Application of pharmacy policy is determined by benefits and contracts. Benefits may vary based on product line, group, or contract. Some medications may be subject to precertification, age, gender or quantity restrictions. Individual member benefits must be verified.

This pharmacy policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety, or FDA approval may have changed. This Pharmacy Policy will be regularly updated as scientific and medical literature becomes available. This information may include new FDA-approved indications, withdrawals, or other FDA alerts. This type of information is relevant not only when considering whether this policy should be updated, but also when applying it to current requests for coverage.

Members are advised to use participating pharmacies in order to receive the highest level of benefits.

**Intent:**
The intent of this policy is to communicate the medical necessity criteria for Beyaz, Safyral, and Minastrin 24 FE as provided under the member's pharmacy benefit.

**Description:**
Combination oral contraceptives prevent pregnancy primarily by suppressing ovulation. Additional mechanisms of pregnancy prevention include changes to cervical mucus that prevent sperm penetration and endometrial changes that prevent the likelihood of uterine implantation.

Drospirenone 3 mg, ethinyl estradiol 0.02mg, levomefolate 0.451mg (Beyaz) in indicated for prevention of pregnancy, premenstrual dysphoric disorder, acne, and folate supplementation in women using an oral contraceptive in the event pregnancy occurs during product use or shortly after discontinuation.

Drospirenone 3 mg, ethinyl estradiol 0.03mg, levomefolate 0.451mg (Safyral) in indicated for prevention of pregnancy and folate supplementation in women using an oral contraceptive in the event pregnancy occurs during product use or shortly after discontinuation.

Norethindrone 1mg, ethinyl estradiol 0.02mg, and ferrous fumarate 75mg (Minastrin 24 FE) is indicated for prevention of pregnancy.

**Policy:**
Drospirenone 3 mg, ethinyl estradiol 0.02mg, levomefolate 0.451mg (Beyaz) is approved when there is inability to tolerate BOTH of the following:

A. TWO products containing drospirenone 3 mg and ethinyl estradiol 0.02mg (ie: Gianvi, Loryna, Vestura, Nikki)
B. A third generic oral contraceptive

Drospirenone 3 mg, ethinyl estradiol 0.03mg, levomefolate 0.451mg (Safyral) is approved when there is inability to tolerate BOTH of the following:

A. TWO products containing drospirenone 3 mg and ethinyl estradiol 0.03mg (ie: Ocella, Syeda, Zarah)
B. A third generic oral contraceptive

Norethindrone 1mg, ethinyl estradiol 0.02mg, and ferrous fumerate 75mg (Minastrin 24 FE) is approved when there is inability to tolerate BOTH of the following:

A. TWO products containing norethindrone 1mg, ethinyl estradiol 0.02mg, and ferrous fumerate 75mg (ie: Junel, Gildess, Larin, Microgestin)
B. A third generic oral contraceptive

¶ Black Box Warning:
Beyaz, Safyral, Minastrin 24 FE

Women over 35 who smoke should not use combination oral contraceptives

Cigarette smoking increases the risk of serious cardiovascular events from combination oral contraceptive use

¶ Guidelines:
Refer to the specific manufacturer's prescribing information for administration and dosage details and any applicable Black Box warnings.

BENEFIT APPLICATION

Subject to the terms and conditions of the applicable benefit contract, the applicable drug(s) identified in this policy is (are) covered under the pharmacy benefits of the Company's products when the medical necessity criteria listed in this pharmacy policy are met. Any services that are experimental/ investigational or cosmetic are benefit contract exclusions for all products of the Company.

¶ References:

Minastrin 24 FE (norethindrone 1mg, ethinyl estradiol 0.02mg, and ferrous fumerate 75mg) [package insert]. Parsippany, NJ. Actavis Pharma, Inc. December 2014. Available at: https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=292826e5-3f70-4fcb-b02b-a77c670aff91&type=display#section-1. Accessed December 5, 2016.

**Applicable Drugs:**

Inclusion of a drug in this table does not imply coverage. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.

<table>
<thead>
<tr>
<th>Brand name</th>
<th>Generic name</th>
</tr>
</thead>
<tbody>
<tr>
<td>Beyaz</td>
<td>Drospirone, ethinyl estradiol, levomefolate</td>
</tr>
<tr>
<td>Minastrin 24 FE</td>
<td>Norethindrone, ethinyl estradiol and ferrous fumerate</td>
</tr>
<tr>
<td>Safyral</td>
<td>Drospirone, ethinyl estradiol, levomefolate</td>
</tr>
</tbody>
</table>

**Cross References:**

N/A

**Policy Version Number:** 1.00

**P&T Approval Date:** October 13, 2016

**Policy Effective Date:** January 01, 2017

**Next Required Review Date:** October 13, 2017

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