



STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BUDESONIDE - ORTIKOS

| Generic | Brand | HICL | GCN | Medi-Span | Exception/Other |
|------------|---------|------|----------------|------------------------------------------------|-----------------|
| BUDESONIDE | ORTIKOS | | 46496 46497 | GPI-14 (22100012007025) (22100012007030) | |

GUIDELINES FOR USE

1. Does the patient have a diagnosis of mild to moderate active Crohn's Disease and meet **ALL** of the following criteria?
 - The patient is 8 years of age or older
 - The patient had a trial of generic budesonide 3mg capsules **OR** the patient cannot tolerate the pill burden associated with the generic product

If yes, **approve for 6 months for all strengths by GPID or GPI-14 with a quantity limit of #1 per day.**
If no, continue to #2.

2. Does the patient have a diagnosis of mild to moderate Crohn's Disease and meet **ALL** of the following criteria?
 - The patient is 18 years of age or older
 - The requested medication is being used for the maintenance of clinical remission
 - The patient had a trial of generic budesonide 3mg capsules **OR** the patient cannot tolerate the pill burden associated with the generic product

If yes, **approve for 6 months for all strengths by GPID or GPI-14 with a quantity limit of #1 per day.**
If no, do not approve.

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 **BUDESONIDE - ORTIKOS** requires the following rule(s) be met for approval:

- A. You have mild to moderate Crohn's Disease (a type of bowel disorder)
- B. **If you have mild to moderate active Crohn's Disease, approval also requires:**
 1. You are 8 years of age or older
 2. You have tried generic budesonide 3mg capsules OR you cannot tolerate the pill burden associated with the generic product

(Denial text continued on the next page)

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BUDESONIDE - ORTIKOS

GUIDELINES FOR USE (CONTINUED)

C. If you have mild to moderate Crohn's Disease, approval also requires:

1. You are 18 years of age or older
2. The requested medication is being used for the maintenance of clinical remission (signs and symptoms of disease have either improved or disappeared)
3. You have tried generic budesonide 3mg capsules OR you cannot tolerate the pill burden associated with the generic product

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 Ortikos.

REFERENCES

- Ortikos [Prescribing Information]. Cranbury, NJ: Sun Pharmaceuticals Industries, Inc. June 2019.

| | | |
|---------|------------|-----|
| Library | Commercial | NSA |
| Yes | Yes | No |

Part D Effective: N/A

Commercial Effective: 01/17/22

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P&T Approval: 10/20