Market Applicability														
Market	**DC**	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	NA

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Siliq (brodalumab)

DRUG.00077

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Siliq (brodalumab) 210 mg/1.5 mL*	2 prefilled syringes per 28 days

*Initiation of therapy for Plaque Psoriasis (Psoriasis Vulgaris): May approve up to 2 (two) additional syringes (210 mg) in the first 28 days (4 weeks) of treatment.

APPROVAL CRITERIA

I. Siliq (brodalumab) may be approved for the treatment of plaque psoriasis (psoriasis vulgaris) when each of the following criteria are met:
   A. Individual is 18 years of age or older with moderate to severe plaque psoriasis (psoriasis vulgaris) with either of the following:
      1. Plaque psoriasis (psoriasis vulgaris) involving greater than 5% body surface area (BSA); **OR**
      2. Plaque psoriasis (psoriasis vulgaris) involving less than or equal to 5% BSA involving sensitive areas or areas that significantly impact daily function (such as, palms, soles of feet, head, neck, or genitalia); **AND**
   B. Agent is used for any of the following reasons:
      1. To reduce signs or symptoms; **OR**
      2. To induce or maintain clinical response; **AND**
   C. Individual has failed to respond to, is intolerant of, or has a medical contraindication to phototherapy or other systemic therapy (such as acitretin, cyclosporine, or methotrexate);

AND

II. Individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) and inadequate response or intolerance of TWO (2) preferred biologic agents [Current preferred biologics include - (Enbrel (etanercept), Humira (adalimumab)] unless the following criteria is met:
   A. Individual has been receiving and is maintained on a stable dose of Siliq (brodalumab); **OR**

Market Applicability														
Market	**DC**	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	NA

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B. The preferred agents are not FDA-approved and do not have an accepted off-label use per the off-label policy for the prescribed indication and Siliq (brodalumab) does; **OR**
C. The preferred agents are not acceptable due to concomitant clinical conditions, such as but not limited to the following:
    1. Known hypersensitivity to any active or inactive component which is not also associated with Siliq (brodalumab); **OR**
    2. Individual's age; **OR**
    3. Pregnant or planning on becoming pregnant; **OR**
    4. Serious infections or concurrent sepsis; **OR**
D. The individual has either concomitant clinical condition:
    1. Demyelinating disease; **OR**
    2. Heart failure with documented left ventricular dysfunction; **OR**
E. The preferred agent(s) do not have activity against a concomitant clinical condition and Siliq (brodalumab) does. Examples include but may not be limited to the following:
    1. Concomitant Crohn's Disease: TNFi (agents FDA-approved for both indications) or Stelara are preferred; **OR**
    2. Concomitant Ulcerative Colitis: TNFi (agents FDA-approved for both indications) are preferred.

Siliq (brodalumab) may **not** be approved for an individual with any of the following:

A. Use of Siliq (brodalumab) in combination with other immunosuppressive therapy or phototherapy; **OR**
B. Use of Siliq (brodalumab) in combination with other biologic drugs [such as, Cimzia (certolizumab pegol), Cosentyx (secukinumab), Enbrel (etanercept), Humira (adalimumab), Remicade (infliximab), Stelara (ustekinumab), or Taltz (ixekizumab)]; **OR**
C. Tuberculosis, invasive fungal infection, other active serious infections, or a history of recurrent infections; **OR**
D. Individual has not had a tuberculin skin test (TST) or a Centers for Disease Control and Prevention (CDC)-recommended equivalent test to evaluate for latent tuberculosis prior to initiating brodalumab.

Siliq (brodalumab) may not be approved for all other conditions including, but not limited to:

A. Asthma; **OR**
B. Crohn's disease; **OR**
C. Psoriatic arthritis; **OR**
D. Rheumatoid arthritis.

Market Applicability														
Market	**DC**	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	NA

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State Specific Mandates		
State name N/A	Date effective N/A	Mandate details (including specific bill if applicable) N/A

Key References:

1. American Academy of Dermatology (AAD). American Academy of Dermatology Association (AADA). Guidelines of care for management of psoriasis and psoriatic arthritis. May 2008. Available at: http://www.aad.org/education-and-quality-care/clinical-guidelines. Accessed on February 16, 2017.
2. Centers for Disease Control (CDC) and Prevention. Updated guidelines for using interferon gamma release assays to detect Mycobacterium tuberculosis infection - United States, 2010; 59(No. RR 5):1-28. Available at: http://www.cdc.gov/mmwr/pdf/rr/rr5905.pdf. Accessed on February 16, 2017.
3. Siliq [Product Infomration]. Bridgewater, NJ. Valeant Pharmaceuticals North America, LLC, Inc.; February 15, 2017. Available at: http://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=761032. Accessed on February 16, 2017.
4. U.S. Food and Drug Administration (FDA). FDA approves new psoriasis drug (Siliq). February 15, 2017. Available at: http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm541981.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery. Accessed on February 16, 2017.
5. Siliq [Package insert]. Bridgewater, NJ. Valeant Pharmaceuticals North America LLC; 2017. Available from: http://www.accessdata.fda.gov/drugsatfda_docs/label/2017/761032lbl.pdf. Accessed on: March 3, 2017.

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.
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