PREMERA HMO

An Independent Licensee of the Blue Cross Blue Shield Association

PHARMACY / MEDICAL POLICY – 5.01.629

Pharmacologic Treatment of Psoriasis

Effective Date:	**Oct. 3, 2025***
Last Revised:	Jun. 10, 2025
Replaces:	N/A
*View current policy here.	

RELATED MEDICAL POLICIES:

5.01.550	Pharmacotherapy of Arthropathies
5.01.563	Pharmacotherapy of Inflammatory Bowel Disorder
5.01.564	Pharmacotherapy of Miscellaneous Autoimmune Diseases
5.01.575	Dupixent (dupilumab)
5.01.607	Continuity of Coverage for Maintenance Medications
5.01.628	Pharmacologic Treatment of Atopic Dermatitis
5.01.647	Medical Necessity Criteria for Custom Open and Preferred Formularies
5.01.652	Miscellaneous Pharmacologic Treatments of Psoriasis
11.01.523	Site of Service: Infusion Drugs and Biologic Agents

The Site of Service Medical Necessity criteria within this policy DOES NOT apply to Alaska fully-insured members; refer to the infusion and injection drug Medical Necessity criteria only.

Site of Service *and* the infusion and injection drug Medical Necessity criteria apply to all other plan members.

Please contact Customer Service for more information.

Select a hyperlink below to be directed to that section.

∞ Clicking this icon returns you to the hyperlinks menu above.

Introduction

Psoriasis is a skin condition caused by inflammation. It causes a red, scaly rash that can occur anywhere on the body. The patches of rash are called plaques, and the condition can be described as plaque psoriasis. Another less common type of psoriasis is known as pustular psoriasis, which can appear suddenly and may also cause a fever and fatigue. The treatment of psoriasis often starts with medications that are applied to the skin. If these don't help clear the

skin, or if psoriasis affects a large part of the body, light therapy and drugs that are taken by mouth may be used. The newest type of therapy includes medications called "biologics." This policy discusses when each type of therapy may be considered medically necessary for psoriasis.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Policy Coverage Criteria

Site of Service (SOS) Medical Necessity criteria applies ONLY to medical benefit reviews. SOS Medical Necessity criteria does NOT apply to Alaska fully-insured members; refer to the infusion and injection drug Medical Necessity criteria only. Please contact Customer Service for more information.

We will review specific intravenous (IV) and injectable drugs for medical necessity for all ages.

For those age 13 and older, we also will review the site of service for medical necessity. Site of service is defined as the location where the drug is administered, such as a hospital-based outpatient setting, an infusion center, a physician's office, or at home. Click **here** to be directed to the site of service review criteria.

Drugs subject to site of service review addressed in this policy are:

- Avsola (infliximab-axxq)
- Inflectra (infliximab-dyyb)
- Infliximab (Janssen – unbranded)
- Remicade (infliximab)
- Renflexis (infliximab-abda)

Site of Service Administration	Medical Necessity
Medically necessary sites of service • **Physician's office** • **Infusion center** • **Home infusion**	**IV infusion and injection therapy of various medical or biologic agents will be covered in the most appropriate, safe and cost-effective site:** • These are the preferred **medically necessary** sites of service for specified drugs.
Hospital-based outpatient setting • **Outpatient hospital IV infusion department** • **Hospital-based outpatient clinical level of care**	**IV infusion and injection therapy of various medical or biologic agents will be covered in the most appropriate, safe and cost-effective site.** **This site is considered medically necessary for the first 90 days for the following:** • The initial course of infusion or injection of a pharmacologic or biologic agent **OR** • Re-initiation of an agent after 6 months or longer following discontinuation of therapy* ***Note:** This does not include when standard dosing between infusions or injections is 6 months or longer **This site is considered medically necessary when there is no outpatient infusion center within 50 miles of the individual's home and there is no contracted home infusion agency that will travel to their home, or a hospital is the only place that offers infusions or injections of this drug.** **This site is considered medically necessary only when the individual has a clinical condition which puts him or her at increased risk of complications for infusions or injections, including any 1 of the following:** • Known cardiac condition (e.g., symptomatic cardiac arrhythmia) or pulmonary condition (e.g., significant respiratory disease, serious obstructive airway disease, %FVC less than or equal to 40%) that may increase the risk of an adverse reaction

Site of Service Administration	Medical Necessity

	• Unstable renal function which decreases the ability to respond to fluids
	• Difficult or unstable vascular access
	• Acute mental status changes or cognitive conditions that impact the safety of infusion or injection therapy
	• A known history of severe adverse drug reactions and/or anaphylaxis to prior treatment with a related or similar drug
	
	This site is considered medically necessary when the individual has cytokine release syndrome (CRS) and all the following are met:
	• CRS is grade 3 or 4 as evidenced by ALL the following:
	  ○ Temperature at least 38 °C
	  ○ Hypotension that requires 1 or more vasopressors
	  ○ Hypoxia that requires oxygen through a high-flow nasal cannula, face mask, non-rebreather mask, or Venturi mask OR positive pressure (continuous positive airway pressure [CPAP], bilevel positive airway pressure [BiPAP], intubation, or mechanical ventilation)
	AND
	• The individual will be admitted into an inpatient setting as soon as possible

Hospital-based outpatient setting • **Outpatient hospital IV infusion department** • **Hospital-based outpatient clinical level of care**	**These sites are considered not medically necessary for infusion and injectable therapy services of various medical and biologic agents when the site-of-service criteria in this policy are not met.**

This policy contains separate criteria to be used based on the member's formulary. Please check the member Plan booklet or member ID card for coverage and click the links below to navigate to the appropriate section:

Section 1: Open, Preferred, and Select Formulary Plans (Rx Plan A1, A2, B3, B4, C4, F1, and G3) and Plans with No Pharmacy Benefit Coverage

Section 2: Essentials Formulary Plans (Rx Plan E1, E3, E4)

Section 3: Individual/Small Group/Student ISHIP Metallic Formulary Plans (Rx Plan M1, M2, and M4)

The following section applies to Open, Preferred, and Select formulary plans (Rx Plan A1, A2, B3, B4, C4, F1, and G3) and plans with no pharmacy benefit coverage only. Please refer to the member plan booklet or member ID card.

Section 1: Open, Preferred, and Select Formulary Plans (Rx Plan A1, A2, B3, B4, C4, F1, and G3) and Plans with No Pharmacy Benefit Coverage ONLY

Plaque Psoriasis Systemic Treatments – First Line

IL-23 Inhibitors	TNF-α Inhibitors	TYK2 Inhibitor	IL-17 Inhibitor	IL-12/23 Inhibitors	PDE-4 Inhibitor
• Skyrizi (SC)	• Inflectra (IV) • Infliximab (Janssen – unbranded) (IV) • Remicade (IV)	• Sotyktu (oral)	• Taltz (SC)	• Stelara (SC) • Steqeyma (SC) • Yesintek (SC)	• Otezla (oral)
• Tremfya (SC)	• Adalimumab-adaz (Hyrimoz unbranded) (SC) • Adalimumab-adbm (Cyltezo unbranded) (SC) • Adalimumab-ryvk (Simlandi unbranded) (SC) • Cyltezo (SC) • Enbrel (SC) • Simlandi (SC)				

Second Line

IL-23 Inhibitor	IL-12/23 Inhibitors	TNF-α Inhibitors	IL-17 Inhibitors
• Ilumya (SC)	• Imuldosa (SC) • Otulfi (SC)	• Avsola (IV) • Renflexis (IV)	• Bimzelx (SC) • Cosentyx (SC)

Section 1: Open, Preferred, and Select Formulary Plans (Rx Plan A1, A2, B3, B4, C4, F1, and G3) and Plans with No Pharmacy Benefit Coverage ONLY			
	• Pyzchiva (SC) • Selarsdi (SC) • Brand ustekinumab (Stelara unbranded) (SC) • Brand ustekinumab-aekn (Selarsdi unbranded) (SC) • Brand ustekinumab-ttwe (Pyzchiva unbranded) (SC) • Wezlana (SC)	• Abrilada (SC) • Adalimumab-aacf (Idacio unbranded (SC) • Adalimumab-fkjp (Hulio unbranded) (SC) • Amjevita (SC) • Hadlima (SC) • Hulio (SC) • Humira (SC) • Hyrimoz (SC) • Idacio (SC) • Yuflyma (SC) • Yusimry (SC) • Cimzia (SC)	• Siliq (SC)

Step therapy tiers are listed below; please refer to the Policy section for details.

Section 1: Open, Preferred, and Select Formulary Plans (Rx Plan A1, A2, B3, B4, C4, F1, and G3) and Plans with No Pharmacy Benefit Coverage ONLY	
Drug	**Medical Necessity**
TNF-α Antagonists – First Line	
Enbrel (etanercept) SC	**Enbrel (etanercept) may be considered medically necessary for the treatment of plaque psoriasis when:** • The individual is aged 4 years or older **AND** • Has a diagnosis of chronic plaque psoriasis involving at least 10% of his or her body surface area (BSA) ○ **Exception**: This may be granted when **ANY** of the following are true: ▪ There is extensive recalcitrant facial involvement **OR** ▪ There is pustular involvement of the hands and feet **OR** ▪ There is genital involvement which interferes with normal sexual function **AND**

Section 1: Open, Preferred, and Select Formulary Plans (Rx Plan A1, A2, B3, B4, C4, F1, and G3) and Plans with No Pharmacy Benefit Coverage ONLY	
Drug	**Medical Necessity**
	• Has a history of an adequate trial and treatment failure with at least 1 approved systemic therapy (e.g., methotrexate, cyclosporine, acitretin or psoralen plus ultraviolet A light [PUVA]) unless contraindicated or not tolerated **AND** • Medication is being prescribed by or in consultation with a dermatologist
• **Adalimumab-adaz (Hyrimoz unbranded) SC** • **Adalimumab-adbm (Cyltezo unbranded) SC** • **Adalimumab-ryvk (Simlandi unbranded) SC** • **Cyltezo (adalimumab-adbm) SC** • **Simlandi (adalimumab-ryvk) SC**	**Adalimumab-adaz (Hyrimoz unbranded), adalimumab-adbm (Cyltezo unbranded), and adalimumab-ryvk (Simlandi unbranded), Cyltezo (adalimumab-adbm), and Simlandi (adalimumab-ryvk) may be considered medically necessary for the treatment of plaque psoriasis when:** • The individual is aged 18 years or older **AND** • Has a diagnosis of chronic plaque psoriasis involving at least 10% of his or her body surface area (BSA) ○ **Exception**: This may be granted when **ANY** of the following are true: ▪ There is extensive recalcitrant facial involvement **OR** ▪ There is pustular involvement of the hands and feet **OR** ▪ There is genital involvement which interferes with normal sexual function **AND** • Has a history of an adequate trial and treatment failure with at least 1 approved systemic therapy (e.g., methotrexate, cyclosporine, acitretin or psoralen plus ultraviolet A light [PUVA]) unless contraindicated or not tolerated **AND** • Medication is being prescribed by or in consultation with a dermatologist

Section 1: Open, Preferred, and Select Formulary Plans (Rx Plan A1, A2, B3, B4, C4, F1, and G3) and Plans with No Pharmacy Benefit Coverage ONLY	
Drug	**Medical Necessity**
	Note: This medical necessity criteria does not apply to one Open formulary (Formulary ID: 6062; Rx Plan F1) and one Preferred formulary (Formulary ID: 6064; Rx Plan G3). The criteria for members with these custom Open and Preferred formulary plans can be found in policy **5.01.647 Medical Necessity Criteria for Custom Open and Preferred Formularies**. Please check the member Plan booklet or member ID card to determine whether this policy criteria applies.
• **Inflectra (infliximab-dyyb) IV** • **Infliximab (Janssen – unbranded) IV** • **Remicade (infliximab) IV**	**Inflectra (infliximab-dyyb), Infliximab (Janssen – unbranded), and Remicade (infliximab) are subject to review for site of service administration.** **Inflectra (infliximab-dyyb), Infliximab (Janssen – unbranded), and Remicade (infliximab) may be considered medically necessary for the treatment of moderate to severe plaque psoriasis when:** • The individual is aged 18 years or older **AND** • Has a diagnosis of chronic plaque psoriasis involving at least 10% of his or her body surface area (BSA) ○ **Exception**: This may be granted when **ANY** of the following are true: ▪ There is extensive recalcitrant facial involvement **OR** ▪ There is pustular involvement of the hands and feet **OR** ▪ There is genital involvement which interferes with normal sexual function **AND** • Has a history of an adequate trial and treatment failure with at least 1 approved systemic therapy (e.g., methotrexate, cyclosporine, acitretin or psoralen plus ultraviolet A light [PUVA]) unless contraindicated or not tolerated **AND** • Medication is being prescribed by or in consultation with a dermatologist

Section 1: Open, Preferred, and Select Formulary Plans (Rx Plan A1, A2, B3, B4, C4, F1, and G3) and Plans with No Pharmacy Benefit Coverage ONLY	
Drug	**Medical Necessity**
	Inflectra (infliximab-dyyb), Infliximab (Janssen – unbranded), and Remicade (infliximab) may be considered medically necessary as emergent treatment for severe pustular, exfoliative or inflammatory psoriasis without prior use or failure/intolerance of a first-line drug, in contrast to stable plaque psoriasis.
IL-17 Inhibitors – First Line	
Taltz (ixekizumab) SC	**Taltz (ixekizumab) may be considered medically necessary for the treatment of moderate to severe plaque psoriasis when:** • The individual is aged 6 years or older **AND** • Has a diagnosis of chronic plaque psoriasis involving at least 10% of his or her body surface area (BSA) o **Exception**: This may be granted when **ANY** of the following are true: ▪ There is extensive recalcitrant facial involvement **OR** ▪ There is pustular involvement of the hands and feet **OR** ▪ There is genital involvement which interferes with normal sexual function **AND** • Has a history of an adequate trial and treatment failure with at least 1 approved systemic therapy (e.g., methotrexate, cyclosporine, acitretin or psoralen plus ultraviolet A light [PUVA]) unless contraindicated or not tolerated **AND** • Medication is being prescribed by or in consultation with a dermatologist
IL-12/23 Inhibitors – First Line	
• **Stelara (ustekinumab) SC** • **Steqeyma (ustekinumab-stba) SC**	**Steqeyma (ustekinumab-stba) SC and Yesintek (ustekinumab-kfce) SC may be considered medically necessary for the treatment of moderate to severe plaque psoriasis when:** • The individual is aged 6 years or older

Section 1: Open, Preferred, and Select Formulary Plans (Rx Plan A1, A2, B3, B4, C4, F1, and G3) and Plans with No Pharmacy Benefit Coverage ONLY	
Drug	**Medical Necessity**

• **Yesintek (ustekinumab-kfce) SC**	**AND**
	• Has a diagnosis of chronic plaque psoriasis involving at least 10% of his or her body surface area (BSA)
	  ○ **Exception**: This may be granted when **ANY** of the following are true:
	  ▪ There is extensive recalcitrant facial involvement
	  OR
	  ▪ There is pustular involvement of the hands and feet
	  OR
	  ▪ There is genital involvement which interferes with normal sexual function
	AND
	• Has a history of an adequate trial and treatment failure with at least 1 approved systemic therapy (e.g., methotrexate, cyclosporine, acitretin or psoralen plus ultraviolet A light [PUVA]) unless contraindicated or not tolerated
	AND
	• Medication is being prescribed by or in consultation with a dermatologist
	
	Stelara (ustekinumab) SC may be considered medically necessary for the treatment of moderate to severe plaque psoriasis when:
	• The individual is aged 6 years or older
	AND
	• Has a diagnosis of chronic plaque psoriasis involving at least 10% of his or her body surface area (BSA)
	  ○ **Exception**: This may be granted when **ANY** of the following are true:
	  ▪ There is extensive recalcitrant facial involvement
	  OR
	  ▪ There is pustular involvement of the hands and feet
	  OR

Section 1: Open, Preferred, and Select Formulary Plans (Rx Plan A1, A2, B3, B4, C4, F1, and G3) and Plans with No Pharmacy Benefit Coverage ONLY	
Drug	**Medical Necessity**
	▪ There is genital involvement which interferes with normal sexual function **AND** • Has a history of an adequate trial and treatment failure with at least 1 approved systemic therapy (e.g., methotrexate, cyclosporine, acitretin or psoralen plus ultraviolet A light [PUVA]) unless contraindicated or not tolerated **AND** • Medication is being prescribed by or in consultation with a dermatologist **AND** • Has had an inadequate response or intolerance to ALL the following agents:[1] ○ Steqeyma (ustekinumab-stba) SC ○ Yesintek (ustekinumab-kfce) SC [1]**Note:** Only applies to individuals not previously treated with requested therapy
IL-23 Inhibitors – First Line	
Skyrizi (risankizumab-rzaa) SC	**Skyrizi (risankizumab-rzaa) may be considered medically necessary for the treatment of moderate to severe plaque psoriasis when:** • The individual is aged 18 years or older **AND** • Has a diagnosis of chronic plaque psoriasis involving at least 10% of his or her body surface area (BSA) ○ **Exception**: This may be granted when **ANY** of the following are true: ▪ There is extensive recalcitrant facial involvement **OR** ▪ There is pustular involvement of the hands and feet **OR** ▪ There is genital involvement which interferes with normal sexual function

Section 1: Open, Preferred, and Select Formulary Plans (Rx Plan A1, A2, B3, B4, C4, F1, and G3) and Plans with No Pharmacy Benefit Coverage ONLY	
Drug	**Medical Necessity**
	AND • Has a history of an adequate trial and treatment failure with at least 1 approved systemic therapy (e.g., methotrexate, cyclosporine, acitretin or psoralen plus ultraviolet A light [PUVA]) unless contraindicated or not tolerated **AND** • Medication is being prescribed by or in consultation with a dermatologist
Tremfya (guselkumab) SC	**Tremfya (guselkumab) may be considered medically necessary for the treatment of moderate to severe plaque psoriasis when:** • The individual is aged 18 years or older **AND** • Has a diagnosis of chronic plaque psoriasis involving at least 10% of his or her body surface area (BSA) o **Exception**: This may be granted when **ANY** of the following are true: ▪ There is extensive recalcitrant facial involvement **OR** ▪ There is pustular involvement of the hands and feet **OR** ▪ There is genital involvement which interferes with normal sexual function **AND** • Has a history of an adequate trial and treatment failure with at least 1 approved systemic therapy (e.g., methotrexate, cyclosporine, acitretin or psoralen plus ultraviolet A light [PUVA]) unless contraindicated or not tolerated **AND** • Medication is being prescribed by or in consultation with a dermatologist
PDE4 Inhibitor – First Line	
Otezla (apremilast) oral	**Otezla (apremilast) may be considered medically necessary for the treatment of moderate to severe plaque psoriasis when:**

Section 1: Open, Preferred, and Select Formulary Plans (Rx Plan A1, A2, B3, B4, C4, F1, and G3) and Plans with No Pharmacy Benefit Coverage ONLY	
Drug	**Medical Necessity**
	• The individual is aged 6 years or older **AND** • Weighs at least 20 kg **AND** • Has a diagnosis of chronic plaque psoriasis involving at least 10% of his or her body surface area (BSA) ○ **Exception**: This may be granted when **ANY** of the following are true: ▪ There is extensive recalcitrant facial involvement **OR** ▪ There is pustular involvement of the hands and feet **OR** ▪ There is genital involvement which interferes with normal sexual function **AND** • Has a history of an adequate trial and treatment failure at least 1 approved systemic therapy (e.g., methotrexate, cyclosporine, acitretin or psoralen plus ultraviolet A light [PUVA]) unless contraindicated or not tolerated **AND** • Medication is being prescribed by or in consultation with a dermatologist
Tyrosine Kinase 2 (TYK2) Inhibitors – First Line	
Sotyktu (deucravacitinib) oral	**Sotyktu (deucravacitinib) may be considered medically necessary for the treatment of moderate to severe plaque psoriasis when:** • The individual is aged 18 years or older **AND** • Has a diagnosis of chronic plaque psoriasis involving at least 10% of his or her body surface area (BSA) ○ **Exception**: This may be granted when **ANY** of the following are true: ▪ There is extensive recalcitrant facial involvement **OR**

Section 1: Open, Preferred, and Select Formulary Plans (Rx Plan A1, A2, B3, B4, C4, F1, and G3) and Plans with No Pharmacy Benefit Coverage ONLY	
Drug	**Medical Necessity**
	▪ There is pustular involvement of the hands and feet **OR** ▪ There is genital involvement which interferes with normal sexual function **AND** • Has a history of an adequate trial and treatment failure with at least 1 approved systemic therapy (e.g., methotrexate, cyclosporine, acitretin or psoralen plus ultraviolet A light [PUVA]) unless contraindicated or not tolerated **AND** • Medication is being prescribed by or in consultation with a dermatologist
IL-17 Inhibitors – Second Line	
Bimzelx (bimekizumab-bkzx) SC	**Bimzelx (bimekizumab-bkzx) may be considered medically necessary for the treatment of moderate to severe plaque psoriasis when:** • The individual is aged 18 years or older **AND** • Has a diagnosis of chronic plaque psoriasis involving at least 10% of his or her body surface area (BSA) ○ **Exception**: This may be granted when **ANY** of the following are true: ▪ There is extensive recalcitrant facial involvement **OR** ▪ There is pustular involvement of the hands and feet **OR** ▪ There is genital involvement which interferes with normal sexual function **AND** • Has a history of an adequate trial and treatment failure with at least 1 approved systemic therapy (e.g., methotrexate, cyclosporine, acitretin or psoralen plus ultraviolet A light [PUVA]) unless contraindicated or not tolerated **AND**

Section 1: Open, Preferred, and Select Formulary Plans (Rx Plan A1, A2, B3, B4, C4, F1, and G3) and Plans with No Pharmacy Benefit Coverage ONLY	
Drug	**Medical Necessity**

	• Has had an inadequate response or is intolerant to 1 of the following agents:
	  ○ Enbrel (etanercept)
	  ○ Adalimumab-adaz (Hyrimoz unbranded) **OR** adalimumab-adbm (Cyltezo unbranded) **OR** adalimumab-ryvk (Simlandi unbranded) **OR** Cyltezo (adalimumab-adbm) **OR** Simlandi (adalimumab-ryvk)
	  ○ Otezla (apremilast)
	  ○ Skyrizi (risankizumab-rzaa) SC
	  ○ Sotyktu (deucravacitinib)
	  ○ Stelara (ustekinumab) SC **OR** Steqeyma (ustekinumab-stba) SC **OR** Yesintek (ustekinumab-kfce) SC
	  ○ Taltz (ixekizumab)
	  ○ Tremfya (guselkumab)
	AND
	• Medication is being prescribed by or in consultation with a dermatologist
	
	Note: This medical necessity criteria does not apply to one Open formulary (Formulary ID: 6062; Rx Plan F1) and one Preferred formulary (Formulary ID: 6064; Rx Plan G3). The criteria for members with these custom Open and Preferred formulary plans can be found in policy **5.01.647 Medical Necessity Criteria for Custom Open and Preferred Formularies**. Please check the member Plan booklet or member ID card to determine whether this policy criteria applies.

Siliq (brodalumab) SC	**Siliq (brodalumab) may be considered medically necessary for the treatment of moderate to severe plaque psoriasis when:**
	• The individual is aged 18 years or older
	AND
	• Has a diagnosis of chronic plaque psoriasis involving at least 10% of his or her body surface area (BSA)
	  ○ **Exception**: This may be granted when **ANY** of the following are true:
	  ▪ There is extensive recalcitrant facial involvement
	  OR

Section 1: Open, Preferred, and Select Formulary Plans (Rx Plan A1, A2, B3, B4, C4, F1, and G3) and Plans with No Pharmacy Benefit Coverage ONLY	
Drug	**Medical Necessity**
	▪ There is pustular involvement of the hands and feet **OR** ▪ There is genital involvement which interferes with normal sexual function **AND** • Has a history of an adequate trial and treatment failure with at least 1 approved systemic therapy (e.g., methotrexate, cyclosporine, acitretin or psoralen plus ultraviolet A light [PUVA]) unless contraindicated or not tolerated **AND** • Has had an inadequate response or is intolerant to 2 of the following agents: o Enbrel (etanercept) o Cyltezo (adalimumab-adbm) **OR** adalimumab-adaz (Hyrimoz unbranded) **OR** adalimumab-adbm (Cyltezo unbranded) **OR** Simlandi (adalimumab-ryvk) **OR** adalimumab-ryvk (Simlandi unbranded) o Otezla (apremilast) o Skyrizi (risankizumab-rzaa) SC o Sotyktu (deucravacitinib) o Stelara (ustekinumab) SC **OR** Steqeyma (ustekinumab-stba) SC **OR** Yesintek (ustekinumab-kfce) SC o Taltz (ixekizumab) o Tremfya (guselkumab) **AND** • Medication is being prescribed by or in consultation with a dermatologist **Note:** This medical necessity criteria does not apply to one Open formulary (Formulary ID: 6062; Rx Plan F1) and one Preferred formulary (Formulary ID: 6064; Rx Plan G3). The criteria for members with these custom Open and Preferred formulary plans can be found in policy **5.01.647 Medical Necessity Criteria for Custom Open and Preferred Formularies**. Please check the member Plan booklet or member ID card to determine whether this policy criteria applies.

Section 1: Open, Preferred, and Select Formulary Plans (Rx Plan A1, A2, B3, B4, C4, F1, and G3) and Plans with No Pharmacy Benefit Coverage ONLY	
Drug	**Medical Necessity**
Cosentyx (secukinumab) SC	**Cosentyx (secukinumab) may be considered medically necessary for the treatment of moderate to severe plaque psoriasis when:** • The individual is aged 6 years or older **AND** • Has a diagnosis of chronic plaque psoriasis involving at least 10% of his or her body surface area (BSA) ○ **Exception**: This may be granted when **ANY** of the following are true: ▪ There is extensive recalcitrant facial involvement **OR** ▪ There is pustular involvement of the hands and feet **OR** ▪ There is genital involvement which interferes with normal sexual function **AND** • Has a history of an adequate trial and treatment failure with at least 1 approved systemic therapy (e.g., methotrexate, cyclosporine, acitretin or psoralen plus ultraviolet A light [PUVA]) unless contraindicated or not tolerated **AND** • Has had an inadequate response or intolerance to 2 of the following agents: ○ Enbrel (etanercept) ○ Cyltezo (adalimumab-adbm) **OR** adalimumab-adaz (Hyrimoz unbranded) **OR** adalimumab-adbm (Cyltezo unbranded) **OR** Simlandi (adalimumab-ryvk) **OR** adalimumab-ryvk (Simlandi unbranded) ○ Otezla (apremilast) ○ Skyrizi (risankizumab-rzaa) SC ○ Sotyktu (deucravacitinib) ○ Stelara (ustekinumab) SC **OR** Steqeyma (ustekinumab-stba) SC **OR** Yesintek (ustekinumab-kfce) SC ○ Taltz (ixekizumab)

Section 1: Open, Preferred, and Select Formulary Plans (Rx Plan A1, A2, B3, B4, C4, F1, and G3) and Plans with No Pharmacy Benefit Coverage ONLY	
Drug	**Medical Necessity**
	○ Tremfya (guselkumab) **AND** • Medication is being prescribed by or in consultation with a dermatologist **Note:** This medical necessity criteria does not apply to one Open formulary (Formulary ID: 6062; Rx Plan F1) and one Preferred formulary (Formulary ID: 6064; Rx Plan G3). The criteria for members with these custom Open and Preferred formulary plans can be found in policy **5.01.647 Medical Necessity Criteria for Custom Open and Preferred Formularies**. Please check the member Plan booklet or member ID card to determine whether this policy criteria applies.
TNF-α Antagonists – Second Line	
• **Abrilada (adalimumab-afzb) SC** • **Adalimumab-aacf (Idacio unbranded)** • **Adalimumab-aaty (Yuflyma unbranded) SC** • **Adalimumab-fkjp (Hulio unbranded) SC** • **Amjevita (adalimumab-atto) SC** • **Hadlima (adalimumab-bwwd) SC** • **Hulio (adalimumab-fkjp) SC** • **Humira (adalimumab) SC** • **Hyrimoz (adalimumab-adaz) SC** • **Idacio (adalimumab-aacf) SC** • **Yuflyma (adalimumab-aaty) SC** • **Yusimry (adalimumab-aqvh) SC**	**Abrilada (adalimumab-afzb), adalimumab-aacf (Idacio unbranded), adalimumab-aaty (Yuflyma unbranded), adalimumab-fkjp (Hulio unbranded), Amjevita (adalimumab-atto), Hadlima (adalimumab-bwwd), Hulio (adalimumab-fkjp), Humira (adalimumab), Hyrimoz (adalimumab-adaz), Idacio (adalimumab-aacf), Yuflyma (adalimumab-aaty), and Yusimry (adalimumab-aqvh) may be considered medically necessary for the treatment of plaque psoriasis when:** • The individual is aged 18 years or older **AND** • Has a diagnosis of chronic plaque psoriasis involving at least 10% of his or her body surface area (BSA) ○ **Exception**: This may be granted when **ANY** of the following are true: ▪ There is extensive recalcitrant facial involvement **OR** ▪ There is pustular involvement of the hands and feet **OR** ▪ There is genital involvement which interferes with normal sexual function **AND**

Section 1: Open, Preferred, and Select Formulary Plans (Rx Plan A1, A2, B3, B4, C4, F1, and G3) and Plans with No Pharmacy Benefit Coverage ONLY	
Drug	**Medical Necessity**

	• Has a history of an adequate trial and treatment failure with at least 1 approved systemic therapy (e.g., methotrexate, cyclosporine, acitretin or psoralen plus ultraviolet A light [PUVA]) unless contraindicated or not tolerated
	AND
	• Has had an inadequate response or is intolerant to ALL the following agents:
	  ○ Cyltezo (adalimumab-adbm) OR adalimumab-adbm (Cyltezo unbranded)
	  ○ Adalimumab-adaz (Hyrimoz unbranded)
	  ○ Simlandi (adalimumab-ryvk) OR adalimumab-ryvk (Simlandi unbranded)
	AND
	• Medication is being prescribed by or in consultation with a dermatologist
	
	Note: This medical necessity criteria does not apply to one Open formulary (Formulary ID: 6062; Rx Plan F1) and one Preferred formulary (Formulary ID: 6064; Rx Plan G3). The criteria for members with these custom Open and Preferred formulary plans can be found in policy **5.01.647 Medical Necessity Criteria for Custom Open and Preferred Formularies**. Please check the member Plan booklet or member ID card to determine whether this policy criteria applies.

Cimzia (certolizumab pegol) SC	**Cimzia (certolizumab pegol) may be considered medically necessary for the treatment of plaque psoriasis when:**
	• The individual is aged 18 years or older
	AND
	• Has a diagnosis of chronic plaque psoriasis involving at least 10% of his or her body surface area (BSA)
	  ○ **Exception**: This may be granted when **ANY** of the following are true:
	  ▪ There is extensive recalcitrant facial involvement
	  OR
	  ▪ There is pustular involvement of the hands and feet
	  OR

Section 1: Open, Preferred, and Select Formulary Plans (Rx Plan A1, A2, B3, B4, C4, F1, and G3) and Plans with No Pharmacy Benefit Coverage ONLY	
Drug	**Medical Necessity**
	▪ There is genital involvement which interferes with normal sexual function **AND** • Has a history of an adequate trial and treatment failure with at least 1 approved systemic therapy (e.g., methotrexate, cyclosporine, acitretin or psoralen plus ultraviolet A light [PUVA]) unless contraindicated or not tolerated **AND** • Has had an inadequate response or is intolerant to 2 of the following agents: o Enbrel (etanercept) o Cyltezo (adalimumab-adbm) **OR** Simlandi (adalimumab-ryvk) **OR** adalimumab-adaz (Hyrimoz unbranded) **OR** adalimumab-adbm (Cyltezo unbranded) **OR** adalimumab-ryvk (Simlandi unbranded) o Otezla (apremilast) o Skyrizi (risankizumab-rzaa) SC o Sotyktu (deucravacitinib) o Stelara (ustekinumab) SC **OR** Steqeyma (ustekinumab-stba) SC **OR** Yesintek (ustekinumab-kfce) SC o Taltz (ixekizumab) o Tremfya (guselkumab) **AND** • Medication is being prescribed by or in consultation with a dermatologist **Note:** This medical necessity criteria does not apply to one Open formulary (Formulary ID: 6062; Rx Plan F1) and one Preferred formulary (Formulary ID: 6064; Rx Plan G3). The criteria for members with these custom Open and Preferred formulary plans can be found in policy **5.01.647 Medical Necessity Criteria for Custom Open and Preferred Formularies**. Please check the member Plan booklet or member ID card to determine whether this policy criteria applies.
• **Avsola (infliximab-axxq) IV,**	**Avsola (infliximab-axxq) and Renflexis (infliximab-abda) are subject to review for site of service administration.**

Section 1: Open, Preferred, and Select Formulary Plans (Rx Plan A1, A2, B3, B4, C4, F1, and G3) and Plans with No Pharmacy Benefit Coverage ONLY	
Drug	**Medical Necessity**
• **Renflexis (infliximab-abda) IV**	**Avsola (infliximab-axxq) and Renflexis (infliximab-abda) may be considered medically necessary for the treatment of moderate to severe plaque psoriasis when:** • The individual is aged 18 years or older **AND** • Has a diagnosis of chronic plaque psoriasis involving at least 10% of his or her body surface area (BSA) ○ **Exception**: This may be granted when **ANY** of the following are true: ▪ There is extensive recalcitrant facial involvement **OR** ▪ There is pustular involvement of the hands and feet **OR** ▪ There is genital involvement which interferes with normal sexual function **AND** • Has a history of an adequate trial and treatment failure with at least 1 approved systemic therapy (e.g., methotrexate, cyclosporine, acitretin or psoralen plus ultraviolet A light [PUVA]) unless contraindicated or not tolerated **AND** • Has had a documented trial and treatment failure with Inflectra (infliximab-dyyb), Infliximab (Janssen – unbranded), or Remicade (infliximab) **AND** • Medication is being prescribed by or in consultation with a dermatologist **Avsola (infliximab-axxq) and Renflexis (infliximab-abda) may be considered medically necessary as emergent treatment for severe pustular, exfoliative or inflammatory psoriasis without prior use or failure/intolerance of a first-line agent, in contrast to stable plaque psoriasis.**

Section 1: Open, Preferred, and Select Formulary Plans (Rx Plan A1, A2, B3, B4, C4, F1, and G3) and Plans with No Pharmacy Benefit Coverage ONLY	
Drug	**Medical Necessity**
IL-12/23 Inhibitors – Second Line	
• **Imuldosa (ustekinumab-srlf) SC** • **Otulfi (ustekinumab-aauz) SC** • **Pyzchiva (ustekinumab-ttwe) SC** • **Selarsdi (ustekinumab-ackn) SC** • **Ustekinumab (Stelara unbranded) SC** • **Ustekinumab-aekn (Selarsdi unbranded) SC** • **Ustekinumab-ttwe (Pyzchiva unbranded) SC** • **Wezlana (ustekinumab-auub) SC**	**Imuldosa (ustekinumab-srlf) SC, Otulfi (ustekinumab-aauz) SC, Pyzchiva (ustekinumab-ttwe) SC, Selarsdi (ustekinumab-ackn) SC, ustekinumab (Stelara unbranded) SC, ustekinumab-aekn (Selarsdi unbranded) SC, ustekinumab-ttwe (Pyzchiva unbranded) SC, and Wezlana (ustekinumab-auub) SC may be considered medically necessary for the treatment of moderate to severe plaque psoriasis when:** • The individual is aged 6 years or older **AND** • Has a diagnosis of chronic plaque psoriasis involving greater than or equal to 10% of his or her body surface area (BSA) o **Exception**: This may be granted when **ANY** of the following are true: ▪ There is extensive recalcitrant facial involvement **OR** ▪ There is pustular involvement of the hands and feet **OR** ▪ There is genital involvement which interferes with normal sexual function **AND** • Has a history of an adequate trial and treatment failure with greater than or equal to 1 approved systemic therapy (e.g., methotrexate, cyclosporine, acitretin or psoralen plus ultraviolet A light [PUVA]) unless contraindicated or not tolerated **AND** • Has had an inadequate response or is intolerant to ALL the following agents: o Stelara (ustekinumab) SC o Steqeyma (ustekinumab-stba) SC o Yesintek (ustekinumab-kfce) SC **AND** • Medication is being prescribed by or in consultation with a dermatologist

Section 1: Open, Preferred, and Select Formulary Plans (Rx Plan A1, A2, B3, B4, C4, F1, and G3) and Plans with No Pharmacy Benefit Coverage ONLY	
Drug	**Medical Necessity**
IL-23 Inhibitors – Second Line	
Ilumya (tildrakizumab-asmn) SC	**Ilumya (tildrakizumab-asmn) may be considered medically necessary for the treatment of moderate to severe plaque psoriasis when:** • The individual is aged 18 years or older **AND** • Has a diagnosis of chronic plaque psoriasis involving at least 10% of his or her body surface area (BSA) o **Exception**: This may be granted when **ANY** of the following are true: ▪ There is extensive recalcitrant facial involvement **OR** ▪ There is pustular involvement of the hands and feet **OR** ▪ There is genital involvement which interferes with normal sexual function **AND** • Has a history of an adequate trial and treatment failure with at least 1 approved systemic therapy (e.g., methotrexate, cyclosporine, acitretin or psoralen plus ultraviolet A light [PUVA]) unless contraindicated or not tolerated **AND** • Has had an inadequate response or is intolerant to 2 of the following agents: o Enbrel (etanercept) o Cyltezo (adalimumab-adbm) **OR** adalimumab-adaz (Hyrimoz unbranded) **OR** adalimumab-adbm (Cyltezo unbranded) **OR** Simlandi (adalimumab-ryvk) **OR** adalimumab-ryvk (Simlandi unbranded) o Otezla (apremilast) o Skyrizi (risankizumab-rzaa) SC o Sotyktu (deucravacitinib) o Stelara (ustekinumab) SC **OR** Steqeyma (ustekinumab-stba) SC **OR** Yesintek (ustekinumab-kfce) SC

Section 1: Open, Preferred, and Select Formulary Plans (Rx Plan A1, A2, B3, B4, C4, F1, and G3) and Plans with No Pharmacy Benefit Coverage ONLY	
Drug	**Medical Necessity**
	○ Taltz (ixekizumab) ○ Tremfya (guselkumab) **AND** • Medication is being prescribed by or in consultation with a dermatologist **Note:** This medical necessity criteria does not apply to one Open formulary (Formulary ID: 6062; Rx Plan F1) and one Preferred formulary (Formulary ID: 6064; Rx Plan G3). The criteria for members with these custom Open and Preferred formulary plans can be found in policy **5.01.647 Medical Necessity Criteria for Custom Open and Preferred Formularies**. Please check the member Plan booklet or member ID card to determine whether this policy criteria applies.

Section 2: Essentials Formulary Plans (Rx Plan E1, E3, and E4) ONLY					
Plaque Psoriasis Systemic Treatments – First Line					
IL-23 Inhibitors	**TNF-α Inhibitors**	**TYK2 Inhibitor**	**IL-17 Inhibitor**	**IL-12/23 Inhibitors**	**PDE-4 Inhibitor**
• Skyrizi (SC)	• Inflectra (IV) • Infliximab (Janssen – unbranded) (IV) • Remicade (IV)	• Sotyktu (oral)	• Taltz (SC)	• Steqeyma (SC) • Yesintek (SC)	• Otezla (oral)
• Tremfya (SC)	• Adalimumab-adaz (Hyrimoz unbranded) (SC) • Adalimumab-adbm (Cyltezo unbranded) (SC) • Adalimumab-ryvk (Simlandi unbranded) (SC) • Cyltezo (SC) • Enbrel (SC) • Simlandi (SC)				
Second Line					
IL-23 Inhibitor	**IL-12/23 Inhibitors**	**TNF-α Inhibitors**	**IL-17 Inhibitors**		
• Ilumya (SC)	• Imuldosa (SC) • Otulfi (SC)	• Avsola (IV) • Renflexis (IV)	• Bimzelx (SC) • Cosentyx (SC)		

Section 2: Essentials Formulary Plans (Rx Plan E1, E3, and E4) ONLY			
	• Pyzchiva (SC) • Selarsdi (SC) • Stelara (SC) • Brand ustekinumab (Stelara unbranded) (SC) • Brand ustekinumab-aekn (Selarsdi unbranded) (SC) • Brand ustekinumab-ttwe (Pyzchiva unbranded) (SC) • Wezlana (SC)	• Abrilada (SC) • Adalimumab-aacf (Idacio unbranded (SC) • Adalimumab-fkjp (Hulio unbranded) (SC) • Amjevita (SC) • Hadlima (SC) • Hulio (SC) • Humira (SC) • Hyrimoz (SC) • Idacio (SC) • Yuflyma (SC) • Yusimry (SC) • Cimzia (SC)	• Siliq (SC)

Step therapy tiers are listed below; please refer to the Policy section for details.

Section 2: Essentials Formulary Plans (Rx Plan E1, E3, and E4) ONLY	
Drug	**Medical Necessity**
TNF-α Antagonists – First Line	
Enbrel (etanercept) SC	**Enbrel (etanercept) may be considered medically necessary for the treatment of plaque psoriasis when:** • The individual is aged 4 years or older **AND** • Has a diagnosis of chronic plaque psoriasis involving at least 10% of his or her body surface area (BSA) ○ **Exception**: This may be granted when **ANY** of the following are true: ▪ There is extensive recalcitrant facial involvement **OR** ▪ There is pustular involvement of the hands and feet **OR** ▪ There is genital involvement which interferes with normal sexual function **AND** • Has a history of an adequate trial and treatment failure with at least 1 approved systemic therapy (e.g., methotrexate,

Section 2: Essentials Formulary Plans (Rx Plan E1, E3, and E4) ONLY	
Drug	**Medical Necessity**
	cyclosporine, acitretin or psoralen plus ultraviolet A light [PUVA]) unless contraindicated or not tolerated **AND** • Medication is being prescribed by or in consultation with a dermatologist
• **Adalimumab-adaz (Hyrimoz unbranded) SC** • **Adalimumab-adbm (Cyltezo unbranded) SC** • **Adalimumab-ryvk (Simlandi unbranded) SC** • **Cyltezo (adalimumab-adbm) SC** • **Simlandi (adalimumab-ryvk) SC**	**Adalimumab-adaz (Hyrimoz unbranded), adalimumab-adbm (Cyltezo unbranded), and adalimumab-ryvk (Simlandi unbranded), Cyltezo (adalimumab-adbm), and Simlandi (adalimumab-ryvk) may be considered medically necessary for the treatment of plaque psoriasis when:** • The individual is aged 18 years or older **AND** • Has a diagnosis of chronic plaque psoriasis involving at least 10% of his or her body surface area (BSA) ○ **Exception**: This may be granted when **ANY** of the following are true: ▪ There is extensive recalcitrant facial involvement **OR** ▪ There is pustular involvement of the hands and feet **OR** ▪ There is genital involvement which interferes with normal sexual function **AND** • Has a history of an adequate trial and treatment failure with at least 1 approved systemic therapy (e.g., methotrexate, cyclosporine, acitretin or psoralen plus ultraviolet A light [PUVA]) unless contraindicated or not tolerated **AND** • Medication is being prescribed by or in consultation with a dermatologist **Note:** This medical necessity criteria does not apply to one Open formulary (Formulary ID: 6062; Rx Plan F1) and one Preferred formulary (Formulary ID: 6064; Rx Plan G3). The criteria for members with these custom Open and Preferred formulary plans can be found in policy **5.01.647 Medical Necessity Criteria for**

Section 2: Essentials Formulary Plans (Rx Plan E1, E3, and E4) ONLY	
Drug	**Medical Necessity**
	Custom Open and Preferred Formularies. Please check the member Plan booklet or member ID card to determine whether this policy criteria applies.
• **Inflectra (infliximab-dyyb) IV** • **Infliximab (Janssen – unbranded) IV** • **Remicade (infliximab) IV**	**Inflectra (infliximab-dyyb), Infliximab (Janssen – unbranded), and Remicade (infliximab) are subject to review for site of service administration.** **Inflectra (infliximab-dyyb), Infliximab (Janssen – unbranded), and Remicade (infliximab) may be considered medically necessary for the treatment of moderate to severe plaque psoriasis when:** • The individual is aged 18 years or older **AND** • Has a diagnosis of chronic plaque psoriasis involving at least 10% of his or her body surface area (BSA) ○ **Exception**: This may be granted when **ANY** of the following are true: ▪ There is extensive recalcitrant facial involvement **OR** ▪ There is pustular involvement of the hands and feet **OR** ▪ There is genital involvement which interferes with normal sexual function **AND** • Has a history of an adequate trial and treatment failure with at least 1 approved systemic therapy (e.g., methotrexate, cyclosporine, acitretin or psoralen plus ultraviolet A light [PUVA]) unless contraindicated or not tolerated **AND** • Medication is being prescribed by or in consultation with a dermatologist **Inflectra (infliximab-dyyb), Infliximab (Janssen – unbranded), and Remicade (infliximab) may be considered medically necessary as emergent treatment for severe pustular, exfoliative or inflammatory psoriasis without prior use or**

Section 2: Essentials Formulary Plans (Rx Plan E1, E3, and E4) ONLY	
Drug	**Medical Necessity**
	failure/intolerance of a first-line drug, in contrast to stable plaque psoriasis.
IL-17 Inhibitors – First Line	
Taltz (ixekizumab) SC	**Taltz (ixekizumab) may be considered medically necessary for the treatment of moderate to severe plaque psoriasis when:** • The individual is aged 6 years or older **AND** • Has a diagnosis of chronic plaque psoriasis involving at least 10% of his or her body surface area (BSA) ○ **Exception**: This may be granted when **ANY** of the following are true: ▪ There is extensive recalcitrant facial involvement **OR** ▪ There is pustular involvement of the hands and feet **OR** ▪ There is genital involvement which interferes with normal sexual function **AND** • Has a history of an adequate trial and treatment failure with at least 1 approved systemic therapy (e.g., methotrexate, cyclosporine, acitretin or psoralen plus ultraviolet A light [PUVA]) unless contraindicated or not tolerated **AND** • Medication is being prescribed by or in consultation with a dermatologist
IL-12/23 Inhibitors – First Line	
• **Steqeyma (ustekinumab-stba) SC** • **Yesintek (ustekinumab-kfce) SC**	**Steqeyma (ustekinumab-stba) SC and Yesintek (ustekinumab-kfce) SC may be considered medically necessary for the treatment of moderate to severe plaque psoriasis when:** • The individual is aged 6 years or older **AND** • Has a diagnosis of chronic plaque psoriasis involving at least 10% of his or her body surface area (BSA) ○ **Exception**: This may be granted when **ANY** of the following are true:

Section 2: Essentials Formulary Plans (Rx Plan E1, E3, and E4) ONLY	
Drug	**Medical Necessity**
	▪ There is extensive recalcitrant facial involvement **OR** ▪ There is pustular involvement of the hands and feet **OR** ▪ There is genital involvement which interferes with normal sexual function **AND** • Has a history of an adequate trial and treatment failure with at least 1 approved systemic therapy (e.g., methotrexate, cyclosporine, acitretin or psoralen plus ultraviolet A light [PUVA]) unless contraindicated or not tolerated **AND** • Medication is being prescribed by or in consultation with a dermatologist
IL-23 Inhibitors – First Line	
Skyrizi (risankizumab-rzaa) SC	**Skyrizi (risankizumab-rzaa) may be considered medically necessary for the treatment of moderate to severe plaque psoriasis when:** • The individual is aged 18 years or older **AND** • Has a diagnosis of chronic plaque psoriasis involving at least 10% of his or her body surface area (BSA) ○ **Exception**: This may be granted when **ANY** of the following are true: ▪ There is extensive recalcitrant facial involvement **OR** ▪ There is pustular involvement of the hands and feet **OR** ▪ There is genital involvement which interferes with normal sexual function **AND** • Has a history of an adequate trial and treatment failure with at least 1 approved systemic therapy (e.g., methotrexate, cyclosporine, acitretin or psoralen plus ultraviolet A light [PUVA]) unless contraindicated or not tolerated

Section 2: Essentials Formulary Plans (Rx Plan E1, E3, and E4) ONLY	
Drug	**Medical Necessity**
	AND • Medication is being prescribed by or in consultation with a dermatologist
Tremfya (guselkumab) SC	**Tremfya (guselkumab) may be considered medically necessary for the treatment of moderate to severe plaque psoriasis when:** • The individual is aged 18 years or older **AND** • Has a diagnosis of chronic plaque psoriasis involving at least 10% of his or her body surface area (BSA) ○ **Exception**: This may be granted when **ANY** of the following are true: ▪ There is extensive recalcitrant facial involvement **OR** ▪ There is pustular involvement of the hands and feet **OR** ▪ There is genital involvement which interferes with normal sexual function **AND** • Has a history of an adequate trial and treatment failure with at least 1 approved systemic therapy (e.g., methotrexate, cyclosporine, acitretin or psoralen plus ultraviolet A light [PUVA]) unless contraindicated or not tolerated **AND** • Medication is being prescribed by or in consultation with a dermatologist
PDE4 Inhibitor – First Line	
Otezla (apremilast) oral	**Otezla (apremilast) may be considered medically necessary for the treatment of moderate to severe plaque psoriasis when:** • The individual is aged 6 years or older **AND** • Weighs at least 20 kg **AND** • Has a diagnosis of chronic plaque psoriasis involving at least 10% of his or her body surface area (BSA)

Section 2: Essentials Formulary Plans (Rx Plan E1, E3, and E4) ONLY	
Drug	**Medical Necessity**
	○ **Exception**: This may be granted when **ANY** of the following are true: ▪ There is extensive recalcitrant facial involvement **OR** ▪ There is pustular involvement of the hands and feet **OR** ▪ There is genital involvement which interferes with normal sexual function **AND** • Has a history of an adequate trial and treatment failure at least 1 approved systemic therapy (e.g., methotrexate, cyclosporine, acitretin or psoralen plus ultraviolet A light [PUVA]) unless contraindicated or not tolerated **AND** • Medication is being prescribed by or in consultation with a dermatologist
Tyrosine Kinase 2 (TYK2) Inhibitors – First Line	
Sotyktu (deucravacitinib) oral	**Sotyktu (deucravacitinib) may be considered medically necessary for the treatment of moderate to severe plaque psoriasis when:** • The individual is aged 18 years or older **AND** • Has a diagnosis of chronic plaque psoriasis involving at least 10% of his or her body surface area (BSA) ○ **Exception**: This may be granted when **ANY** of the following are true: ▪ There is extensive recalcitrant facial involvement **OR** ▪ There is pustular involvement of the hands and feet **OR** ▪ There is genital involvement which interferes with normal sexual function **AND** • Has a history of an adequate trial and treatment failure with at least 1 approved systemic therapy (e.g., methotrexate,

Section 2: Essentials Formulary Plans (Rx Plan E1, E3, and E4) ONLY	
Drug	**Medical Necessity**
	cyclosporine, acitretin or psoralen plus ultraviolet A light [PUVA]) unless contraindicated or not tolerated **AND** • Medication is being prescribed by or in consultation with a dermatologist
IL-17 Inhibitors – Second Line	
Bimzelx (bimekizumab-bkzx) SC	**Bimzelx (bimekizumab-bkzx) may be considered medically necessary for the treatment of moderate to severe plaque psoriasis when:** • The individual is aged 18 years or older **AND** • Has a diagnosis of chronic plaque psoriasis involving at least 10% of his or her body surface area (BSA) o **Exception**: This may be granted when **ANY** of the following are true: ▪ There is extensive recalcitrant facial involvement **OR** ▪ There is pustular involvement of the hands and feet **OR** ▪ There is genital involvement which interferes with normal sexual function **AND** • Has a history of an adequate trial and treatment failure with at least 1 approved systemic therapy (e.g., methotrexate, cyclosporine, acitretin or psoralen plus ultraviolet A light [PUVA]) unless contraindicated or not tolerated **AND** • Has had an inadequate response or is intolerant to 1 of the following agents: o Enbrel (etanercept) o Adalimumab-adaz (Hyrimoz unbranded) **OR** adalimumab-adbm (Cyltezo unbranded) **OR** adalimumab-ryvk (Simlandi unbranded) **OR** Cyltezo (adalimumab-adbm) **OR** Simlandi (adalimumab-ryvk) o Otezla (apremilast)

Section 2: Essentials Formulary Plans (Rx Plan E1, E3, and E4) ONLY	
Drug	**Medical Necessity**
	○ Skyrizi (risankizumab-rzaa) SC ○ Sotyktu (deucravacitinib) ○ Steqeyma (ustekinumab-stba) SC **OR** Yesintek (ustekinumab-kfce) SC ○ Taltz (ixekizumab) ○ Tremfya (guselkumab) **AND** • Medication is being prescribed by or in consultation with a dermatologist **Note:** This medical necessity criteria does not apply to one Open formulary (Formulary ID: 6062; Rx Plan F1) and one Preferred formulary (Formulary ID: 6064; Rx Plan G3). The criteria for members with these custom Open and Preferred formulary plans can be found in policy **5.01.647 Medical Necessity Criteria for Custom Open and Preferred Formularies**. Please check the member Plan booklet or member ID card to determine whether this policy criteria applies.
Siliq (brodalumab) SC	**Siliq (brodalumab) may be considered medically necessary for the treatment of moderate to severe plaque psoriasis when:** • The individual is aged 18 years or older **AND** • Has a diagnosis of chronic plaque psoriasis involving at least 10% of his or her body surface area (BSA) ○ **Exception**: This may be granted when **ANY** of the following are true: ▪ There is extensive recalcitrant facial involvement **OR** ▪ There is pustular involvement of the hands and feet **OR** ▪ There is genital involvement which interferes with normal sexual function **AND** • Has a history of an adequate trial and treatment failure with at least 1 approved systemic therapy (e.g., methotrexate, cyclosporine, acitretin or psoralen plus ultraviolet A light [PUVA]) unless contraindicated or not tolerated

Section 2: Essentials Formulary Plans (Rx Plan E1, E3, and E4) ONLY	
Drug	**Medical Necessity**

	AND
	• Has had an inadequate response or is intolerant to 2 of the following agents:
	  ○ Enbrel (etanercept)
	  ○ Cyltezo (adalimumab-adbm) **OR** adalimumab-adaz (Hyrimoz unbranded) **OR** adalimumab-adbm (Cyltezo unbranded) **OR** Simlandi (adalimumab-ryvk) **OR** adalimumab-ryvk (Simlandi unbranded)
	  ○ Otezla (apremilast)
	  ○ Skyrizi (risankizumab-rzaa) SC
	  ○ Sotyktu (deucravacitinib)
	  ○ Steqeyma (ustekinumab-stba) SC **OR** Yesintek (ustekinumab-kfce) SC
	  ○ Taltz (ixekizumab)
	  ○ Tremfya (guselkumab)
	AND
	• Medication is being prescribed by or in consultation with a dermatologist
	
	Note: This medical necessity criteria does not apply to one Open formulary (Formulary ID: 6062; Rx Plan F1) and one Preferred formulary (Formulary ID: 6064; Rx Plan G3). The criteria for members with these custom Open and Preferred formulary plans can be found in policy **5.01.647 Medical Necessity Criteria for Custom Open and Preferred Formularies**. Please check the member Plan booklet or member ID card to determine whether this policy criteria applies.

Cosentyx (secukinumab) SC	**Cosentyx (secukinumab) may be considered medically necessary for the treatment of moderate to severe plaque psoriasis when:**
	• The individual is aged 6 years or older
	AND
	• Has a diagnosis of chronic plaque psoriasis involving at least 10% of his or her body surface area (BSA)
	  ○ **Exception**: This may be granted when **ANY** of the following are true:
	  ▪ There is extensive recalcitrant facial involvement

Section 2: Essentials Formulary Plans (Rx Plan E1, E3, and E4) ONLY	
Drug	**Medical Necessity**
	OR ▪ There is pustular involvement of the hands and feet **OR** ▪ There is genital involvement which interferes with normal sexual function **AND** • Has a history of an adequate trial and treatment failure with at least 1 approved systemic therapy (e.g., methotrexate, cyclosporine, acitretin or psoralen plus ultraviolet A light [PUVA]) unless contraindicated or not tolerated **AND** • Has had an inadequate response or intolerance to 2 of the following agents: o Enbrel (etanercept) o Cyltezo (adalimumab-adbm) **OR** adalimumab-adaz (Hyrimoz unbranded) **OR** adalimumab-adbm (Cyltezo unbranded) **OR** Simlandi (adalimumab-ryvk) **OR** adalimumab-ryvk (Simlandi unbranded) o Otezla (apremilast) o Skyrizi (risankizumab-rzaa) SC o Sotyktu (deucravacitinib) o Steqeyma (ustekinumab-stba) SC **OR** Yesintek (ustekinumab-kfce) SC o Taltz (ixekizumab) o Tremfya (guselkumab) **AND** • Medication is being prescribed by or in consultation with a dermatologist **Note:** This medical necessity criteria does not apply to one Open formulary (Formulary ID: 6062; Rx Plan F1) and one Preferred formulary (Formulary ID: 6064; Rx Plan G3). The criteria for members with these custom Open and Preferred formulary plans can be found in policy **5.01.647 Medical Necessity Criteria for Custom Open and Preferred Formularies**. Please check the member Plan booklet or member ID card to determine whether this policy criteria applies.

Section 2: Essentials Formulary Plans (Rx Plan E1, E3, and E4) ONLY	
Drug	**Medical Necessity**
TNF-α Antagonists – Second Line	

• **Abrilada (adalimumab-afzb) SC**
• **Adalimumab-aacf (Idacio unbranded)**
• **Adalimumab-aaty (Yuflyma unbranded) SC**
• **Adalimumab-fkjp (Hulio unbranded) SC**
• **Amjevita (adalimumab-atto) SC**
• **Hadlima (adalimumab-bwwd) SC**
• **Hulio (adalimumab-fkjp) SC**
• **Humira (adalimumab) SC**
• **Hyrimoz (adalimumab-adaz) SC**
• **Idacio (adalimumab-aacf) SC**
• **Yuflyma (adalimumab-aaty) SC**
• **Yusimry (adalimumab-aqvh) SC**
	Abrilada (adalimumab-afzb), adalimumab-aacf (Idacio unbranded), adalimumab-aaty (Yuflyma unbranded), adalimumab-fkjp (Hulio unbranded), Amjevita (adalimumab-atto), Hadlima (adalimumab-bwwd), Hulio (adalimumab-fkjp), Humira (adalimumab), Hyrimoz (adalimumab-adaz), Idacio (adalimumab-aacf), Yuflyma (adalimumab-aaty), and Yusimry (adalimumab-aqvh) may be considered medically necessary for the treatment of plaque psoriasis when:
	• The individual is aged 18 years or older
	AND
	• Has a diagnosis of chronic plaque psoriasis involving at least 10% of his or her body surface area (BSA)
	  ○ **Exception**: This may be granted when **ANY** of the following are true:
	  ▪ There is extensive recalcitrant facial involvement
	  OR
	  ▪ There is pustular involvement of the hands and feet
	  OR
	  ▪ There is genital involvement which interferes with normal sexual function
	AND
	• Has a history of an adequate trial and treatment failure with at least 1 approved systemic therapy (e.g., methotrexate, cyclosporine, acitretin or psoralen plus ultraviolet A light [PUVA]) unless contraindicated or not tolerated
	AND
	• Has had an inadequate response or is intolerant to ALL the following agents:
	  ○ Cyltezo (adalimumab-adbm) OR adalimumab-adbm (Cyltezo unbranded)
	  ○ Adalimumab-adaz (Hyrimoz unbranded)
	  ○ Simlandi (adalimumab-ryvk) OR adalimumab-ryvk (Simlandi unbranded)
	AND

Section 2: Essentials Formulary Plans (Rx Plan E1, E3, and E4) ONLY	
Drug	**Medical Necessity**
	• Medication is being prescribed by or in consultation with a dermatologist **Note:** This medical necessity criteria does not apply to one Open formulary (Formulary ID: 6062; Rx Plan F1) and one Preferred formulary (Formulary ID: 6064; Rx Plan G3). The criteria for members with these custom Open and Preferred formulary plans can be found in policy **5.01.647 Medical Necessity Criteria for Custom Open and Preferred Formularies**. Please check the member Plan booklet or member ID card to determine whether this policy criteria applies.
Cimzia (certolizumab pegol) SC	**Cimzia (certolizumab pegol) may be considered medically necessary for the treatment of plaque psoriasis when:** • The individual is aged 18 years or older **AND** • Has a diagnosis of chronic plaque psoriasis involving at least 10% of his or her body surface area (BSA) ○ **Exception**: This may be granted when **ANY** of the following are true: ▪ There is extensive recalcitrant facial involvement **OR** ▪ There is pustular involvement of the hands and feet **OR** ▪ There is genital involvement which interferes with normal sexual function **AND** • Has a history of an adequate trial and treatment failure with at least 1 approved systemic therapy (e.g., methotrexate, cyclosporine, acitretin or psoralen plus ultraviolet A light [PUVA]) unless contraindicated or not tolerated **AND** • Has had an inadequate response or is intolerant to 2 of the following agents: ○ Enbrel (etanercept) ○ Cyltezo (adalimumab-adbm) **OR** Simlandi (adalimumab-ryvk) **OR** adalimumab-adaz (Hyrimoz unbranded) **OR**

Section 2: Essentials Formulary Plans (Rx Plan E1, E3, and E4) ONLY	
Drug	**Medical Necessity**
	adalimumab-adbm (Cyltezo unbranded) **OR** adalimumab-ryvk (Simlandi unbranded) ○ Otezla (apremilast) ○ Skyrizi (risankizumab-rzaa) SC ○ Sotyktu (deucravacitinib) ○ Steqeyma (ustekinumab-stba) SC **OR** Yesintek (ustekinumab-kfce) SC ○ Taltz (ixekizumab) ○ Tremfya (guselkumab) **AND** • Medication is being prescribed by or in consultation with a dermatologist **Note:** This medical necessity criteria does not apply to one Open formulary (Formulary ID: 6062; Rx Plan F1) and one Preferred formulary (Formulary ID: 6064; Rx Plan G3). The criteria for members with these custom Open and Preferred formulary plans can be found in policy **5.01.647 Medical Necessity Criteria for Custom Open and Preferred Formularies**. Please check the member Plan booklet or member ID card to determine whether this policy criteria applies.
• **Avsola (infliximab-axxq) IV,** • **Renflexis (infliximab-abda) IV**	**Avsola (infliximab-axxq) and Renflexis (infliximab-abda) are subject to review for site of service administration.** **Avsola (infliximab-axxq) and Renflexis (infliximab-abda) may be considered medically necessary for the treatment of moderate to severe plaque psoriasis when:** • The individual is aged 18 years or older **AND** • Has a diagnosis of chronic plaque psoriasis involving at least 10% of his or her body surface area (BSA) ○ **Exception**: This may be granted when **ANY** of the following are true: ▪ There is extensive recalcitrant facial involvement **OR** ▪ There is pustular involvement of the hands and feet **OR**

Section 2: Essentials Formulary Plans (Rx Plan E1, E3, and E4) ONLY	
Drug	**Medical Necessity**
	▪ There is genital involvement which interferes with normal sexual function **AND** • Has a history of an adequate trial and treatment failure with at least 1 approved systemic therapy (e.g., methotrexate, cyclosporine, acitretin or psoralen plus ultraviolet A light [PUVA]) unless contraindicated or not tolerated **AND** • Has had a documented trial and treatment failure with Inflectra (infliximab-dyyb), Infliximab (Janssen – unbranded), or Remicade (infliximab) **AND** • Medication is being prescribed by or in consultation with a dermatologist **Avsola (infliximab-axxq) and Renflexis (infliximab-abda) may be considered medically necessary as emergent treatment for severe pustular, exfoliative or inflammatory psoriasis without prior use or failure/intolerance of a first-line agent, in contrast to stable plaque psoriasis.**
IL-12/23 Inhibitors – Second Line	
• **Imuldosa (ustekinumab-srlf) SC** • **Otulfi (ustekinumab-aauz) SC** • **Pyzchiva (ustekinumab-ttwe) SC** • **Selarsdi (ustekinumab-ackn) SC** • **Stelara (ustekinumab) SC** • **Ustekinumab (Stelara unbranded) SC** • **Ustekinumab-aekn (Selarsdi unbranded) SC** • **Ustekinumab-ttwe (Pyzchiva unbranded) SC**	**Imuldosa (ustekinumab-srlf) SC, Otulfi (ustekinumab-aauz) SC, Pyzchiva (ustekinumab-ttwe) SC, Selarsdi (ustekinumab-ackn) SC, Stelara (ustekinumab) SC, ustekinumab (Stelara unbranded) SC, ustekinumab-aekn (Selarsdi unbranded) SC, ustekinumab-ttwe (Pyzchiva unbranded) SC, and Wezlana (ustekinumab-auub) SC may be considered medically necessary for the treatment of moderate to severe plaque psoriasis when:** • The individual is aged 6 years or older **AND** • Has a diagnosis of chronic plaque psoriasis involving greater than or equal to 10% of his or her body surface area (BSA) ○ **Exception**: This may be granted when **ANY** of the following are true:

Section 2: Essentials Formulary Plans (Rx Plan E1, E3, and E4) ONLY	
Drug	**Medical Necessity**
• **Wezlana (ustekinumab-auub) SC**	▪ There is extensive recalcitrant facial involvement **OR** ▪ There is pustular involvement of the hands and feet **OR** ▪ There is genital involvement which interferes with normal sexual function **AND** • Has a history of an adequate trial and treatment failure with greater than or equal to 1 approved systemic therapy (e.g., methotrexate, cyclosporine, acitretin or psoralen plus ultraviolet A light [PUVA]) unless contraindicated or not tolerated **AND** • Has had an inadequate response or is intolerant to ALL the following agents: ○ Steqeyma (ustekinumab-stba) SC ○ Yesintek (ustekinumab-kfce) SC **AND** • Medication is being prescribed by or in consultation with a dermatologist
IL-23 Inhibitors – Second Line	
Ilumya (tildrakizumab-asmn) SC	**Ilumya (tildrakizumab-asmn) may be considered medically necessary for the treatment of moderate to severe plaque psoriasis when:** • The individual is aged 18 years or older **AND** • Has a diagnosis of chronic plaque psoriasis involving at least 10% of his or her body surface area (BSA) ○ **Exception**: This may be granted when **ANY** of the following are true: ▪ There is extensive recalcitrant facial involvement **OR** ▪ There is pustular involvement of the hands and feet **OR** ▪ There is genital involvement which interferes with normal sexual function

Section 2: Essentials Formulary Plans (Rx Plan E1, E3, and E4) ONLY	
Drug	**Medical Necessity**

	AND
	• Has a history of an adequate trial and treatment failure with at least 1 approved systemic therapy (e.g., methotrexate, cyclosporine, acitretin or psoralen plus ultraviolet A light [PUVA]) unless contraindicated or not tolerated
	AND
	• Has had an inadequate response or is intolerant to 2 of the following agents:
	  ○ Enbrel (etanercept)
	  ○ Cyltezo (adalimumab-adbm) **OR** adalimumab-adaz (Hyrimoz unbranded) **OR** adalimumab-adbm (Cyltezo unbranded) **OR** Simlandi (adalimumab-ryvk) **OR** adalimumab-ryvk (Simlandi unbranded)
	  ○ Otezla (apremilast)
	  ○ Skyrizi (risankizumab-rzaa) SC
	  ○ Sotyktu (deucravacitinib)
	  ○ Steqeyma (ustekinumab-stba) SC **OR** Yesintek (ustekinumab-kfce) SC
	  ○ Taltz (ixekizumab)
	  ○ Tremfya (guselkumab)
	AND
	• Medication is being prescribed by or in consultation with a dermatologist
	
	Note: This medical necessity criteria does not apply to one Open formulary (Formulary ID: 6062; Rx Plan F1) and one Preferred formulary (Formulary ID: 6064; Rx Plan G3). The criteria for members with these custom Open and Preferred formulary plans can be found in policy **5.01.647 Medical Necessity Criteria for Custom Open and Preferred Formularies**. Please check the member Plan booklet or member ID card to determine whether this policy criteria applies.

Section 3: Individual/Small Group/Student ISHIP METALLIC Formulary Plans (Rx Plan M1, M2, and M4) ONLY
Plaque Psoriasis Systemic Treatments – First Line

Section 3: Individual/Small Group/Student ISHIP METALLIC Formulary Plans (Rx Plan M1, M2, and M4) ONLY					
IL-23 Inhibitors	**TNF-α Inhibitors**	**TYK2 Inhibitor**	**IL-17 Inhibitor**	**IL-12/23 Inhibitors**	**PDE-4 Inhibitor**
• Skyrizi (SC)	• Inflectra (IV) • Infliximab (Janssen – unbranded) (IV) • Remicade (IV)	• Sotyktu (oral)	• Taltz (SC)	• Steqeyma (SC) • Yesintek (SC)	• Otezla (oral)
• Tremfya (SC)	• Adalimumab-adaz (Hyrimoz unbranded) (SC) • Adalimumab-adbm (Cyltezo unbranded) (SC) • Adalimumab-ryvk (Simlandi unbranded) (SC) • Cyltezo (SC) • Enbrel (SC) • Simlandi (SC)				
Second Line					
IL-23 Inhibitor	**IL-12/23 Inhibitors**	**TNF-α Inhibitors**	**IL-17 Inhibitors**		
• Ilumya (SC)	• Imuldosa (SC) • Otulfi (SC) • Pyzchiva (SC) • Selarsdi (SC) • Stelara (SC) • Brand ustekinumab (Stelara unbranded) (SC) • Brand ustekinumab-aekn (Selarsdi unbranded) (SC) • Brand ustekinumab-ttwe (Pyzchiva unbranded) (SC) • Wezlana (SC)	• Avsola (IV) • Renflexis (IV) • Abrilada (SC) • Adalimumab-aacf (Idacio unbranded (SC) • Adalimumab-fkjp (Hulio unbranded) (SC) • Amjevita (SC) • Hadlima (SC) • Hulio (SC) • Humira (SC) • Hyrimoz (SC) • Idacio (SC) • Yuflyma (SC) • Yusimry (SC) • Cimzia (SC)	• Bimzelx (SC) • Cosentyx (SC) • Siliq (SC)		

Step therapy tiers are listed below; please refer to the Policy section for details.

Section 3: Individual/Small Group/Student ISHIP METALLIC Formulary Plans (Rx Plan M1, M2, and M4) ONLY	
Drug	**Medical Necessity**
TNF-α Antagonists – First Line	

Section 3: Individual/Small Group/Student ISHIP METALLIC Formulary Plans (Rx Plan M1, M2, and M4) ONLY	
Drug	**Medical Necessity**

Enbrel (etanercept) SC	**Enbrel (etanercept) may be considered medically necessary for the treatment of plaque psoriasis when:**
	• The individual is aged 4 years or older
	AND
	• Has a diagnosis of chronic plaque psoriasis involving at least 10% of his or her body surface area (BSA)
	  ○ **Exception**: This may be granted when **ANY** of the following are true:
	  ▪ There is extensive recalcitrant facial involvement
	  OR
	  ▪ There is pustular involvement of the hands and feet
	  OR
	  ▪ There is genital involvement which interferes with normal sexual function
	AND
	• Has a history of an adequate trial and treatment failure with at least 1 approved systemic therapy (e.g., methotrexate, cyclosporine, acitretin or psoralen plus ultraviolet A light [PUVA]) unless contraindicated or not tolerated
	AND
	• Medication is being prescribed by or in consultation with a dermatologist

• **Adalimumab-adaz (Hyrimoz unbranded) SC**
• **Adalimumab-adbm (Cyltezo unbranded) SC**
• **Adalimumab-ryvk (Simlandi unbranded) SC**
• **Cyltezo (adalimumab-adbm) SC**
• **Simlandi (adalimumab-ryvk) SC**
	Adalimumab-adaz (Hyrimoz unbranded), adalimumab-adbm (Cyltezo unbranded), and adalimumab-ryvk (Simlandi unbranded), Cyltezo (adalimumab-adbm), and Simlandi (adalimumab-ryvk) may be considered medically necessary for the treatment of plaque psoriasis when:
	• The individual is aged 18 years or older
	AND
	• Has a diagnosis of chronic plaque psoriasis involving at least 10% of his or her body surface area (BSA)
	  ○ **Exception**: This may be granted when **ANY** of the following are true:
	  ▪ There is extensive recalcitrant facial involvement

Section 3: Individual/Small Group/Student ISHIP METALLIC Formulary Plans (Rx Plan M1, M2, and M4) ONLY	
Drug	**Medical Necessity**
	OR ▪ There is pustular involvement of the hands and feet **OR** ▪ There is genital involvement which interferes with normal sexual function **AND** • Has a history of an adequate trial and treatment failure with at least 1 approved systemic therapy (e.g., methotrexate, cyclosporine, acitretin or psoralen plus ultraviolet A light [PUVA]) unless contraindicated or not tolerated **AND** • Medication is being prescribed by or in consultation with a dermatologist **Note:** This medical necessity criteria does not apply to one Open formulary (Formulary ID: 6062; Rx Plan F1) and one Preferred formulary (Formulary ID: 6064; Rx Plan G3). The criteria for members with these custom Open and Preferred formulary plans can be found in policy **5.01.647 Medical Necessity Criteria for Custom Open and Preferred Formularies**. Please check the member Plan booklet or member ID card to determine whether this policy criteria applies.
• **Inflectra (infliximab-dyyb) IV** • **Infliximab (Janssen – unbranded) IV** • **Remicade (infliximab) IV**	**Inflectra (infliximab-dyyb), Infliximab (Janssen – unbranded), and Remicade (infliximab) are subject to review for site of service administration.** **Inflectra (infliximab-dyyb), Infliximab (Janssen – unbranded), and Remicade (infliximab) may be considered medically necessary for the treatment of moderate to severe plaque psoriasis when:** • The individual is aged 18 years or older **AND** • Has a diagnosis of chronic plaque psoriasis involving at least 10% of his or her body surface area (BSA) ○ **Exception**: This may be granted when **ANY** of the following are true:

Section 3: Individual/Small Group/Student ISHIP METALLIC Formulary Plans (Rx Plan M1, M2, and M4) ONLY	
Drug	**Medical Necessity**
	▪ There is extensive recalcitrant facial involvement **OR** ▪ There is pustular involvement of the hands and feet **OR** ▪ There is genital involvement which interferes with normal sexual function **AND** • Has a history of an adequate trial and treatment failure with at least 1 approved systemic therapy (e.g., methotrexate, cyclosporine, acitretin or psoralen plus ultraviolet A light [PUVA]) unless contraindicated or not tolerated **AND** • Medication is being prescribed by or in consultation with a dermatologist **Inflectra (infliximab-dyyb), Infliximab (Janssen – unbranded), and Remicade (infliximab) may be considered medically necessary as emergent treatment for severe pustular, exfoliative or inflammatory psoriasis without prior use or failure/intolerance of a first-line drug, in contrast to stable plaque psoriasis.**
IL-17 Inhibitors – First Line	
Taltz (ixekizumab) SC	**Taltz (ixekizumab) may be considered medically necessary for the treatment of moderate to severe plaque psoriasis when:** • The individual is aged 6 years or older **AND** • Has a diagnosis of chronic plaque psoriasis involving at least 10% of his or her body surface area (BSA) ○ **Exception**: This may be granted when **ANY** of the following are true: ▪ There is extensive recalcitrant facial involvement **OR** ▪ There is pustular involvement of the hands and feet **OR**

Section 3: Individual/Small Group/Student ISHIP METALLIC Formulary Plans (Rx Plan M1, M2, and M4) ONLY	
Drug	**Medical Necessity**
	▪ There is genital involvement which interferes with normal sexual function **AND** • Has a history of an adequate trial and treatment failure with at least 1 approved systemic therapy (e.g., methotrexate, cyclosporine, acitretin or psoralen plus ultraviolet A light [PUVA]) unless contraindicated or not tolerated **AND** • Medication is being prescribed by or in consultation with a dermatologist
IL-12/23 Inhibitors – First Line	
• **Steqeyma (ustekinumab-stba) SC** • **Yesintek (ustekinumab-kfce) SC**	**Steqeyma (ustekinumab-stba) SC and Yesintek (ustekinumab-kfce) SC may be considered medically necessary for the treatment of moderate to severe plaque psoriasis when:** • The individual is aged 6 years or older **AND** • Has a diagnosis of chronic plaque psoriasis involving at least 10% of his or her body surface area (BSA) ○ **Exception**: This may be granted when **ANY** of the following are true: ▪ There is extensive recalcitrant facial involvement **OR** ▪ There is pustular involvement of the hands and feet **OR** ▪ There is genital involvement which interferes with normal sexual function **AND** • Has a history of an adequate trial and treatment failure with at least 1 approved systemic therapy (e.g., methotrexate, cyclosporine, acitretin or psoralen plus ultraviolet A light [PUVA]) unless contraindicated or not tolerated **AND** • Medication is being prescribed by or in consultation with a dermatologist

Section 3: Individual/Small Group/Student ISHIP METALLIC Formulary Plans (Rx Plan M1, M2, and M4) ONLY	
Drug	**Medical Necessity**
IL-23 Inhibitors – First Line	
Skyrizi (risankizumab-rzaa) SC	**Skyrizi (risankizumab-rzaa) may be considered medically necessary for the treatment of moderate to severe plaque psoriasis when:** • The individual is aged 18 years or older **AND** • Has a diagnosis of chronic plaque psoriasis involving at least 10% of his or her body surface area (BSA) ○ **Exception**: This may be granted when **ANY** of the following are true: ▪ There is extensive recalcitrant facial involvement **OR** ▪ There is pustular involvement of the hands and feet **OR** ▪ There is genital involvement which interferes with normal sexual function **AND** • Has a history of an adequate trial and treatment failure with at least 1 approved systemic therapy (e.g., methotrexate, cyclosporine, acitretin or psoralen plus ultraviolet A light [PUVA]) unless contraindicated or not tolerated **AND** • Medication is being prescribed by or in consultation with a dermatologist
Tremfya (guselkumab) SC	**Tremfya (guselkumab) may be considered medically necessary for the treatment of moderate to severe plaque psoriasis when:** • The individual is aged 18 years or older **AND** • Has a diagnosis of chronic plaque psoriasis involving at least 10% of his or her body surface area (BSA) ○ **Exception**: This may be granted when **ANY** of the following are true: ▪ There is extensive recalcitrant facial involvement

Section 3: Individual/Small Group/Student ISHIP METALLIC Formulary Plans (Rx Plan M1, M2, and M4) ONLY	
Drug	**Medical Necessity**
	OR ▪ There is pustular involvement of the hands and feet **OR** ▪ There is genital involvement which interferes with normal sexual function **AND** • Has a history of an adequate trial and treatment failure with at least 1 approved systemic therapy (e.g., methotrexate, cyclosporine, acitretin or psoralen plus ultraviolet A light [PUVA]) unless contraindicated or not tolerated **AND** • Medication is being prescribed by or in consultation with a dermatologist
PDE4 Inhibitor – First Line	
Otezla (apremilast) oral	**Otezla (apremilast) may be considered medically necessary for the treatment of moderate to severe plaque psoriasis when:** • The individual is aged 6 years or older **AND** • Weighs at least 20 kg **AND** • Has a diagnosis of chronic plaque psoriasis involving at least 10% of his or her body surface area (BSA) ○ **Exception**: This may be granted when **ANY** of the following are true: ▪ There is extensive recalcitrant facial involvement **OR** ▪ There is pustular involvement of the hands and feet **OR** ▪ There is genital involvement which interferes with normal sexual function **AND** • Has a history of an adequate trial and treatment failure at least 1 approved systemic therapy (e.g., methotrexate, cyclosporine,

Section 3: Individual/Small Group/Student ISHIP METALLIC Formulary Plans (Rx Plan M1, M2, and M4) ONLY	
Drug	**Medical Necessity**
	acitretin or psoralen plus ultraviolet A light [PUVA]) unless contraindicated or not tolerated **AND** • Medication is being prescribed by or in consultation with a dermatologist
Tyrosine Kinase 2 (TYK2) Inhibitors – First Line	
Sotyktu (deucravacitinib) oral	**Sotyktu (deucravacitinib) may be considered medically necessary for the treatment of moderate to severe plaque psoriasis when:** • The individual is aged 18 years or older **AND** • Has a diagnosis of chronic plaque psoriasis involving at least 10% of his or her body surface area (BSA) ○ **Exception**: This may be granted when **ANY** of the following are true: ▪ There is extensive recalcitrant facial involvement **OR** ▪ There is pustular involvement of the hands and feet **OR** ▪ There is genital involvement which interferes with normal sexual function **AND** • Has a history of an adequate trial and treatment failure with at least 1 approved systemic therapy (e.g., methotrexate, cyclosporine, acitretin or psoralen plus ultraviolet A light [PUVA]) unless contraindicated or not tolerated **AND** • Medication is being prescribed by or in consultation with a dermatologist
IL-17 Inhibitors – Second Line	
Bimzelx (bimekizumab-bkzx) SC	**Bimzelx (bimekizumab-bkzx) may be considered medically necessary for the treatment of moderate to severe plaque psoriasis when:** • The individual is aged 18 years or older

Section 3: Individual/Small Group/Student ISHIP METALLIC Formulary Plans (Rx Plan M1, M2, and M4) ONLY	
Drug	**Medical Necessity**

	AND
	• Has a diagnosis of chronic plaque psoriasis involving at least 10% of his or her body surface area (BSA)
	  ○ **Exception**: This may be granted when **ANY** of the following are true:
	  ▪ There is extensive recalcitrant facial involvement
	  OR
	  ▪ There is pustular involvement of the hands and feet
	  OR
	  ▪ There is genital involvement which interferes with normal sexual function
	AND
	• Has a history of an adequate trial and treatment failure with at least 1 approved systemic therapy (e.g., methotrexate, cyclosporine, acitretin or psoralen plus ultraviolet A light [PUVA]) unless contraindicated or not tolerated
	AND
	• Has had an inadequate response or is intolerant to 1 of the following agents:
	  ○ Enbrel (etanercept)
	  ○ Adalimumab-adaz (Hyrimoz unbranded) **OR** adalimumab-adbm (Cyltezo unbranded) **OR** adalimumab-ryvk (Simlandi unbranded) **OR** Cyltezo (adalimumab-adbm) **OR** Simlandi (adalimumab-ryvk)
	  ○ Otezla (apremilast)
	  ○ Skyrizi (risankizumab-rzaa) SC
	  ○ Sotyktu (deucravacitinib)
	  ○ Steqeyma (ustekinumab-stba) SC **OR** Yesintek (ustekinumab-kfce) SC
	  ○ Taltz (ixekizumab)
	  ○ Tremfya (guselkumab)
	AND
	• Medication is being prescribed by or in consultation with a dermatologist

Section 3: Individual/Small Group/Student ISHIP METALLIC Formulary Plans (Rx Plan M1, M2, and M4) ONLY	
Drug	**Medical Necessity**
	Note: This medical necessity criteria does not apply to one Open formulary (Formulary ID: 6062; Rx Plan F1) and one Preferred formulary (Formulary ID: 6064; Rx Plan G3). The criteria for members with these custom Open and Preferred formulary plans can be found in policy **5.01.647 Medical Necessity Criteria for Custom Open and Preferred Formularies**. Please check the member Plan booklet or member ID card to determine whether this policy criteria applies.
Siliq (brodalumab) SC	**Siliq (brodalumab) may be considered medically necessary for the treatment of moderate to severe plaque psoriasis when:** • The individual is aged 18 years or older **AND** • Has a diagnosis of chronic plaque psoriasis involving at least 10% of his or her body surface area (BSA) o **Exception**: This may be granted when **ANY** of the following are true: ▪ There is extensive recalcitrant facial involvement **OR** ▪ There is pustular involvement of the hands and feet **OR** ▪ There is genital involvement which interferes with normal sexual function **AND** • Has a history of an adequate trial and treatment failure with at least 1 approved systemic therapy (e.g., methotrexate, cyclosporine, acitretin or psoralen plus ultraviolet A light [PUVA]) unless contraindicated or not tolerated **AND** • Has had an inadequate response or is intolerant to 2 of the following agents: o Enbrel (etanercept) o Cyltezo (adalimumab-adbm) **OR** adalimumab-adaz (Hyrimoz unbranded) **OR** adalimumab-adbm (Cyltezo unbranded) **OR** Simlandi (adalimumab-ryvk) **OR** adalimumab-ryvk (Simlandi unbranded)

Section 3: Individual/Small Group/Student ISHIP METALLIC Formulary Plans (Rx Plan M1, M2, and M4) ONLY	
Drug	**Medical Necessity**
	○ Otezla (apremilast) ○ Skyrizi (risankizumab-rzaa) SC ○ Sotyktu (deucravacitinib) ○ Steqeyma (ustekinumab-stba) SC **OR** Yesintek (ustekinumab-kfce) SC ○ Taltz (ixekizumab) ○ Tremfya (guselkumab) **AND** • Medication is being prescribed by or in consultation with a dermatologist **Note:** This medical necessity criteria does not apply to one Open formulary (Formulary ID: 6062; Rx Plan F1) and one Preferred formulary (Formulary ID: 6064; Rx Plan G3). The criteria for members with these custom Open and Preferred formulary plans can be found in policy **5.01.647 Medical Necessity Criteria for Custom Open and Preferred Formularies**. Please check the member Plan booklet or member ID card to determine whether this policy criteria applies.
Cosentyx (secukinumab) SC	**Cosentyx (secukinumab) may be considered medically necessary for the treatment of moderate to severe plaque psoriasis when:** • The individual is aged 6 years or older **AND** • Has a diagnosis of chronic plaque psoriasis involving at least 10% of his or her body surface area (BSA) ○ **Exception**: This may be granted when **ANY** of the following are true: ▪ There is extensive recalcitrant facial involvement **OR** ▪ There is pustular involvement of the hands and feet **OR** ▪ There is genital involvement which interferes with normal sexual function **AND**

Section 3: Individual/Small Group/Student ISHIP METALLIC Formulary Plans (Rx Plan M1, M2, and M4) ONLY	
Drug	**Medical Necessity**
	• Has a history of an adequate trial and treatment failure with at least 1 approved systemic therapy (e.g., methotrexate, cyclosporine, acitretin or psoralen plus ultraviolet A light [PUVA]) unless contraindicated or not tolerated **AND** • Has had an inadequate response or intolerance to 2 of the following agents: o Enbrel (etanercept) o Cyltezo (adalimumab-adbm) **OR** adalimumab-adaz (Hyrimoz unbranded) **OR** adalimumab-adbm (Cyltezo unbranded) **OR** Simlandi (adalimumab-ryvk) **OR** adalimumab-ryvk (Simlandi unbranded) o Otezla (apremilast) o Skyrizi (risankizumab-rzaa) SC o Sotyktu (deucravacitinib) o Steqeyma (ustekinumab-stba) SC **OR** Yesintek (ustekinumab-kfce) SC o Taltz (ixekizumab) o Tremfya (guselkumab) **AND** • Medication is being prescribed by or in consultation with a dermatologist **Note:** This medical necessity criteria does not apply to one Open formulary (Formulary ID: 6062; Rx Plan F1) and one Preferred formulary (Formulary ID: 6064; Rx Plan G3). The criteria for members with these custom Open and Preferred formulary plans can be found in policy **5.01.647 Medical Necessity Criteria for Custom Open and Preferred Formularies**. Please check the member Plan booklet or member ID card to determine whether this policy criteria applies.
TNF-α Antagonists – Second Line	
• **Abrilada (adalimumab-afzb) SC** • **Adalimumab-aacf (Idacio unbranded)**	**Abrilada (adalimumab-afzb), adalimumab-aacf (Idacio unbranded), adalimumab-aaty (Yuflyma unbranded), adalimumab-fkjp (Hulio unbranded), Amjevita (adalimumab-atto), Hadlima (adalimumab-bwwd), Hulio (adalimumab-fkjp),**

Section 3: Individual/Small Group/Student ISHIP METALLIC Formulary Plans (Rx Plan M1, M2, and M4) ONLY	
Drug	**Medical Necessity**

• **Adalimumab-aaty (Yuflyma unbranded) SC**
• **Adalimumab-fkjp (Hulio unbranded) SC**
• **Amjevita (adalimumab-atto) SC**
• **Hadlima (adalimumab-bwwd) SC**
• **Hulio (adalimumab-fkjp) SC**
• **Humira (adalimumab) SC**
• **Hyrimoz (adalimumab-adaz) SC**
• **Idacio (adalimumab-aacf) SC**
• **Yuflyma (adalimumab-aaty) SC**
• **Yusimry (adalimumab-aqvh) SC**
	Humira (adalimumab), Hyrimoz (adalimumab-adaz), Idacio (adalimumab-aacf), Yuflyma (adalimumab-aaty), and Yusimry (adalimumab-aqvh) may be considered medically necessary for the treatment of plaque psoriasis when:
	• The individual is aged 18 years or older
	AND
	• Has a diagnosis of chronic plaque psoriasis involving at least 10% of his or her body surface area (BSA)
	  ○ **Exception**: This may be granted when **ANY** of the following are true:
	  ▪ There is extensive recalcitrant facial involvement
	  OR
	  ▪ There is pustular involvement of the hands and feet
	  OR
	  ▪ There is genital involvement which interferes with normal sexual function
	AND
	• Has a history of an adequate trial and treatment failure with at least 1 approved systemic therapy (e.g., methotrexate, cyclosporine, acitretin or psoralen plus ultraviolet A light [PUVA]) unless contraindicated or not tolerated
	AND
	• Has had an inadequate response or is intolerant to ALL the following agents:
	  ○ Cyltezo (adalimumab-adbm) OR adalimumab-adbm (Cyltezo unbranded)
	  ○ Adalimumab-adaz (Hyrimoz unbranded)
	  ○ Simlandi (adalimumab-ryvk) OR adalimumab-ryvk (Simlandi unbranded)
	AND
	• Medication is being prescribed by or in consultation with a dermatologist

Section 3: Individual/Small Group/Student ISHIP METALLIC Formulary Plans (Rx Plan M1, M2, and M4) ONLY	
Drug	**Medical Necessity**
	Note: This medical necessity criteria does not apply to one Open formulary (Formulary ID: 6062; Rx Plan F1) and one Preferred formulary (Formulary ID: 6064; Rx Plan G3). The criteria for members with these custom Open and Preferred formulary plans can be found in policy **5.01.647 Medical Necessity Criteria for Custom Open and Preferred Formularies**. Please check the member Plan booklet or member ID card to determine whether this policy criteria applies.
Cimzia (certolizumab pegol) SC	**Cimzia (certolizumab pegol) may be considered medically necessary for the treatment of plaque psoriasis when:** • The individual is aged 18 years or older **AND** • Has a diagnosis of chronic plaque psoriasis involving at least 10% of his or her body surface area (BSA) ○ **Exception**: This may be granted when **ANY** of the following are true: ▪ There is extensive recalcitrant facial involvement **OR** ▪ There is pustular involvement of the hands and feet **OR** ▪ There is genital involvement which interferes with normal sexual function **AND** • Has a history of an adequate trial and treatment failure with at least 1 approved systemic therapy (e.g., methotrexate, cyclosporine, acitretin or psoralen plus ultraviolet A light [PUVA]) unless contraindicated or not tolerated **AND** • Has had an inadequate response or is intolerant to 2 of the following agents: ○ Enbrel (etanercept) ○ Cyltezo (adalimumab-adbm) **OR** Simlandi (adalimumab-ryvk) **OR** adalimumab-adaz (Hyrimoz unbranded) **OR** adalimumab-adbm (Cyltezo unbranded) **OR** adalimumab-ryvk (Simlandi unbranded) ○ Otezla (apremilast) ○ Skyrizi (risankizumab-rzaa) SC

Section 3: Individual/Small Group/Student ISHIP METALLIC Formulary Plans (Rx Plan M1, M2, and M4) ONLY	
Drug	**Medical Necessity**
	○ Sotyktu (deucravacitinib) ○ Steqeyma (ustekinumab-stba) SC **OR** Yesintek (ustekinumab-kfce) SC ○ Taltz (ixekizumab) ○ Tremfya (guselkumab) **AND** • Medication is being prescribed by or in consultation with a dermatologist **Note:** This medical necessity criteria does not apply to one Open formulary (Formulary ID: 6062; Rx Plan F1) and one Preferred formulary (Formulary ID: 6064; Rx Plan G3). The criteria for members with these custom Open and Preferred formulary plans can be found in policy **5.01.647 Medical Necessity Criteria for Custom Open and Preferred Formularies**. Please check the member Plan booklet or member ID card to determine whether this policy criteria applies.
• **Avsola (infliximab-axxq) IV,** • **Renflexis (infliximab-abda) IV**	**Avsola (infliximab-axxq) and Renflexis (infliximab-abda) are subject to review for site of service administration.** **Avsola (infliximab-axxq) and Renflexis (infliximab-abda) may be considered medically necessary for the treatment of moderate to severe plaque psoriasis when:** • The individual is aged 18 years or older **AND** • Has a diagnosis of chronic plaque psoriasis involving at least 10% of his or her body surface area (BSA) ○ **Exception**: This may be granted when **ANY** of the following are true: ▪ There is extensive recalcitrant facial involvement **OR** ▪ There is pustular involvement of the hands and feet **OR** ▪ There is genital involvement which interferes with normal sexual function **AND**

Section 3: Individual/Small Group/Student ISHIP METALLIC Formulary Plans (Rx Plan M1, M2, and M4) ONLY	
Drug	**Medical Necessity**
	• Has a history of an adequate trial and treatment failure with at least 1 approved systemic therapy (e.g., methotrexate, cyclosporine, acitretin or psoralen plus ultraviolet A light [PUVA]) unless contraindicated or not tolerated **AND** • Has had a documented trial and treatment failure with Inflectra (infliximab-dyyb), Infliximab (Janssen – unbranded), or Remicade (infliximab) **AND** • Medication is being prescribed by or in consultation with a dermatologist **Avsola (infliximab-axxq) and Renflexis (infliximab-abda) may be considered medically necessary as emergent treatment for severe pustular, exfoliative or inflammatory psoriasis without prior use or failure/intolerance of a first-line agent, in contrast to stable plaque psoriasis.**
IL-12/23 Inhibitors – Second Line	
• **Imuldosa (ustekinumab-srlf) SC** • **Otulfi (ustekinumab-aauz) SC** • **Pyzchiva (ustekinumab-ttwe) SC** • **Selarsdi (ustekinumab-ackn) SC** • **Stelara (ustekinumab) SC** • **Ustekinumab (Stelara unbranded) SC** • **Ustekinumab-aekn (Selarsdi unbranded) SC** • **Ustekinumab-ttwe (Pyzchiva unbranded) SC** • **Wezlana (ustekinumab-auub) SC**	**Imuldosa (ustekinumab-srlf) SC, Otulfi (ustekinumab-aauz) SC, Pyzchiva (ustekinumab-ttwe) SC, Selarsdi (ustekinumab-ackn) SC, Stelara (ustekinumab) SC, ustekinumab (Stelara unbranded) SC, ustekinumab-aekn (Selarsdi unbranded) SC, ustekinumab-ttwe (Pyzchiva unbranded) SC, and Wezlana (ustekinumab-auub) SC may be considered medically necessary for the treatment of moderate to severe plaque psoriasis when:** • The individual is aged 6 years or older **AND** • Has a diagnosis of chronic plaque psoriasis involving greater than or equal to 10% of his or her body surface area (BSA) ○ **Exception**: This may be granted when **ANY** of the following are true: ▪ There is extensive recalcitrant facial involvement **OR**

Section 3: Individual/Small Group/Student ISHIP METALLIC Formulary Plans (Rx Plan M1, M2, and M4) ONLY	
Drug	**Medical Necessity**
	▪ There is pustular involvement of the hands and feet **OR** ▪ There is genital involvement which interferes with normal sexual function **AND** • Has a history of an adequate trial and treatment failure with greater than or equal to 1 approved systemic therapy (e.g., methotrexate, cyclosporine, acitretin or psoralen plus ultraviolet A light [PUVA]) unless contraindicated or not tolerated **AND** • Has had an inadequate response or is intolerant to ALL the following agents: ○ Steqeyma (ustekinumab-stba) SC ○ Yesintek (ustekinumab-kfce) SC **AND** • Medication is being prescribed by or in consultation with a dermatologist
IL-23 Inhibitors – Second Line	
Ilumya (tildrakizumab-asmn) SC	**Ilumya (tildrakizumab-asmn) may be considered medically necessary for the treatment of moderate to severe plaque psoriasis when:** • The individual is aged 18 years or older **AND** • Has a diagnosis of chronic plaque psoriasis involving at least 10% of his or her body surface area (BSA) ○ **Exception**: This may be granted when **ANY** of the following are true: ▪ There is extensive recalcitrant facial involvement **OR** ▪ There is pustular involvement of the hands and feet **OR** ▪ There is genital involvement which interferes with normal sexual function **AND**

Section 3: Individual/Small Group/Student ISHIP METALLIC Formulary Plans (Rx Plan M1, M2, and M4) ONLY	
Drug	**Medical Necessity**

	• Has a history of an adequate trial and treatment failure with at least 1 approved systemic therapy (e.g., methotrexate, cyclosporine, acitretin or psoralen plus ultraviolet A light [PUVA]) unless contraindicated or not tolerated
	AND
	• Has had an inadequate response or is intolerant to 2 of the following agents:
	  ○ Enbrel (etanercept)
	  ○ Cyltezo (adalimumab-adbm) **OR** adalimumab-adaz (Hyrimoz unbranded) **OR** adalimumab-adbm (Cyltezo unbranded) **OR** Simlandi (adalimumab-ryvk) **OR** adalimumab-ryvk (Simlandi unbranded)
	  ○ Otezla (apremilast)
	  ○ Skyrizi (risankizumab-rzaa) SC
	  ○ Sotyktu (deucravacitinib)
	  ○ Steqeyma (ustekinumab-stba) SC **OR** Yesintek (ustekinumab-kfce) SC
	  ○ Taltz (ixekizumab)
	  ○ Tremfya (guselkumab)
	AND
	• Medication is being prescribed by or in consultation with a dermatologist
	
	Note: This medical necessity criteria does not apply to one Open formulary (Formulary ID: 6062; Rx Plan F1) and one Preferred formulary (Formulary ID: 6064; Rx Plan G3). The criteria for members with these custom Open and Preferred formulary plans can be found in policy **5.01.647 Medical Necessity Criteria for Custom Open and Preferred Formularies**. Please check the member Plan booklet or member ID card to determine whether this policy criteria applies.

Drug	Not Medically Necessary
As listed	**All other uses of the drugs for approved conditions listed in this policy are considered not medically necessary.**

Drug	Investigational
As listed	**The medications listed in this policy are subject to the product's US Food and Drug Administration (FDA) dosage and administration prescribing information.** **All other uses of the above-named agents when used in combination with each other or for conditions not outlined in this policy or Related Medical Policies are considered investigational.**

Length of Approval	
Approval	**Criteria**
Initial authorization	**Non-formulary exception reviews and all other reviews for all drugs listed in the policy may be approved up to 12 months.**
Re-authorization criteria	**Non-formulary exception reviews and all other reviews for all drugs listed in the policy may be approved up to 12 months as long as the drug-specific coverage criteria are met and chart notes demonstrate that the individual continues to show a positive clinical response to therapy.**

Documentation Requirements
The individual's medical records submitted for review for all conditions should document that medical necessity criteria are met. The record should include the following: • Office visit notes that contain the diagnosis, relevant history, physical evaluation, and medication history

Coding

Code	Description
HCPCS	
J0135	Injection, adalimumab (Humira), 20 mg (code terminated 01/01/25)
J0139	Injection, adalimumab, 1 mg (new code effective 01/01/25)

Code	Description
J0717	Injection, certolizumab pegol (Cimzia), 1 mg (code may be used for Medicare when drug administered under the direct supervision of a physician, not for use when drug is self-administered)
J1438	Injection, etanercept (Enbrel), 25 mg (code may be used for Medicare when drug administered under the direct supervision of a physician, not for use when drug is self-administered)
J1628	Injection, guselkumab (Tremfya), 1 mg
J1745	Injection, infliximab, excludes biosimilar (Remicade or Janssen unbranded), 10 mg
J3245	Injection, tildrakizumab (Ilumya), 1 mg
J3357	Injection, ustekinumab (Stelara), 1 mg
J3590	Unclassified biologics (use only to report Amjevita, Cosentyx, Siliq, Skyrizi, Spevigo, Taltz, Cyltezo, Hyrimoz HCF, Adalimumab-adaz HCF (Sandoz – unbranded), Abrilada, Hadlima, Hulio, Hyrimoz LCF, Yuflyma, Yusimry and Bimzelx)
Q5098	Injection, ustekinumab-srlf (Imuldosa), biosimilar, 1 mg (new code effective 07/01/25)
Q5099	Injection, ustekinumab-stba (Steqeyma), biosimilar, 1 mg (new code effective 07/01/25)
Q5100	Injection, ustekinumab-kfce (Yesintek), biosimilar, 1 mg (new code effective 07/01/25)
Q5103	Injection, infliximab-dyyb, biosimilar, (Inflectra), 10 mg
Q5104	Injection, infliximab-abda, biosimilar, (Renflexis), 10 mg
Q5121	Injection, infliximab-axxq, biosimilar, (Avsola), 10 mg
Q5137	Injection, ustekinumab-auub (Wezlana), biosimilar, SC, 1 mg
Q5140	Injection, adalimumab-fkjp, biosimilar, 1 mg (new code effective 01/01/25)
Q5141	Injection, adalimumab-aaty, biosimilar, 1 mg (new code effective 01/01/25)
Q5142	Injection, adalimumab-ryvk biosimilar, 1 mg (new code effective 01/01/25)
Q5143	Injection, adalimumab-adbm, biosimilar, 1 mg (new code effective 01/01/25)
Q5144	Injection, adalimumab-aacf (idacio), biosimilar, 1 mg (new code effective 01/01/25)
Q5145	Injection, adalimumab-afzb (abrilada), biosimilar, 1 mg (new code effective 01/01/25)
Q9996	Injection, ustekinumab-ttwe (Pyzchiva), subcutaneous, 1 mg
Q9998	Injection, ustekinumab-aekn (Selarsdi), 1 mg
Q9999	Injection, ustekinumab-aauz (Otulfi), biosimilar, 1 mg

Note: HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

Related Information

Consideration of Age

Age limits specified in this policy are determined according to FDA-approved indications, where applicable.

For site of service for medical necessity the age described in this policy is 13 years of age or older. Site of service is defined as the location where the drug is administered, such as a hospital-based outpatient setting, an infusion center, a physician's office, or at home. The age criterion for site of service for medical necessity is based on the following: Pediatric individuals are not small adults. Pediatric individuals differ physiologically, developmentally, cognitively, and emotionally from adult individuals, and vary by age groups from infancy to teen. Children often require smaller doses than adults, lower infusion rates, appropriately sized equipment, the right venipuncture site determined by therapy and age, and behavioral management during administration of care. Specialty infusion training is therefore necessary for pediatric IV insertions and therapy. Due to pediatrics unique physiology and psychology, site of service review is limited to individuals above the age of 13.

Benefit Application

Pharmacy Benefit

Bimzelx (bimekizumab-bkzx), Otezla (apremilast), and Sotyktu (deucravacitinib) are managed through the pharmacy benefit.

Medical Benefit

Avsola (infliximab-axxq), Inflectra (infliximab-dyyb), Infliximab (Janssen – unbranded), Remicade (infliximab), and Renflexis (infliximab-abda) are managed through the medical benefit.

Medical / Pharmacy Benefit

Abrilada (adalimumab-afzb), adalimumab-adbm (Cyltezo unbranded), adalimumab-aacf (Idacio unbranded), adalimumab-adaz (Hyrimoz unbranded), Amjevita (adalimumab-atto), Cimzia (certolizumab pegol), Cosentyx (secukinumab), Cyltezo (adalimumab-adbm), Enbrel (etanercept), Hadlima (adalimumab-bwwd), Hulio (adalimumab-fkjp), Humira (adalimumab), Hyrimoz (adalimumab-adaz), Ilumya (tildrakizumab-asmn), Imuldosa (ustekinumab-srlf), Otulfi (ustekinumab-aauz), Pyzchiva (ustekinumab-ttwe), Selarsdi (ustekinumab-ackn), Siliq (brodalumab), Skyrizi (risankizumab-rzaa), Stelara (ustekinumab), Steqeyma (ustekinumab-stba), Taltz (ixekizumab), Tremfya (guselkumab), Yesintek (ustekinumab-kfce), Yuflyma (adalimumab-aaty), and Yusimry (adalimumab-aqvh) are managed through both the pharmacy and medical benefit.

Evidence Review

Psoriasis

Psoriasis is a chronic, multifactorial, noncontagious skin disorder that affects about 2.1% of the US population and 1-3% of persons worldwide. About 4.5 million, or 1 in 65, Americans have psoriasis. Onset is typically between the ages of 15 and 35 and prevalence is slightly greater in women. It is also more common in some ethnic groups (Caucasians) than others (African American or Asians). A genetic component has also been identified. There are several forms of psoriasis, but plaque psoriasis (or psoriasis vulgaris) is the most common form of the disease, affecting about 80% of psoriatic individuals.

About 20-30% of people with psoriasis have cases that are considered moderate to severe (covering more than 3% of their body). Although not typically life-threatening, psoriasis can have a large impact on quality of life. Seventy-five percent of people with moderate to severe psoriasis report their disease has a moderate to large impact on their everyday lives. Individuals with palmar-plantar disease may have less than 3% involvement, but often have debilitating and recalcitrant disease. Further, approximately 7% of psoriatic individuals have concurrent arthritis (which may be particularly relevant to one's choice of therapy).

Psoriasis is a chronic immune-mediated inflammatory disease characterized by T-cell activation and accumulation in the epidermis and dermis, leading to abnormal differentiation and hyperproliferation of keratinocytes. Recent advances in the understanding of the cellular

mechanisms underlying psoriasis have given rise to a generation of highly targeted biotechnologies for this indication.

As the severity of psoriasis ranges from mild to severe, with or without concurrent arthritis, available treatments lie along a spectrum from minimally invasive with a low risk of systemic side effects, to systemic therapy with a risk of potentially severe side effects. Non-invasive, topical treatments may also have significant side effects; for example, topical corticosteroids applied to large areas of skin may result in significant levels of systemic absorption. Many treatments have a cumulative toxicity potential, but the benefit of prolonged remissions makes the use of the more potent treatments relatively attractive.

Topical therapy, usually corticosteroids, is recommended as first-line treatment in psoriasis because these products are easy to administer, inexpensive, and safe. However, application to large areas of involvement can be time-consuming, expensive, and messy. Most individuals with moderate to severe disease will not achieve clearance or long-term remission. Tachyphylaxis may also develop with long-term use of topical corticosteroids. In individuals whose moderate to severe psoriasis fails topical therapy, the therapeutic options that remain are systemic agents, phototherapy and biologics.

Approved systemic agents (methotrexate, cyclosporine, and acitretin) are highly effective in the treatment of psoriasis; however, these therapies have limitations due to serious toxicities that require monitoring. Methotrexate can cause hepatotoxicity. Methotrexate is also associated with bone marrow toxicity, severe pulmonary toxicity, and serious drug-drug interactions (e.g., trimethoprim-sulfamethoxazole). Cyclosporine is nephrotoxic and can cause interstitial fibrosis and renal tubular atrophy in individuals treated for more than two years. Hypertension, laboratory abnormalities (electrolytes, liver function tests, lipids), and numerous drug-drug interactions are also among the problems associated with cyclosporine. Because methotrexate and cyclosporine are potent immunosuppressive drugs, individuals are at increased risk of infections and malignancies, including skin cancers and lymphoproliferative disorders. Like all retinoids, acitretin is highly teratogenic, posing a long-lasting risk (up to three years) in women of childbearing potential. Elevation in liver function tests, hyperlipidemia, and mucocutaneous reactions are additional adverse events associated with acitretin. Systemic corticosteroids are generally avoided as they may be associated with severe exacerbations, both during and after treatment.

Phototherapy (e.g., UVB, narrowband UVB, PUVA) is used for individuals who fail topicals or those with disease too extensive for topical therapy. Phototherapy can be effective for many individuals, but may be inconvenient and time-consuming, if frequent office or clinic visits are required and the availability of specialized phototherapy clinics may be limited. Individuals with a durable medical equipment (DME) benefit may purchase a home unit for easier access.

Cumulative exposure to PUVA is associated with an increased risk of squamous cell carcinoma and malignant melanoma.

Various other strategies using traditional therapies have also been used to maintain remission and decrease the risk of cumulative end-organ toxicities. Rotational therapy involves the use of a therapy for some time and then switching to another form of therapy. Combination therapy uses low-dosages of different treatments concurrently to minimize toxicity and enhance efficacy. Traditionally, these strategies usually involve topicals, phototherapy, and systemics in various combinations.

Biologic agents have been shown effective for many individuals in randomized, double-blind, placebo-controlled clinical trials, but few head-to-head clinical trials comparing these agents with traditional therapies exist. NBUVB continues to appear a very effective therapy in terms of achievement of greater than or equal to 75% response, global assessment ("clear or almost clear"), and length of remission. While the long-term risks of PUVA, methotrexate, and cyclosporine use in psoriatic individuals have become more clearly identified, these data are not available for the biologics in this population. The new biologic agents are clearly more widely available and convenient than the mainstay of psoriasis therapy, NBUVB, which may require anywhere from 30-100 outpatient visits to specialized facilities per year, unless a home system is purchased. On the other hand, biologics are all administered by injection, making them less convenient than systemic oral therapy.

Remicade (infliximab) is approved for the treatment of adults with chronic severe plaque psoriasis who are candidates for systemic therapies and clinical trial results for Humira (adalimumab), Remicade, and Enbrel (etanercept) have been published. Of these, three Humira studies added enough new information to warrant off-label use consideration. In the first multicenter, randomized, double-blind, placebo-controlled study, 147 individuals received Humira 80 mg at week 0, then 40 mg every other week beginning week 1, Humira 80 mg at week 0 and 1, then 40 mg every week beginning at week 1, or placebo for 12 weeks, after which placebo individuals were crossed over to Humira 40 mg every other week in a 48-week open label extension trial. At week 12, 53% of individuals taking Humira every other week, 80% of individuals taking Humira weekly, and 4% of individuals taking placebo achieved 75% improvement in Psoriasis Area and Severity Index score (Pless than 0 .001). Responses were sustained for 60 weeks. Humira was safe and well tolerated in this population.

In the Phase III REVEAL study (Randomized Controlled Evaluation of adalimumab Every Other Week Dosing in Moderate to Severe Psoriasis TriAL), 1,212 individuals with moderate to severe chronic plaque psoriasis were randomized to treatment with Humira 80 mg at week 0, then 40 mg every other week beginning at week 1 or placebo. The trial was comprised of 3 periods, a 16-week, double-blind period for assessment of initial response; a 17-week open-label sustained

response period, in which responders to either treatment (those achieving a PASI-75) received Humira 40 mg every other week; and a final 19-week, double-blind loss of response period, in which individuals receiving Humira throughout the previous 2 study periods were re-randomized to either Humira every other week or placebo. In the initial response phase, more Humira-treated individuals achieved a PASI-75 compared to those receiving placebo beginning at week 4 and at every visit throughout the 16-week evaluation period. At week 16, 71% of Humira- and 6.5% of placebo-treated individuals achieved a PASI-75 (Pless than 0.001). In Humira responders, mean PASI scores were maintained throughout the subsequent maintenance of response period (weeks 16-33) of the study. In the last period of the study examining loss of response, 28.4% of individuals re-randomized to placebo lost response by week 52 compared to 4.9% of individuals maintaining Humira (Pless than 0.001). Humira was generally well tolerated, and no unexpected adverse events were observed over the 52 weeks of the trial.

In a second Phase III trial, CHAMPION (Comparative Study of Humira vs. Methotrexate vs. Placebo In PsOriasis Patients), 271 individuals were randomized to treatment with Humira 80 mg at week 0, then 40 mg every other week beginning at week 1 (n=108), methotrexate 7.5 mg x 2 weeks, 10 mg x 2 weeks, then 15 mg orally (n=110), or placebo (n=53) for a total of 16 weeks. At week 16, more Humira-treated individuals achieved a PASI-75 response (80%) than individuals receiving either methotrexate (36%, Pless than 0.001) or placebo (19%, Pless than 0.001). Similar results were observed for PASI-90 response and PGA “clear” or “minimal” response. Humira was generally well-tolerated, with a safety profile similar to that known for an arthritis population.

In September 2009, the FDA approved the use of ustekinumab to treat plaque psoriasis. Ustekinumab is a human IgG1κ monoclonal antibody that binds to the shared p40 subunit of interleukins 12 and 23, blocking signaling of their cognate receptors. It is known that IL-12 and IL-23 plays important roles in the pathogenesis of psoriasis. IL-12 causes differentiation of CD4+ T cells to interferon-gamma (IFN-gamma)-producing T helper 1 (Th1) cells, while IL-23 induces differentiation to IL-17-producing pathogenic Th17 cells. In in vitro models, ustekinumab was shown to disrupt IL-12 and IL-23 mediated signaling and cytokine cascades by disrupting the interaction of these cytokines with a shared cell-surface receptor chain, IL-12 β1.

The evidence of efficacy consists mainly of two pivotal trials (PHOENIX I and PHOENIX II) submitted for FDA approval. Both studies showed robust clinical results against placebo. The primary endpoint for both studies was the proportion of individuals achieving a PASI 75 in the 12-week placebo-controlled trial. Both the 45mg and 90 mg groups achieved statistically significantly higher PASI 75 rate compared to placebo (67.1%, 66.4%, 3.1%, respectively; each pless than 0.0001 vs. placebo). Both studies also showed favorable secondary endpoint results for PGA score and DLQI vs. placebo. Ustekinumab was found to be more efficacious compared

to etanercept during a Phase III, multi-center, active controlled trial with 930 individuals (ACCEPT trial). For the primary efficacy endpoint of PASI 75 at week 12, a greater proportion of individuals treated with ustekinumab 45mg and 90mg achieved a PASI 75 compared to those receiving etanercept 50mg.

More recently, phosphodiesterase 4 inhibitor apremilast has been now approved for moderate to severe plaque psoriasis. Two multicenter, randomized, double-blind, placebo-controlled trials (PSOR-1 and PSOR-2) enrolled a total of 1257 subjects with moderate to severe plaque psoriasis. In both studies, subjects were randomized 2:1 to apremilast 30 mg BID or placebo for 16 weeks. Primary endpoints were the proportion of subjects who achieved PASI-75 at Week 16 and the proportion of subjects who achieved a sPGA score of clear (0) or almost clear (1) at Week 16. Approximately 30% of all subjects had received prior phototherapy and 54% had received prior conventional systemic and/or biologic therapy for the treatment of psoriasis with 37% receiving prior conventional systemic therapy and 30% receiving prior biologic therapy. A total of 18% of subjects had a history of psoriatic arthritis. Approximately 33% of individuals receiving apremilast in PSOR-1 achieved a PASI-75 (vs. 5% on placebo), and 29% of apremilast individuals in PSOR-2 (vs. 6% on placebo). In all groups, approximately two-thirds of individuals achieving PASI-75 also had sPGA scores of clear (0) or almost clear (1).

Tremfya (guselkumab): Evidence of efficacy comes from three phase 3 clinical trials: VOYAGE-1, VOYAGE-2, and NAVIGATE in which guselkumab yielded significantly increased symptomatic improvement for individuals with moderate to severe PsO symptoms vs adalimumab and among individuals who had an inadequate response to ustekinumab. In VOYAGE-1, symptom resolution occurred in significantly more guselkumab individuals vs adalimumab as assessed by achieving IGA 0/1 (85.1% vs 65.9%), PASI 90 (73.3% vs 49.7%), and PASI 75 (91.2% vs 73.1%) (Pless than 0.001 for each). In VOYAGE-2, guselkumab yielded higher rates of symptom resolution vs adalimumab as measured by the proportion of individuals achieving IGA 0/1 (84.1% vs 67.7%), PASI 90 (70.0% vs 46.8%), and PASI 75 (86.3% vs 68.5%) (Pless than 0.001 for each). In NAVIGATE, guselkumab yielded higher rates of symptom resolution vs ustekinumab at weeks 28 and 52 as measured by the proportion of individuals achieving IGA 0/1 (31.1% and 36.3% vs 14.3% and 17.3%), and PASI 90 (48.1% and 51.1% vs 22.6% and 24.1%) (Pless than or equal to 0.001 for each).

The approval of Bimzelx was supported by safety and efficacy data from three Phase 3, multicenter, randomized, placebo- and/or active comparator-controlled trials (BE VIVID, BE READY, and BE SURE) in 1480 adults with moderate to severe PsO. In total, 1480 individuals aged 18 years and older with moderate to severe plaque psoriasis who were eligible for systemic plaque psoriasis therapy and/or phototherapy were included in the trials. Individuals included in the trials had a BSA involvement of greater than or equal to 10%, an Investigator's Global

Assessment (IGA) score of greater than or equal to 3 ("moderate") in the overall assessment of plaque psoriasis on a severity scale of 0 to 4, and a Psoriasis Area and Severity Index (PASI) score greater than or equal to 12 (the PASI ranges from 0 to 72, where 0–5 = "no to mild PsO," 6–10 = "moderate," and greater than or equal to 11 = "severe"; scores greater than 40 are considered rare). Bimzelx showed superior efficacy compared to placebo, Stelara, and Humira in trial results submitted to the FDA to support its approval. By Week 4, a greater proportion of individuals receiving Bimzelx achieved PASI 75 compared to placebo. The most common adverse reactions (greater than or equal to 1%) with Bimzelx are upper respiratory tract infections, oral candidiasis, headache, injection site reactions, tinea infections, gastroenteritis, herpes simplex infections, acne, folliculitis, other Candida infections, and fatigue.

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8. Hyrimoz (adalimumab-adaz). Prescribing Information. Sandoz Inc; Princeton, NJ. Revised April 2024.
9. Yuflyma (adalimumab-aaty). Prescribing Information. Celltrion USA, Inc; Jersey City, NJ. Revised January 2024.
10. Cyltezo (adalimumab-adbm). Prescribing Information. Boehringer Ingelheim Pharmaceuticals, Inc; Ridgefield, CT. Revised April 2024.
11. Hadlima (adalimumab-bwwd). Prescribing Information. Merck Sharp & Dohme Corp; Whitehouse Station, NJ. Revised June 2024.

12. Abrilada (adalimumab-afzb). Prescribing Information. Pfizer Inc; New York, NY. Revised April 2024.
13. Hulio (adalimumab-fkjp). Prescribing Information. Mylan Pharmaceuticals Inc; Morgantown, WV. Revised December 2023.
14. Yusimry (adalimumab-aqvh). Prescribing Information. Coherus BioSciences, Inc., Redwood City, California. Revised September 2023.
15. Bimzelx (bimekizumab-bkzx). Prescribing Information. UCB, Inc. Smyrna, GA. Revised November 2024.
16. Sotyktu (deucravacitinib). Prescribing Information. Bristol-Myers Squibb. Princeton, NJ. Revised September 2022.

History

Date	Comments
11/01/22	New policy, approved October 11, 2022, effective for dates of service on or after November 1, 2022. For the treatment of plaque psoriasis moved Enbrel, Humira, Infliximab (Janssen – unbranded), Inflectra, Remicade, Taltz, Stelara SC, Skyrizi, Tremfya, Otezla, Siliq, Cosentyx, Cimzia, Renflexis, Avsola, and Ilumya from Policy 5.01.550 to Policy 5.01.629 with no changes to coverage criteria. Added coverage for the topical drugs Vtama (tapinarof) and Zoryve (roflumilast) for the treatment of plaque psoriasis. Added coverage for Spevigo (spesolimab-sbzo) for the treatment of generalized pustular psoriasis flares in adults.
12/01/22	Interim Review, approved November 8, 2022. Added coverage for Sotyktu (deucravacitinib) for the treatment of plaque psoriasis.
02/01/23	Interim Review, approved January 10, 2023. Added coverage for the biosimilar Amjevita (adalimumab-atto) for the treatment of plaque psoriasis with the identical coverage criteria as Humira (adalimumab). Added Amjevita as a prerequisite medication, on par with Humira, for the treatment of plaque psoriasis to Siliq, Cosentyx, Cimzia, Ilumya, and Sotyktu. Added coverage for brand calcipotriene foam, Dovonex (calcipotriene), Duobrii (halobetasol and tazarotene), Enstilar (betamethasone and calcipotriene), Sorilux (calcipotriene), Taclonex (betamethasone and calcipotriene), Vectical (calcitriol), and Wynzora (betamethasone and calcipotriene) for the topical treatment of plaque psoriasis. Added coverage for Soriatane (acitretin) for the systemic treatment of psoriasis. Added Amjevita to HCPC code J3590.
04/01/23	Annual Review, approved March 14, 2023. Added clarification of coverage for the biosimilar Amjevita (adalimumab-atto) with NDCs starting with 55513 versus NDCs starting with 72511. Changed the wording from "patient" to "individual" throughout the policy for standardization. Added new HCPCS code J1747.
07/01/23	Interim Review, approved June 13, 2023. Minor update made to Sotyktu criteria. Instead of two, individuals need to try three of the following agents: Enbrel, Humira, Amjevita, Otezla, Skyrizi, Stelara, Taltz, Tremfya.
08/01/23	Interim Review, approved July 11, 2023. Added coverage for the biosimilars Hyrimoz LCF (adalimumab-adaz) SC, Abrilada (adalimumab-afzb) SC, Hulio ((adalimumab-fkjp)

Date	Comments
	SC, Yusimry (adalimumab-aqvh) SC, Hadlima (adalimumab-bwwd) SC and Yuflyma (adalimumab-aaty) SC for the treatment of plaque psoriasis as non-preferred products and with the identical coverage criteria as Amjevita (adalimumab-atto) [NDCs starting with 72511]. Added coverage for Cyltezo LCF (adalimumab-adbm), Hyrimoz HCF (adalimumab-adaz) and Adalimumab-adaz HCF (Sandoz – unbranded) SC for the treatment of plaque psoriasis as preferred products and with the identical coverage criteria as Amjevita (adalimumab-atto) [NDCs starting with 55513]. Added Cyltezo, Hyrimoz HCF, Adalimumab-adaz HCF (Sandoz – unbranded), Abrilada, Hadlima, Hulio, Hyrimoz LCF, Yuflyma and Yusimry to code J3590.
08/01/23	Interim Review, approved July 24, 2023. Updated preferred Humira biosimilars (Cyltezo LCF, Hyrimoz HCF, Adalimumab-adaz HCF (Sandoz-unbranded)) along with Humira and Amjevita (NDC starting with 55513) in the list of agents to be tried and failed prior to using nonpreferred agents, such as Siliq, Cosentyx, Ilumya, Sotyktu.
09/01/23	Interim Review, approved August 8, 2023. The following policy changes are effective September 1, 2023: Added Humira biosimilars Adalimumab-fkjp (Biocon-unbranded) and Idacio (adalimumab-aacf) as non-preferred products with similar criteria as Amjevita (adalimumab-atto) [NDCs starting with 72511]. Updated Cosentyx coverage criteria for psoriasis to require two agents (instead of four) and removed requirements of trying agents from two or more different drug classes. The following policy changes are effective January 1, 2024 following a 90-day provider notification due to changes in the preferred medical benefit drugs: moved Avsola to 1st line (preferred); added Avsola to the list of preferred infliximab products to be tried and failed prior to non-preferred infliximab products; moved Inflectra to 2nd line (non-preferred) infliximab products; removed Inflectra from the list of preferred infliximab products to be tried and failed prior to trying non-preferred infliximab products.
01/01/24	Interim Review, approved December 12, 2023. Updated Amjevita [NDCs starting with 55513] to a non-preferred product. Added Hyrimoz (Cordavis) [NDCs starting with 83457] as a non-preferred product. Added adalimumab-adbm (Cyltezo unbranded) as a preferred product. Updated Hyrimoz LCF (Sandoz) from a non-preferred to a preferred product.
02/01/24	Annual Review, approved January 9, 2024. Added coverage for Bimzelx (bimekizumab-bkzx) for the treatment of plaque psoriasis. Updated Zoryve (roflumilast) coverage criteria to treatment of individuals 6 years of age and older. Added Bimzelx to HCPC code J3590.
03/01/24	Interim Review, approved February 13, 2024. Removed Stelara (ustekinumab) subcutaneous (SC) injection site of service requirement.
04/01/24	Interim Review, approved March 12, 2024. Updated brand preferred product step therapy requirement for Sotyktu (deucravacitinib) from trial of three agents to one agent.
05/01/24	Interim Review, approved April 9, 2024. Added Humira (adalimumab) (Cordavis) [NDCs starting with 83457] as a non-preferred product. Added Spevigo (spesolimab-sbzo) SC

Date	Comments
	injection coverage criteria. Updated age requirement for Spevigo (spesolimab-sbzo) coverage criteria to 12 years or older.
07/01/24	Interim Review, approved June 11, 2024. Added adalimumab-aaty (Yuflyma unbranded) as a non-preferred product. Added Simlandi (adalimumab-ryvk) and adalimumab-ryvk (Simlandi unbranded) as preferred products. Updated non-preferred adalimumab coverage criteria to require trial and treatment failure with all preferred adalimumab products. Updated Otezla (apremilast) age requirement from adults to individuals 6 years of age and older who weigh at least 20 kg. Added Simlandi to J3590.
08/01/24	Interim Review, approved July 22, 2024. Updated Sotyktu (deucravacitinib) from a non-preferred to a preferred product.
09/01/24	Interim Review, approved August 26, 2024. Updated Zoryve (roflumilast) to indicate coverage criteria is limited to the 0.3% cream. The following policy changes are effective December 5, 2024, following 90-day provider notification. Added Spevigo IV (spesolimab-sbzo) to site of service requirement.
10/01/24	Interim Review, approved September 10, 2024. The following changes are effective January 3, 2025, following a 90-day provider notification, Changed Inflectra (infliximab-dyyb) to a first-line agent. Changed Avsola (infliximab-axxq) to a second-line agent. Updated coverage criteria for Avsola and Renflexis to require the individual to have an adequate trial and failure with Inflectra, Infliximab (Janssen – unbranded), or Remicade. Updated Hyrimoz (Sandoz) (adalimumab-adaz) [NDCs starting with 61314] from a preferred product to a non-preferred product. Updated Humira (AbbVie) (adalimumab) [NDCs starting with 00074] to require that the individual has had an inadequate response or intolerance to a preferred product for new starts.
12/01/24	Interim Review, approved November 12, 2024. Updated Bimzelx (bimekizumab-bkzx) brand step therapy requirement from trial and inadequate response or intolerance to two agents to trial and inadequate response or intolerance to one agent.
01/01/25	Interim Review, approved December 23, 2024. Clarified that the medications listed in this policy are subject to the product's FDA dosage and administration prescribing information. Added the following to note to all criteria for adalimumab products: This medical necessity criteria does not apply to one Open formulary (Formulary ID: 6062; Rx Plan F1) and one Preferred formulary (Formulary ID: 6064; Rx Plan G3). The criteria for members with these custom Open and Preferred formulary plans can be found in policy 5.01.647 Medical Necessity Criteria for Custom Preferred and Open Formularies. Please check the member Plan booklet or member ID card to determine whether this policy criteria applies. Added new HCPCS codes J0139, Q5140, Q5141, Q5142, Q5143, Q5144, Q5145.
02/01/25	Annual Review, approved January 27, 2025. Policy updated to indicate that Site of Service Medical Necessity criteria does not apply to Alaska fully-insured members; only Medical Necessity criteria for the infusion drug applies pursuant to Alaska HB 226 (link added). Clarified that non-formulary exception review authorizations for all drugs listed in this policy may be approved up to 12 months. Added an exception to the site-

Date	Comments
	of-service requirements for certain individuals receiving treatment for cytokine release syndrome (CRS).
03/01/25	Interim Review, approved February 11, 2025. The following policy changes are effective July 1, 2025, following a 90-day provider notification. Updated Humira (adalimumab) (AbbVie) [NDCs starting with 00074] from a preferred to a non-preferred adalimumab product.
05/01/25	Interim Review, approved April 8, 2025. Updated re-authorization duration of approval from 3 years to 12 months.
07/01/25	Interim Review, approved June 10, 2025. Added coverage criteria for Imuldosa (ustekinumab-srlf), Otulfi (ustekinumab-aauz), Pyzchiva (ustekinumab-ttwe), Selarsdi (ustekinumab-ackn), Steqeyma (ustekinumab-stba), ustekinumab (Stelara unbranded), ustekinumab-aekn (Selarsdi unbranded), ustekinumab-ttwe (Pyzchiva unbranded), Yesintek (ustekinumab-kfce), and Wezlana (ustekinumab-auub). Added the following to note to all criteria for Bimzelx (bimekizumab-bkzx), Cimzia (certolizumab pegol), Cosentyx (secukinumab), Ilumya (tildrakizumab-asmn), and Siliq (brodalumab): This medical necessity criteria does not apply to one Open formulary (Formulary ID: 6062; Rx Plan F1) and one Preferred formulary (Formulary ID: 6064; Rx Plan G3). The criteria for members with these custom Open and Preferred formulary plans can be found in policy 5.01.647 Medical Necessity Criteria for Custom Open and Preferred Formularies. Added HCPCS codes Q5098 (Imuldosa), Q5099 (Steqeyma), Q5100 (Yesintek), Q5137, Q9996, Q9998 (Selarsdi) and Q9999 (Otulfi). The following policy changes are effective October 3, 2025, following 90-day provider notification. Clarified that the Site of Service Medical Necessity criteria can apply to injection drugs. Moved the following drugs from policy 5.01.629 to policy 5.01.652: Vtama (tapinarof), Zoryve (roflumilast) cream, Duobrii (halobetasol and tazarotene), Enstilar (betamethasone and calcipotriene), Taclonex (betamethasone and calcipotriene), Wynzora (betamethasone and calcipotriene), brand calcipotriene foam, Dovonex (calcipotriene), Sorilux (calcipotriene), Vectical (calcitriol), Soriatane (acitretin), and Spevigo (spesolimab-sbzo). Updated Stelara (ustekinumab) coverage criteria to require trial with Steqeyma (ustekinumab-aauz) and Yesintek (ustekinumab-kfce) for individuals not previously treated. New policy sections for Metallic (individual/small group/student ISHIP) formulary plans, Essentials formulary plans, and Open/Preferred/Select formulary plans and plans with no pharmacy benefit coverage. Added different coverage criteria for Metallic (individual/small group/student ISHIP) formulary and Essentials formulary plans for the following drugs: Enbrel (etanercept), adalimumab products, infliximab products, Taltz (ixekizumab), ustekinumab products, Skyrizi (risankizumab-rzaa), Tremfya (guselkumab), Otezla (apremilast), Sotyktu (deucravacitinib), Bimzelx (bimekizumab-bkzx), Siliq (brodalumab), Cosentyx (secukinumab), Cimzia (certolizumab pegol), and Ilumya (tildrakizumab-asmn).

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and

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