarcoidosis
 - b. Has a history of therapeutic failure of or a contraindication or an intolerance to a conventional non-biologic DMARD;

AND

24. For a non-preferred Cytokine and CAM Antagonist, **one** of the following:

- a. Has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Cytokine and CAM Antagonists approved or medically accepted for the beneficiary's diagnosis
- b. Has a current history (within the past 90 days) of being prescribed the same non-preferred Cytokine and CAM Antagonist (does not apply to non-preferred brands when the therapeutically equivalent generic is preferred or to non-preferred generics when the therapeutically equivalent brand is preferred [NOTE: biosimilars are NOT therapeutically equivalent generics])

¹⁷ e.g., EULAR, International Study Group for Behçet's Disease



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See the Preferred Drug List (PDL) for the list of preferred Cytokine and CAM Antagonists at: https://papdl.com/preferred-drug-list;

NOTE: If the beneficiary does not meet the clinical review guidelines above but, in the professional judgement of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

FOR RENEWALS OF PRIOR AUTHORIZATION FOR CYTOKINE AND CAM ANTAGONISTS: The determination of medical necessity of a request for renewal of a prior authorization for a Cytokine and CAM Antagonist that was previously approved will take into account whether the beneficiary:

1. One of the following:

- a. Experienced improvement in disease activity and/or level of functioning since initiating therapy with the requested Cytokine and CAM Antagonist
- b. Is prescribed an increased dose or more frequent administration of the requested Cytokine and CAM Antagonist that is supported by peer-reviewed medical literature or national treatment guidelines;

AND

- 2. Is prescribed the Cytokine and CAM Antagonist by or in consultation with an appropriate specialist (e.g., gastroenterologist, dermatologist, rheumatologist, ophthalmologist, immunologist, genetic specialist, pulmonologist, oncologist, etc.); **AND**
- Is prescribed a dose and duration of therapy that is consistent with the FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature;
 AND
- 4. For a Cytokine and CAM Antagonist associated with behavioral and/or mood changes as stated in the FDA-approved package labeling, was recently reevaluated for behavioral and mood changes as recommended in the FDA-approved package labeling.

NOTE: If the beneficiary does not meet the clinical review guidelines above but, in the professional judgement of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a Cytokine and CAM Antagonist. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.



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CYTOKINE AND CAM ANTAGONISTS PRIOR AUTHORIZATION FORM (form effective 1/3/2022)

■New request ■ Renewal request	# of pages:	Prescriber name:		
Name of office contact:		Specialty:		
Contact's phone number:		NPI:		State license #:
LTC facility contact/phone:		Street address:		
Beneficiary name:		Suite #: City/state/zip:		
Beneficiary ID#:	DOB:	Phone:		Fax:
CLINICAL INFORMATION				
STARTER PACK requested (name/strength):		MAINTENANCE product/packaging requested (name/strength):		
Quantity per fill: Refills:		Quantity per fill: Refills:		
Directions:		Directions:		
Diagnosis (submit documentation):			Dx cod	le (<u>required</u>):
Is the beneficiary currently being treated with the requested medication?		☐Yes – date of last dose: Submit documentation. ☐No		
Is the requested medication prescribed by or	☐Yes If prescriber is not a specialist, submit documentation of			
cardiologist, endocrinologist, or other lipid disc	□No consultation. L requests			
Tried and failed or has a contraindication or intolerance to the preferred drugs in this class approved or medically accepted for the beneficiary's condition (<i>Refer to https://papal.com/preferred-drug-list for a list of preferred and non-preferred drugs in this class.</i>) Requested drug is OTEZLA (apremilast) or SILIO (brodalumab): Was evaluated for history of prior suicide attempt, bipolar disorder, or major depressive disorder Complete the sections below that are applicable to the beneficiary and this request and SUBMIT DOCUMENTATION for each item. ALL diagnoses: Screened for hepatitis B (surface antigen, surface antibody, and core antibody) Screened for tuberculosis Adult-onset Still's disease: Has predominantly systemic disease: Has predominantly systemic disease: Has predominantly joint disease: Tried and failed or has a contraindication or intolerance to systemic glucocorticoids Has predominantly joint disease: Tried and failed or as a contraindication or intolerance to conventional DMARDs (eg. MTX) Ankylosing spondylitis & non-radiographic axial spondyloarthritis: Tried and failed a 2-week trial of or has a contraindication or intolerance to 2 different oral NSAIDs Altopic dermatitis (eczema): Tried and failed or has a contraindication or an intolerance to: For the face or skin folds, low-potency (or higher) topical corticosteroids For other body areas, a topical corticosteroid with a potency appropriate for the beneficiary's age and affected area(s) of the body Elidel (pimecrolimus) or Protopic (tacrolimus) Phototherapylphotochemotherapy (e.g., PUVA, UVB light) Systemic immunosuppressives (e.g., azathioprine, cyclosporine, methotrexate, mycophenolate) Has recurrent oral ulcers associated with Behçet's syndrome Has recurrent oral ulcers associated with Behçet's syndrome Has moderate-to-severe disease Has moderate-to-severe disease Has moderate-to-severe disease Has moderate-to-severe disease Has disease that is associated with high-risk or poor pro				

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Familial Mediterranean fever:				
Tried and failed a 3-month trial of or has a contraindication or intolerance to colchicine at maximally tolerated doses				
Giant cell arteritis:				
☐Tried and failed or has a contraindication or intolerance to systemic glucocorticoids				
☐ Is at high risk for glucocorticoid-related complications				
Has steroid-dependent disease				
Hidradenitis suppurativa (HS):				
Has Hurley stage II or stage III disease				
Is a candidate for or has a history of surgical intervention for HS				
Tried and failed a 3-month trial of or has a contraindication or intolerance to topical clindamycin				
Tried and failed or has a contraindication or intolerance to <u>systemic</u> antibiotics (eg, doxycycline, minocycline, tetracycline, clindamycin)				
Juvenile idiopathic arthritis:				
Has systemic disease with active systemic features				
Has disease associated with any of the following:				
Positive anti-CCP antibodies Presence of joint damage High disease activity				
Positive rheumatoid factor At high risk of disabling joint damage Involvement of high-risk joints (cervical spine, hip, wrist)				
Tried and failed a 3-month trial of or has a contraindication or intolerance to conventional DMARDs (eg, MTX)				
Has active sacroiliitis and/or enthesitis: Tried and failed a 2-week trial of or has a contraindication or intolerance to oral NSAIDs				
Plaque psoriasis: Has a BSA of ≥ 3% that is affected				
Has involvement of critical areas of the body (eg, skin folds, face, genitals) Has psoriasis that causes significant disability or impaired physical or mental functioning				
Tried and failed or has a contraindication or intolerance to topical corticosteroids				
Tried and failed or has a contraindication or intolerance to topical conteosteroids Tried and failed or has a contraindication or intolerance to non-steroid topical medications (eg, anthralin, calcineurin inhibitor, tazarotene, etc				
Tried and failed or has a contraindication or intolerance to intriscrotid topical medications (eg., antinalin, calcined in limbion, tazarotene, etc				
Tried and failed a 3-month trial of or has a contraindication or intolerance to oral systemic medications (eg, MTX, cyclosporine, acitretin)				
Psoriatic arthritis:				
Has severe disease				
Has comorbid moderate-to-severe nail psoriasis				
Has predominantly axial disease and/or enthesitis				
Has predominantly peripheral disease:				
Tried and failed an 8-week trial of or has a contraindication or intolerance to conventional DMARDs (eg, AZA, leflunomide, MTX, SSZ)				
Rheumatoid arthritis:				
Tried and failed a 3-month trial of or has a contraindication or intolerance to conventional DMARDs (eg, AZA, leflunomide, MTX, etc)				
Sarcoidosis:				
☐Tried and failed or has a contraindication or intolerance to systemic glucocorticoids				
Has steroid-dependent disease				
Tried and failed or has a contraindication or intolerance to a conventional DMARD (eg, AZA, leflunomide, MTX, mycophenolate)				
Ulcerative colitis:				
Has moderate-to-severe disease				
Has disease associated with multiple poor prognostic factors				
Tried and failed to achieve remission with or has a contraindication or intolerance to an induction course of corticosteroids				
Tried and failed to maintain remission with or has a contraindication or intolerance to immunomodulators (eg, AZA, cyclosporine, 6-MP, MTX				
Uveitis (non-infectious):				
Has comorbid juvenile idiopathic arthritis				
Has comorbid Behçet's syndrome				
Has steroid-dependent disease				
Tried and failed or has a contraindication or intolerance to systemic, topical, intraocular, or periocular corticosteroids				
Tried and failed or has a contraindication or intolerance to conventional systemic immunosuppressives (eg, AZA, MTX, MMF, etc)				
RENEWAL requests				
Experienced an improvement in disease severity or level of functioning since starting therapy with the requested medication				
Is prescribed an increased dose or more frequent administration of the requested medication				
New dose/frequency is within the FDA-approved recommended dosing OR is supported by national compendia or peer-reviewed medical				
Requested drug is OTEZLA (apremilast) or SILIQ (brodalumab): Was recently reevaluated for behavioral and mood changes				
PLEASE <u>FAX</u> COMPLETED FORM TO GATEWAY – PHARMACY DIVISION				
rescriber Signature: Date:				

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