Clinical Policy: Levonorgestrel/Ethinyl Estradiol with Folic Acid (Falessa Kit)
Reference Number: CP.CPA.79
Effective Date: 11.16.16
Last Review Date: 08.18
Line of Business: Commercial

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Levonorgestrel/ethinyl estradiol with folic acid (Falessa™ Kit) is a combination oral contraceptive (COC).

FDA Approved Indication(s)
Falessa Kit is indicated for the prevention of pregnancy in women who elect to use oral contraceptives as a method of contraception.

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that Falessa Kit is medically necessary when the following criteria are met:

I. Initial Approval Criteria
   A. Oral Contraception (must meet all):
      1. Failure of two generic levonorgestrel 0.1 mg and ethinyl estradiol 0.02 mg-containing products (e.g. Aubra®, Aviane®, Delyla®, Falmina®, Larissia®, Lessina®, Lutera®, Orsytia®, Sronyx®, Vienva®) unless contraindicated or clinically significant adverse effects are experienced;
      2. Dose does not exceed 1 tablet/day.
   Approval duration: Length of Benefit

   B. Other diagnoses/indications
      1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial.

II. Continued Therapy
   A. Oral Contraception (must meet all):
      1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
      2. Member is responding positively to therapy;
      3. If request is for a dose increase, new dose does not exceed 1 tablet/day.
   Approval duration: Length of Benefit
B. Other diagnoses/indications (must meet 1 or 2):
   1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
      Approval duration: Duration of request or 12 months (whichever is less); or
   2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial.

III. Diagnoses/Indications for which coverage is NOT authorized:
   A. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial.

IV. Appendices/General Information
   Appendix A: Abbreviation/Acronym Key
   COC: combination oral contraceptive
   FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

<table>
<thead>
<tr>
<th>Drug</th>
<th>Dosing Regimen</th>
<th>Maximum Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>levonorgestrel and ethinyl estradiol</td>
<td>1 tablet PO QD</td>
<td>1 tablet PO QD</td>
</tr>
<tr>
<td>(Aubra, Aviane, Delyla, Falmina, Larissia, Lessina, Lutera, Orsytia, Sronyx, Vienva)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>folic acid 1 mg</td>
<td>1 tablet PO QD</td>
<td>Varies</td>
</tr>
</tbody>
</table>

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications
Not applicable

Appendix D: General Information
- Black Box warning: cigarette smoking increases the risk of serious cardiovascular side effects from oral contraceptive use. The risk increases with age and with heavy smoking (15 or more cigarettes per day) and is quite marked in women over 35 years of age. Women who use oral contraceptives should be strongly advised not to smoke.

V. Dosage and Administration

<table>
<thead>
<tr>
<th>Indication</th>
<th>Dosing Regimen</th>
<th>Maximum Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oral Contraception</td>
<td>Day 1-21: levonorgestrel/ethinyl estradiol 0.1-0.02 mg - 1 tablet PO QD</td>
<td>1 tablet/day</td>
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</tbody>
</table>
CLINICAL POLICY
Levonorgestrel/ethinyl estradiol with folic acid

<table>
<thead>
<tr>
<th>Indication</th>
<th>Dosing Regimen</th>
<th>Maximum Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Day 22—28: 7 inactive tablets - 1 tablet PO QD</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Day 1-28: Folic acid 1 mg - 1 tablet PO QD</td>
<td></td>
</tr>
</tbody>
</table>

VI. Product Availability
Oral contraceptive tablets: Each blister card contains 28 tablets: 21 orange tablets containing 0.1 mg levonorgestrel and 0.02 mg ethinyl estradiol, followed by 7 white inert tablets
Folate tablets: Each blister card contains 28 tablets containing 1 mg folic acid

VII. References
1. Falessa Kit Prescribing Information. Atlanta, GA: Avion Pharmaceuticals, LLC; September 2014.

<table>
<thead>
<tr>
<th>Reviews, Revisions, and Approvals</th>
<th>Date</th>
<th>P&amp;T Approval Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Converted to new template. Minor changes to verbiage and grammar. References updated.</td>
<td>01.12.17</td>
<td>8.17</td>
</tr>
<tr>
<td>3Q 2018 annual review: modified redirection to more specifically require two generic levonorgestrel 0.1 mg and ethinyl estradiol 0.02 mg containing products (previously required Lessina and one additional generic contraceptive); references reviewed and updated.</td>
<td>04.11.18</td>
<td>05.18</td>
</tr>
</tbody>
</table>

Important Reminder
This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of
insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

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