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: 08.19
Line of Business: Commercial

Revision Log

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 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 [generic Loestrin® Fe, Junel® Fe 24, Gildess® 24 Fe, Microgestin® 24 Fe, Lomedia™ 24 Fe]) unless contraindicated or clinically significant adverse effects are experienced;
2. For Minastrin 24 FE: Documentation supports inability to swallow tablets or capsules;
3. Dose does not exceed 1 tablet or capsule 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 or capsule 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. 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 or evidence of coverage documents.

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.

Drug	Dosing Regimen	Dose Limit/ Maximum Dose
norethindrone acetate 1 mg/ethinyl estradiol 0.02 mg and ferrous fumarate 75 mg (Junel Fe 24, Loestrin Fe, Gildess 24 Fe, Microgestin 24 Fe, Lomedia 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/Boxed Warnings

- Contraindication(s): high risk of arterial or venous thrombotic disease; liver tumors or liver disease; undiagnosed abnormal uterine bleeding; pregnancy; breast cancer or other estrogen- or progesterone-sensitive cancer; co-administration with Hepatitis C drug combinations containing ombitasvir/paritaprevir/ritonavir, with or without dasabuvir
- Boxed warning(s): cigarette smoking and serious cardiovascular events

Appendix D: General Information

- Lomedia 24 Fe is the generic equivalent to Loestrin 24 Fe.

- The efficacy of Taytulla and Minastrin 24 Fe in women with a body mass index (BMI) of more than 35 kg/m^2 has not been evaluated.

V. Dosage and Administration

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

VI. Product Availability

Drug	Availability
Norethindrone acetate and ethinyl estradiol and ferrous fumarate (Minastrin 24 FE)	Tablets (chewable): 24 each containing 1 mg norethindrone acetate and 20 mcg ethinyl estradiol, 4 each containing 75 mg ferrous fumarate
Norethindrone acetate and ethinyl estradiol and ferrous fumarate (Taytulla)	Capsules: 24 each containing 1 mg norethindrone acetate and 20 mcg ethinyl estradiol; 4 each containing 75 mg ferrous fumarate

VII. References

1. Minastrin 24 Fe Prescribing Information. Irvine, CA: Allergan USA, Inc.; August 2017. Available at: www.minastrin24.com. Accessed May 6, 2019.
2. Taytulla Prescribing Information Irvine, CA: Allergan USA, Inc.; August 2017. Available at: www.taytulla.com. Accessed May 6, 2019.
3. Micromedex Healthcare Series [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed May 6, 2019.
4. Estrogen-Progestin Combinations. American Hospital Formulary Service Drug Information. Available at: http://www.medicinescomplete.com/mc/ahfs/current/. Accessed May 6, 2019.
5. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2018. Available at: http://www.clinicalpharmacology-ip.com/. Accessed May 6, 2019.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Converted to new template. Minor changes to verbiage and grammar. References updated.	06.16.17	11.17
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.	04.11.18	08.18
3Q 2019 annual review: no significant changes; references reviewed and updated.	05.06.19	08.19

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.

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