

## Sample Letter of Medical Necessity\*

(\*This template is intended only as an example. It should be customized with patient-specific details and any other information deemed necessary, then printed on your letterhead prior to submission to the payer.)

[Insert physician letterhead]

[Insert Date]  
[Insert Payer Name]  
[Insert Address]  
[Insert City, State, ZIP]  
[Insert Fax]

**Re: Patient Name:** [Insert Name]  
**Patient Date of Birth:** [XX/YY/ZZZZ]

**Member Number:** [Insert Member Number]  
**Group Number:** [Insert Group Number]  
**Claim Number:** [Insert Claim Number]

**REQUEST:** Authorization for treatment with SILIQ® (brodalumab)

**DIAGNOSIS:** [Insert Diagnosis] [Insert ICD]

**REQUEST TYPE:**  Standard  Expedited

Dear [Insert Medical Director's Name or Individual Responsible for Prior Authorization]

I have reviewed and recognize your guidelines of the responsible management of medications. I understand that your reason of denial is (**insert the reason for denial verbatim from the denial letter**). I am requesting that you reassess your recent denial of SILIQ (brodalumab) coverage based on the following:

### Summary of Patient's Diagnosis:

[Insert:

- Patient's diagnosis, ICD10 code, date of diagnosis
- Any relevant lab results and dates

### Summary of Patient's History:

[Insert:

- Description of patient's recent symptoms/condition, including photographs of plaques/location of plaques, if applicable
- Disease severity as measured by PASI Score and/or BSA
- Disease characteristics that may make patient difficult to treat, such as obesity, scalp psoriasis, nail psoriasis, or resistant plaques.
- Patient's TB Status: If treated, dates of treatment.
- Patient's Serious Infection Status: If patient does have an infection, please list site, treatment, and anticipated resolution dates.
- Allergies, if applicable
- Patient global assessment, physician global assessment, if applicable
- Functional status, ie, Health Assessment Questionnaire Disability Index (HAQ-DI), if applicable
- Patient co-morbidities, including those that could serve as contraindications to certain other treatments, if applicable
- Summary of your professional opinion of the patient's likely prognosis or disease progression without treatment with SILIQ®

*Note: exercise your medical judgment and discretion when providing a diagnosis and characterization of the patient's medical condition.*

### Previously Tried Medications For Plaque Psoriasis

Name	Start Date – Stop Date	Outcome of Previously Tried Therapy or Reason for Stopping Therapy

### Rationale for Treatment

[Insert summary statement for rationale for treatment such as:

Considering the patient's history, condition, and the full Prescribing Information for SILIQ®, I believe treatment with SILIQ® at this time is medically necessary and should be a covered and reimbursed service.

You may consider including documents that provide additional clinical information to support the recommendation for SILIQ® for this patient, such as the full Prescribing Information, peer-reviewed journal articles, or clinical guidelines. See below for a short list of supporting publications]

[Given the urgent nature of this request,] please provide a timely authorization. Contact my office at [Insert Phone Number] if I can provide you with any additional information.

Sincerely,

[Insert Healthcare Provider's Name and Participating Provider Number]

If this request is denied, I am requesting an expedited exception review by a professional in my specialty.

Enclosures [Include full Prescribing Information and the additional support noted above, including medical records, photos, and peer review articles, if applicable.]

**For full Prescribing Information, visit [www.siliq.com](http://www.siliq.com) or call Bausch Health Medical Information at (877) 361-2719 to request that it be faxed, emailed or mailed instead.**

**Before prescribing SILIQ, please see Boxed Warning about suicidal ideation and behavior, as well as the link to full prescribing information below.**

#### **WARNING: SUICIDAL IDEATION AND BEHAVIOR**

**Suicidal ideation and behavior, including completed suicides, have occurred in patients treated with SILIQ. Prior to prescribing SILIQ, 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 [see Warnings and Precautions in the full Prescribing Information].**

**Because of the observed suicidal behavior in subjects treated with SILIQ, SILIQ is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the SILIQ REMS Program [see Warnings and Precautions in the full Prescribing Information].**

For your convenience, below is a short list of peer-reviewed literature that you may consider including with your medical necessity letter, as supporting evidence given the appropriate patient case. The literature below describe data that is consistent with FDA required label and supplemental to the data described from pivotal phase 3 trials in the prescribing information.

#### □ Mechanism of Action

SILIQ is the only commercially available drug that is an IL-17RA blocker. SILIQ is a human monoclonal IgG2 antibody and the only treatment option that selectively binds to human IL-17RA subtype with high affinity and inhibits its interactions with cytokines IL-17A, IL-17F, IL-17C, IL-17A/F heterodimer, and IL-25 to inhibit the release of pro-inflammatory cytokines and chemokines<sup>1</sup>.

Russel et al. in a 2014 study, examined the genetic changes in 25 patients with moderate to severe plaque psoriasis who were treated with a single dose of brodalumab (n = 4, 140mg s.c.; n = 8, 350mg s.c.; n = 8, 700mg i.v.) or placebo (n = 5). Biopsies were obtained from lesional and non-lesional skin in each patient and analyzed for histology and RNA expression. Thousands of aberrantly expressed genes in lesional skin normalized within 2 weeks following brodalumab treatment, when compared to the psoriasis transcriptome seen in non-lesional skin. Keratinocyte-expressed genes appeared to normalize in 2 weeks, whereas T cell-specific normalization occurred over six weeks. The three IL-17 ligand genes that are upregulated in lesional skin, IL17A, IL17C, and IL17F, were all downregulated in a dose-dependent manner following brodalumab treatment<sup>2</sup>.

In a narrative review, Armstrong et al. discuss brodalumab's unique mechanism of action that targets the IL17 receptor, thus impacting multiple cytokines. The paper states that although multiple biologics target IL-17A are available for psoriasis treatment, patients may lack or lose response to these treatments, potentially because of the overexpression of multiple IL-17 family members and functional redundancy among IL-17 cytokines<sup>3</sup>.

Please see full articles for more information.

1. SILIQ [prescribing information]. Bridgewater, NJ: Bausch Health US, LLC.
2. Russell C B et al. *J Immunol.* 2014;192(8):3828-2836
3. Armstrong A, et al. *J Drugs Dermatol.* 2023 Oct 1;22(10):994-1000.

#### □ SILIQ Efficacy in Patients with Prior Biologic Treatment Failure

In a post-hoc analysis of two phase 3 trials from the subgroup of patients who reported failing on TNF-alpha inhibitor therapy prior to entering the study (n=150) at week 12, 63% were able to obtain a PASI 90 response, and 32% became totally clear with SILIQ<sup>3</sup>. Treatment failure was defined as either a primary (lack of efficacy) or secondary (loss of efficacy) failure or the development of an intolerance to the biologic agent<sup>4</sup>.

An open-label study evaluated the efficacy of brodalumab treatment in 39 patients at three sites who had previously failed treatment with ixekizumab (N=19; 49%) or secukinumab (N=16; 41%); failure was defined as not achieving 75% clearance after 3 months of treatment or a 50% loss of original improvement. Among those patients, at week 16, 44% were able to obtain 90% clearance with SILIQ, and 28% were able to obtain total clearance<sup>5</sup>.

In a post-hoc analysis of pooled data from two Phase 3 studies (AMAGINE-2 and AMAGINE-3) from the subgroup of patients who failed on ustekinumab and then switched to SILIQ (N=124), 58% reached PASI 90 by week 52, while 36% reached PASI 100 by week 52. Failure was defined as patients with sPGA score of 3 or greater or persistent sPGA score of 2 over a  $\geq 4$ -week period, after at least 16 weeks of treatment with ustekinumab<sup>6</sup>.

Please see full articles for more information.

4. Papp KA et al. *Br J Dermatol.* 2018;179(2):320-328.
5. Kimmel G et al. *J Am Acad. Dermatol.* 2019;81(3):857-859.
6. Langley RG et al. *Br J Dermatol.* 2019;180:255-256.

#### □ SILIQ Efficacy in Scalp Psoriasis and Nail Psoriasis

In AMAGINE-1, phase 3 clinical trial, a subgroup of patients had scalp psoriasis with PSSI  $\geq 15$  (average baseline score of 20) who received SILIQ treatment (n=82) or placebo treatment (n=95). A post-hoc analysis (NRI) showed that at week 12, 89% and 63% of patients receiving brodalumab 210 mg achieved 75% and 100% improvement from

baseline PSSI, respectively compared to 10% and 3% of patients receiving placebo. At week 12, treatment with brodalumab 210 mg had 93% mean percent improvement from baseline PSSI compared to 14% with placebo<sup>7</sup>.

In AMGINE-2 and AMAGINE-3, two phase 3 clinical trials, a subgroup of patients had a baseline NAPSI of  $\geq 6$ , received brodalumab 210 mg or Stelara every 12 weeks through week 52. A post-hoc analysis (as observed) showed that at Week 52, 64% of patients treated with SILIQ (n=69) achieved NAPSI 0, compared to 39% of patients treated with Stelara (n=87)<sup>7</sup>.

Please see full article for more information.

7. Elewski B, et al. *J Dermatolog Treat.* 2022 Feb;33(1):261-265.

#### SILIQ Efficacy in Obese and Non-obese Patients

In a post hoc analysis<sup>8</sup> of the phase 3 clinical trials (AMAGINE-2 and AMAGINE-3), patients were categorized by BMI category ( $< 30$  or  $\geq 30$  kg/m<sup>2</sup>) and efficacy was evaluated using improvement in PASI scores. Skin clearance was comparable across BMI subgroups in brodalumab-treated patients. PASI 100% improvement rates in nonobese and obese patients at week 12 were 54.1% and 49.5%, respectively, and at week 52 they were 72.6% and 64.8%, respectively. The efficacy and safety of brodalumab did not differ between patients with moderate-to-severe psoriasis who had a BMI  $< 30$  kg/m<sup>2</sup> or a BMI  $\geq 30$  kg/m<sup>2</sup>.

Please see full article for more information.

8. Hsu S. et al. *Br J Dermatol.* 2020 Apr;182(4):880-888.

#### SILIQ Recapture Data

AMAGINE-1 was a phase 3 study in which patients initially treated with brodalumab and then placebo were eligible to return to brodalumab if disease returned (sPGA $\geq 3$ ) any time after Week 16. The average time for the disease to return after stopping SILIQ was 75 days, with the median time being 56 days. Of patients that initially achieved PASI90 at Week 12 (n=71), and were randomized to placebo and retreated with brodalumab, 97% recaptured PASI90 clearance. Similarly, 95% of patients who initially achieved PASI100, recaptured complete clearance with retreatment after disease return<sup>9</sup>.

Please see full article for more information.

9. Papp KA et al. *Br J Dermatol.* 2016;175:273-286.

#### SILIQ Long-Term Data

Safety and efficacy data were pooled for patients from AMAGINE-2 and -3 who received continuous brodalumab 210mg every 2 weeks, or brodalumab 210mg every 2 weeks after receiving either brodalumab 140mg or placebo through Week 12. Based on observed data at Week 120, 86% of the continuous brodalumab 210mg group achieved PASI 90 and 74% achieved PASI 100. At Week 12, 58% of this group achieved absolute PASI  $\leq 1$ ; this proportion increased to approximately 80% at Week 52 and persisted through Week 120.

Among patients receiving continuous brodalumab 210 mg, median duration of brodalumab exposure was 747 days and the overall exposure-adjusted event rate of treatment emergent adverse events per 100 patient-years was 329. Safety through 120 weeks was comparable to the results of the primary AMAGINE-2 and -3 studies. Patients who switched to brodalumab 210 mg after receiving either brodalumab 140 mg or placebo through Week 12 showed similar skin clearance and safety profiles<sup>10</sup>.

Please see full article for more information.

10. Reich K, et al. *J Eur Acad Dermatol Venereol.* 2022 Aug;36(8):1275-1283.