



STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BEROTRALSTAT

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
BEROTRALSTAT HYDROCHLORIDE	ORLADEYO	47016		GPI-10 (8584001020)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of hereditary angioedema (HAE) and meet **ALL** of the following criteria?
 - The patient is 12 years of age or older
 - The diagnosis of HAE is confirmed via documentation of complement testing
 - Orladeyo is being used for prophylaxis against HAE attacks
 - Therapy is prescribed by or in consultation with an allergist, immunologist or hematologist
 - The patient is NOT on concurrent treatment with an alternative prophylactic agent for HAE (e.g., Takhzyro, Haegarda, Cinryze, danazol)

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**

If no, do not approve.

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 **BEROTRALSTAT (Orladeyo)** requires the following rule(s) be met for approval:

- A. You have hereditary angioedema (HAE: a type of gene condition with severe body swelling)
- B. Your diagnosis is confirmed by documented complement testing (a type of blood test)
- C. You are 12 years of age or older
- D. Orladeyo is being used for prevention of hereditary angioedema attacks
- E. Therapy is prescribed by or in consultation with an allergist, immunologist (allergy or immune system doctor) or hematologist (blood doctor)
- F. You will NOT use Orladeyo concurrently (at the same time) with an alternative preventive agent for HAE (such as Takhzyro, Haegarda, Cinryze, danazol)

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.

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BEROTRALSTAT

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of hereditary angioedema (HAE) and meet **ALL** of the following criteria?
 - The patient has experienced improvement (i.e., reductions in attack frequency or attack severity) compared to baseline in HAE attacks
 - The patient is NOT on concurrent treatment with an alternative prophylactic agent for HAE (e.g., Takhzyro, Haegarda, Cinryze, danazol)

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**

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 **BEROTRALSTAT (Orladeyo)** requires the following rule(s) be met for renewal:

- A. You have hereditary angioedema (HAE: a type of gene condition with severe body swelling)
- B. You have experienced improvement (reductions in attack frequency or attack severity) compared to baseline in HAE attacks
- C. You will NOT use Orladeyo concurrently (at the same time) with an alternative preventive agent for HAE (such as Takhzyro, Haegarda, Cinryze, danazol)

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 Orladeyo.

REFERENCES

- Orladeyo [Prescribing Information]. Durham, NC: BioCryst Pharmaceuticals, Inc.; December 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 07/01/22

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P&T Approval: 04/22