| AFTNA BE | TTER HEALTH® | | ♥a | etna | | |
|---------------------------|--------------------|-----------|------------------|----------|--|--|
| Coverage Policy/Guideline | | | | | | |
| Name: | Mifepristone 300m | ng | Page: | 1 of 2 | | |
| Effective Date: 8/19/2024 | | | Last Review Date | : 7/2024 | | |
| Analica | ⊠Illinois | □Florida | ⊠Florida Kids | | | |
| Applies to: | □ New Jersey | ⊠Maryland | ⊠Michigan | | | |
| | ⊠Pennsylvania Kids | ⊠Virginia | □Texas | | | |

Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for mifepristone 300 mg under the patient's prescription drug benefit.

Description:

FDA-Approved Indication

Mifepristone 300 mg is a cortisol receptor blocker indicated to control hyperglycemia secondary to hypercortisolism in adult patients with endogenous Cushing's syndrome who have type 2 diabetes mellitus or glucose intolerance and have failed surgery or are not candidates for surgery.

Limitations of Use: Mifepristone 300 mg should not be used in the treatment of patients with type 2 diabetes unless it is secondary to Cushing's syndrome.

All other indications are considered experimental/investigational and not medically necessary.

Applicable Drug List:

Mifepristone 300mg

Policy/Guideline:

Documentation:

Submission of the following information is necessary to initiate the prior authorization review: pretreatment hemoglobin A1C level (for initial requests).

Criteria for Initial Approval:

Cushing's syndrome/disease

Authorization of 6 months may be granted for treatment of Cushing's syndrome/disease when all of the following criteria are met:

- A. Member has type 2 diabetes mellitus or glucose intolerance
- B. Mifepristone 300 mg is being prescribed to control hyperglycemia secondary to hypercortisolism
- C. Member has had surgery that was not curative OR member is not a candidate for surgery

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D. If the member is able to become pregnant, a negative pregnancy test is required before initiating therapy

Criteria for Continuation of Therapy:

Cushing's syndrome/disease

Authorization of 12 months for continuation of therapy may be granted if the member has achieved or maintained adequate positive response, or there is improvement in signs and symptoms of the condition.

Approval Duration and Quantity Restrictions:

Approval:

• Initial approval: 6 months

Renewal: 12 months

Quantity Level Limit:

Mifepristone 300 mg tablet: 120 per 30 days

References:

- 1. Korlym [package insert]. Menlo Park, CA: Corcept Therapeutics Incorporated; November 2019.
- 2. Mifepristone [package insert]. Parsippany, NJ: Teva Pharmaceuticals; February 2022.
- 3. Nieman LK, Biller BM, Findling JW, et al. Treatment of Cushing's Syndrome: An Endocrine Society Clinical Practice Guideline. *J Clin Endocrinol Metab*. 2015;100(8):2807-2831. doi:10.1210/jc.2015-1818
- Fleseriu M, Auchus R, Bancos I, et al. Consensus on Diagnosis and Management of Cushing's Disease: A Guideline Update. *Lancet Diabetes Endocrinol*. 2021;9(12):847-875. doi:10.1016/S2213-8587(21)00235-7