

09-J2000-79

Original Effective Date: 06/15/17

Reviewed: 11/13/24

Revised: 01/01/25

Subject: Brodalumab (Siliq®) Injection

THIS MEDICAL COVERAGE GUIDELINE IS NOT AN AUTHORIZATION, CERTIFICATION, EXPLANATION OF BENEFITS, OR A GUARANTEE OF PAYMENT, NOR DOES IT SUBSTITUTE FOR OR CONSTITUTE MEDICAL ADVICE. ALL MEDICAL DECISIONS ARE SOLELY THE RESPONSIBILITY OF THE PATIENT AND PHYSICIAN. BENEFITS ARE DETERMINED BY THE GROUP CONTRACT, MEMBER BENEFIT BOOKLET, AND/OR INDIVIDUAL SUBSCRIBER CERTIFICATE IN EFFECT AT THE TIME SERVICES WERE RENDERED. THIS MEDICAL COVERAGE GUIDELINE APPLIES TO ALL LINES OF BUSINESS UNLESS OTHERWISE NOTED IN THE PROGRAM EXCEPTIONS SECTION.

Dosage/ Administration	Position Statement	Billing/Coding	Reimbursement	Program Exceptions	Definitions
Related Guidelines	Other	References	Updates		

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- α 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- α 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- α inhibitor does not preclude successful response to a different TNF- α 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 list of self-administered products with prerequisites for certain indications can be found at [Preferred Agents and Drug List](#).

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 1, 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 for the requested indication
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), Leqselvi (deuruxolitinib), 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)]
5. **ANY** of the following (“a”, “b”, “c”, or “d”):
 - 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 member has an FDA labeled indication for the requested agent, **AND EITHER** of the following (“i” or “ii”):
- i. The requested quantity (dose) does **NOT** exceed the maximum FDA labeled dose 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
 - ii. **ALL** of the following (“1”, “2”, and “3”):
 1. The requested quantity (dose) exceeds the FDA maximum labeled dose for the requested indication
 2. The member has tried and had an inadequate response to at least a 3-month trial of the maximum FDA labeled dose for the requested indication (medical records required)
 3. **EITHER** of the following (“a” or “b”):
 - a. The requested quantity (dose) does **NOT** exceed the maximum compendia supported dose 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
 - b. The requested quantity (dose) exceeds the maximum FDA labeled dose **AND** the maximum compendia supported dose for the requested indication, **AND** there is support for therapy with a higher dose or shortened dosing interval for the requested indication (submitted copy of clinical trials, phase III studies, guidelines required)
- c. The member has a compendia supported indication for the requested agent, **AND EITHER** of the following (“i” or “ii”):
- i. The requested quantity (dose) does **NOT** exceed the maximum compendia supported dose 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
 - ii. The requested quantity (dose) exceeds the maximum compendia supported dose for the requested indication, **AND** there is support for therapy with a higher dose or shortened dosing interval for the requested indication (submitted copy of clinical trials, phase III studies, guidelines required)
- d. The member does **NOT** have an FDA labeled indication **NOR** a compendia supported indication for the requested agent, **AND BOTH** of the following (“i” and “ii”):
- i. 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
 - ii. There is support for therapy with a higher dose or shortened dosing interval for the requested indication (submitted copy of clinical trials, phase III studies, guidelines required)

Compendia Allowed: AHFS, DrugDex 1 or 2a level of evidence, or NCCN 1 or 2a recommended use

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 1

Diagnosis	Criteria
Moderate to severe plaque psoriasis (PS)	<p>BOTH of the following:</p> <ol style="list-style-type: none"> 1. ONE of the following: <ol style="list-style-type: none"> a. The member has tried and had an inadequate response to ONE 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 OR b. The member has an intolerance or hypersensitivity to ONE conventional agent used in the treatment of PS OR c. The member has an FDA labeled contraindication to ALL conventional agents used in the treatment of PS OR 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) OR 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) OR f. The member’s medication history indicates use of another biologic immunomodulator agent OR Otezla that is FDA labeled or supported in DrugDex with 1 or 2a level of evidence or AHFS for the treatment of PS AND 2. ANY of the following (submitted medical records/chart notes are required for confirmation): <ol style="list-style-type: none"> a. The member has tried and had an inadequate response to at least THREE of the following preferred products after at least a 3-month trial per product:

- Adalimumab-aaty
- Adalimumab-adaz
- Cosentyx (secukinumab)
- Enbrel (etanercept)
- Hadlima (adalimumab-bwwd)
- Humira (adalimumab)
- Otezla (apremilast)
- Simlandi (adalimumab-ryvk)
- Skyrizi (risankizumab)
- Sotyktu (deucravacitinib)
- 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:

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

OR

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

- Adalimumab-aaty
- Adalimumab-adaz

	<ul style="list-style-type: none"> • Cosentyx (secukinumab) • Enbrel (etanercept) • Hadlima (adalimumab-bwwd) • Humira (adalimumab) • Otezla (apremilast) • Simlandi (adalimumab-ryvk) • Skyrizi (risankizumab) • Sotyktu (deucravacitinib) • Stelara (ustekinumab) • Tremfya (guselkumab) <p>OR</p> <p>d. ALL of the following are not clinically appropriate for the member, AND the prescriber has provided a complete list of previously tried agents for the requested indication:</p> <ul style="list-style-type: none"> • Adalimumab-aaty • Adalimumab-adaz • Cosentyx (secukinumab) • Enbrel (etanercept) • Hadlima (adalimumab-bwwd) • Humira (adalimumab) • Otezla (apremilast) • Simlandi (adalimumab-ryvk) • Skyrizi (risankizumab) • Sotyktu (deucravacitinib) • Stelara (ustekinumab) • Tremfya (guselkumab)
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), Leqselvi (deuruxolitinib), 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", "c", or "d"):
 - 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 member has an FDA labeled indication for the requested agent, **AND EITHER** of the following ("i" or "ii"):
 - i. The requested quantity (dose) does **NOT** exceed the maximum FDA labeled dose 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
 - ii. **ALL** of the following ("1", "2", and "3"):
 1. The requested quantity (dose) exceeds the FDA maximum labeled dose for the requested indication
 2. The member has tried and had an inadequate response to at least a 3-month trial of the maximum FDA labeled dose for the requested indication (medical records required)
 3. **EITHER** of the following ("a" or "b"):
 - a. The requested quantity (dose) does **NOT** exceed the maximum compendia supported dose 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
 - b. The requested quantity (dose) exceeds the maximum FDA labeled dose **AND** the maximum compendia supported dose for the requested indication, **AND** there is support for therapy with a higher dose or shortened dosing interval for the requested indication (submitted copy of clinical trials, phase III studies, guidelines required)
 - c. The member has a compendia supported indication for the requested agent, **AND EITHER** of the following ("i" or "ii"):
 - i. The requested quantity (dose) does **NOT** exceed the maximum compendia supported dose 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
 - ii. The requested quantity (dose) exceeds the maximum compendia supported dose for the requested indication, **AND** there is support for therapy with a higher dose or shortened

dosing interval for the requested indication (submitted copy of clinical trials, phase III studies, guidelines required)

- d. The member does **NOT** have an FDA labeled indication **NOR** a compendia supported indication for the requested agent, **AND BOTH** of the following (“i” and “ii”):
- i. 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
 - ii. There is support for therapy with a higher dose or shortened dosing interval for the requested indication (submitted copy of clinical trials, phase III studies, guidelines required)

Compendia Allowed: AHFS, DrugDex 1 or 2a level of evidence, or NCCN 1 or 2a recommended use

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
- Patient with clinically significant hypersensitivity to brodalumab or to any of the excipients in Siliq or component of the container.

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 or by calling the SILIQ REMS Program Call Center at 855-511-6135.

- **Hypersensitivity Reactions:** Serious hypersensitivity reactions, including anaphylaxis, have been reported with postmarket use of brodalumab. Some cases required hospitalization. If a serious hypersensitivity reaction occurs, immediately discontinue brodalumab and initiate appropriate therapy.
- **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
-------	------------------------

ICD-10 Diagnosis Codes That Support Medical Necessity

L40.0	Psoriasis vulgaris
-------	--------------------

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:

NOTE: The list of biologic immunomodulator agents not permitted as concomitant therapy can be found at [Biologic Immunomodulator Agents Not Permitted as Concomitant Therapy](#).

REFERENCES:

1. Armstrong AW, Siegel MP, Bagel J, et al. From the Medical Board of the National Psoriasis Foundation: Treatment targets for plaque psoriasis. *J Am Acad Dermatol*. 2017 Feb;76(2):290-298.
2. Attia A, Abushouk AI, Ahmed H, et al. Safety and Efficacy of Brodalumab for Moderate-to-Severe Plaque Psoriasis: A Systematic Review and Meta-Analysis. *Clin Drug Investig*. 2017 Feb 14.
3. Canadian Psoriasis Guidelines Addendum Committee. 2016 Addendum to the Canadian Guidelines for the Management of Plaque Psoriasis 2009. *J Cutan Med Surg*. 2016 Sep;20(5):375-431.
4. Clinical Pharmacology powered by ClinicalKey [Internet]. Tampa, FL: Elsevier.; 2024. Available at: <https://www.clinicalkey.com/pharmacology/>. Accessed 10/29/24.
5. Dogra S, Jain A, Kanwar AJ. Efficacy and safety of acitretin in three fixed doses of 25, 35 and 50 mg in adult patients with severe plaque type psoriasis: a randomized, double blind, parallel group, dose ranging study. *J Eur Acad Dermatol Venereol*. 2012; 27:305-311.
6. Dogra S, Krishna V, Kanwar AJ. Efficacy and safety of systemic methotrexate in two fixed doses of 10 mg or 25 mg orally once weekly in adult patients with severe plaque-type psoriasis: a prospective, randomized, double-blind, dose-ranging study. *Clin Exp Dermatol*. 2012 Oct;37(7):729-34.
7. Elmets CA, Leonardi CL, Davis DM, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with awareness and attention to comorbidities. *J Am Acad Dermatol*. 2019 Apr;80(4):1073-1113. Epub 2019 Feb 13.
8. Elmets CA, Lim HW, Stoff H, et al. Joint American Academy of Dermatology–National Psoriasis Foundation guidelines of care for the management and treatment of psoriasis with phototherapy. *J Am Acad Dermatol*. Epub 2019 July 25.
9. Griffiths CEM, Armstrong AW, Gudjonsson JE, Barker JNWN. Psoriasis. *Lancet*. 2021;397(10281):1301-1315.
10. Heydendael VM, Spuls PI, Opmeer BC, et al. Methotrexate versus cyclosporine in moderate-to-severe chronic plaque psoriasis. *N Engl J Med* 2003; 349:658-65.
11. Lebwohl M, Strober B, Menter A, et al. Phase 3 studies comparing brodalumab with ustekinumab in psoriasis. *N Engl J Med* 2015; 373(14):1318-1328.
12. Kalb RE, Strober B, Weinstein G, Lebwohl M. Methotrexate and psoriasis: 2009 National Psoriasis Foundation Consensus Conference. *J Am Acad Dermatol* 2009; 60:824-37.
13. Krause ML, Amin A, and Makol A. Use of DMARDs and biologics during pregnancy and lactation in rheumatoid arthritis: what the rheumatologist needs to know. *Ther Adv Musculoskelet Dis*. 2014 Oct; 6(5): 169–184.
14. Menter A, Korman NJ, Elmets CA, Feldman SR, Gelfand JM, Gordon KB, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis: Section 4. Guidelines of care for the

management and treatment of psoriasis with traditional systemic agents. *J Am Acad Dermatol*. 2009 Sep;61(3):451-85.

15. Menter A, Korman, NJ, Elmets, CA, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis: Section 6. Guidelines of care for the treatment of psoriasis and psoriatic arthritis: Case-based presentations and evidence-based conclusions. *J Am Acad Dermatol* 2011; 65:137-74.
16. Menter A, Strober BE, Kaplan DH et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. *J Am Acad Dermatol*. 2019 Apr;80(4):1029-1072. Epub 2019 Feb 13.
17. Micromedex Healthcare Series [Internet Database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed 10/29/24.
18. Orphan Drug Designations and Approval [Internet]. Silver Spring (MD): US Food and Drug Administration; 2024 [cited 2024 Oct 29]. Available from: <http://www.accessdata.fda.gov/scripts/opdlisting/oopd/index.cfm/>.
19. Papp KA, Reich K, Paul C, et al. A prospective phase III, randomized, double-blind, placebo-controlled study of brodalumab in patients with moderate-to-severe plaque psoriasis. *Br J Dermatol* 2016; 175(2):273-286.
20. Rahimi R, Nikfar S, Rezaie A, et al. Pregnancy outcome in women with inflammatory bowel disease following exposure to 5-aminosalicylic acid drugs: a meta-analysis. *Reprod. Toxicol*; 2008;25, 271–275.
21. Sbidian E, Chaimani A, Garcia-Doval, et al. Systemic pharmacological treatments for chronic plaque psoriasis: a network meta-analysis. *Cochrane Database Syst Rev*. 2021 Apr 19;4(4):CD011535. Update in: *Cochrane Database Syst Rev*. 2022 May 23;5:CD011535.
22. Siliq (brodalumab) [prescribing information]. Valeant; Bridgewater, NJ. August 2024.
23. Smith CH, Jabbar-Lopez JK, Yiu ZZ, et al. British Association of Dermatologists guidelines for biologic therapy for psoriasis 2017. *Br J Dermatol* 2017; 177: 628-136.
24. Targan SR, Feagan B, Vermeire S, et al. A Randomized, Double-Blind, Placebo-Controlled Phase 2 Study of Brodalumab in Patients with Moderate-to-Severe Crohn's Disease. *Am J Gastroenterol*. 2016 Nov;111(11):1599-1607.

COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Pharmacy Policy Committee on 11/13/24.

GUIDELINE UPDATE INFORMATION:

06/15/17	New Medical Coverage Guideline.
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.
01/01/25	Review and revision to guideline consisting of updating the position statement, precautions, other section, and references. Adalimumab-aaty, Adalimumab-adaz, and Sotyktu added among the prerequisite therapies for PS. Update to original Table 1 which is now a link out from the Position Statement. Table titles updated. Revised wording regarding maximum dosage exceptions. New drugs were added to the list of drugs that are not permitted for use in combination.

