BELIMUMAB - SQ

Generic	Brand	HICL	GCN	Exception/Other
BELIMUMAB	BENLYSTA		43658 43661	

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA, SEE BELOW)

1. Does the patient have a diagnosis of autoantibody positive systemic lupus erythematosus (SLE) and meet **ALL** of the following criteria?
   - The patient does **NOT** have severe active lupus nephritis or severe active central nervous system lupus
   - The medication will **NOT** be used in combination with biologics (e.g., Rituxan) or intravenous cyclophosphamide
   - The patient is currently using corticosteroids, antimalarials, NSAIDs, or immunosuppressives
   - The patient is 18 years of age or older

   If yes, **approve for 6 months by GPID for all formulations as follows:**
   - **200mg/mL autoinjector (GPID 43658): #4mL (#4 200 mg/mL autoinjectors) per 28 days**
   - **200mg/mL syringe (GPID 43661): #4mL (#4 200 mg/mL syringes) per 28 days**

   APPROVAL TEXT: Renewal requires that the patient has achieved or maintained at least a 4 point reduction in their Safety of Estrogens in Erythematosus National Assessment-Systemic Lupus Erythematosus Disease Activity Index (SELENA-SLEDAI) score from baseline.

   If no, do not approve.
   INITIAL DENIAL TEXT: The guideline named **BELIMUMAB (Benlysta SQ)** requires that the patient has a diagnosis of autoantibody positive systemic lupus erythematosus (SLE) and meets **ALL** of the following criteria:
   - The patient does **NOT** have severe active lupus nephritis or severe active central nervous system lupus
   - The medication will **NOT** be used in combination with biologics (e.g., Rituxan) or intravenous cyclophosphamide
   - The patient is currently using corticosteroids, antimalarials, nonsteroidal anti-inflammatory drugs (NSAIDs), or immunosuppressives
   - The patient is 18 years of age or older

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BELIMUMAB - SQ

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of autoantibody positive systemic lupus erythematosus (SLE) **AND** meet the following criterion?
   - The patient has achieved or maintained at least a 4 point reduction in their Safety of Estrogens in Erythematosus National Assessment-Systemic Lupus Erythematosus Disease Activity Index (SELENA-SLEDAI) score from baseline

     If yes, **approve for 12 months by GPID for all formulations as follows:**
     - **200mg/mL autoinjector (GPID 43658): #4mL (#4 200 mg/mL autoinjectors) per 28 days**
     - **200mg/mL syringe (GPID 43661): #4mL (#4 200 mg/mL syringes) per 28 days**

     If no, do not approve.
     RENEWAL DENIAL TEXT: The guidelines named **BELIMUMAB (Benlysta SQ)** requires that the patient have a diagnosis of autoantibody positive systemic lupus erythematosus (SLE) and has achieved or maintained at least a 4 point reduction in their Safety of Estrogens in Erythematosus National Assessment-Systemic Lupus Erythematosus Disease Activity Index (SELENA-SLEDAI) score from baseline for renewal.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Benlysta.

REFERENCES

- Benlysta [Prescribing Information]. Rockville, Maryland: Human Genome Sciences, Inc. April 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/19
Created: 08/17
Client Approval: 05/19
P&T Approval: 07/19