

09-J2000-79

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## Subject: Brodalumab (Siliq<sup>®</sup>) Injection

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### DESCRIPTION:

Brodalumab (Siliq) is an injectable human monoclonal IgG2k antibody directed against interleukin-17 receptor A (IL-17RA). Blocking IL-17RA inhibits IL-17 cytokine-induced responses including the release of pro-inflammatory cytokines and chemokines. Brodalumab was approved by the US Food and Drug Administration (FDA) in February 2017 for “the treatment of moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy and have failed to respond or have lost response to other systemic therapies.” Because of an observed risk of suicidal ideation and behavior during clinical trials, the labeling includes a Boxed Warning and the drug is only available through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS), the SILIQ REMS Program. Brodalumab is the third biologic agent that specifically targets the IL-17 pathway to be approved by the FDA for treatment of psoriasis. Secukinumab (Cosentyx), approved in January 2015, was the first followed by ixekizumab (Taltz) approved in March 2016. In October 2022, brodalumab was granted orphan drug designation by the FDA for the treatment of systemic sclerosis.

### Psoriasis (PS)

Psoriasis (PS) is a chronic inflammatory skin condition that is often associated with systemic manifestations, especially arthritis. Diagnosis is usually clinical, based on the presence of typical erythematous scaly patches, papules, and plaques that are often pruritic and sometimes painful.

Treatment goals for psoriasis include improvement of skin, nail, and joint lesions plus enhanced quality of life.

The American Academy of Family Physicians (AAFP) categorizes psoriasis severity into mild to moderate (less than 5% of body surface area [BSA]) and moderate to severe (5% or more of BSA). The AAFP psoriasis treatment guidelines recommend basing treatment on disease severity:

- Mild to moderate (less than 5% of BSA and sparing the genitals, hands, feet, and face):
  - Candidate for intermittent therapy: topical corticosteroids, vitamin D analogs (calcipotriene and calcitriol), or tazarotene (Tazorac)
  - Candidate for continuous therapy: calcineurin inhibitors (tacrolimus and pimecrolimus)
- Severe (5% or more of BSA or involving the genitals, hands, feet, and face):
  - Less than 20% of BSA affected: vitamin D analogs (calcipotriene and calcitriol) with or without phototherapy. These agents have a slower onset of action but a longer disease-free interval than topical corticosteroids
  - 20% or more of BSA affected: systemic therapy with MTX, cyclosporine, acitretin, or biologics. Biologics are recommended for those with concomitant PsA
- Less commonly used topical therapies include non-medicated moisturizers, salicylic acid, coal tar, and anthralin

The American Academy of Dermatology (AAD) and National Psoriasis Foundation (NPF) categorize psoriasis severity as limited or mild (less than 3% of BSA), moderate (3% to 10% of BSA), or severe (greater than 10% of BSA). The AAD/NPF guidelines also note that psoriasis can be considered severe irrespective of BSA when it occurs in select locations (e.g., hands, feet, scalp, face, or genital area) or when it causes intractable pruritus. The AAD psoriasis treatment guidelines recommend the following:

- Mild to moderate disease (less than 5% of BSA):
  - Topical corticosteroids (strength of recommendation A)
  - Off-label use of 0.1% tacrolimus for psoriasis involving the face as well as inverse psoriasis (strength of recommendation B)
  - Long-term use (up to 52 weeks) of topical vitamin D analogs including calcipotriene, calcitriol, tacalcitol, and maxacalcitol (strength of recommendation A)
  - Use of calcipotriene foam and calcipotriene plus betamethasone dipropionate gel for the treatment of mild to moderate scalp psoriasis (strength of recommendation A)
  - Use of tacalcitol ointment or calcipotriene combined with hydrocortisone for facial psoriasis (strength of recommendation B)
  - Vitamin D analogs in combination with topical corticosteroids (strength of recommendation A)
  - Topical tazarotene alone or in combination with narrowband ultraviolet B (NB-UVB) (strength of recommendation B), or topical corticosteroids (strength of recommendation A)
  - Topical salicylic acid alone or in combination with topical corticosteroids (strength of recommendation B)
  - Coal tar preparations (strength of evidence A)
- Moderate to severe disease without PsA (5% or more of BSA or psoriasis in vulnerable areas [e.g., face, genitals, hands, and feet] that adversely affects quality of life):
  - Methotrexate (adults) (strength of evidence A)
  - Methotrexate is less effective than TNF-inhibitors (strength of evidence B)
  - Combination therapy with methotrexate and NB-UVB (adult patients) (strength of evidence B)

- Cyclosporine for patients with severe, recalcitrant (strength of recommendation A), erythrodermic, generalized pustular, and/or palmoplantar psoriasis (strength of recommendation B)
- Acitretin as monotherapy or in combination with psoralen plus ultraviolet light (PUVA) or broad band ultraviolet light (BB-UVA [strength of evidence B])
- If UV-therapy is unavailable, first line therapies include MTX, cyclosporine, acitretin, and biologics
- Apremilast (strength of recommendation A)
- TNF- $\alpha$  inhibitors monotherapy (strength of evidence A) or in combination with topical corticosteroids with or without a vitamin D analogue (strength of evidence B) or in combination with acitretin (strength of evidence C)
- TNF- $\alpha$  inhibitors should be considered as a preferred treatment option for patients with concomitant PsA
- Infliximab (strength of evidence A)
- IL-12/IL-23 Inhibitors monotherapy (strength of evidence A) or in combination with topical corticosteroids with or without a vitamin D analogue (strength of evidence C) or in combination with acitretin or methotrexate (strength of evidence B)
- IL-12/IL-23 inhibitors in combination with apremilast or cyclosporine (strength of evidence C)
- IL-17 inhibitors monotherapy (strength of evidence A)
- IL-23 inhibitors monotherapy for moderate to severe plaque psoriasis or as monotherapy for generalized pustular psoriasis (strength of evidence B)

\*Strength of recommendation and descriptions

Strength of recommendation	Description
A	Recommendation based on consistent and good-quality patient-oriented evidence
B	Recommendation based on inconsistent or limited-quantity patient-oriented evidence
C	Recommendation based on consensus, opinion, case studies, or disease-oriented evidence

Biologics are routinely used when one or more traditional systemic agents fail to produce adequate response, but are considered first line in patients with moderate to severe psoriasis with concomitant severe PsA. Primary failure is defined as initial nonresponse to treatment. Primary failure to a TNF- $\alpha$  inhibitor does not preclude successful response to a different TNF- $\alpha$  inhibitor. Failure of another biologic therapy does not preclude successful response to ustekinumab.

The National Psoriasis Foundation (NPF) medical board recommend a treat-to-target approach to therapy for psoriasis that include the following:

- The preferred assessment instrument for determining disease severity is BSA
- Target response after treatment initiation should be BSA  $\leq$ 1% after 3 months

- Acceptable response is either a BSA  $\leq 3\%$  or a BSA improvement  $\geq 75\%$  from baseline at 3 months after treatment initiation

## POSITION STATEMENT:

### Comparative Effectiveness

The FDA has deemed the drug(s) or biological product(s) in this coverage policy to be appropriate for self-administration or administration by a caregiver (i.e., not a healthcare professional). Therefore, coverage (i.e., administration) in a provider-administered setting such as an outpatient hospital, ambulatory surgical suite, physician office, or emergency facility is not considered medically necessary.

**NOTE:** The self-administered products with prerequisites for certain indications are as follows:

Table 1

Disease State	Step 1		Step 2 (Directed to ONE step 1 agent)	Step 3a (Directed to TWO step 1 agents)	Step 3b (Directed to TWO agents from step 1 and/or step 2)	Step 3c (Directed to THREE step 1 agents)
	Step 1a	Step 1b (Directed to ONE TNF inhibitor) NOTE: Please see Step 1a for preferred TNF inhibitors				
<b>Rheumatoid Disorders</b>						
Ankylosing Spondylitis (AS)	SQ: Cosentyx, Enbrel, Hadlima, Humira, Simlandi	Oral: Rinvoq, Xeljanz, Xeljanz XR	N/A	SQ: Cimzia, Simponi, Taltz	N/A	SQ: Abrilada**, Adalimumab-ryvk**, Amjevita**, Cyltezo**, Hulio**, Hyrimoz**, Idacio**, Yuflyma**, Yusimry**
Nonradiographic Axial Spondyloarthritis (nr-axSpA)	SQ: Cimzia, Cosentyx	Oral: Rinvoq	N/A	SQ: Taltz	N/A	N/A
Polyarticular Juvenile Idiopathic Arthritis (PJIA)	SQ: Enbrel, Hadlima, Humira, Simlandi	Oral: Rinvoq, Rinvoq LQ, Xeljanz	SQ: Actemra (Hadlima, Humira, or Simlandi is a required Step 1 agent)	N/A	SQ: Orencia	SQ: Abrilada**, Adalimumab-ryvk**, Amjevita**, Cyltezo**, Hulio**, Hyrimoz**, Idacio**, Kevzara, Yuflyma**, Yusimry**
Psoriatic Arthritis (PsA)	SQ: Cosentyx, Enbrel, Hadlima, Humira, Simlandi, Skyrizi, Stelara, Tremfya	Oral: Rinvoq, Rinvoq LQ, Xeljanz, Xeljanz XR	N/A	SQ: Cimzia, Orencia, Simponi, Taltz	N/A	SQ: Abrilada**, Adalimumab-ryvk**, Amjevita**, Cyltezo**, Hulio**, Hyrimoz**, Idacio**, Kevzara, Yuflyma**, Yusimry**

	Oral: Otezla					Hyrimoz**, Idacio**, Simlandi**, Yuflyma**, Yusimry**
Rheumatoid Arthritis (RA)	SQ: Enbrel, Hadlima, Humira, Simlandi	Oral: Rinvoq, Xeljanz, Xeljanz XR	SQ: Actemra (Hadlima, Humira, or Simlandi is a required Step 1 agent)	Oral: Olumiant  SQ: Cimzia, Kevzara, Kineret, Orencia, Simponi	N/A	SQ: Abrilada**, Adalimumab-ryvk**, Amjevita**, Cyltezo**, Hulio**, Hyrimoz**, Idacio**, Yuflyma**, Yusimry**
<b>Dermatological Disorders</b>						
Hidradenitis Suppurativa (HS)	SQ: Cosentyx, Hadlima, Humira, Simlandi	N/A	N/A	N/A	N/A	SQ: Abrilada**, Adalimumab-ryvk**, Amjevita**, Cyltezo**, Hulio**, Hyrimoz**, Idacio**, Yuflyma**, Yusimry**
Psoriasis (PS)	SQ: Cosentyx, Enbrel, Hadlima, Humira, Simlandi, Skyrizi, Stelara, Tremfya  Oral: Otezla	N/A	Oral: Sotyktu	SQ: Cimzia	N/A	SQ: Abrilada**, Adalimumab-ryvk**, Amjevita**, Bimzelx, Cyltezo**, Hulio**, Hyrimoz**, Idacio**, <b>Siliq</b> , Taltz, Yuflyma**, Yusimry**
<b>Inflammatory Bowel Disease</b>						
Crohn's Disease (CD)	SQ: Hadlima, Humira, Simlandi, Skyrizi, Stelara	Oral: Rinvoq	N/A	SQ: Cimzia (Hadlima, Humira, or Simlandi is a required Step 1 agent)	SQ: Entyvio	SQ: Abrilada**, Adalimumab-ryvk**, Amjevita**, Cyltezo**, Hulio**, Hyrimoz**, Idacio**, Yusimry**, Zymfentra
Ulcerative Colitis (UC)	SQ: Hadlima, Humira, Simlandi, Skyrizi, Stelara	Oral: Rinvoq, Xeljanz, Xeljanz XR	SQ: Simponi (Hadlima, Humira, or Simlandi is a required Step 1 agent)	N/A	SQ: Entyvio. Oral: Zeposia (Hadlima, Humira, Rinvoq, Simlandi, Skyrizi, Stelara, OR Xeljanz/Xeljanz XR are required Step agents)	SQ: Abrilada**, Adalimumab-ryvk**, Amjevita**, Cyltezo**, Hulio**, Hyrimoz**, Idacio**, Yuflyma**, Yusimry**, Zymfentra

						Oral: Velsipity
<b>Other\</b>						
Uveitis	SQ: Hadlima, Humira, Simlandi	N/A	N/A	N/A	N/A	SQ: Abridada**, Adalimumab-ryvk**, Amjevita**, Cyltezo**, Hulio**, Hyrimoz**, Idacio**, Yuflyma**, Yusimry**
<b>Indications Without Prerequisite Biologic Immunomodulators</b>						
Alopecia Areata (AA)						
Atopic Dermatitis (AD)						
Deficiency of IL-1 Receptor Antagonist (DIRA)						
Enthesitis Related Arthritis (ERA)						
Giant Cell Arteritis (GCA)						
Juvenile Psoriatic Arthritis (JPsA)	N/A	N/A	N/A	N/A	N/A	N/A
Neonatal-Onset Multisystem Inflammatory Disease (NOMID)						
Polymyalgia Rheumatica (PMR)						
Systemic Juvenile Idiopathic Arthritis (SJIA)						
Systemic Sclerosis-associated Interstitial Lung Disease (SSc-ILD)						

\*\*Note: Hadlima, Humira, and Simlandi are required Step 1 agents

**Note:** For Xeljanz products (Xeljanz and Xeljanz XR) and Rinvoq products (Rinvoq and Rinvoq LQ), a trial of either or both dosage forms collectively counts as **ONE** product

**Note:** Branded generic available for Cyltezo, Hulio, Hyrimoz, Idacio, and Yuflyma are included as a target at the same step level in this program

Initiation of brodalumab (Siliq) meets the definition of medical necessity when **ALL** of the following are met (“1” to “5”):

1. **ONE** of the following (“a”, “b”, or “c”):

- a. The member has been treated with brodalumab (starting on samples is not approvable) within the past 90 days
  - b. The prescriber states the member has been treated with brodalumab (starting on samples is not approvable) within the past 90 days **AND** is at risk if therapy is changed
  - c. **BOTH** of the following (“i” and “ii”):
    - i. Brodalumab will be used for the treatment of an indication listed in Table 2, and **ALL** of the indication-specific criteria are met
    - ii. **EITHER** of the following if the member has an FDA-approved indication (“I” or “II”)
      - I. The member’s age is within FDA labeling for the requested indication for brodalumab
      - II. The prescriber has provided information in support of using brodalumab for the member’s age
2. The prescriber is a specialist in the area of the member’s diagnosis (e.g., dermatologist for PS) or the prescriber has consulted with a specialist in the area of the member’s diagnosis
  3. Member does **NOT** have any FDA labeled contraindications to brodalumab
  4. Member will **NOT** be using brodalumab in combination with another biologic immunomodulator agent (full list in “Other” section); Janus kinase (JAK) inhibitor [Cibinqo (abrocitinib), Litfulo (ritlicitinib), Olumiant (baricitinib), Opzelura (ruxolitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Xeljanz (tofacitinib), and Xeljanz XR (tofacitinib extended release)]; Otezla (apremilast); Sotyktu (deucravacitinib); or sphingosine-1-phosphate (S1P) modulator [Velsipity (etrasimod) and Zeposia (ozanimod)]
  5. **ANY** of the following (“a”, “b”, or “c”):
    - a. The dosage does not exceed:
      - Loading dose - 210 mg at weeks 0, 1, and 2
      - Maintenance dose - 210 mg every 2 weeks, starting 2 weeks after week 2 (i.e., on week 4):
        - QL: 210 mg/1.5 mL syringe - 2 syringes (3 mL)/28 days
    - b. The requested quantity (dose) exceeds the program quantity limit but does **NOT** exceed the maximum FDA labeled dose **OR** the maximum compendia-supported dose (i.e., DrugDex with 1 or 2a level of evidence, AHFS, or NCCN compendium recommended use 1 or 2a) for the requested indication, **AND** the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength and/or package size that does not exceed the program quantity limit
    - c. The requested quantity (dose) exceeds the program quantity limit and exceeds the maximum FDA labeled dose **AND** the maximum compendia-supported dose (i.e., DrugDex with 1 or 2a level of evidence, AHFS, or NCCN compendium recommended use 1 or 2a) for the requested indication, **AND** the prescriber has provided information in support of therapy with a higher dose or shortened dosing interval for the requested indication (submitted copy of clinical trials, phase III studies, guidelines required)

**Approval duration:** Loading dose (doses on week 0, 1, and 2) for 4 weeks, then maintenance dose for 12 additional weeks [16 weeks for total duration of approval]

**Table 2**

Diagnosis	Criteria
Moderate to severe plaque psoriasis (PS)	<p><b>BOTH</b> of the following:</p> <ol style="list-style-type: none"> <li>1. <b>ONE</b> of the following:           <ol style="list-style-type: none"> <li>a. The member has tried and had an inadequate response to <b>ONE</b> conventional agent (i.e., acitretin, anthralin, calcipotriene, calcitriol, coal tar products, cyclosporine, methotrexate, pimecrolimus, PUVA [phototherapy], tacrolimus, tazarotene, topical corticosteroids) used in the treatment of PS after at least a 3-month duration of therapy</li> <li><b>OR</b></li> <li>b. The member has an intolerance or hypersensitivity to <b>ONE</b> conventional agent used in the treatment of PS</li> <li><b>OR</b></li> <li>c. The member has an FDA labeled contraindication to <b>ALL</b> conventional agents used in the treatment of PS</li> <li><b>OR</b></li> <li>d. The member has severe active PS (e.g., greater than 10% body surface area involvement, occurring on select locations [i.e., hands, feet, scalp, face, or genitals], intractable pruritus, serious emotional consequences)</li> <li><b>OR</b></li> <li>e. The member has concomitant severe psoriatic arthritis (PsA) (e.g., erosive disease, elevated markers of inflammation [e.g., ESR, CRP] attributable to PsA, long-term damage that interferes with function [i.e., joint deformities], rapidly progressive)</li> <li><b>OR</b></li> <li>f. The member’s medication history indicates use of another biologic immunomodulator agent <b>OR</b> Otezla that is FDA labeled or supported in DrugDex with 1 or 2a level of evidence or AHFS for the treatment of PS</li> </ol> </li> <li><b>AND</b></li> <li>2. <b>ANY</b> of the following (submitted medical records/chart notes are required for confirmation):           <ol style="list-style-type: none"> <li>a. The member has tried and had an inadequate response to at least <b>THREE</b> of the following preferred products after at least a 3-month trial per product:</li> </ol> </li> </ol>



- Cosentyx (secukinumab)
- Enbrel (etanercept)
- Hadlima (adalimumab-bwwd)
- Humira (adalimumab)
- Otezla (apremilast)
- Simlandi (adalimumab-ryvk)
- Skyrizi (risankizumab)
- Stelara (ustekinumab)
- Tremfya (guselkumab)

**OR**

b. The member has an intolerance (defined as an intolerance to the drug or its excipients, not to the route of administration) or hypersensitivity to **THREE** of the following:

- Cosentyx (secukinumab)
- Enbrel (etanercept)
- Hadlima (adalimumab-bwwd)
- Humira (adalimumab)
- Otezla (apremilast)
- Simlandi (adalimumab-ryvk)
- Skyrizi (risankizumab)
- Stelara (ustekinumab)
- Tremfya (guselkumab)

**OR**

c. The member has an FDA labeled contraindication to **ALL** of the following:

- Cosentyx (secukinumab)
- Enbrel (etanercept)
- Hadlima (adalimumab-bwwd)
- Humira (adalimumab)
- Otezla (apremilast)
- Simlandi (adalimumab-ryvk)
- Skyrizi (risankizumab)
- Stelara (ustekinumab)

	<ul style="list-style-type: none"> <li>• Tremfya (guselkumab)</li> </ul> <p><b>OR</b></p> <p>d. <b>ALL</b> of the following are not clinically appropriate for the member, <b>AND</b> the prescriber has provided a complete list of previously tried agents for the requested indication:</p> <ul style="list-style-type: none"> <li>• Cosentyx (secukinumab)</li> <li>• Enbrel (etanercept)</li> <li>• Hadlima (adalimumab-bwwd)</li> <li>• Humira (adalimumab)</li> <li>• Otezla (apremilast)</li> <li>• Simlandi (adalimumab-ryvk)</li> <li>• Skyrizi (risankizumab)</li> <li>• Stelara (ustekinumab)</li> <li>• Tremfya (guselkumab)</li> </ul>
Other indications	The member has another FDA labeled indication or an indication supported in DrugDex with 1 or 2a level of evidence, AHFS, or NCCN compendium recommended use 1 or 2a

Continuation of brodalumab (Siliq) **meets the definition of medical necessity** when **ALL** of the following are met (“1” to “6”):

1. An authorization or reauthorization for brodalumab has been previously approved by Florida Blue [Note: members not previously approved for the requested agent will require initial evaluation review]
2. Member has had clinical benefit with brodalumab therapy
3. The prescriber is a specialist in the area of the member’s diagnosis (e.g., dermatologist for PS) or the prescriber has consulted with a specialist in the area of the member’s diagnosis
4. Member does **NOT** have any FDA labeled contraindications to brodalumab
5. Member will **NOT** be using brodalumab in combination with another biologic immunomodulator agent (full list in “Other” section); Janus kinase (JAK) inhibitor [Cibinqo (abrocitinib), Litfulo (ritlecitinib), Olumiant (baricitinib), Opzelura (ruxolitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Xeljanz (tofacitinib), and Xeljanz XR (tofacitinib extended release)]; Otezla (apremilast); Sotyktu (deucravacitinib); or sphingosine-1-phosphate (S1P) modulator [Velsipity (etrasimod) and Zeposia (ozanimod)]
6. **ANY** of the following (“a”, “b”, or “c”):
  - a. The dosage does not exceed 210 mg every 2 weeks
    - QL: 210 mg/1.5 mL syringe - 2 syringes (3 mL)/28 days

- b. The requested quantity (dose) exceeds the program quantity limit but does **NOT** exceed the maximum FDA labeled dose **OR** the maximum compendia-supported dose (i.e. DrugDex with 1 or 2a level of evidence, AHFS, or NCCN compendium recommended use 1 or 2a) for the requested indication, **AND** the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength and/or package size that does not exceed the program quantity limit
- c. The requested quantity (dose) exceeds the program quantity limit and exceeds the maximum FDA labeled dose **AND** the maximum compendia-supported dose (i.e., DrugDex with 1 or 2a level of evidence, AHFS, or NCCN compendium recommended use 1 or 2a) for the requested indication, **AND** the prescriber has provided information in support of therapy with a higher dose or shortened dosing interval for the requested indication (submitted copy of clinical trials, phase III studies, guidelines required).

**Approval duration:** 12 months

## **DOSAGE/ADMINISTRATION:**

**THIS INFORMATION IS PROVIDED FOR INFORMATIONAL PURPOSES ONLY AND SHOULD NOT BE USED AS A SOURCE FOR MAKING PRESCRIBING OR OTHER MEDICAL DETERMINATIONS. PROVIDERS SHOULD REFER TO THE MANUFACTURER'S FULL PRESCRIBING INFORMATION FOR DOSAGE GUIDELINES AND OTHER INFORMATION RELATED TO THIS MEDICATION BEFORE MAKING ANY CLINICAL DECISIONS REGARDING ITS USAGE.**

### **FDA-approved**

- Indicated for the treatment of moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy and have failed to respond or have lost response to other systemic therapies.
- The recommended dose is 210 mg administered by subcutaneous injection at Weeks 0, 1, and 2 followed by 210 mg every 2 weeks. If an adequate response has not been achieved after 12 to 16 weeks of treatment, consider discontinuing therapy. Continued treatment beyond 16 weeks in patients who have not achieved an adequate response is not likely to result in greater success.
- Brodalumab is intended for use under the guidance and supervision of a healthcare professional. Patients may self-inject when deemed appropriate by a healthcare professional and after proper training in subcutaneous injection technique using the prefilled syringe.

### **Dose Adjustments**

- No specific guidelines for dosage adjustments for renal or hepatic impairment are available. It appears that no dosage adjustments are needed.

### **Drug Availability**

- Injection: 210 mg/1.5 mL solution in a single-dose prefilled syringe. Each prefilled syringe is for single-dose only.

## **PRECAUTIONS:**

### **Boxed Warning**

- Suicidal ideation and behavior, including completed suicides, have occurred in patients treated with brodalumab. Prior to prescribing brodalumab, weigh the potential risks and benefits in patients with a history of depression and/or suicidal ideation or behavior. Patients with new or worsening suicidal ideation and behavior should be referred to a mental health professional, as appropriate. Advise patients and caregivers to seek medical attention for manifestations of suicidal ideation or behavior, new onset or worsening depression, anxiety, or other mood changes.
- Because of the observed suicidal behavior in subjects treated with brodalumab, brodalumab is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the SILIQ REMS Program.

### Contraindications

- Patients with Crohn's disease because brodalumab may cause worsening of disease

### Precautions/Warnings

- **SILIQ REMS Program:** Notable requirements of the program include the following:
  - Prescribers must be certified with the program.
  - Patients must sign a Patient-Prescriber Agreement Form.
  - Pharmacies must be certified with the program and must only dispense to patients who are authorized to receive brodalumab.

Further information, including a list of qualified pharmacies, is available at [www.SILIQREMS.com](http://www.SILIQREMS.com) or by calling the SILIQ REMS Program Call Center at 855-511-6135.

- **Infections:** Serious infections have occurred. Consider the risks and benefits prior to initiating brodalumab in patients with a chronic infection or a history of recurrent infection. Instruct patients to seek medical advice if signs or symptoms of clinically important chronic or acute infection occur. If a serious infection develops, discontinue brodalumab until the infection resolves.
- **Tuberculosis (TB):** Evaluate patients for TB infection prior to initiating treatment with brodalumab.
- **Crohn's Disease:** Crohn's disease occurred during clinical trials. Discontinue brodalumab if patient develops Crohn's disease while taking brodalumab.
- **Immunizations:** Avoid using live vaccines concurrently with brodalumab.
- **CYP450 Substrates:** The formation of CYP450 enzymes can be altered by increased levels of certain cytokines during chronic inflammation, and treatment with brodalumab may modulate serum levels of some cytokines. Therefore, upon initiation or discontinuation of brodalumab in patients who are receiving concomitant drugs which are CYP450 substrates, particularly those with a narrow therapeutic index, consider monitoring for effect (e.g., for warfarin) or drug concentration (e.g., for cyclosporine) and consider dosage modification of the CYP450 substrate.
- **Pregnancy:** There are no human data on brodalumab use in pregnant women to inform a drug associated risk. Human IgG antibodies are known to cross the placental barrier; therefore, brodalumab may be transmitted from the mother to the developing fetus. See the package insert for additional information.

## BILLING/CODING INFORMATION

### HCPCS Coding

J3590	Unclassified biologics
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### ICD-10 Diagnosis Codes That Support Medical Necessity

L40.0	Psoriasis vulgaris
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## REIMBURSEMENT INFORMATION:

Refer to section entitled [POSITION STATEMENT](#).

## PROGRAM EXCEPTIONS:

**Federal Employee Program (FEP):** Follow FEP guidelines.

**State Account Organization (SAO):** Follow SAO guidelines.

**Medicare Part D:** Florida Blue has delegated to Prime Therapeutics authority to make coverage determinations for the Medicare Part D services referenced in this guideline.

**Medicare Advantage:** No National Coverage Determination (NCD) and/or Local Coverage Determination (LCD) were found at the time of guideline creation.

## DEFINITIONS:

**Plaque psoriasis:** It is the most common form of psoriasis. It affects 80 to 90% of people with psoriasis. Plaque psoriasis typically appears as raised areas of inflamed skin covered with silvery white scaly skin. These areas are called plaques.

## RELATED GUIDELINES:

[Adalimumab Products, 09-J0000-46](#)

[Apremilast \(Otezla\) Tablet, 09-J2000-19](#)

[Bimekizumab \(Bimzelx\), 09-J4000-70](#)

[Certolizumab pegol \(Cimzia\), 09-J0000-77](#)

[Deucravacitinib \(Sotyktu\), 09-J4000-37](#)

[Etanercept \(Enbrel\), 09-J0000-38](#)

[Guselkumab \(Tremfya\), 09-J2000-87](#)

[Infliximab Products, 09-J0000-39](#)

[Ixekizumab \(Taltz\), 09-J2000-62](#)

[Psoralens with Ultraviolet A \(PUVA\), 09-10000-16](#)

[Risankizumab \(Skyrizi\), 09-J3000-45](#)

[Secukinumab \(Cosentyx\), 09-J2000-30](#)

[Tildrakizumab-asmn \(Ilumya\), 09-J3000-04](#)

[Ustekinumab \(Stelara\), 09-J1000-16](#)

## OTHER:

### **Biologic Immunomodulator Agents Not Permitted as Concomitant Therapy**

Abrilada (adalimumab-afzb)  
Actemra (tocilizumab)  
Adalimumab  
Adbry (tralokinumab-ldrm)  
Amjevita (adalimumab-atto)  
Arcalyst (rilonacept)  
Avsola (infliximab-axxq)  
Benlysta (belimumab)  
Bimzelx (bimekizumab-bkzx)  
Cimzia (certolizumab)  
Cinqair (reslizumab)  
Cosentyx (secukinumab)  
Cyltezo (adalimumab-adbm)  
Dupixent (dupilumab)  
Enbrel (etanercept)  
Entyvio (vedolizumab)  
Fasenra (benralizumab)  
Hadlima (adalimumab-bwwd)  
Hulio (adalimumab-fkjp)  
Humira (adalimumab)  
Hyrimoz (adalimumab-adaz)  
Idacio (adalimumab-aacf)  
Ilaris (canakinumab)  
Ilumya (tildrakizumab-asmn)  
Inflectra (infliximab-dyyb)  
Infliximab  
Kevzara (sarilumab)  
Kineret (anakinra)  
Nucala (mepolizumab)  
Omvoh (mirikizumab-mrkz)  
Orencia (abatacept)  
Remicade (infliximab)  
Renflexis (infliximab-abda)  
Riabni (rituximab-arrx)  
Rituxan (rituximab)  
Rituxan Hycela (rituximab/hyaluronidase human)  
Ruxience (rituximab-pvvr)  
Selarsdi (ustekinumab-aekn)  
Siliq (brodalumab)  
Simlandi (adalimumab-ryvk)  
Simponi (golimumab)  
Simponi Aria (golimumab)

Skyrizi (risankizumab-rzaa)  
Spevigo (spesolimab-sbzo)  
Stelara (ustekinumab)  
Taltz (ixekizumab)  
Tezspire (tezepelumab-ekko)  
Tofidence ((tocilizumab-bavi)  
Tremfya (guselkumab)  
Truxima (rituximab-abbs)  
Tyenne (tocilizumab-aazg)  
Tyruko (natalizumab-sztn)  
Tysabri (natalizumab)  
Wezlana (ustekinumab-auub)  
Xolair (omalizumab)  
Yuflyma (adalimumab-aaty)  
Yusimry (adalimumab-aqvh)  
Zymfentra (infliximab-dyyb)

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### COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Pharmacy Policy Committee on 11/08/23.

### GUIDELINE UPDATE INFORMATION:

06/15/17	New Medical Coverage Guideline.
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01/01/18	Revision to guideline consisting of updating the preferred self-administered biologic products according to indication for use. Secukinumab (Cosentyx) is now a preferred product for plaque psoriasis.
07/01/18	Revision to guideline consisting of updating the position statement.
10/15/18	Review and revision to guideline consisting of updating the position statement, related guidelines, and references.
09/01/19	Revision to guideline consisting of updating the position statement.
10/15/19	Review and revision to guideline consisting of updating the description, position statement, definitions, and references.
01/01/20	Revision to guideline consisting of updating the position statement due to changes in preferred and non-preferred products.
07/01/20	Revision to guideline consisting of updating the description, position statement, and definitions.
01/01/21	Review and revision to guideline consisting of updating the position statement and references.
03/15/21	Revision to guideline consisting of updating Table 1 in the position statement.
09/15/21	Update to Table 1 in Position Statement.
11/15/21	Revision to guideline consisting of updating the position statement.
01/01/22	Review and revision to guideline consisting of updating the position statement and references.
02/15/22	Update to Table 1 in Position Statement.
03/15/22	Revision to guideline consisting of updating the position statement and other sections.
05/15/22	Update to Table 1 in Position Statement.
07/15/22	Update to Table 1 in Position Statement.
09/15/22	Update to Table 1 in Position Statement.
01/01/23	Review and revision to guideline consisting of updating the description section, position statement, other section, and references. New drugs were added to the list of drugs that are not permitted for use in combination.
04/15/23	Revision to guideline consisting of updating the position statement and other section.
07/01/23	Revision to guideline consisting of updating the position statement and other section. Amjevita and Hadlima added as Step 1a agents. Humira biosimilar products added to list of Biologic Immunomodulator Agents Not Permitted as Concomitant Therapy.
01/01/24	Review and revision to guideline consisting of updating the position statement, other section, and references. Amjevita low-concentration [10 mg/0.2 mL, 20 mg/0.4 mL, and 40 mg/0.8 mL concentrations only] clarified as the preferred prerequisite product. Update to Table 1 in Position Statement. New drugs were added to the list of drugs that are not permitted for use in combination.
07/01/24	Revision to guideline consisting of updating the description, position statement, related guidelines, and other section. Amjevita low-concentration removed as a required prerequisite agent. Updates to the positioning of agents in Table 1. Removal of latent TB testing requirement. New drugs added to the list of Biologic Immunomodulator Agents Not Permitted as Concomitant Therapy.

10/01/24	Revision to guideline consisting of updating the position statement. Updates to Table 1. Simlandi added among the required prerequisite agents.
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