Medimpact

STANDARD COMMERCIAL DRUG FORMULARY PRIOR AUTHORIZATION GUIDELINES

BELIMUMAB - SQ

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
BELIMUMAB	BENLYSTA		43658	GPI-14	
			43661	(9942201500D520,	
				9942201500E520)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

- 1. Does the patient have a diagnosis of systemic lupus erythematosus (SLE) and meet **ALL** of the following criteria?
 - The patient is 18 years of age or older
 - Therapy is prescribed by or in consultation with a rheumatologist
 - The patient is currently using corticosteroids, antimalarials, NSAIDs, or immunosuppressives

If yes, approve for 6 months by GPID or GPI-14 for the requested product with a quantity limit of #4mL per 28 days.

If no, continue to #2.

- 2. Does the patient have a diagnosis of lupus nephritis and meet ALL of the following criteria?
 - The patient is 18 years of age or older
 - Therapy is prescribed by or in consultation with a rheumatologist or nephrologist
 - The patient is receiving standard therapy (e.g., steroids, antimalarials, NSAIDs, immunosuppressives)

If yes, approve for a total of 6 months by GPID or GPI-14 for the requested product as follows:

FIRST APPROVAL:

• 200mg/mL: Approve for 1 month with a quantity limit of #8mL per 28 days. <u>SECOND APPROVAL</u>:

• 200mg/mL: Approve for 5 months with a quantity limit of #4mL per 28 days (Please enter a start date 3 weeks after the start date of the first approval).

If no, do not approve.

DENIAL TEXT: See the initial denial text at the end of the guideline.

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BELIMUMAB - SQ

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **BELIMUMAB - SQ (Benlysta)** requires the following rule(s) be met for approval:

- A. You have ONE of the following diagnoses:
 - 1. Systemic lupus erythematosus (SLE: a type of immune condition)
 - 2. Lupus nephritis (LN: A type of immune condition that affects the kidneys)

B. If you have systemic lupus erythematosus, approval also requires:

- 1. You are 18 years of age or older
- 2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
- You are currently using corticosteroids, antimalarials (drugs that treat parasites), nonsteroidal anti-inflammatory drugs (NSAIDS), or immunosuppressives (drugs that weaken your immune system)

C. If you have lupus nephritis, approval also requires:

- 1. You are 18 years of age or older
- 2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or nephrologist (a type of kidney doctor)
- 3. You are receiving standard treatment (such as steroids, antimalarials, nonsteroidal antiinflammatory drugs (NSAIDs), or immunosuppressives (drugs that weaken your immune system)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

- 1. Does the patient have a diagnosis of systemic lupus erythematosus (SLE) **AND** meet the following criterion?
 - The patient has had clinical improvement while on Benlysta

If yes, approve for 12 months by GPID or GPI-14 for the requested product with a quantity limit of #4mL per 28 days.

If no, continue to #2.

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BELIMUMAB - SQ

RENEWAL CRITERIA (CONTINUED)

- 2. Does the patient have a diagnosis of lupus nephritis AND meet the following criterion?
 - The patient has had clinical improvement in renal response as compared to baseline laboratory values (i.e., eGFR or proteinuria) and/or clinical parameters (e.g., fluid retention, use of rescue drugs, glucocorticoid dose)

If yes, approve for 12 months by GPID or GPI-14 for the requested product with a quantity limit of #4mL per 28 days.

If no, do not approve.

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **BELIMUMAB - SQ (Benlysta)** requires the following rule(s) be met for renewal:

- A. You have ONE of the following diagnoses:
 - 1. Systemic lupus erythematosus (SLE: a type of immune condition)
 - 2. Lupus nephritis (LN: a type of immune condition that affects the kidneys)
- B. If you have systemic lupus erythematosus, renewal also requires:
 - 1. You have had clinical improvement while on Benlysta
- C. If you have lupus nephritis, renewal also requires:
 - You have had clinical improvement in renal (kidney) response as compared to baseline laboratory values (eGFR [measurement of kidney function] or proteinuria [level of protein in urine]), and/or clinical parameters (such as fluid retention, use of rescue drugs, glucocorticoid dose)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

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

REFERENCES

• Benlysta [Prescribing Information]. Philadelphia, PA: GlaxoSmithKline LLC; February 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A Commercial Effective: 05/01/23 Created: 08/17 Client Approval: 04/23

P&T Approval: 01/21

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