POLICY Document for CIMZIA (certolizumab pegol)

The overall objective of this policy is to support the appropriate and cost-effective use of the medication, specific to use of preferred medication options, and overall, clinically appropriate use. This document provides specific information to both sections of the overall policy.

Section 1: Preferred Product
- Policy information specific to preferred medications

Section 2: Clinical Criteria
- Policy information specific to the clinical appropriateness for the medication

Section 1: Preferred Product

CAREFIRST: EXCEPTIONS CRITERIA
AUTOIMMUNE CONDITIONS

PRIMARY PREFERRED PRODUCTS: ENTYVIO, SIMPONI ARIA, SKYRIZI, STELARA

Client Requested: The intent of the criteria is to ensure that patients follow selection elements as established by CareFirst.

POLICY
This policy informs prescribers of preferred products and provides an exception process for targeted products through prior authorization.

I. PLAN DESIGN SUMMARY

This program applies to the autoimmune drug products specified in this policy. Coverage for targeted product is provided based on clinical circumstances that would exclude the use of the preferred products and may be based on previous use of a product. The coverage review process will ascertain situations where a clinical exception can be made. This program applies to all members requesting treatment with a targeted product.

Each referral is reviewed based on all utilization management (UM) programs implemented for the client.

Table. Autoimmune Products

	Product(s)
Preferred	• **Entyvio** (vedolizumab) • **Simponi Aria** (golimumab, intravenous) • **Skyrizi** (risankizumab-rzaa) • **Stelara** (ustekinumab)
Targeted	• **Actemra** (tocilizumab) • **Cimzia** (certolizumab pegol) • **Cosentyx** (Secukinumab) • **Ilumya** (tildrakizumab-asmn) • **Orencia** (abatacept)

	• **Tofidence** (Tocilizumab-bavi) • **Tremfya** (guselkumab) • **Tyenne** (Tocilizumab-aazg) • **Tysabri** (natalizumab)

*: Medications considered formulary or preferred on your plan may still require a clinical prior authorization review

II. EXCEPTION CRITERIA

This program applies to members requesting treatment for an indication that is FDA-approved for the preferred products.

Coverage for a targeted product is provided when any of the following criteria is met:

A. For Actemra, Tofidence, or Tyenne when any of the following criteria is met:
   1. When the request is for Systemic Juvenile Idiopathic Arthritis
   2. When the request is for Giant Cell Arteritis
   3. Member is currently receiving treatment with the requested targeted product, excluding when the requested targeted product is obtained as samples or via manufacturer's patient assistance programs.
   4. Member has a documented inadequate response, contraindication, or intolerable adverse event to Simponi Aria.

B. For Cimzia, when any of the following criteria is met:
   1. When the request is for Axial Spondylarthritis
   2. Member is pregnant, breastfeeding, or of childbearing potential
   3. Member suffers from Trypanophobia (needle-phobic) and cannot self-inject
   4. Member is currently receiving treatment with the requested targeted product, excluding when the requested targeted product is obtained as samples or via manufacturer's patient assistance programs.
   5. Member has a documented inadequate response, contraindication, or intolerable adverse event to Simponi Aria, Stelara, Entyvio, and Skyrizi.

C. For Cosentyx, when any of the following criteria is met:
   1. When the request is for Axial Spondylarthritis
   2. Member is currently receiving treatment with the requested targeted product, excluding when the requested targeted product is obtained as samples or via manufacturer's patient assistance programs.
   3. Member has a documented inadequate response, contraindication, or intolerable adverse event to Simponi Aria, Stelara, and Skyrizi.

D. For Ilumya, when any of the following criteria is met:
   1. Member is currently receiving treatment with the requested targeted product, excluding when the requested targeted product is obtained as samples or via manufacturer's patient assistance programs.
   2. Member has a documented inadequate response, contraindication, or intolerable adverse event to Stelara and Skyrizi

E. For Orencia, when any of the following criteria is met:
   1. Member is currently receiving treatment with the requested targeted product, excluding when the requested targeted product is obtained as samples or via manufacturer's patient assistance programs.
   2. Member has a documented inadequate response, contraindication, or intolerable adverse event to Simponi Aria, Stelara, and Skyrizi.

F. For Tremfya, when any of the following criteria is met:
   1. Member is currently receiving treatment with the requested targeted product, excluding when the requested targeted product is obtained as samples or via manufacturer's patient assistance programs.
   2. Member has a documented inadequate response, contraindication, or intolerable adverse event to Simponi Aria, Stelara, Entyvio, and Skyrizi.

G. For Tysabri, when any of the following criteria is met:

1. When the request is for Multiple Sclerosis
2. Member is currently receiving treatment with the requested targeted product, excluding when the requested targeted product is obtained as samples or via manufacturer's patient assistance programs.
3. Member has a documented inadequate response, contraindication, or intolerable adverse event to Stelara, Entyvio, and Skyrizi.

Section 2: Clinical Criteria

Enhanced Specialty Guideline Management
Treatment Of Plaque Psoriasis

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Abrilada	adalimumab-afzb
adalimumab (unbranded Humira)	adalimumab
adalimumab-aacf (unbranded Idacio)	adalimumab-aacf
adalimumab-aaty (unbranded Yuflyma)	adalimumab-aaty
adalimumab-adaz (unbranded Hyrimoz)	adalimumab-adaz
adalimumab-adbm (unbranded Cyltezo)	adalimumab-adbm
adalimumab-fkjp (unbranded Hulio)	adalimumab-fkjp
adalimumab-ryvk (unbranded Simlandi)	adalimumab-ryvk
Amjevita	adalimumab-atto
Avsola	infliximab-axxq
Bimzelx	bimekizumab-bkzx
Cimzia	certolizumab pegol
Cosentyx	secukinumab
Cyltezo	adalimumab-adbm
Enbrel	etanercept
Hadlima	adalimumab-bwwd
Hulio	adalimumab-fkjp
Humira	adalimumab
Hyrimoz	adalimumab-adaz

Brand Name	Generic Name
Idacio	adalimumab-aacf
Ilumya	tildrakizumab
Imuldosa	ustekinumab-srlf
Inflectra	infliximab-dyyb
infliximab (unbranded Remicade)	infliximab
Otezla	apremilast
Otulfi	ustekinumab-aauz
Pyzchiva	ustekinumab-ttwe
Remicade	infliximab
Renflexis	infliximab-abda
Selarsdi	ustekinumab-aekn
Siliq	brodalumab
Simlandi	adalimumab-ryvk
Skyrizi	risankizumab-rzaa
Sotyktu	deucravacitinib
Stelara	ustekinumab
Steqeyma	ustekinumab-stba
Taltz	ixekizumab
Tremfya	guselkumab
ustekinumab (unbranded Stelara)	ustekinumab
ustekinumab-aauz (unbranded Otulfi)	ustekinumab-aauz
ustekinumab-aekn (unbranded Selarsdi)	ustekinumab-aekn
ustekinumab-stba (unbranded Steqeyma)	ustekinumab-stba
ustekinumab-ttwe (unbranded Pyzchiva)	ustekinumab-ttwe
Wezlana	ustekinumab-auub
Yesintek	ustekinumab-kfce
Yuflyma	adalimumab-aaty
Yusimry	adalimumab-aqvh

Program Rationale

This program applies to the following products that are FDA-approved for the treatment of plaque psoriasis (Abrilada, adalimumab, adalimumab-aacf, adalimumab-aaty, adalimumab-adaz, adalimumab-adbm, adalimumab-fkjp, adalimumab-ryvk, Amjevita, Avsola, Bimzelx, Cimzia, Cosentyx, Cyltezo, Enbrel, Hadlima, Hulio, Humira, Hyrimoz, Idacio, Ilumya, Imuldosa, Inflectra, infliximab, Otezla, Otulfi, Pyzchiva, Remicade, Renflexis, Selarsdi, Siliq, Simlandi, Skyrizi, Sotyktu, Stelara, Steqeyma, Taltz, Tremfya, ustekinumab, ustekinumab-aauz, ustekinumab-aekn, ustekinumab-stba, ustekinumab-ttwe, Wezlana, Yesintek, Yuflyma, Yusimry). Members with coexistent psoriatic arthritis will not be subject to these enhanced criteria. Members less than 18 years of age will not be subject to these enhanced criteria.

Coverage will be provided if all coverage criteria are met and the member has no exclusions to the prescribed therapy.

Documentation

The following information is necessary to initiate the prior authorization review:

Initial requests

Chart notes or medical record documentation of the following at the time of diagnosis (where applicable): psoriasis involvement of body surface area (BSA), Psoriasis Area Severity Index (PASI) score, and severe psoriasis affected area(s) with significant functional impairment and/or high levels of distress.

Chart notes, medical record documentation, or claims history of all prior and current use of treatment regimens (e.g., topical agents, phototherapy, systemic non-biological agents, and biological agents) for plaque psoriasis (if applicable), including dosage, duration, and response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy.

Continuation requests

Chart notes or medical record documentation of any of the following: current psoriasis involvement percent of BSA, percent improvement of BSA from baseline, percent reduction of PASI from baseline, or Dermatology Life Quality Index (DLQI) score.

Prescriber Specialties

This medication must be prescribed by or in consultation with a dermatologist.

Coverage Criteria

Authorization of 12 months may be granted for members who have previously received a biologic or a targeted synthetic drug (e.g., Sotyktu, Otezla) indicated for the treatment of moderate to severe plaque psoriasis within the past 120 days.

Authorization of 12 months may be granted for treatment of moderate to severe plaque psoriasis in members when both of the following criteria are met:

- The member has met one of following criteria:
  - At least 10% of body surface area (BSA) is affected.
  - At least 3% of BSA is affected and has a Psoriasis Area Severity Index (PASI) score of ≥ 10.
  - The affected area is severe at localized sites and associated with significant functional impairment and/or high levels of distress (e.g., nail disease or involvement of high-impact and difficult-to-treat sites such as face, scalp, palms, soles, flexures and genitals).

- The member had an inadequate response at the maximum tolerated dose with all of the following:
    - Topical pharmacologic therapy (e.g., corticosteroids, calcineurin inhibitors, vitamin D analogs, retinoids) unless the patient has any of the following reasons to avoid topical pharmacologic therapies:
        - BSA > 10% is affected.
        - Crucial body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected.
        - Failure of topical pharmacologic therapy at the maximum tolerated dose and specified duration from any of the following classes:
            - Medium to super-high potency topical corticosteroid therapy (see Appendix A) for a duration of at least 4 weeks.
            - Topical calcineurin inhibitor therapy for a duration of at least 8 weeks.
            - Topical vitamin D analog therapy for a duration of at least 12 weeks.
            - Topical retinoid therapy for a duration of at least 12 weeks.
            - Topical aryl hydrocarbon receptor agonist therapy for a duration of at least 12 weeks.
            - Topical phosphodiesterase 4 inhibitor therapy for a duration of at least 8 weeks.
    - Phototherapy (e.g., UVB, PUVA) for a duration of at least 3 months unless the member has experienced an intolerable adverse event, has a clinical reason to avoid phototherapy, or the member does not have access to phototherapy.
    - Any of the following:
        - Methotrexate at a dose of at least 25 mg/week or at the maximum tolerated dose for a duration of at least 3 months.
        - Cyclosporine at a dose of at least 5 mg/kg/day or at the maximum tolerated dose for a duration of at least 6 weeks.
        - Acitretin at a dose of at least of 50 mg/day or at the maximum tolerated dose for a duration of at least 3 months.
        - The member has a clinical reason to avoid systemic pharmacologic treatment with methotrexate, cyclosporine, and acitretin (see Appendix B).

Continuation of Therapy

Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for an indication outlined in the coverage criteria section who achieve or maintain a positive clinical response with the requested medication as evidenced by low disease activity or improvement in signs and symptoms of the condition when any of the following criteria is met:

- Member has a psoriasis involvement of ≤ 3% body surface area (BSA)
- Member has a ≥ 75% BSA improvement from baseline
- Member has at least a 75% reduction in the PASI score from baseline
- Member has at least a 50% reduction in the PASI score from baseline and a Dermatology Life Quality Index (DLQI) score 5 or less

Other

For all drugs other than Otezla, member has had a documented negative tuberculosis (TB) test (which can include a tuberculosis skin test [TST] or an interferon-release assay [IGRA]) within 12 months of initiating therapy for persons who are naïve to biologic drugs or targeted synthetic drugs associated with an increased risk of TB.

If the screening testing for TB is positive, there must be further testing to confirm there is no active disease (e.g., chest x-ray). Do not administer the requested medication to members with active TB infection. If there is latent disease, TB treatment must be started before initiation of the requested medication.

For Sotyktu, member cannot use the requested medication concomitantly with any other biologic drug or targeted synthetic drug. For all other drugs, member cannot use the requested medication concomitantly with any other biologic drug or targeted synthetic drug for the same indication.

Dosage And Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Appendix

Appendix A. Table. Relative Potency of Select Topical Corticosteroid Products

Potency	Drug	Dosage form	Strength
I. Super-high potency (group 1)	Augmented betamethasone dipropionate	Ointment, Lotion, Gel	0.05%
I. Super-high potency (group 1)	Clobetasol propionate	Cream, Gel, Ointment, Solution, Cream (emollient), Lotion, Shampoo, Foam, Spray	0.05%
I. Super-high potency (group 1)	Fluocinonide	Cream	0.1%
I. Super-high potency (group 1)	Flurandrenolide	Tape	4 mcg/cm^2
I. Super-high potency (group 1)	Halobetasol propionate	Cream, Lotion, Ointment, Foam	0.05%
II. High potency (group 2)	Amcinonide	Ointment	0.1%
II. High potency (group 2)	Augmented betamethasone dipropionate	Cream	0.05%
II. High potency (group 2)	Betamethasone dipropionate	Ointment	0.05%

Potency	Drug	Dosage form	Strength
II. High potency (group 2)	Clobetasol propionate	Cream	0.025%
II. High potency (group 2)	Desoximetasone	Cream, Ointment, Spray	0.25%
II. High potency (group 2)	Desoximetasone	Gel	0.05%
II. High potency (group 2)	Diflorasone diacetate	Ointment, Cream (emollient)	0.05%
II. High potency (group 2)	Fluocinonide	Cream, Ointment, Gel, Solution	0.05%
II. High potency (group 2)	Halcinonide	Cream, Ointment	0.1%
II. High potency (group 2)	Halobetasol propionate	Lotion	0.01%
III. High potency (group 3)	Amcinonide	Cream, Lotion	0.1%
III. High potency (group 3)	Betamethasone dipropionate	Cream, hydrophilic emollient	0.05%
III. High potency (group 3)	Betamethasone valerate	Ointment	0.1%
III. High potency (group 3)	Betamethasone valerate	Foam	0.12%
III. High potency (group 3)	Desoximetasone	Cream, Ointment	0.05%
III. High potency (group 3)	Diflorasone diacetate	Cream	0.05%
III. High potency (group 3)	Fluocinonide	Cream, aqueous emollient	0.05%
III. High potency (group 3)	Fluticasone propionate	Ointment	0.005%
III. High potency (group 3)	Mometasone furoate	Ointment	0.1%
III. High potency (group 3)	Triamcinolone acetonide	Cream, Ointment	0.5%
IV. Medium potency (group 4)	Betamethasone dipropionate	Spray	0.05%
IV. Medium potency (group 4)	Clocortolone pivalate	Cream	0.1%
IV. Medium potency (group 4)	Fluocinolone acetonide	Ointment	0.025%
IV. Medium potency (group 4)	Flurandrenolide	Ointment	0.05%
IV. Medium potency (group 4)	Hydrocortisone valerate	Ointment	0.2%
IV. Medium potency (group 4)	Mometasone furoate	Cream, Lotion, Solution	0.1%
IV. Medium potency (group 4)	Triamcinolone acetonide	Cream	0.1%

Potency	Drug	Dosage form	Strength
IV. Medium potency (group 4)	Triamcinolone acetonide	Ointment	0.05% and 0.1%
IV. Medium potency (group 4)	Triamcinolone acetonide	Aerosol Spray	0.2 mg per 2-second spray
V. Lower-mid potency (group 5)	Betamethasone dipropionate	Lotion	0.05%
V. Lower-mid potency (group 5)	Betamethasone valerate	Cream	0.1%
V. Lower-mid potency (group 5)	Desonide	Ointment, Gel	0.05%
V. Lower-mid potency (group 5)	Fluocinolone acetonide	Cream	0.025%
V. Lower-mid potency (group 5)	Flurandrenolide	Cream, Lotion	0.05%
V. Lower-mid potency (group 5)	Fluticasone propionate	Cream, Lotion	0.05%
V. Lower-mid potency (group 5)	Hydrocortisone butyrate	Cream, Lotion, Ointment, Solution	0.1%
V. Lower-mid potency (group 5)	Hydrocortisone probutate	Cream	0.1%
V. Lower-mid potency (group 5)	Hydrocortisone valerate	Cream	0.2%
V. Lower-mid potency (group 5)	Prednicarbate	Cream (emollient), Ointment	0.1%
V. Lower-mid potency (group 5)	Triamcinolone acetonide	Lotion	0.1%
V. Lower-mid potency (group 5)	Triamcinolone acetonide	Ointment	0.025%
VI. Low potency (group 6)	Alclometasone dipropionate	Cream, Ointment	0.05%
VI. Low potency (group 6)	Betamethasone valerate	Lotion	0.1%
VI. Low potency (group 6)	Desonide	Cream, Lotion, Foam	0.05%
VI. Low potency (group 6)	Fluocinolone acetonide	Cream, Solution, Shampoo, Oil	0.01%
VI. Low potency (group 6)	Triamcinolone acetonide	Cream, lotion	0.025%
VII. Least potent (group 7)	Hydrocortisone (base, greater than or equal to 2%)	Cream, Ointment, Solution	2.5%
VII. Least potent (group 7)	Hydrocortisone (base, greater than or equal to 2%)	Lotion	2%
VII. Least potent (group 7)	Hydrocortisone (base, less than 2%)	Cream, Ointment, Gel, Lotion, Spray, Solution	1%
VII. Least potent (group 7)	Hydrocortisone (base, less than 2%)	Cream, Ointment	0.5%
VII. Least potent (group 7)	Hydrocortisone acetate	Cream	2.5%

Potency	Drug	Dosage form	Strength
VII. Least potent (group 7)	Hydrocortisone acetate	Lotion	2%
VII. Least potent (group 7)	Hydrocortisone acetate	Cream	1%

Appendix B. Examples of Clinical Reasons to Avoid Pharmacologic Treatment with Methotrexate, Cyclosporine, or Acitretin[55]

- Clinical diagnosis of alcohol use disorder, alcoholic liver disease, or other chronic liver disease
- Drug interaction
- Risk of treatment-related toxicity
- Pregnancy or currently planning pregnancy
- Breastfeeding
- Significant comorbidity prohibits use of systemic agents (e.g., liver or kidney disease, blood dyscrasias, uncontrolled hypertension)
- Hypersensitivity
- History of intolerance or adverse event

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