I. Medication Description

Mifepristone is a synthetic steroid with potent antiprogesterone and antiglucocorticoid activity. It is a selective antagonist of the progesterone receptor at low doses and blocks the glucocorticoid receptor at higher doses. It has little or no estrogenic, antiestrogenic, mineralocorticoid, or antimineralocorticoid activity. It is a derivative of the synthetic progestin norethindrone.

II. Position Statement

Coverage is determined through a prior authorization process with supporting clinical documentation for every request.

III. Policy

Coverage is provided when the following criteria are met:

- Medication is prescribed by or managed by an endocrinologist AND
- Member has been diagnosed with Cushing’s syndrome AND
- Member has type II diabetes mellitus or glucose intolerance AND
- Member is not a candidate for surgery or surgery has failed AND
- When requesting coverage of a brand medication for which an A/B rated generic is available, there is sufficient evidence that the use of the A/B rated generic equivalent has resulted in inadequate results AND
- Member has experienced intolerance or failure with one plan-preferred medication (ketoconazole or Metopirone) first OR when at least ONE of the following criteria have been met:
  - The plan-preferred medications are contraindicated or will likely cause an adverse reaction by or physical or mental harm to the member.
  - The plan-preferred medications are expected to be ineffective based on the known clinical history and conditions of the member and the member’s prescription drug regimen.
  - The member has tried the plan-preferred medications or another prescription drug in the same pharmacologic class or with the same mechanism of action and such prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event.
  - The member is stable on the medication selected by their healthcare professional for the medical condition under consideration (where “stable” is defined as receiving the medication for an adequate period of time, have achieved optimal response, and continued favorable outcomes are expected UNLESS the medication was initially selected solely due to the availability of a drug sample or a coupon card and the member does not otherwise meet the definition of “stable”).
  - The plan-preferred medication is not in the best interest of the member because it will likely cause a significant barrier to the member’s adherence or to compliance with the member’s plan of care, will likely worsen a comorbid condition of the member, or will likely decrease the member’s ability to achieve or maintain reasonable functional ability in performing daily
activities.

IV. **Quantity Limitations**

120 of the 300mg tablets are covered per month.

V. **Coverage Duration**

Coverage is granted for one year and may be renewed.

VI. **Coverage Renewal Criteria**

Coverage can be renewed based upon the following criteria:
- Stabilization of disease or in absence of disease progression **AND**
- Absence of unacceptable toxicity from the drug

VII. **Billing/Coding Information**

Available as 300mg tablets

VIII. **Summary of Policy Changes**

- 9/15/13: Moved from Abbreviated Criteria to own policy
- 9/15/14: quantity limits added to policy
- 7/1/15: formulary distinctions made
- 9/15/15: no policy changes
- 7/19/16: no policy changes
- 5/1/17: step therapy criteria added
- 6/21/17: no policy changes
- 6/15/18: no policy changes

IX. **References**


*The Plan fully expects that only appropriate and medically necessary services will be rendered. The Plan reserves the right to conduct pre-payment and post-payment reviews to assess the medical appropriateness of the above-referenced therapies.*

*The preceding policy applies only to members for whom the above named pharmacy benefit medications are included on their covered formulary. Members with closed formulary benefits are subject to trying all appropriate formulary alternatives before a coverage exception for a non-formulary medication will be considered.*

*The preceding policy is a guideline to allow for coverage of the pertinent medication/product, and is not meant to serve as a clinical practice guideline.*