A Public Entity
Inland Empire Health Plan

Drug Class Prior Authorization Criteria
Rheumatic and Inflammatory Diseases

Line of Business: Medicaid
P & T Approval Date: August 6, 2021 **Effective Date:** September 17, 2021

These criteria have been developed through review of medical literature, consideration of medical necessity, generally accepted medical practice standards, and approved by the IEHP Pharmacy and Therapeutics Subcommittee.

Drugs Requiring Prior Authorization Review: Enbrel (etanercept), **Humira** (adalimumab), **Otezla** (apremilast), **Rituxan** (rituximab)

Indication / Medication	Ankylosing spondylitis (AS)	Crohn's disease (CD)	Hidradenitis suppurativa (HS)	Plaque psoriasis (PP)	Psoriatic arthritis (PsA)	Rheumatoid arthritis (RA)	Ulcerative colitis (UC)
Enbrel (etanercept)	x			x	x	x	
Humira (adalimumab)	x	x	x	x	x	x	x
Otezla (apremilast)				x	x		
Rituxan (rituximab)						x	

- X = indicates that there is a PA criteria on the medication for the indication

CRITERIA:

ENBREL (ETANERCEPT)

Covered Uses: Ankylosing spondylitis

Excluding Criteria: N/A

Required Medical Information: Must meet the following requirement:
a. Failure or clinically significant adverse effects to at least one-month treatment course of NSAID therapy at maximal recommended dose or maximally tolerated dose

Age Restrictions: N/A

Prescriber Restrictions: Rheumatologist

Other Criteria: Reauthorization Criteria: Must meet all of the following requirements:

a. Documentation of meeting therapeutic goal (e.g., disease stability, improvement in daily activities and/or reduction in frequency of disease attacks)
b. Requested dosage and administration are consistent with the FDA recommendations

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Covered Uses: Plaque psoriasis

Excluding Criteria: N/A

Required Medical Information:

Must meet all of the following requirements:
a. Must meet "1" of the following requirements:
    i. Documented psoriasis involvement of at least 10% of the body surface area
    ii. Documented psoriasis involvement of the face, ears, hands, feet, or genitalia
    iii. Documented significant functional disability (i.e., unable to do daily activities)
b. Trial and failure of at least one non-biologic DMARD (e.g., methotrexate, cyclosporine, azathioprine, etc.)

Age Restrictions: N/A

Prescriber Restrictions: Dermatologist, Rheumatologist

Other Criteria:

Reauthorization Criteria: Must meet all of the following requirements:
a. Documentation of meeting therapeutic goal (e.g., disease stability, improvement in daily activities and/or reduction in frequency of disease attacks)
b. Requested dosage and administration are consistent with the FDA recommendations

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Covered Uses: Psoriatic arthritis

Exclusion Criteria: N/A

Required Medical Information:

Must meet the following requirement:
a. Failure or clinically significant adverse effects to at least one non-biologic DMARD (e.g., methotrexate, leflunomide, sulfasalazine, etc.)

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Age Restrictions: N/A

Prescriber Restrictions: Dermatologist, Rheumatologist

Other Criteria: Reauthorization Criteria: Must meet all of the following requirements:
a. Documentation of meeting therapeutic goal (e.g., disease stability, improvement in daily activities and/or reduction in frequency of disease attacks)
b. Requested dosage and administration are consistent with the FDA recommendations

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Covered Uses: Rheumatoid arthritis

Exclusion Criteria: CCS eligible

Required Medical Information: Must meet the following requirement:
a. Failure or clinically significant adverse effects to at least one non-biologic DMARD: methotrexate, hydroxychloroquine, leflunomide or sulfasalazine

Age Restrictions: N/A

Prescriber Restrictions: Rheumatologist

Other Criteria: Reauthorization Criteria: Must meet all of the following requirements:
a. Documentation of meeting therapeutic goal (e.g., disease stability, improvement in daily activities and/or reduction in frequency of disease attacks)
b. Requested dosage and administration are consistent with the FDA recommendations

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HUMIRA (ADALIMUMAB)

Covered Uses: Ankylosing spondylitis

Exclusion Criteria: N/A

Required Medical

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Information:
Must meet the following requirement:
a. Failure or clinically significant adverse effects to at least one-month treatment course of NSAID therapy at maximal recommended dose or maximally tolerated dose

Age Restrictions:
N/A

Prescriber Restrictions:
Rheumatologist

Other Criteria:
Reauthorization Criteria: Must meet all of the following requirements:
a. Documentation of meeting therapeutic goal (e.g., disease stability, improvement in daily activities and/or reduction in frequency of disease attacks)
b. Requested dosage and administration are consistent with the FDA recommendations

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Covered Uses:
Crohn's disease

Exclusion Criteria:
CCS eligible

Required Medical Information:
Must meet all of the following requirements:
a. Must meet "1" of the following requirements:
    i. Failure or clinically significant adverse effects to an adequate course of corticosteroids (e.g., oral budesonide 9 mg/day, prednisone 40-60 mg daily)
    ii. Documentation that patient has been unable to taper corticosteroid therapy without experiencing worsening of disease
b. Treatment with at least a two-month course of DMARD (e.g., azathioprine, mercaptopurine or methotrexate) was not effective or not tolerated, unless all are contraindicated.

Age Restrictions:
N/A

Prescriber Restrictions:
Gastroenterologist

Other Criteria:
Reauthorization Criteria: Must meet all of the following requirements:
a. Documentation of meeting therapeutic goal (e.g., disease stability, improvement in daily activities and/or reduction in frequency of disease attacks)
b. Requested dosage and administration are consistent with the FDA recommendations

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Covered Uses: Hidradenitis suppurativa

Exclusion Criteria: CCS eligible

Required Medical Information:

Must meet "1" of the following requirements:

a. Diagnosis of severe hidradenitis suppurativa (e.g., Hurley Stage III)
b. Diagnosis of moderate hidradenitis suppurativa (e.g., Hurley Stage II); and Failure or clinically significant adverse effects to 12-weeks of antibiotic therapy: clindamycin, doxycycline, minocycline, or tetracycline

Age Restrictions: N/A

Prescriber Restrictions: Dermatologist, Rheumatologist

Other Criteria:

Reauthorization Criteria: Must meet all of the following requirements:

a. Documentation of meeting therapeutic goal (e.g., disease stability, improvement in daily activities and/or reduction in frequency of disease attacks)
b. Requested dosage and administration are consistent with the FDA recommendations

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Covered Uses: Plaque psoriasis

Exclusion Criteria: N/A

Required Medical Information:

Must meet all of the following requirements:

a. Must meet "1" of the following requirements:
    i. Documented psoriasis involvement of at least 10% of the body surface area
    ii. Documented psoriasis involvement of the face, ears, hands, feet, or genitalia
    iii. Documented significant functional disability (i.e., unable to do daily activities)
b. Trial and failure of at least one non-biologic DMARD (e.g., methotrexate, cyclosporine, azathioprine, etc.)

Age Restrictions: N/A

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Prescriber Restrictions: Dermatologist, Rheumatologist

Other Criteria: Reauthorization Criteria: Must meet all of the following requirements:
a. Documentation of meeting therapeutic goal (e.g., disease stability, improvement in daily activities and/or reduction in frequency of disease attacks)
b. Requested dosage and administration are consistent with the FDA recommendations

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Covered Uses: Psoriatic arthritis

Exclusion Criteria: N/A

Required Medical Information: Must meet the following requirement:
a. Failure or clinically significant adverse effects to at least one non-biologic DMARD (e.g., methotrexate, leflunomide, sulfasalazine, etc.)

Age Restrictions: N/A

Prescriber Restrictions: Dermatologist, Rheumatologist

Other Criteria: Reauthorization Criteria: Must meet all of the following requirements:
a. Documentation of meeting therapeutic goal (e.g., disease stability, improvement in daily activities and/or reduction in frequency of disease attacks)
b. Requested dosage and administration are consistent with the FDA recommendations

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Covered Uses: Rheumatoid arthritis

Exclusion Criteria: CCS eligible

Required Medical Information: Must meet the following requirement:
a. Failure or clinically significant adverse effects to at least one non-biologic DMARD: methotrexate, hydroxychloroquine, leflunomide or sulfasalazine

Age Restrictions: N/A

Prescriber Restrictions: Rheumatologist

Other Criteria: Reauthorization Criteria: Must meet all of the following requirements:
a. Documentation of meeting therapeutic goal (e.g., disease stability, improvement in daily activities and/or reduction in frequency of disease attacks)
b. Requested dosage and administration are consistent with the FDA recommendations

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Covered Uses: Ulcerative colitis

Exclusion Criteria: CCS eligible

Required Medical Information: Must meet all of the following requirements:
a. Failure or clinically significant adverse effects to "2" of the following:
    i. An adequate course of corticosteroids (e.g., oral budesonide 9 mg/day, prednisone 40-60 mg daily or budesonide rectal for 7-14 days)
    ii. At least one aminosalicylate: mesalamine, balsalazide, sulfasalazine
    iii. Treatment with at least a two-month course of DMARD (e.g., azathioprine, mercaptopurine, methotrexate) was not effective or not tolerated, unless all are contraindicated

Age Restrictions: N/A

Prescriber Restrictions: Gastroenterologist

Other Criteria: Reauthorization Criteria: Must meet all of the following requirements:
a. Documentation of meeting therapeutic goal (e.g., disease stability, improvement in daily activities and/or reduction in frequency of disease attacks)
b. Requested dosage and administration are consistent with the FDA recommendations

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OTEZLA (APREMILAST)

Covered Uses: Plaque psoriasis,

	Psoriatic arthritis
Exclusion Criteria:	N/A
Required Medical Information:	Must meet the following requirement: a. Must meet "1" of the following requirements: i. Failure or clinically significant adverse effects to one of the preferred biologic therapies: **Enbrel** or **Humira**
Age Restrictions:	N/A
Prescriber Restrictions:	Dermatologist, Rheumatologist
Other Criteria:	Reauthorization Criteria: Must meet all of the following requirements: a. Documentation of meeting therapeutic goal (e.g., disease stability, improvement in daily activities and/or reduction in frequency of disease attacks) b. Requested dosage and administration are consistent with the FDA recommendations

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RITUXAN (RITUXIMAB)

Covered Uses:	Rheumatoid arthritis
Exclusion Criteria:	N/A
Required Medical Information:	Must meet all of the following requirements: a. Failure or clinically significant adverse effects to "1" of the following: azathioprine, cyclosporine, hydroxychloroquine, leflunomide, methotrexate, OR sulfasalazine b. Failure or clinically significant adverse effects to ALL of the following: **Enbrel** AND **Humira**
Age Restrictions:	N/A
Prescriber Restrictions:	Dermatologist, Rheumatologist
Other Criteria:	Reauthorization Criteria: Must meet all of the following requirements:

a. Documentation of meeting therapeutic goal (e.g., disease stability, improvement in daily activities and/or reduction in frequency of disease attacks)
b. Requested dosage and administration are consistent with the FDA recommendations

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Change Control		
Date	**Change**	**Author**
07/15/2021	• Relocated **Rituxan** (rituximab) PA criteria for RA indication from the PA table	SV
08/28/2020	• Renew with no changes	RR
08/21/2019	• Added an indication table on page 1 for overview purpose • Retired PA criteria for non-preferred agents: ○ **Actemra, Cimzia, Cosentyx, Entyvio, Kevzara, Kineret, Orencia, Renflexis, Simponi, Simponi Aria, Stelara, Taltz, Tremfya, Tysabri, Xeljanz** • Retired PA criteria for low volume utilization ○ **Humira**: NIU (non-infectious uveitis) criteria retired • Created PA criteria for high PA volume indication: ○ **Humira**: HS (hidradenitis suppurativa) criteria added	SV
05/15/2019	• Revise **Xeljanz** criteria: remove trial and failure requirement through Humira, Simponi and Renflexis per new updated 2019 ACG guidelines	ND
08/17/2018	• Post P&T changes: Remove **Inflectra** and **Remicade** from document; **Renflexis** is the preferred infliximab agent	HC
08/06/2018	• Added double lines to all drug names for consistency	IK
07/15/2018	• Added new FDA indication of plaque psoriasis to **Cimzia** • Added new FDA indication of ulcerative colitis to **Xeljanz** • **Remicade**: Documented intolerance or contraindication to an inactive ingredient in **Renflexis** and **Inflectra** • **Inflectra**: Documented intolerance or contraindication to an inactive ingredient in **Renflexis** • Remove **Ilaris** criteria due to rare indications	HC
07/11/2018	• Reformatted document	IK