RXADVANCE
136 Turnpike Road
Southborough, MA 01772

Clinical Policy Title:	norethindrone acetate/ethinyl estradiol/ferrous fumarate
Policy Number:	RxA.207
Drug(s) Applied:	Minastrin® 24 Fe, Taytulla®, Gemmily™
Original Policy Date:	02/07/2020
Last Review Date:	03/09/2021
Line of Business Policy Applies to:	All lines of business

Background

Norethindrone acetate and ethinyl estradiol and ferrous fumarate (Minastrin® 24 Fe, Taytulla®, Gemmily™) is an estrogen/progestin combination oral contraceptive (COC). They are indicated for use by females of reproductive age to prevent pregnancy.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
norethindrone acetate/ ethinyl estradiol/ferrous fumarate (Minastrin® 24 Fe, Taytulla®, Gemmily™)	Indicated for use by females of reproductive age to prevent pregnancy.	Day 1-24 (NA/EE): 1 tablet or capsule PO once daily Day 25-28 (FF only): 1 tablet or capsule PO once daily	1 tablet or capsule/day

Dosage Forms

- Minastrin 24 FE® tablets (chewable): 24 tablets each containing 1 mg norethindrone acetate and 20 mcg ethinyl estradiol; 4 tablets each containing 75 mg ferrous fumarate
- Taytulla® capsules: 24 capsules each containing 1 mg norethindrone acetate and 20 mcg ethinyl estradiol; 4 capsules each containing 75 mg ferrous fumarate

Clinical Policy

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

I. Initial Approval Criteria

A. Oral Contraception (must see all):

1. Failure of two (2) preferred 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, Tarina 24 Fe®, ss® 24 Fe, Lomedia® 24 Fe]) unless contraindicated or clinically significant adverse effects are experienced;
2. For Minastrin 24 FE® and its generics: Documentation supports inability to swallow tablets or capsules;

3. Dose does not exceed 1 tablet or capsule per day.

Approval Duration
Commercial: 12 months
Medicaid: 12 months

II. Continued Therapy Approval

A. Oral contraception (must see all):

1. Member is currently receiving medication that has been authorized by RxAdvance or member has previously met initial approval criteria listed in this policy.
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
Commercial: 12 months
Medicaid: 12 months

III. Appendices

APPENDIX A: Abbreviation/Acronym Key
BMI: Body Mass Index
COC: Combination oral contraceptive
EE: Ethinyl Estradiol
FDA: Food and Drug Administration
FF: Ferrous Fumarate
NA: Norethindrone Acetate

APPENDIX B: Therapeutic Alternatives
Below are suggested therapeutic alternatives based on clinical guidance. Please check drug formulary for preferred agents and utilization management requirements.

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®, Tarina 24 Fe®, Microgestin 24 Fe® , Lomedia 24 Fe®)	Day 1-24 (NA/EE): 1 tablet PO once daily Day 25-28 (FF only): 1 tablet PO once daily	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.

References

1. Minastrin 24 Fe® Prescribing Information. Irvine, CA: Allergan USA, Inc.; August 2017. Available at: www.minastrin24.com. Accessed January 15, 2021.
2. Taytulla® Prescribing Information Irvine, CA: Allergan USA, Inc.; October 2019. Available at: www.taytulla.com. Accessed January 15, 2021.
3. Micromedex Healthcare Series [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed January 15, 2021.
4. Estrogen-Progestin Combinations. American Hospital Formulary Service Drug Information. Available at: http://www.medicinescomplete.com/mc/ahfs/current/. Accessed January 15, 2021.
5. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2018. Available at: http://www.clinicalpharmacology-ip.com/. Accessed January 15, 2021.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy was established.	01/2020	02/07/2020
Policy was reviewed: • Approval duration was updated to 12 months • Preferred alternative Gildess 24 Fe was replaced with Tarina 24 Fe • Continued Therapy criteria II.A.1 was rephrased to "Currently receiving medication that has been authorized by RxAdvance"	05/2020	05/21/2020
Policy was reviewed: 1. Clinical policy title was updated. 2. Line of Business Policy was updated. 3. Continued therapy criteria II.A.1 was rephrased to "Currently receiving medication that has been authorized by RxAdvance…". 4. References were reviewed and updated.	01/15/2021	03/09/2021