Clinical Policy: Norethindrone Acetate/Ethinyl Estradiol/Ferrous Fumarate (Minastrin 24 Fe, Taytulla)
Reference Number: CP.CPA.282
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
Norethindrone acetate and ethinyl estradiol and ferrous fumarate (Minastrin™ 24 Fe, Taytulla®) is an estrogen/progestin combination oral contraceptive (COC).

FDA Approved Indication(s)
Minastrin 24 Fe and Taytulla are indicated for use by females of reproductive age to prevent pregnancy.

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 Minastrin 24 Fe and Taytulla are medically necessary when the following criteria are met:

I. Initial Approval Criteria
   A. Oral Contraception (must meet all):
      1. Failure of a trial of two generic norethindrone acetate/ethinyl estradiol/ferrous fumarate containing products (e.g., norethindrone acetate 1 mg/ethinyl estradiol 0.02 mg and ferrous fumarate 75 mg, Junel® Fe 24, Gildess® 24 Fe, Microgestin® 24 Fe) unless contraindicated or clinically significant adverse effects are experienced;
      2. For Minastrin 24 FE only: Documentation supports inability to swallow tablets or capsules;
      3. Dose does not exceed 1 tablet or capsule/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 or capsule/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. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.CPA.09 for commercial.

**IV. Appendices/General Information**

*Appendix A: Abbreviation/Acronym Key*
BMI: body mass index  
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>Dose Limit/Maximum Dose</th>
</tr>
</thead>
</table>
| norethindrone acetate 1 mg/ethinyl estradiol 0.02 mg and ferrous fumarate 75 mg (Junel™ Fe 24, Gildess™ 24 Fe, Microgestin™ 24 Fe) | Oral Contraceptive  
Day 1-24: 1 tablet PO QD  
Ferrous Fumarate  
Day 25-28: 1 tablet PO QD | 1 tablet/day |
| Lomeida™ 24 Fe                           | Oral Contraceptive  
Day 1-24: 1 tablet PO QD  
Ferrous Fumarate  
Day 25-28: 1 tablet PO QD | 1 tablet/day |

*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*
- Lomedia 24 Fe is the generic equivalent to Loestrin 24 Fe
- Black Box warning: cigarette smoking increases the risk of serious cardiovascular events from COC use; smoking women over 35 years old should not use.
• The efficacy of Taytulla and Minastrin 24 Fe in women with a body mass index (BMI) of more than 35 kg/m² has not been evaluated.
• Minastrin 24 Fe or Taytulla should not be prescribed to women who are known to have the following conditions:
  o A high risk of arterial or venous thrombotic diseases. Examples include women who are known to:
    ▪ Smoke, if over age 35
    ▪ Have deep vein thrombosis or pulmonary embolism, now or in the past
    ▪ Have cerebrovascular disease
    ▪ Have coronary artery disease
    ▪ Have thrombogenic valvular or thrombogenic rhythm diseases of the heart (for example, subacute bacterial endocarditis with valvular disease, or atrial fibrillation)
    ▪ Have inherited or acquired hypercoagulopathies
    ▪ Have uncontrolled hypertension
    ▪ Have diabetes mellitus with vascular disease
    ▪ Have headaches with focal neurological symptoms or have migraine headaches with aura
    ▪ All women over age 35 with migraine headache
  o Liver tumors, benign or malignant, or liver disease
  o Undiagnosed abnormal uterine bleeding
  o Pregnancy, because there is no reason to use COCs during pregnancy
  o Breast cancer or other estrogen- or progestin-sensitive cancer, now or in the past
  o Use of Hepatitis C drug combinations containing ombitasvir/paritaprevir/ritonavir, with or without dasabuvir, due to the potential for ALT elevations

V. Dosage and Administration

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Dosing Regimen</th>
<th>Maximum Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Norethindrone acetate and ethinyl estradiol and ferrous fumarate (Minastrin 24 FE, Taytulla)</td>
<td>Oral Contraceptive Day 1-24: 1 tablet or capsule PO QD Ferrous Fumarate Day 25-28: 1 tablet or capsule PO QD</td>
<td>1 tablet or capsule/day</td>
</tr>
</tbody>
</table>

VI. Product Availability

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Availability</th>
</tr>
</thead>
<tbody>
<tr>
<td>Norethindrone acetate and ethinyl estradiol and ferrous fumarate (Minastrin 24 FE)</td>
<td>Tablets (chewable): 24 each containing 1 mg norethindrone acetate and 20 mcg ethinyl estradiol, 4 each containing 75 mg ferrous fumarate</td>
</tr>
<tr>
<td>Norethindrone acetate and ethinyl estradiol and ferrous fumarate (Taytulla)</td>
<td>Capsules: 24 each containing 1 mg norethindrone acetate and 20 mcg ethinyl estradiol; 4 each containing 75 mg ferrous fumarate</td>
</tr>
</tbody>
</table>
VII. References

Reviews, Revisions, and Approvals

<table>
<thead>
<tr>
<th>Description</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>06.16.17</td>
<td>11.17</td>
</tr>
<tr>
<td>3Q 2018 annual review: modified redirection to more specifically require two norethindrone acetate/ethinyl estradiol/ferrous fumarate containing products (previously required Lomedia 24 Fe and one additional generic contraceptive); references reviewed and updated.</td>
<td>04.11.18</td>
<td>08.18</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.

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CLINICAL POLICY
Norethindrone Acetate/Ethinyl Estradiol/Ferrous Fumarate

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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.

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