



MASSACHUSETTS

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Pharmacy Medical Policy Immune Modulating Drugs

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Policy Number: 004

BCBSA Reference Number: N/A

Related Policies

- Quality Care Dosing guidelines may apply and can be found in Medical Policy #[621B](#)

Prior Authorization Information

Policy	<input checked="" type="checkbox"/> Prior Authorization <input checked="" type="checkbox"/> Step Therapy <input checked="" type="checkbox"/> Quantity Limit	Reviewing Department Policy Effective Date	Pharmacy Operations: Tel: 1-800-366-7778 Fax: 1-800-583-6289 1/2025
Pharmacy (Rx) or Medical (MED) benefit coverage	<input checked="" type="checkbox"/> Rx <input type="checkbox"/> MED	To request for coverage: Providers may call, fax, or mail the attached form (Formulary Exception/Prior Authorization form) to the address below.	
Policy applies to Commercial Members: <ul style="list-style-type: none"> • Managed Care (HMO and POS), • PPO and Indemnity • MEDEX with Rx plan • Managed Major Medical with Custom BCBSMA Formulary • Comprehensive Managed Major Medical with Custom BCBSMA Formulary • Managed Blue for Seniors with Custom BCBSMA Formulary Policy does NOT apply to: <ul style="list-style-type: none"> • Medicare Advantage 		Blue Cross Blue Shield of Massachusetts Pharmacy Operations Department 25 Technology Place Hingham, MA 02043 Tel: 1-800-366-7778 Fax: 1-800-583-6289 Individual Consideration for the atypical patient: Policy for requests that do not meet clinical criteria of this policy, see section labeled Individual Consideration	

Summary

This policy covers prior authorization, step therapy and quantity limit requirements for immune modulating drugs for some FDA-approved indications.

The FDA-approved indications covered in this policy:

The FDA-approved indications covered in this policy are listed below. You may select a condition by clicking on the name or if preferred, by scrolling down the document to the desired indication to see the formulary and prior authorization requirements.

Non-Preferred – Required to try and fail **ONE** (1) preferred prior to coverage.

Note: nothing after a diagnosis in the last column implies 18 years and older whereas an example of ≥ 6 YO means greater than or equal to 6 years of age.

QCD - Quality Care Dosing (quantity limits policy #621B); **SPBO** – Specialty Pharmacy benefit only coverage; **PA** – Prior Authorization; **ST** – Step Therapy; **NFNC** – Non-formulary, Non-Covered

<u>Drug</u>	<u>Drug class</u>	<u>Coverage</u>	<u>Diag / Topic</u>
Avsola (infliximab) (Remicade Biosimilar)	TNF	Preferred, PA	Ankylosing Spondylitis Crohn's Disease ≥ 6 YO Psoriasis Psoriatic Arthritis Rheumatoid Arthritis Ulcerative Colitis ≥ 6 YO
Cordavis Humira (adalimumab) (Humira Biosimilar)	TNF	Preferred, PA, QCD, SPBO	Ankylosing Spondylitis Crohn's Disease ≥ 6 YO Hidradenitis Suppurativa ≥ 12 YO Juvenile Idiopathic Arthritis ≥ 2 YO Panuveitis / Uveitis ≥ 2 YO Psoriasis Psoriatic Arthritis Rheumatoid Arthritis Ulcerative Colitis ≥ 5 YO
Enbrel (etanercept)	TNF	Preferred, PA, QCD, SPBO	Ankylosing Spondylitis Juvenile Idiopathic Arthritis ≥ 2 YO Psoriasis ≥ 4 YO Psoriatic Arthritis ≥ 2 YO Rheumatoid Arthritis

<u>Drug</u>	<u>Drug class</u>	<u>Coverage</u>	<u>Diag / Topic</u>
Hadlima (adalimumab) (Humira Biosimilar)	TNF	Preferred, PA, QCD	Ankylosing Spondylitis Crohn's Disease ≥ 6 YO Hidradenitis Suppurativa ≥ 12 YO Juvenile Idiopathic Arthritis ≥ 2 YO Panuveitis / Uveitis ≥ 2 YO Psoriasis Psoriatic Arthritis Rheumatoid Arthritis Ulcerative Colitis ≥ 5 YO
Humira (adalimumab)	TNF	Preferred, PA, QCD, SPBO	Ankylosing Spondylitis Crohn's Disease ≥ 6 YO Hidradenitis Suppurativa ≥ 12 YO Juvenile Idiopathic Arthritis ≥ 2 YO Panuveitis / Uveitis ≥ 2 YO Psoriasis Psoriatic Arthritis Rheumatoid Arthritis Ulcerative Colitis ≥ 5 YO
Inflectra (infliximab) (Remicade Biosimilar)	TNF	Preferred, PA	Ankylosing Spondylitis Crohn's Disease ≥ 6 YO Psoriasis Psoriatic Arthritis Rheumatoid Arthritis Ulcerative Colitis ≥ 6 YO

<u>Drug</u>	<u>Drug class</u>	<u>Coverage</u>	<u>Diag / Topic</u>
Simlandi (adalimumab) (Humira Biosimilar)	TNF	Preferred, PA, QCD	Ankylosing Spondylitis Crohn's Disease ≥ 6 YO Hidradenitis Suppurativa ≥ 12 YO Juvenile Idiopathic Arthritis ≥ 2 YO Panuveitis / Uveitis ≥ 2 YO Psoriasis Psoriatic Arthritis Rheumatoid Arthritis Ulcerative Colitis ≥ 5 YO
Ilaris (canakinumab)	IL1β	Preferred, PA, SPBO	Cryopyrin-associated Periodic Syndromes (CAPs) and Other FDA-approved Indications ≥ 4 YO Juvenile Idiopathic Arthritis ≥ 2 YO (Requires treatment failure with TWO (2) drugs on the preferred drug list)
Taltz (ixekizumab)	IL17a	Preferred, PA, QCD	Ankylosing Spondylitis Non-radiographic Axial Spondylarthritis Psoriasis ≥ 6 YO Psoriatic Arthritis
Skyrizi (risankizumab)	IL23	Preferred, PA, QCD, SPBO	Crohn's Disease Psoriasis Psoriatic Arthritis Ulcerative Colitis

<u>Drug</u>	<u>Drug class</u>	<u>Coverage</u>	<u>Diag / Topic</u>
Tremfya (guselkumab)	IL23	Preferred, PA, QCD, SPBO	Psoriasis Psoriatic Arthritis Ulcerative Colitis
Stelara (ustekinumab)	IL12/23	Preferred, PA, QCD, SPBO	Crohn's Disease Psoriasis ≥ 6 YO Psoriatic Arthritis ≥ 6 YO Ulcerative Colitis
Spevigo (spesolimab)	IL36	Preferred, PA	Generalized Pustular Psoriasis (GPP) ≥ 12 YO
Otezla (apremilast)	PDE4	Preferred, PA, QCD	Psoriasis ≥ 6 YO Psoriatic Arthritis
Velsipity (etrasimod)	S1PR	Preferred, PA, QCD, SPBO	Ulcerative Colitis
Adalimumab-aacf (Humira Biosimilar)	TNF	Non-Preferred, PA, QCD, SPBO	Ankylosing Spondylitis Crohn's Disease ≥ 6 YO Hidradenitis Suppurativa ≥ 12 YO Juvenile Idiopathic Arthritis ≥ 2 YO Panuveitis / Uveitis ≥ 2 YO Psoriasis Psoriatic Arthritis Rheumatoid Arthritis Ulcerative Colitis ≥ 5 YO

<u>Drug</u>	<u>Drug class</u>	<u>Coverage</u>	<u>Diag / Topic</u>
Adalimumab-aaty (Humira Biosimilar)	TNF	Non-Preferred, PA, QCD, SPBO	Ankylosing Spondylitis Crohn's Disease ≥ 6 YO Hidradenitis Suppurativa ≥ 12 YO Juvenile Idiopathic Arthritis ≥ 2 YO Panuveitis / Uveitis ≥ 2 YO Psoriasis Psoriatic Arthritis Rheumatoid Arthritis Ulcerative Colitis ≥ 5 YO
Adalimumab-adaz (Humira Biosimilar)	TNF	Non-Preferred, PA, QCD, SPBO	Ankylosing Spondylitis Crohn's Disease ≥ 6 YO Hidradenitis Suppurativa ≥ 12 YO Juvenile Idiopathic Arthritis ≥ 2 YO Panuveitis / Uveitis ≥ 2 YO Psoriasis Psoriatic Arthritis Rheumatoid Arthritis Ulcerative Colitis ≥ 5 YO
Adalimumab-adbm (Humira Biosimilar)	TNF	Non-Preferred, PA, QCD, SPBO	Ankylosing Spondylitis Crohn's Disease ≥ 6 YO Hidradenitis Suppurativa ≥ 12 YO Juvenile Idiopathic Arthritis ≥ 2 YO Panuveitis / Uveitis ≥ 2 YO Psoriasis Psoriatic Arthritis Rheumatoid Arthritis Ulcerative Colitis ≥ 5 YO

<u>Drug</u>	<u>Drug class</u>	<u>Coverage</u>	<u>Diag / Topic</u>
Adalimumab-fkjp (Humira Biosimilar)	TNF	Non-Preferred, PA, QCD, SPBO	Ankylosing Spondylitis Crohn's Disease ≥ 6 YO Hidradenitis Suppurativa ≥ 12 YO Juvenile Idiopathic Arthritis ≥ 2 YO Panuveitis / Uveitis ≥ 2 YO Psoriasis Psoriatic Arthritis Rheumatoid Arthritis Ulcerative Colitis ≥ 5 YO
Adalimumab-ryvk (Humira Biosimilar)	TNF	Non-Preferred, PA, QCD, SPBO	Ankylosing Spondylitis Crohn's Disease ≥ 6 YO Hidradenitis Suppurativa ≥ 12 YO Juvenile Idiopathic Arthritis ≥ 2 YO Panuveitis / Uveitis ≥ 2 YO Psoriasis Psoriatic Arthritis Rheumatoid Arthritis Ulcerative Colitis ≥ 5 YO
Infliximab \$ (Remicade Biosimilar)	TNF	Non-Preferred, PA [\$=Must try either ONE (1) preferred infliximab]	Ankylosing Spondylitis Crohn's Disease ≥ 6 YO Psoriasis Psoriatic Arthritis Rheumatoid Arthritis Ulcerative Colitis ≥ 6 YO

<u>Drug</u>	<u>Drug class</u>	<u>Coverage</u>	<u>Diag / Topic</u>
Renflexis [§] (infliximab) (Remicade Biosimilar)	TNF	Non-Preferred, PA [§=Must try either ONE (1) preferred infliximab]	Ankylosing Spondylitis Crohn's Disease ≥ 6 YO Psoriasis Psoriatic Arthritis Rheumatoid Arthritis Ulcerative Colitis ≥ 6 YO
Zymfentra [§] (infliximab) (Remicade Biosimilar)	TNF	Non-Preferred, PA [§=Must try either ONE (1) preferred infliximab]	Ankylosing Spondylitis Crohn's Disease ≥ 6 YO Psoriasis Psoriatic Arthritis Rheumatoid Arthritis Ulcerative Colitis ≥ 6 YO
Rinvoq / LQ [^] (upadacitinib)	JAK	Non-Preferred, PA, QCD (^ = must try a preferred TNF blocker prior to coverage)	Ankylosing Spondylitis Crohn's Disease Juvenile Idiopathic Arthritis ≥ 2 YO Non-radiographic Axial Spondylarthritis Psoriatic Arthritis ≥ 2 YO Rheumatoid Arthritis Ulcerative Colitis
Xeljanz [^] (tofacitinib)	JAK	Non-Preferred, PA (^ = must try a preferred TNF blocker prior to coverage)	Ankylosing Spondylitis Juvenile Idiopathic Arthritis ≥ 2 YO Psoriatic Arthritis Rheumatoid Arthritis Ulcerative Colitis

<u>Drug</u>	<u>Drug class</u>	<u>Coverage</u>	<u>Diag / Topic</u>
Xeljanz XR ^ (tofacitinib)	JAK	Non-Preferred, PA, QCD (^ = must try a preferred TNF blocker prior to coverage)	Ankylosing Spondylitis Juvenile Idiopathic Arthritis ≥ 2 YO Psoriatic Arthritis Rheumatoid Arthritis Ulcerative Colitis
Kevzara (sarilumab)	IL6	Non-Preferred, PA, QCD, SPBO	Juvenile Idiopathic Arthritis 63kG+ Rheumatoid Arthritis
Tofidence (tocilizumab) (Actemra Biosimilar)	IL6	Non-Preferred, PA	Juvenile Idiopathic Arthritis ≥ 2 YO Rheumatoid Arthritis
Tyenne (tocilizumab) (Actemra Biosimilar)	IL6	Non-Preferred, PA	Juvenile Idiopathic Arthritis ≥ 2 YO Rheumatoid Arthritis
Sotyktu (deucravacitinib)	TYK2	Non-Preferred, PA, QCD	Psoriasis
Abrilada (adalimumab) (Humira Biosimilar)	TNF	NFNC, PA, QCD, SPBO	Ankylosing Spondylitis Crohn's Disease ≥ 6 YO Hidradenitis Suppurativa ≥ 12 YO Juvenile Idiopathic Arthritis ≥ 2 YO Panuveitis / Uveitis ≥ 2 YO (Required to try and fail ONE (1) preferred prior to coverage.) Psoriasis Psoriatic Arthritis Rheumatoid Arthritis Ulcerative Colitis ≥ 5 YO

<u>Drug</u>	<u>Drug class</u>	<u>Coverage</u>	<u>Diag / Topic</u>
Amjevita (adalimumab) (Humira Biosimilar)	TNF	NFNC, PA, QCD, SPBO	Ankylosing Spondylitis Crohn's Disease ≥ 6 YO Hidradenitis Suppurativa ≥ 12 YO Juvenile Idiopathic Arthritis ≥ 2 YO Panuveitis / Uveitis ≥ 2 YO (Required to try and fail ONE (1) preferred prior to coverage.) Psoriasis Psoriatic Arthritis Rheumatoid Arthritis Ulcerative Colitis ≥ 5 YO
Cimzia (certolizumab)	TNF	NFNC, PA, QCD, SPBO	Ankylosing Spondylitis Crohn's Disease Non-radiographic Axial Spondylarthritis (Required to try and fail ONE (1) preferred prior to coverage.) Psoriasis Psoriatic Arthritis Rheumatoid Arthritis
Cyltezo (adalimumab) (Humira Biosimilar)	TNF	NFNC, PA, QCD, SPBO	Ankylosing Spondylitis Crohn's Disease ≥ 6 YO Hidradenitis Suppurativa ≥ 12 YO Juvenile Idiopathic Arthritis ≥ 2 YO Panuveitis / Uveitis ≥ 2 YO (Required to try and fail ONE (1) preferred prior to coverage.) Psoriasis Psoriatic Arthritis Rheumatoid Arthritis Ulcerative Colitis ≥ 5 YO

<u>Drug</u>	<u>Drug class</u>	<u>Coverage</u>	<u>Diag / Topic</u>
<p>Hulio (adalimumab) (Humira Biosimilar)</p>	TNF	NFNC, PA, QCD, SPBO	<p>Ankylosing Spondylitis</p> <p>Crohn's Disease ≥ 6 YO</p> <p>Hidradenitis Suppurativa ≥ 12 YO</p> <p>Juvenile Idiopathic Arthritis ≥ 2 YO</p> <p>Panuveitis / Uveitis ≥ 2 YO (Required to try and fail ONE (1) preferred prior to coverage.)</p> <p>Psoriasis</p> <p>Psoriatic Arthritis</p> <p>Rheumatoid Arthritis</p> <p>Ulcerative Colitis ≥ 5 YO</p>
<p>Hyrimoz (adalimumab) (Humira Biosimilar)</p>	TNF	NFNC, PA, QCD, SPBO	<p>Ankylosing Spondylitis</p> <p>Crohn's Disease ≥ 6 YO</p> <p>Hidradenitis Suppurativa ≥ 12 YO</p> <p>Juvenile Idiopathic Arthritis ≥ 2 YO</p> <p>Panuveitis / Uveitis ≥ 2 YO (Required to try and fail ONE (1) preferred prior to coverage.)</p> <p>Psoriasis</p> <p>Psoriatic Arthritis</p> <p>Rheumatoid Arthritis</p> <p>Ulcerative Colitis ≥ 5 YO</p>

<u>Drug</u>	<u>Drug class</u>	<u>Coverage</u>	<u>Diag / Topic</u>
Idacio (adalimumab) (Humira Biosimilar)	TNF	NFNC, PA, QCD, SPBO	Ankylosing Spondylitis Crohn's Disease ≥ 6 YO Hidradenitis Suppurativa ≥ 12 YO Juvenile Idiopathic Arthritis ≥ 2 YO Panuveitis / Uveitis ≥ 2 YO (Required to try and fail ONE (1) preferred prior to coverage.) Psoriasis Psoriatic Arthritis Rheumatoid Arthritis Ulcerative Colitis ≥ 5 YO
Remicade ^{\$} (infliximab) (Remicade Biosimilar)	TNF	NFNC, PA, QCD, SPBO [\$=Must try either TWO (2) preferred infliximabs]	Ankylosing Spondylitis Crohn's Disease ≥ 6 YO Psoriasis Psoriatic Arthritis Rheumatoid Arthritis Ulcerative Colitis ≥ 6 YO
Simponi / Aria (golimumab)	TNF	NFNC, PA, QCD, SPBO	Ankylosing Spondylitis Juvenile Idiopathic Arthritis ≥ 2 YO (Aria) Psoriatic Arthritis ≥ 2 YO (Aria) Rheumatoid Arthritis Ulcerative Colitis

<u>Drug</u>	<u>Drug class</u>	<u>Coverage</u>	<u>Diag / Topic</u>
Yuflyma (adalimumab) (Humira Biosimilar)	TNF	NFNC, PA, QCD, SPBO	Ankylosing Spondylitis Crohn's Disease ≥ 6 YO Hidradenitis Suppurativa ≥ 12 YO Juvenile Idiopathic Arthritis ≥ 2 YO Panuveitis / Uveitis ≥ 2 YO (Required to try and fail ONE (1) preferred prior to coverage.) Psoriasis Psoriatic Arthritis Rheumatoid Arthritis Ulcerative Colitis ≥ 5 YO
Yusimry (adalimumab) (Humira Biosimilar)	TNF	NFNC, PA, QCD	Ankylosing Spondylitis Crohn's Disease ≥ 6 YO Hidradenitis Suppurativa ≥ 12 YO Juvenile Idiopathic Arthritis ≥ 2 YO Panuveitis / Uveitis ≥ 2 YO (Required to try and fail ONE (1) preferred prior to coverage.) Psoriasis Psoriatic Arthritis Rheumatoid Arthritis Ulcerative Colitis ≥ 5 YO
Olumiant (baricitinib)	JAK	NFNC, PA, QCD	Rheumatoid Arthritis
Kineret (anakinra)	IL1	NFNC, PA, QCD, SPBO	Cryopyrin-associated Periodic Syndromes (CAPs) and Other FDA-approved Indications ≥ 2 YO Rheumatoid Arthritis
Actemra (tocilizumab)	IL6	NFNC, PA, QCD, SPBO	Juvenile Idiopathic Arthritis ≥ 2 YO Rheumatoid Arthritis

<u>Drug</u>	<u>Drug class</u>	<u>Coverage</u>	<u>Diag / Topic</u>
Cosentyx (secukinumab)	IL17a	NFNC, PA, QCD, SPBO	Ankylosing Spondylitis Enthesitis-Related Arthritis ≥ 4 YO (Requires Diag only) Hidradenitis Suppurativa ≥ 18 YO Non-radiographic Axial Spondylarthritis (Required to try and fail ONE (1) preferred prior to coverage) Psoriasis ≥ 6 YO Psoriatic Arthritis ≥ 2 YO
Bimzelx (bimekizumab)	IL17a & f	NFNC, PA, QCD, SPBO	Ankylosing Spondylitis Non-radiographic Axial Spondylarthritis (Required to try and fail ONE (1) preferred prior to coverage) Psoriasis Psoriatic Arthritis
Siliq (brodalumab)	IL17RA	NFNC, PA, QCD, SPBO	Psoriasis
Ilumya (tildrakizumab)	IL23	NFNC, PA, QCD, SPBO	Psoriasis
Omvoh (mirikizumab)	IL23	NFNC, PA, QCD, SPBO	Ulcerative Colitis
Orencia (abatacept)	T cell costimulation modulator	NFNC, PA, QCD	Juvenile Idiopathic Arthritis ≥ 2 YO Prophylaxis for Acute Graft versus Host Disease ≥ 2 YO (Requires diagnosis only) Psoriatic Arthritis ≥ 2 YO Rheumatoid Arthritis

<u>Drug</u>	<u>Drug class</u>	<u>Coverage</u>	<u>Diag / Topic</u>
Zeposia (ozanimod)	S1PR	NF, PA Non- formulary and requires TWO (2) preferred prior to coverage	Ulcerative Colitis
(This table is reproduced at the Top and Bottom of the table)			
Non-Preferred – Required to try and fail ONE (1) preferred prior to coverage.			
Note: nothing after a diagnosis in the last column implies 18 years and older whereas an example of > 6 YO means greater than or equal to 6 years of age.			
QCD - Quality Care Dosing (quantity limits policy #621B); SPBO – Specialty Pharmacy benefit only coverage; PA – Prior Authorization; ST – Step Therapy; NFNC – Non-formulary, Non-Covered			

Rheumatology Subsection Index with Preferred drug names included

Ankylosing Spondylitis (Avsola, Cordavis Humira, Enbrel, Hadlima, Humira, Inflectra, Simlandi, & Taltz)	Panuveitis / Uveitis (Cordavis Humira, Hadlima, Humira, & Simlandi)
Cryopyrin-associated Periodic Syndromes (CAPs) and Other FDA-approved Indications (Ilaris)	Psoriatic Arthritis Avsola, Cordavis Humira, Enbrel, Hadlima, Humira, Inflectra, Simlandi, Taltz, Skyrizi, Tremfya, & Otezla)
Juvenile Idiopathic Arthritis (Cordavis Humira, Enbrel, Hadlima, Humira, & Simlandi)	Rheumatoid Arthritis Avsola, Cordavis Humira, Enbrel, Hadlima, Humira, Inflectra, & Simlandi)
Non-radiographic Axial Spondylarthritis (Taltz)	

Dermatology Subsection Index with Preferred drug names included

Generalized Pustular Psoriasis (GPP) (Spevigo)
Hidradenitis Suppurativa (Cordavis Humira, Hadlima, Humira, & Simlandi)
Psoriasis

(Avsola, Cordavis Humira, Enbrel, Hadlima, Humira, Inflectra, Simlandi, Taltz, Skyrizi, Tremfya, Stelara & Otezla)

GI Subsection Index with Preferred drug names included

[Crohn's Disease](#)
(Avsola, Cordavis Humira, Hadlima, Humira, Inflectra, Simlandi, Skyrizi, & Stelara)

[Ulcerative Colitis](#)
(Avsola, Cordavis Humira, Hadlima, Humira, Inflectra, Simlandi, Skyrizi, Stelara & Tremfya)

Policy

Rheumatology Subsection

Ankylosing Spondylitis

Length of Approval	12 months
Formulary Status	All requests must meet the preferred/non-preferred drug sequence and prior authorization requirements. For non-covered or non-formulary medications, the member must also have had a previous treatment failure with, or contraindication to, at least two covered formulary alternatives when available. See section on individual consideration for more information if you require an exception to any of these criteria requirements for an atypical patient.
Member cost share consideration	A higher non-preferred cost share may be applied if an exception request is approved for coverage of a non-preferred or a non-formulary/non-covered drug.

Prior Authorization Requirements for Ankylosing Spondylitis

Preferred drugs listed on the [drug coverage table for ankylosing spondylitis](#), may be considered **MEDICALLY NECESSARY** and may be covered when **ALL** of the following criteria are met:

1. A documented diagnosis of active ankylosing spondylitis, **AND**
2. Age according to FDA approval, **AND**
3. The drug is prescribed by a board-certified or board eligible rheumatologist, **AND**
4. Treatment failure with, or contraindication to, one prescription NSAID **OR** Previous use and failure or clinical rationale for not using the preferred medication for ankylosing spondylitis, **AND**
5. Documented Dose and Frequency must be submitted and must be within the FDA approved Dosing and Frequency%, **AND**

6. For a **Non-Preferred Drug or Non-Formulary, Non-Covered**, there has been previous use of preferred drugs and failure or clinical rationale for not using the preferred medication for Ankylosing Spondylitis (see [table above](#) for preferred drug failure requirements)

% - this criterion is only for Infliximab class.

[Return to condition list](#)

Ilaris for Cryopyrin-Associated Periodic Syndromes (CAPS) and Other FDA-approved Indications

Length of Approval	12 months
Formulary Status	All requests must meet the preferred/non-preferred drug sequence and prior authorization requirements. For non-covered or non-formulary medications, the member must also have had a previous treatment failure with, or contraindication to, at least two covered formulary alternatives when available. See section on individual consideration for more information if you require an exception to any of these criteria requirements for an atypical patient.
Member cost share consideration	A higher non-preferred cost share may be applied if an exception request is approved for coverage of a non-preferred or a non-formulary/non-covered drug.

Prior Authorization Requirements

Preferred drugs on the [drug table for CAPs](#) may be considered **MEDICALLY NECESSARY** and may be covered when **ALL** of the following criteria are met:

1. A documented diagnosis of:
 - a. Cryopyrin-associated periodic syndrome (CAPS) which includes Familial Cold Autoinflammatory Syndrome (FCAS), Muckle-Wells Syndrome (MWS), and Neonatal-Onset Multisystem Inflammatory Disorder (NOMID, aka Chronic Infantile Neurologic Cutaneous & Articular Syndrome [CINCAS]), **OR**
 - b. Other FDA-approved indication for Ilaris (Gout, FMF, MKD, TRAPS, and HIDS), **AND**
2. The drug is prescribed by a board-certified or board-eligible rheumatologist or dermatologist, **AND**
3. For a **Non-Preferred Drug**, there has been previous use of preferred drugs and failure or clinical rationale for not using the preferred medication for CAPs (see [drug coverage table](#) for preferred drug failure requirements)

[Return to condition list](#)

Juvenile Idiopathic Arthritis (JIA)

Length of Approval	12 months
Formulary Status	All requests must meet the preferred/non-preferred drug sequence and prior authorization requirements. For non-covered or non-formulary medications, the member must also have had a previous treatment failure with, or contraindication to, at least two covered formulary alternatives when available. See section on individual consideration for more information if you require an exception to any of these criteria requirements for an atypical patient.

Member cost share consideration	A higher non-preferred cost share may be applied if an exception request is approved for coverage of a non-preferred or a non-formulary/non-covered drug.
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Prior Authorization Criteria for Juvenile Idiopathic Arthritis (JIA)

Preferred drugs on the [drug coverage table for JIA](#), may be considered **MEDICALLY NECESSARY** and may be covered when **ALL** of the following criteria are met:

1. A documented diagnosis of moderate to severely active JIA, **AND**
 2. Age according to FDA approval
- AND**
3. The drug is prescribed by a board-certified or board-eligible rheumatologist, **AND**
 4. Documented Dose and Frequency must be submitted and must be within the FDA approved Dosing and Frequency^{%%}, **AND**
 5. For a **Formulary Non-Preferred Drugs or Non-Formulary, Non-Covered**, there has been previous use of preferred drugs and failure or clinical rationale for not using the preferred medication for JIA (see [drug table for JIA](#) below for preferred drug failure requirements)

%% - this criterion is only for Actemra (including Biosimilars) and Orencia.

[Return to condition list](#)

Non-radiographic Axial Spondylarthritis

Length of Approval	12 months
Formulary Status	All requests must meet the preferred/non-preferred drug sequence and prior authorization requirements. For non-covered or non-formulary medications, the member must also have had a previous treatment failure with, or contraindication to, at least two covered formulary alternatives when available. See section on individual consideration for more information if you require an exception to any of these criteria requirements for an atypical patient.
Member cost share consideration	A higher non-preferred cost share may be applied if an exception request is approved for coverage of a non-preferred or a non-formulary/non-covered drug.

Prior Authorization Criteria for Non-radiographic Axial Spondylarthritis

Preferred drugs the [drug table for Non-radiographic Axial Spondylarthritis](#) may be considered **MEDICALLY NECESSARY** and may be covered for the treatment when **ALL** of the following criteria are met:

1. A documented diagnosis of non-radiographic axial spondylarthritis, **AND**
2. Age according to FDA approval, **AND**
3. The drug is prescribed by a board-certified or board-eligible rheumatologist, **AND**
4. Treatment failure or contraindication to a prescription NSAID **OR** Previous use and failure or clinical rationale for not using the preferred medication for non-radiographic axial spondylarthritis, **AND**
5. For a **Non-Preferred Drug**, there has been previous use of preferred drugs and failure or clinical rationale for not using the preferred medication for NAS (see [drug coverage table for NAS](#) for preferred drug failure requirements)

[Return to condition list](#)

Panuveitis/Uveitis

Length of Approval	12 months
Formulary Status	All requests must meet the preferred/non-preferred drug sequence and prior authorization requirements. For non-covered or non-formulary medications, the member must also have had a previous treatment failure with, or contraindication to, at least two covered formulary alternatives when available. See section on individual consideration for more information if you require an exception to any of these criteria requirements for an atypical patient.
Member cost share consideration	A higher non-preferred cost share may be applied if an exception request is approved for coverage of a non-preferred or a non-formulary/non-covered drug.

Prior Authorization Criteria for Panuveitis / Uveitis

Preferred drugs listed on the [drug coverage table for Panuveitis/Uveitis](#) may be considered **MEDICALLY NECESSARY** and may be covered when **ALL** of the following criteria are met:

1. A documented diagnosis of non-infectious intermediate, posterior Uveitis or Panuveitis, **AND**
2. Age according to FDA approval, **AND**
Documentation of one (1) of the following:
 - a. Topical Corticosteroids, **OR**
 - b. Topical Cycloplegics, **OR**
 - c. History of preferred drugs for Panuveitis / Uveitis, **OR**
 - d. Severe disease with profoundly limited vision or risk of significant vision loss, including those with macular edema, **OR**.
 - e. Bilateral posterior uveitis, **OR**
 - f. Comorbid glaucoma precluding the use of local glucocorticoid injections, **OR**
 - g. Certain systemic diseases including Behçet syndrome and serpiginous choroiditis
3. For a **Formulary Non-Preferred Drugs or Non-Formulary, Non-Covered**, there has been previous use of preferred drugs and failure or clinical rationale for not using the preferred medication for Panuveitis /Uveitis (see [drug table for Panuveitis / Uveitis](#) above for preferred drug failure requirements)

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Psoriatic Arthritis

Length of Approval	12 months
Formulary Status	All requests must meet the preferred/non-preferred drug sequence and prior authorization requirements. For non-covered or non-formulary medications, the member must also have had a previous treatment failure with, or contraindication to, at least two covered formulary alternatives when available. See section on individual consideration for more information if you require an exception to any of these criteria requirements for an atypical patient.
Member cost share consideration	A higher non-preferred cost share may be applied if an exception request is approved for coverage of a non-preferred or a non-formulary/non-covered drug.

Prior Authorization Criteria for Psoriatic Arthritis

Preferred drugs listed on the [drug coverage table for psoriatic arthritis](#) may be considered **MEDICALLY NECESSARY** and may be covered when **ALL** of the following criteria are met:

1. A documented diagnosis of active Psoriatic Arthritis, **AND**
2. Age according to FDA approval
3. Treatment failure with or contraindication to one oral or injectable DMARD **OR** Previous use of one of the preferred medications for psoriatic arthritis in the table, **AND**
4. The drug is prescribed by a board-certified or board-eligible rheumatologist, **AND**
5. Documented Dose and Frequency must be submitted and must be within the FDA approved Dosing and Frequency^{%%}, **AND**
6. For a **Formulary Non-Preferred Drugs or Non-Formulary, Non-Covered**, there has been previous use of preferred drugs and failure or clinical rationale for not using the preferred medication for Psoriatic Arthritis

%% - this criterion is only for the Infliximab class and Orencia.

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Rheumatoid Arthritis

Length of Approval	12 months
Formulary Status	All requests must meet the preferred/non-preferred drug sequence and prior authorization requirements. For non-covered or non-formulary medications, the member must also have had a previous treatment failure with, or contraindication to, at least two covered formulary alternatives when available. See section on individual consideration for more information if you require an exception to any of these criteria requirements for an atypical patient.
Member cost share consideration	A higher non-preferred cost share may be applied if an exception request is approved for coverage of a non-preferred or a non-formulary/non-covered drug.

Prior Authorization Requirements for Rheumatoid Arthritis

Preferred drugs on the [drug coverage table for rheumatoid arthritis](#) may be considered **MEDICALLY NECESSARY** and may be covered when **ALL** of the following criteria are met:

1. A documented diagnosis of moderate to severely active rheumatoid arthritis, **AND**
2. Age \geq 18 years, **AND**
3. The drug is prescribed by a board-certified or board eligible rheumatologist, **AND**
4. Treatment failure with or contraindication to one conventional DMARD (azathioprine, cyclophosphamide, cyclosporin, hydroxychloroquine, leflunomide, methotrexate, mycophenolate, sulfasalazine,) **OR** Previous use of one of the preferred medications for rheumatoid arthritis in the table, **AND**
5. Documented Dose and Frequency must be submitted and must be within the FDA approved Dosing and Frequency^{%%%}, **AND**

6. For a **Formulary Non-Preferred Drugs or Non-Formulary, Non-Covered**, there has been previous treatment failure with a preferred drug (see [drug coverage table for RA](#) below for preferred drug failure requirements)

%% - this criterion is only for the Infliximab class, Actemra (including Biosimilars) and Orencia.

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Dermatology Subsection

Generalized Pustular Psoriasis (GPP)

Length of Approval	3 months
Formulary Status	All requests must meet the preferred/non-preferred drug sequence and prior authorization requirements. For non-covered or non-formulary medications, the member must also have had a previous treatment failure with, or contraindication to, at least two covered formulary alternatives when available. See section on individual consideration for more information if you require an exception to any of these criteria requirements for an atypical patient.
Member cost share consideration	A higher non-preferred cost share may be applied if an exception request is approved for coverage of a non-preferred or a non-formulary/non-covered drug.

Prior Authorization Criteria for Generalized Pustular Psoriasis (GPP)

Preferred drugs listed on the [drug coverage table for GPP](#), may be considered **MEDICALLY NECESSARY** and may be covered when **ALL** of the following criteria are met:

1. A documented diagnosis of Generalized Pustular Psoriasis, **AND**
2. Age according to FDA approval, **AND**
3. For a **Formulary Non-Preferred Drugs or Non-Formulary, Non-Covered**, there has been previous use of preferred drugs and failure or clinical rationale for not using the preferred medication for GPP (see [drug table above](#) for preferred drug failure requirements)

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Hidradenitis Suppurativa

Length of Approval	12 months
Formulary Status	All requests must meet the preferred/non-preferred drug sequence and prior authorization requirements. For non-covered or non-formulary medications, the member must also have had a previous treatment failure with, or contraindication to, at least two covered formulary alternatives when available. See section on individual consideration for more information if you require an exception to any of these criteria requirements for an atypical patient.
Member cost share consideration	A higher non-preferred cost share may be applied if an exception request is approved for coverage of a non-preferred or a non-formulary/non-covered drug.

Prior Authorization Criteria for Hidradenitis Suppurativa

Preferred drugs listed on the [drug coverage table for hidradenitis suppurativa](#) may be considered **MEDICALLY NECESSARY** and may be covered when **ALL** of the following criteria are met:

1. A documented diagnosis of moderate to severe hidradenitis suppurativa, **AND**
2. Age according to FDA approval.

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Psoriasis

Length of Approval	12 months
Formulary Status	All requests must meet the preferred/non-preferred drug sequence and prior authorization requirements. For non-covered or non-formulary medications, the member must also have had a previous treatment failure with, or contraindication to, at least two covered formulary alternatives when available. See section on individual consideration for more information if you require an exception to any of these criteria requirements for an atypical patient.
Member cost share consideration	A higher non-preferred cost share may be applied if an exception request is approved for coverage of a non-preferred or a non-formulary/non-covered drug.

Prior Authorization Criteria for Psoriasis

Preferred drugs on the [drug coverage table for psoriasis](#) may be considered **MEDICALLY NECESSARY** and covered when **ALL** of the following criteria are met:

1. A documented diagnosis of moderate-severe chronic plaque psoriasis, **AND**
2. Age according to FDA approval, **AND**
3. The drug is prescribed by a board-certified or board-eligible dermatologist, **AND**
4. Treatment failure with or contraindication to systemic therapy for Psoriasis (Methotrexate, Azathioprine, Acitretin, Tacrolimus, Cyclosporine, Mycophenolate, 6-thioguanine, Sulfasalazine, Hydroxyurea, Propylthiouracil, Narrow-band UVB, Oral methoxsalen) **OR** Previous use and failure or clinical rationale for not using the preferred medication for psoriasis, **AND**
5. Documented Dose and Frequency must be submitted and must be within the FDA approved Dosing and Frequency%, **AND**
6. For a **Formulary Non-Preferred Drugs or Non-Formulary, Non-Covered**, there has been previous use of preferred drugs and failure or clinical rationale for not using the preferred medication for Psoriasis (see drug table below for requirements and exceptions)

% - this criterion is only for the Infliximab class.

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GI Subsection

Crohn's Disease

Length of Approval	12 months
Formulary Status	All requests must meet the preferred/non-preferred drug sequence and prior authorization requirements. For non-covered or non-formulary medications, the member must also have had a previous treatment failure with, or contraindication to, at least two covered formulary alternatives when available. See section on individual consideration for more information if you require an exception to any of these criteria requirements for an atypical patient.
Member cost share consideration	A higher non-preferred cost share may be applied if an exception request is approved for coverage of a non-preferred or a non-formulary/non-covered drug.

Prior Authorization Criteria for Crohn's Disease

Preferred drugs listed on the [drug coverage table for Crohn's Disease](#), may be considered **MEDICALLY NECESSARY** and may be covered when **ALL** of the following criteria are met:

1. A documented diagnosis of moderate to severe Crohn's Disease, **AND**
2. Age according to FDA approval, **AND**
3. The drug is prescribed by a board-certified or eligible gastroenterologist, **AND**
4. Not receiving in combination with any of the following:
 - a. Potent Immunosuppressives (JAK inhibitors, TNF inhibitors, IL-1 inhibitor, IL-6 inhibitor, any other applicable categories), **OR**
 - b. Integrin inhibitors (Vedolizumab, Natalizumab), **AND**
5. Documented Dose and Frequency must be submitted and must be within the FDA approved Dosing and Frequency%, **AND**
6. For a **Formulary Non-Preferred Drugs or Non-Formulary, Non-Covered**, there has been previous use of preferred drugs and failure or clinical rationale for not using the preferred medication for Crohn's Disease (see [the drug table above](#) for preferred drug failure requirements)

% - this criterion is only for Infliximab class.

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Ulcerative Colitis

Length of Approval	12 months
Formulary Status	All requests must meet the preferred/non-preferred drug sequence and prior authorization requirements. For non-covered or non-formulary medications, the member must also have had a previous treatment failure with, or contraindication to, at least two covered formulary alternatives when available. See section on individual consideration for more information if you require an exception to any of these criteria requirements for an atypical patient.
Member cost share consideration	A higher non-preferred cost share may be applied if an exception request is approved for coverage of a non-preferred or a non-formulary/non-covered drug.

Prior Authorization Criteria for Ulcerative Colitis (UC)

Preferred drugs on the [drug coverage table for UC](#), may be considered **MEDICALLY NECESSARY** and may be covered when **ALL** of the following criteria are met:

1. A documented diagnosis of moderate to severe Ulcerative Colitis, **AND**
2. Age according to FDA approval, **AND**
3. The drug is prescribed by a board-certified or eligible gastroenterologist, **AND**
4. Documented history of failure, contraindication, or intolerance to at least one of the following therapies:
 - a. Tumor necrosis factor (TNF) blocker (adalimumab, certolizumab, etanercept, infliximab or golimumab), **OR**
 - b. DMARD (azathioprine, cyclophosphamide, cyclosporin, hydroxychloroquine, leflunomide, methotrexate, mycophenolate, sulfasalazine), **OR**
 - c. Systemic Corticosteroid(s), **OR**
 - d. Documented history of previous use and failure or clinical rationale for not using the **preferred medication** for ulcerative colitis.

AND

5. Documented Dose and Frequency must be submitted and must be within the FDA approved Dosing and Frequency%, **AND**
6. Not receiving in combination with any of the following:
 - a. Potent Immunosuppressives (JAK inhibitors, TNF inhibitors, IL-1 inhibitor, IL-6 inhibitor, any other applicable categories), **OR**
 - b. Integrin inhibitors (Vedolizumab, Natalizumab), **AND**
7. For a **Formulary Non-Preferred Drugs[^]** or **Non-Formulary, Non-Covered Drugs**, there has been previous use of preferred drugs and failure or clinical rationale for not using the preferred medication for UC.

% - this criterion is only for the Infliximab class.

[^] -- must try a preferred TNF blockers prior to coverage.

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Provider Documentation Requirements

Documentation from the provider to support a reason preventing trial of formulary alternative(s) must include the name and strength of alternatives tried and failed (if alternatives were tried, including dates if available) and specifics regarding the treatment failure. Documentation to support clinical basis preventing switch to formulary alternative should also provide specifics around clinical reason.

Individual Consideration (For Atypical Patients)

Our medical policies are written for most people with a given condition. Each policy is based on peer reviewed clinical evidence. We also take into consideration the needs of atypical patient populations and diagnoses.

If the coverage criteria outlined is unlikely to be clinically effective for the prescribed purpose, the health care provider may request an exception to cover the requested medication based on an individual's unique clinical circumstances. This is also referred to as "individual consideration" or an "exception request."

Some reasons why you may need us to make an exception include: therapeutic contraindications; history of adverse effects; expected to be ineffective or likely to cause harm (physical, mental, or adverse reaction).

To facilitate a thorough and prompt review of an exception request, we encourage the provider to include additional supporting clinical documentation with their request. This may include:

- Clinical notes or supporting clinical statements;
- The name and strength of formulary alternatives tried and failed (if alternatives were tried) and specifics regarding the treatment failure, if applicable;
- Clinical literature from reputable peer reviewed journals.
- References from nationally recognized and approved drug compendia such as American Hospital Formulary Service® Drug Information (AHFS-DI), Lexi-Drug, Clinical Pharmacology, Micromedex or Drugdex®; and
- References from consensus documents and/or nationally sanctioned guidelines.

Providers may call, fax or mail relevant clinical information, including clinical references for individual patient consideration, to:

Blue Cross Blue Shield of Massachusetts
 Pharmacy Operations Department
 25 Technology Place
 Hingham, MA 02043
 Phone: 1-800-366-7778
 Fax: 1-800-583-6289

We may also use prescription claims records to establish prior use of formulary alternatives or to show if step therapy criteria has been met. We will require the provider to share additional information when prescription claims data is either not available or the medication fill history fails to establish use of preferred formulary medications or that step therapy criteria has been met.

Policy History

Date	Action
1/2025	Updated to add Tremfya's new indication add FDA ages into the criteria and drug table and add Adalimumab-aacf to the policy as Non-Preferred.
11/2024	Reformatted Drug table and added Velsipity to preferred.
8/2024	Updated Spevigo change in age indication and Otezla's age in Psoriasis section, to add Zymfentra to the policy as non-preferred in Remicade table, to add Adalimumab-aaty & Adalimumab-ryvk to the non-preferred section, to add Tofidence & Tyenne to the non-preferred section, and to Clarify coverage for JAK inhibitors and include Rinvoq new liquid plus its JIA indication along with Kevzara's JIA indication.
5/2024	Updated to include Simlandi and Cordavis Humira to the policy.
4/2024	Updated to make Remicade and Amjevita non preferred and clarified age requirements for non-preferred drugs and covered indications of CAPs.
3/2024	Updated Dose and Frequency requirements to coincide with Medical claim edits and to add Omvoh, Bimzelx, and Velsipity to the policy as non-preferred.
1/2024	Updated to add Humira (adalimumab) biosimilars to the policy and to add new indication for Cosentyx.
12/2023	Reformatted policy. Updated IC to align with 118E MGL § 51A. Updated criteria for Ulcerative Colitis and Crohn's Disease. Updated policy format
9/2023	Updated to add new Rinvoq UC indication to the policy and updated IC to align with 118E MGL § 51A.
4/2023	Updated to add Amjevita and Sotyktu to the policy and add Age for Cosentyx for Psoriasis.
3/2023	Announced Skyrizi and Ilumya are joining Policy 071 on 7/1/2023.
1/2023	Updated to move Actemra, Cimzia, Ilumya, Kineret, Olumiant, Orencia, Siliq, and Simponi to non-covered. Also, to add Spevigo to the policy.
11/2022	Updated to add clarifying Footnote to Remicade and Olumiant.

8/2022	Updated to include new indication of CD for Skyrizi [®] and update the criteria for UC and Crohn's.
7/2022	Clarified Age for Psoriasis and added Indication for Simponi Aria (pJIA).
5/2022	Updated to include Rinvoq and additional clarity to RA criteria.
4/2022	Updated to add Avsola in the Infliximab table as Preferred.
2/2022	Updated to add AG biosimilar Infliximab as nonpreferred in the infliximab table and updated to separate Severe types of Ulcerative Colitis and Crohns disease. Lastly, Moved Xeljanz and Rinvoq to non-preferred in line with FDA label update.
1/2022	Updated to include 3rd row for Ulcerative Colitis in the table at the top.
8/2021	Updated criteria for Crohn's Disease and clarified criteria for Psoriasis.
7/2021	Updated to add nonpreferred language to Cosentyx, also new age for Humira in UC and a new indication for Actemra.
1/1/2021	Updated to move Cosentyx and Actemra to non-preferred. Plus Tremfya, Taltz, Enbrel, Stelara, Xeljanz to preferred. A new indication was added to the policy with Cimzia as preferred.
11/2020	Updated to add new diagnosis for Xeljanz to first non-preferred grouping and to move Rituxan to policy 123.
10/2020	Updated to prefer Inflectra as preferred infliximab.
9/2020	Updated to add Avsola to the Infliximab table and Stelara's new age for psoriasis.
6/2020	Updated to move Otezla to preferred for psoriatic arthritis.
2/2020	Updated to move Stelara to move to non-preferred for UC.
1/2020	Updated to move Taltz in all indications and Xeljanz in UC indication to non-preferred.
10/2019	Updated to add Rinvoq to preferred RA and to add expanded indications for Inflectra, Renflexis & Otezla.
7/2019	Updated to add Skyrizi & Tremfya to preferred in Psoriasis and to add Humira first step to Cimzia for Crohn's disease.
1/1/2019	Updated to Add an Infliximab table and make Inflectra a Preferred drug for its indications. Moved Xeljanz /XR to preferred status for all indications. Clarified coding information
10/2018	Updated to add Ilumya and Olumiant to a non-preferred position in the policy.
7/2018	Update to include additional Criteria for Remicade.
2/2018	Update to add Stelara to Preferred in Crohn's, Xeljanz to Psoriatic Arthritis non-preferred and added Tremfya to requiring Humira first instead of two covered alternatives.
1/2018	Clarified coding information and updated to include Tremfya & Siliq as Non-Preferred medications to the policy.
11/2017	Updated to add Kevzara to this policy and add new indications plus update Walgreens specialty.
Date	Action
10/2017	Updated to include Renflexis.
7/2017	Update to include new indications for Actemra and Orencia.
6/2017	Update Address for Pharmacy Operations.
5/2017	Updated to Add hyperlinks for disease states in the medication table to link to specific criteria in the policy.
1/1/2017	Updated criteria to be arranged by diagnosis instead by drug.
10/2016	Updated to add Taltz and to add new Q code for Infliximab.
4/2016	Updated to include new diagnosis and coding for Humira & Cosentyx.
1/2016	Clarified coding information.
10/2015	Updated to included revised language for Pharmacy only medications.
7/2015	Updated to clarify Cosentyx placement and Rituxan [®] IC criteria. Clarified coding information.
4/2015	Updated to include Cosentyx.
1/2015	Update Criteria for Orencia For PJIA.
10/2014	Updated to include Otezla (apremilast) and updated to include Entyvio(vedolizumab)
7/2014	Updated to include ICD-10.
2/2014	Added some already coded ICD9s.(i.e. 556.0). Diagnoses codes: 555.3, 555.4, 555.5, 555.6, 555.7 and 555.8 were previously listed in error as covered diagnoses and have

	been removed to coincide with system edits that remain unchanged.
1/2014	Updated to include new UC indication for Simponi, Stelara and add Xeljanz criteria. Removed Blue Value Formulary information. Added Enbrel and Humira where indication appropriate. Updated ExpressPath language. Updated Reference 1.
1/2013	Updated 1/2013 to include new FDA approved indication for Actemra® of systemic juvenile idiopathic arthritis.
4/2012	Updated with specialty pharmacy contact information.
11/2011-4/2012	Medical policy ICD 10 remediation: Formatting, editing and coding updates. No changes to policy statements.
1/2012	Updated with specialty pharmacy contact information.
11/2011	Reviewed - Medical Policy Group - Plastic Surgery and Dermatology. No changes to policy statements.
11/2010	Reviewed - Medical Policy Group - Gastroenterology, Nutrition and Organ Transplantation. No changes to policy statements.
9/2010	Updated to include coverage criteria for new FDA approved products based on P&T Committee recommendations: Actemra, Ilaris, and Stelara and update of specialty pharmacy contact information.
7/2010	Reviewed - Medical Policy Group - Orthopedics, Rehabilitation Medicine and Rheumatology. No changes to policy statements.
1/2010	Policy updated to include coverage criteria for new drug Simponi®, add new PDA approved diagnosis of rheumatoid arthritis to coverage criteria for Cimzia®, and to add additional coverage criteria to certain Remicade diagnoses®.
12/2009	Reviewed - Medical Policy Group - Plastic Surgery and Dermatology. No changes to policy statements.
10/2009	Policy updated to reflect UM requirements and remove Raptiva from medical policy.
9/2009	Policy updated to change 180 day look back period to 130 days and to remove Medicare Part D criteria from Medical Policy.
7/2009	Reviewed - Medical Policy Group - Orthopedics, Rehabilitation Medicine and Rheumatology. No changes to policy statements.
1/2009	Updated to include coverage criteria for Rituxan® for rheumatoid arthritis and to combine coverage criteria for plaque psoriasis diagnoses for Amevive®, Enbrel®, Humira®, Raptiva™ and Remicade® (Taken from Medical Policy #020 which will be retired on 1/1/09.)
10/2008	Updated to include covered indication for Cimzia®.
7/2008	Reviewed - Medical Policy Group - Orthopedics, Rehabilitation Medicine and Rheumatology. No changes to policy statements.
5/2008	Updated to include new indication for Orenia® for juvenile idiopathic arthritis.
3/2008	Updated to include new indication for Humira™ for juvenile idiopathic arthritis.
2/2008	Updated to include additional retail specialty pharmacy network information.
11/2007	Reviewed - Medical Policy Group - Gastroenterology, Nutrition and Organ Transplantation. No changes to policy statements.
7/2007	Reviewed - Medical Policy Group - Orthopedics, Rehabilitation Medicine and Rheumatology. No changes to policy statements.
5/2007	Updated to include FDA-approved indication for Humira (adalimumab) for Crohn's Disease and Ankylosing Spondylitis.
1/2007	Updated to include coverage for FDA-approved indication for Remicade for Pediatric Crohn's Disease and retail specialty pharmacy network information.
10/2004	New policy, effective 10/2004, describing covered and non-covered indications.

Forms

To request prior authorization using the Massachusetts Standard Form for Medication Prior Authorization Requests (eForm), click the link below:

<https://www.bluecrossma.org/medical-policies/sites/g/files/csphws2091/files/acquiadam-assets/023%20E%20Form%20medication%20prior%20auth%20instruction%20prn.pdf>

References

1. 2012 Update of the 2008 American College of Rheumatology Recommendations for the Use of Disease-Modifying Antirheumatic Drugs and Biologic Agents in the Treatment of Rheumatoid Arthritis. *Arthritis Care & Research* Vol. 64, No. 5, May 2012, pp 625–639.
2. Ledingham J, Deighton C; British Society for Rheumatology Standards, Guidelines and Audit Working Group. Update on the British Society for Rheumatology guidelines for prescribing TNF alpha blockers in adults with rheumatoid arthritis (update of previous guidelines of April 2001). *Rheumatology (Oxford)*. 2005;44:157-163. Epub 2005 Jan 5.
3. Enbrel® [package insert]. Seattle, WA: Immunex September 2011. Manufactured by: Immunex Corporation Thousand Oaks, CA 91320-1799 Marketed by Amgen Inc. and Pfizer Inc.
4. Humira® injection [package insert]. North Chicago, IL: Abbvie Inc.; May 2013.
5. Kineret® injection [package insert]. C/O Quintiles, Inc. 18518 Cornflower Road Boyds, MD 20841. Swedish Orphan Biovitrum AB. December 2012.
6. Remicade® for intravenous infusion [package insert]. Malvern, PA 19335. Janssen Biotech, Inc. March 2013.
7. Orencia™ [package insert]. Princeton, NJ: Bristol-Myers Squibb Company; September 2011.
8. Weinblatt ME, Keystone EC, Furst DE, et al. Adalimumab, a fully human anti-tumor necrosis factor α monoclonal antibody, for the treatment of rheumatoid arthritis in patients taking concomitant methotrexate. The ARMADA trial. *Arthritis Rheum*. 2003;48:35-45.
9. Van de Putte LBA, Atkins C, Malaise M, et al. Adalimumab (D2E7) monotherapy in the treatment of patients with severely active rheumatoid arthritis [abstract]. Presented at: American College of Rheumatology 66th Annual Scientific Meeting; October 25–29, 2002; New Orleans, LA.
10. Cohen S, Hurd E, Cush J, et al. Treatment of rheumatoid arthritis with anakinra, a recombinant human interleukin-1 receptor antagonist, in combination with methotrexate. Results of a twenty-four-week, multicenter, randomized, double-blind, placebo-controlled trial. *Arthritis Rheum*. 2002;46:614-624.
11. Moreland LW, Schiff MH, Baumgartner SW, et al. Etanercept therapy in rheumatoid arthritis. A randomized, controlled trial. *Ann Intern Med*. 1999;130:478-486.
12. Weinblatt ME, Kremer JM, Bankhurst AD, et al. A trial of etanercept, a recombinant tumor necrosis factor receptor:Fc fusion protein, in patients with rheumatoid arthritis receiving methotrexate. *NEJM*. 1999;340:253-259.
13. Bathon JM, Martin RW, Fleischmann RM, et al. A comparison of etanercept and methotrexate in patients with early rheumatoid arthritis. *NEJM*. 2000;343:1586-1593.
14. Genovese MC, Bathon JM, Martin RW, et al. Etanercept versus methotrexate in patients with early rheumatoid arthritis: two-year radiographic and clinical outcomes. *Arthritis Rheum*. 2002;46:1443- 1450.
15. Genovese MC, Martin RW, Fleischmann RM, et al. Etanercept (Enbrel®) in early erosive rheumatoid arthritis (ERA Trial): observations at 4 years [abstract]. Presented at: American College of Rheumatology 66th Annual Scientific Meeting; October 25–29, 2002; New Orleans, LA.
16. Moreland LW, Cohen SB, Baumgartner SW, et al. Etanercept (Enbrel®) monotherapy for more than 5 years in patients with DMARD-refractory rheumatoid arthritis [abstract]. Presented at: American College of Rheumatology 66th Annual Scientific Meeting; October 25–29, 2002; New Orleans, LA.

18. Ilowite NT. Current treatment of juvenile rheumatoid arthritis. *Pediatrics*. 2002;109:109-115.
19. Lovell DJ, Giannini EH, Reiff A, et al. Etanercept in children with polyarticular juvenile rheumatoid arthritis. *NEJM*. 2000;342:763-769.
20. Lovell DJ, Giannini EH, Reiff A, et al for the Pediatric Rheumatology Collaborative Study Group. Long-term efficacy and safety of etanercept in children with polyarticular-course juvenile rheumatoid arthritis: Interim results from an ongoing multicenter, open-label, extended-treatment trial. *Arthritis Rheum*. 2003;48:218-226.
21. Kietz DA, Pepmueller PH, Moore TL. Therapeutic use of etanercept in polyarticular course juvenile idiopathic arthritis over a two year period. *Ann Rheum Dis*. 2002;61:171-173.
22. Haapasaari J, Kautiainen H, Hannula S, et al. Good results from combining etanercept to prevailing DMARD therapy in refractory juvenile idiopathic arthritis. *Clin Exp Rheumatol*. 2002;20:867-870.
23. Russo RA, Katsicas MM, Zelazko M. Etanercept in systemic juvenile idiopathic arthritis. *Clin Exp Rheumatol*. 2002;20:723-726.
24. Khan MA. Update on spondyloarthropathies. *Ann Intern Med*. 2002;136:896-907.
25. Brockbank J, Gladman D. Diagnosis and management of psoriatic arthritis. *Drugs*. 2002;62:2447-2457.
26. Jones G, Crotty M, Brooks P, and the Psoriatic Arthritis Meta-Analysis Study Group. Psoriatic arthritis: a quantitative overview of therapeutic options. *Br J Rheumatol*. 1997;36:95-99.
27. Mease PJ, Goffe BS, Metz J, et al. Etanercept in the treatment of psoriatic arthritis and psoriasis: a randomized trial. *Lancet*. 2000;356:385-390.
28. Mease P, Kivitz A, Burch F, et al. Improvement in disease activity in patients with psoriatic arthritis receiving etanercept (Enbrel®): results of a phase 3 multicenter clinical trial [abstract 226]. Presented at: American College of Rheumatology – 65th Annual Scientific Meeting; November 12-15, 2001; San Francisco, CA.
29. Ory P, Sharp JT, Salonen D, et al. Etanercept (Enbrel®) inhibits radiographic progression in patients with psoriatic arthritis. Abstracts from American College of Rheumatology – 66th Annual Scientific Meeting; October 25-29, 2002; New Orleans, LA.
30. Davis JC Jr, Van Der Heijde D, Braun J, et al. Enbrel Ankylosing Spondylitis Study Group. Recombinant human tumor necrosis factor receptor (etanercept) for treating ankylosing spondylitis: a randomized, controlled trial. *Arthritis Rheum*. 2003; 48: 3230-3236.
31. Gorman JD, Sack KE, Davis Jr JC. Treatment of ankylosing spondylitis by inhibition of tumor necrosis factor α . *NEJM*. 2002;346:1349-1356. [correction *NEJM*. 2003;348:360-361.]
32. Brandt J, Kariouzov A, Listing J, et al. Six months results of a German double-blind placebo controlled, phase-III clinical trial of etanercept in active ankylosing spondylitis. Abstracts from American College of Rheumatology – 66th Annual Scientific Meeting; October 25-29, 2002; New Orleans, LA.
33. Toussirto E, Wendling D. Current guidelines for the drug treatment of ankylosing spondylitis. *Drugs*. 1998;56:225-240.
34. Braun J, Sieper J, Breban M, et al. Anti-tumour necrosis factor alpha therapy for ankylosing spondylitis: international experience. *Ann Rheum Dis*. 2002;61 Suppl 3:iii51-60.
35. Cummins C, Connock M, Fry-Smith A, et al. A systematic review of effectiveness and economic evaluation of new drug treatments for juvenile idiopathic arthritis: etanercept. *Health Technol Assess*. 2002;6:1-43.
36. Keystone E, Kavanaugh AF, Sharp J, et al. Adalimumab (D2E7), a fully human anti-TNF- α monoclonal antibody, inhibits the progression of structural joint damage in patients with active RA despite concomitant methotrexate therapy [abstract]. Presented at: American College of Rheumatology 66th Annual Scientific Meeting; October 25–29, 2002; New Orleans, LA.
37. Furst DE, Schiff M, Fleischmann R, et al. Safety and efficacy of adalimumab (D2E7), a fully human anti- TNF- α monoclonal antibody, given in combination with standard antirheumatic therapy: safety trial of adalimumab in rheumatoid arthritis (STAR) [abstract]. Presented at: American College of Rheumatology 66th Annual Scientific Meeting; October 25–29, 2002; New Orleans, LA.
38. van Riel PLC, van de Putte LBA, Rau R, et al. Long-term treatment with adalimumab (D2E7) using background methotrexate in active rheumatoid arthritis: results of a 3 year study [abstract].

- Presented at: American College of Rheumatology 66th Annual Scientific Meeting; October 25–29, 2002; New Orleans, LA.
39. Cohen SB, Moreland LW, Cush JJ, et al. Anakinra (recombinant interleukin-1 receptor antagonist): a large, placebo controlled efficacy trial of anakinra in patients with erosive rheumatoid arthritis disease. Presented at: American College of Rheumatology 65th Annual Scientific Meeting; November 11-15, 2001; San Francisco, CA. *Arthritis Rheum.* 2001;44 (suppl):Abstract LB-1.
 40. Bresnihan B, Alvaro-Gracia JM, Cobby M, et al. Treatment of rheumatoid arthritis with recombinant human interleukin-1 receptor antagonist. *Arthritis Rheum.* 1998;41:2196-2204.
 41. Nuki G, Bresnihan B, Bear MB, et al for the European Group of Clinical Investigators. Lone-term safety and maintenance of clinical improvement following treatment with anakinra (recombinant human interleukin-1 receptor antagonist) in patient with rheumatoid arthritis. Extension phase of a randomized, double-blind, placebo-controlled trial. *Arthritis Rheum.* 2002;46:2838-2846.
 42. Jiang Y, Genant HK, Watt I, et al. A multicenter, double-blind, dose-ranging, randomized, placebo- controlled study of recombinant human interleukin-1 receptor antagonist in patients with rheumatoid arthritis. Radiologic progression and correlation of Genant and Larsen scores. *Arthritis Rheum.* 2000;43:1001-1009.
 43. Cohen SB, Woolley JM, Chan WW for the Anakinra 960180 Study Group. Interleukin 1 receptor antagonist anakinra improves functional status in patients with rheumatoid arthritis. *J Rehumatol.* 2003;30:225-231.
 44. Lipsky PE, van der Heijde DM, St Clair EW, et al Anti-Tumor Necrosis Factor Trial in Rheumatoid Arthritis with Concomitant Therapy Study Group. Infliximab and methotrexate in the treatment of rheumatoid arthritis. Anti-Tumor Necrosis Factor Trial in Rheumatoid Arthritis with Concomitant Therapy Study Group. *NE JM.* 2000;343:1594-1602.
 45. Maini R, St Clair EW, Breedveld F, et al. Infliximab (chimeric anti-tumour necrosis factor alpha monoclonal antibody) versus placebo in rheumatoid arthritis patients receiving concomitant methotrexate: a randomized phase III trial. ATTRACT Study Group. *Lancet.* 1999;354:1932-1939.
 46. Targan SR, Hanauer SB, van Deventer SJ, et al. A short-term study of chimeric monoclonal antibody cA2 to tumor necrosis factor alpha for Crohn's disease. Crohn's Disease cA2 Study Group. *NE JM.* 1997;337:1029-1035.
 47. Hanauer SB, Feagan BG, Lichtenstein GR, et al. Maintenance infliximab for Crohn's disease: the Accent I randomized trial. *Lancet.* 2002;359:1541-1549.
 48. Rutgeerts P, D'Haens G, Targan S, et al. Efficacy and safety of retreatment with anti-tumor necrosis factor antibody (infliximab) to maintain remission in Crohn's disease. *Gastroenterology.* 1999;117:761- 769.
 49. Sandborn WJ, Hanauer SB. Infliximab in the treatment of Crohn's disease: a user's guide for clinicians. *Am J Gastroenterol.* 2002;97:2962-2972.
 50. Stephens MC, Shepanski MA, Mamula P, et al. Safety and steroid-sparing experience using infliximab for Crohn's disease at a pediatric inflammatory bowel disease center. *Am J Gastroenterol.* 2003;98:104-111.
 51. Hyams JS. Use of infliximab in the treatment of Crohn's disease in children and adolescents. *J Pediatr Gastroenterol Nutr.* 2001;33 Suppl 1:S36-39.
 52. Present DH, Rutgeerts P, Targan S, et al. Infliximab for the treatment of fistulas in patients with Crohn's disease. *NEJM.* 1999;340:1398-1405.
 53. Toussirto E, Wendling D. Current guidelines for the drug treatment of ankylosing spondylitis. *Drugs.* 1998;56:225-240.
 54. Gorman JD, Sack KE, Davis Jr JC. Treatment of ankylosing spondylitis by inhibition of tumor necrosis factor α . *NEJM.* 2002;346:1349-1356. [correction *NEJM.* 2003;348:360-361.]
 55. Brandt J, Kariouzov A, Listing J, et al. Six months results of a German double-blind placebo controlled, phase-III clinical trial of etanercept in active ankylosing spondylitis. Abstracts from American College of Rheumatology – 66th Annual Scientific Meeting; October 25-29, 2002; New Orleans, LA.
 56. Brockbank J, Gladman D. Diagnosis and management of psoriatic arthritis. *Drugs.* 2002;62:2447-2457.

57. Jones G, Crotty M, Brooks P, and the Psoriatic Arthritis Meta-Analysis Study Group. Psoriatic arthritis: a quantitative overview of therapeutic options. *Br J Rheumatol*. 1997;36:95-99.
58. Mease PJ, Goffe BS, Metz J, et al. Etanercept in the treatment of psoriatic arthritis and psoriasis: a randomized trial. *Lancet*. 2000;356:385-390.
59. Mease P, Kivitz A, Burch F, et al. Improvement in disease activity in patients with psoriatic arthritis receiving etanercept (Enbrel®): results of a phase 3 multicenter clinical trial [abstract 226]. Presented at: American College of Rheumatology – 65th Annual Scientific Meeting; November 12-15, 2001; San Francisco, CA.
60. Ory P, Sharp JT, Salonen D, et al. Etanercept (Enbrel®) inhibits radiographic progression in patients with psoriatic arthritis. Abstracts from American College of Rheumatology – 66th Annual Scientific Meeting; October 25-29, 2002; New Orleans, LA.
61. Lahdenne P, Vahasalo P, Honkanen V. Infliximab or etanercept in the treatment of children with refractory juvenile idiopathic arthritis: an open label study. *Ann Rheum Dis*. 2003 Mar;62:245-247.
62. Ilowite NT. Current treatment of juvenile rheumatoid arthritis. *Pediatrics*. 2002;109:109-115.
63. Rutgeerts P, Feagan BF, Olson A, et al. A randomized placebo-controlled trial of infliximab for active ulcerative colitis: Act 1 trial. *Gastroenterology*. 2005;128:A-105 (abstract).
64. Sandborn WJ, Rachmilewitz D, Hanauer S, et al. Infliximab induction and maintenance therapy for ulcerative colitis: the Act 2 trial. *Gastroenterology*. 2005;128:A-104 (abstract).
65. Kornbluth A, Sachar DB; Practice Parameters Committee of the American College of Gastroenterology. Ulcerative colitis practice guidelines in adults (update): American College of Gastroenterology, Practice Parameters Committee. *Am J Gastroenterol*. 2004;99:1371-1385.
66. Järnerot G, Hertervig E, Friis-Liby I, et al. Infliximab as rescue therapy in severe to moderately severe ulcerative colitis: a randomized, placebo-controlled study. *Gastroenterology*. 2005;128:1805-1811.
67. Rutgeerts P, Sandborn WJ, Feagan BG, Reinisch W, Olson A, Johanns J, et al. Infliximab for induction and maintenance therapy for ulcerative colitis. *NEJM* 2005 353;23:2462-2476.
68. Nash P, Clegg DO. Psoriatic arthritis therapy: NSAIDs and traditional DMARDs. *Ann Rheum Dis*. 2005;64 Suppl 2:ii74
69. Brockbank J, Gladman D. Diagnosis and management of psoriatic arthritis. *Drugs*. 2002;62:2447-2457.
70. Mease PJ, Gladman DD, Ritchlin CT, et al. Adalimumab for the treatment of patients with moderately to severely active psoriatic arthritis: results of a double-blind, randomized, placebo-controlled. *Arthritis Rheum*. 2005;52:3279-3289.
71. Mease PJ, Gladman DD, Ritchlin CT, et al. Clinical efficacy and safety of adalimumab for psoriatic arthritis: 48-week results of ADEPT. *Arthritis Rheum*. 2005;52(Suppl 9):S215.
72. Mease PJ, Sharp J, Ory P, et al. Inhibition of joint destruction in PsA with adalimumab: 48-week results of ADEPT. *Arthritis Rheum*. 2005;52(Suppl 9):S63.
73. Genovese MC, Becker JC, Schiff M, et al. Abatacept for rheumatoid arthritis refractory to tumor necrosis factor alpha inhibition. *N Engl J Med*. 2005;353:1114-1123.
74. Kremer JM, Dougados M, Emery P, et al. Treatment of rheumatoid arthritis with the selective co stimulation modulator abatacept: twelve-month results of a phase iib, double-blind, randomized, placebo-controlled trial. *Arthritis Rheum*. 2005;52:2263-2271.
75. Kremer JM, Westhovens R, Leon M, et al. Treatment of rheumatoid arthritis by selective inhibition of T- cell activation with fusion protein CTLA4lg. *N Engl J Med*. 2003;349:1907-1915.
76. Kremer J, Westhovens R, Abud-Mendoza C, et al. Abatacept improves American College of Rheumatology responses and Disease Activity Score 28 remission rates in both recent-onset and more established rheumatoid arthritis: results of the AIM trial. *Arthritis Rheum*. 2005;52(Suppl):S562.
77. Russell A, Kremer J, Zhou Y, et al. Abatacept induces sustained improvements in physical function and pain over 3 years in rheumatoid arthritis patients with inadequate responses to methotrexate. *Arthritis Rheum*. 2005;52(Suppl):S659.
78. Russell A, Sherrer Y, Westhovens R, et al. Abatacept is effective at reducing pain and fatigue, and improving sleep quality in rheumatoid arthritis patients with an inadequate response to anti-TNF therapy in the ATTAIN trial. *Ann Rheum Dis*. 2005;64(Suppl III):397.

79. Moreland LW, Alten R, Van den Bosch F, et al. Costimulatory blockade in patients with rheumatoid arthritis: a pilot, dose-finding, double-blind, placebo-controlled clinical trial evaluating CTLA-4Ig and LEA29Y eighty-five days after the first infusion. *Arthritis Rheum.* 2002;46:1470-1479.
80. Anon. A phase II study of abatacept versus placebo to assess the prevention of rheumatoid arthritis (RA) in adult patients with undifferentiated arthritis who are at high risk for the development of RA. US National Institutes of Health. Available at: <http://www.clinicaltrials.gov/ct/show/NCT00124449?order=30> Accessed 01/04/2006.
81. Cimzia[®] [package insert]. Symrna, GA: UCB, Inc.; April 2008.
82. Rituxan injection [package insert]. South San Francisco, CA: Genentech, Inc; February 21, 2007.
83. American College of Rheumatology Subcommittee on Rheumatoid Arthritis Guidelines. Guidelines for the management of rheumatoid arthritis. *Arthritis Rheum.* 2002;46:328-346
84. Smolen JS, Keystone EC, Emery P, et al; Working Group on the Rituximab Consensus Statement. Consensus statement on the use of rituximab in patients with rheumatoid arthritis. *Ann Rheum Dis.* 2007; 66:143-150
85. Food and Drug Administration, "Center for Drug Evaluation and Research, Office of Drug Safety Annual Report FY2004," <http://www.fda.gov/cder/Offices/ODS/annRep2004/default.htm>.
86. Gordon KB, Leonardi C, Harvey D, et al. Continuous treatment improves outcomes in patients with moderate to severe plaque psoriasis treated with efalizumab (anti-CD11a). Results from the Phase III trial ACD2058g. Poster presented at the 60th Annual Meeting of the American Academy of Dermatology. February 2002. New Orleans, LA.
87. Data on file. South San Francisco, CA: Genentech.
88. Lebwohl M, Miller JL, Goldman M, et al. Continued treatment with subcutaneous efalizumab (anti-CD11a) improves outcome in patients with moderate to severe plaque psoriasis. Poster presented at the 60th Annual Meeting of the American Academy of Dermatology. February 2002, New Orleans, LA.
89. Gordon KB, Siegfried E, Carey W, et al. Impact of 24 weeks of continuous efalizumab therapy on patient-reported outcomes in patients with moderate to severe plaque psoriasis. Poster presented at the Academy 2003 of the American Academy of Dermatology; July 25-29, 2003, Chicago, IL.
90. Gordon KB, Toth D, Papp KA, et al. Efalizumab provides rapid clinical benefit for patients with moderate to severe plaque psoriasis. Poster presented at the 9th International Psoriasis Symposium; June 18-22, 2003; New York, NY.
91. Gottlieb AB, Menter A, Duvic M, et al. Efalizumab (anti-CD11a) induction and maintenance treatment during a 12-month trial in patients with moderate to severe plaque psoriasis: preliminary findings. Poster presented at the 60th Annual Meeting of the American Academy of Dermatology. February 2002, New Orleans, LA.
92. Gottlieb AB, Gordon KB, Wallcke PA, et al. Continuous efalizumab therapy safely maintains psoriasis area and severity index improvement: preliminary results from an open-label trial. Poster presented at the 9th International Psoriasis Symposium; June 18-22, 2003; New York, NY.
93. Gottlieb AB, Gordon KB, Koo JY, et al. Long-term efalizumab treatment maintains clinical benefit in patients with moderate to severe plaque psoriasis: updated findings from an open-label trial. Poster presented at the Academy 2003 of the American Academy of Dermatology; July 25-29, 2003, Chicago, IL.
94. Gordon KB, Tying SK, Hamilton TK, et al. Examining duration of response and rebound during treatment with efalizumab (anti-CD11a). Poster presented at the 61st Annual Meeting of the American Academy of Dermatology; March 21-26, 2003; San Francisco, CA.
95. Gottlieb AB, Miller B, Lowe N, et al. Subcutaneously administered efalizumab (anti-CD11a) improves signs and symptoms of moderate to severe plaque psoriasis. *J Cutan Med Surg.* 2003;7:198-207.
96. Gauvreau GM, Becker AB, Boulet L-P, et al. The effects of an anti-CD11a mAb, efalizumab, on allergen-induced airway responses and airway inflammation in subjects with atopic asthma. *J Allergy Clin Immunol.* 2003;112:331-338.
97. American Academy of Dermatology. Guidelines of care for psoriasis. Committee on Guidelines of Care. Task Force on Psoriasis. *J Am Acad Dermatol.* 1993;28:632-637. Available at: <http://www.aadassociation.org/Guidelines/psoriasis.html>. Accessed 11/14/2003.

98. Lebwohl M, Ali S. Treatment of psoriasis. Part 1. Topical therapy and phototherapy. *J Am Acad Dermatol.* 2001;45:487-498.
99. Peters BP, Weissman FG, Gill MA. Pathophysiology and treatment of psoriasis. *Am J Health-Syst Pharm.* 2000;57:645-662.
100. Lebwohl M, Ali S. Treatment of psoriasis. Part 2. Systemic therapies. *J Am Acad Dermatol.* 2001;45:649-661.
101. Iyer S, Yamauchi P, Lowe NJ. Etanercept for severe psoriasis and psoriatic arthritis: observations on combination therapy. *Br J Dermatol.* 2002;146:118-121.
102. Weinberg JM, Saini R. Biologic therapy for psoriasis: the tumor necrosis factor inhibitors infliximab and etanercept. *Cutis.* 2003;71:25-29.
103. Gottlieb AB, Chaudhari U, Mulcahy LD, et al. Infliximab monotherapy provides rapid and sustained benefit for plaque-type psoriasis. *J Am Acad Dermatol.* 2003;48:829-835.
104. Ellis CN, Krueger GG, for the Alefacept Clinical Study Group. Treatment of chronic plaque psoriasis by selective targeting of memory effector T lymphocytes. *N Engl J Med.* 2001;345:248-255.
105. Krueger GG, Papp KA, Stough DB, for the Alefacept Clinical Study Group. A randomized, double-blind, placebo-controlled phase III study evaluating efficacy and tolerability of 2 courses of alefacept in patients with chronic plaque psoriasis. *J Am Acad Dermatol.* 2002;47:821-833.
106. Cimzia® [package insert]. Smyrna, GA: UCB, Inc.; October, 2013.
107. Simponi® [package insert]. Horsham, PA: Janssen Biotech Inc.; Jan 2013.
108. Ilaris® [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; May, 2013.
109. Actemra® [package insert]. South San Francisco, CA: Genentech, Inc. Member of Roche Group; October, 2013.
110. Stelara™ [package insert]. Horsham, PA: Janssen Biotech, Inc.; September 2013.
111. Xeljanz® [package insert]. New York, NY: Pfizer Inc.; November 2012.
112. *Arthritis Care & Research.* Vol. 64, No. 5, May 2012, pp 625–639. DOI 10.1002/acr.21641. © 2012, American College of Rheumatology 2012 Update of the 2008 American College of Rheumatology Recommendations for the Use of Disease-Modifying Antirhumatic Drugs and Biologic Agents in the Treatment of Rhumatoid Arthritis, Singh et.al.
113. *Arthritis & Rheumatism* Vol. 65, No. 10, October 2013, pp 2499–2512. 2013 Update of the 2011 American College of Rheumatology Recommendations for the Treatment of Juvenile Idiopathic Arthritis
114. Simponi® Aria™ [package insert]. Horsham, PA: Janssen Biotech Inc.; Jan 2013.
115. Otezla® [package insert]. Summit, NJ: Celgene Corporation.; Mar 2014.
116. Cosentyx™ [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation.: 01/2015.
117. Taltz™ [package insert]. Indianapolis, IN: Eli Lilly and Company; 05/2016.
118. Kevzara® [package insert]. Bridgewater, NJ: sanofi-aventis U.S. LLC; 05/2017.
119. Olumiant® [package insert]. Indianapolis, IN: Eli Lilly and Company; 05/2018.
120. Ilumya™ [package insert]. Cranbury, NJ: Sun Pharmaceutical Industries, Inc.; Aug 2018.
121. Zeposia® [package insert]. Summit, NJ: Celgene Corporation.; June 2021.