Clinical Policy: Levonorgestrel/Ethinyl Estradiol with Folic Acid (Falessa Kit)
Reference Number: CP.CPA.79
Effective Date: 11.16.16
Last Review Date: 08.19
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 products containing levonorgestrel 0.1 mg and ethinyl estradiol 0.02 mg (e.g., Aubra®, Aviane®, Delyla®, Falmina®, Larissia®, Lessina®, Lutera®, Orsythia®, Sronyx®, Vienva®) unless contraindicated or clinically significant adverse effects are experienced;
      2. Dose does not exceed 1 tablet per 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 per 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 or evidence of coverage documents.

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/day</td>
</tr>
<tr>
<td>(Aubra, Aviane, Delyla, Falmina, Larissia, Lessina, Lutera, Orsythia, 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/Boxed Warnings
   • Contraindication(s): women who currently have the following conditions:
     o Thrombophlebitis or thromboembolic disorders
     o A history of deep-vein thrombophlebitis or thromboembolic disorders
     o Cerebrovascular or coronary artery disease (current or past history)
     o Valvular heart disease with thrombogenic complications
     o Thrombogenic rhythm disorders
     o Hereditary or acquired thrombophilias
     o Major surgery with prolonged immobilization
     o Diabetes with vascular involvement
     o Headaches with focal neurological symptoms
     o Uncontrolled hypertension
     o Known or suspected carcinoma of the breast or personal history of breast cancer
     o Carcinoma of the endometrium or other known or suspected estrogen-dependent neoplasia
CLINICAL POLICY
Levonorgestrel/ethinyl estradiol with folic acid

- Undiagnosed abnormal genital bleeding
- Cholestatic jaundice of pregnancy or jaundice with prior pill use
- Hepatic adenomas or carcinomas, or active liver disease
- Known or suspected pregnancy
- Hypersensitivity to any of the components of levonorgestrel and ethinyl estradiol
- Boxed warning(s): cigarette smoking increases the risk of serious cardiovascular side effects of oral contraceptive use

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>
</tr>
<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


Reviews, Revisions, and Approvals

<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>08.18</td>
</tr>
<tr>
<td>3Q 2019 annual review: no significant changes; updated Appendix C with contraindication and boxed warnings; references reviewed and updated.</td>
<td>05.06.19</td>
<td>08.19</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.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

©2017 Centene Corporation. All rights reserved. All materials are exclusively owned by Centene Corporation and are protected by United States copyright law and international copyright law. No
part of this publication may be reproduced, copied, modified, distributed, displayed, stored in a retrieval system, transmitted in any form or by any means, or otherwise published without the prior written permission of Centene Corporation. You may not alter or remove any trademark, copyright or other notice contained herein. Centene® and Centene Corporation® are registered trademarks exclusively owned by Centene Corporation.