I. Medication Description

Mifepristone is a synthetic steroid with potent antiprogesterone and antiglucocorticoid activity. It has no estrogenic, antiestrogenic, mineralocorticoid, or antimineralocorticoid activity. It is a derivative of the synthetic progestin norethindrone. Mifepristone is most widely known as a postcoital contraceptive agent and, when used in combination with a prostaglandin, as an abortifacient in early pregnancy.

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
- Member has experienced intolerance or failure with one plan-preferred medication (ketoconazole or metopirone) first OR the following criteria have been met:
  - 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
  - At least one of the following is 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 due to the availability of a drug sample or a coupon card).
    - 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

IX. References