Pharmacy Policy Bulletin

Title: New Jersey Medications with Therapeutic Alternatives

Policy #: Rx.01.199

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, quantity, or formulary restrictions (ie limits on non-preferred drugs). 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 ibuprofen/famotidine (Duexis®), naproxen/esomeprazole (Vimovo®), aspirin/omeprazole (Yosprala®), metformin modified extended release (Glumetza®), fluocinonide 0.1% cream (Vanos®), and omeprazole/sodium bicarbonate (Zegerid®) capsules as provided under the member’s prescription drug benefit.

Description:

Ibuprofen/ famotidine (Duexis®), naproxen/ esomeprazole (Vimovo®), and aspirin/ omeprazole (Yosprala®)

Fixed dose combinations (FDC) contain two or more active ingredients incorporated into a single dosage presentation (eg, tablet, capsule, patch). The value of FDCs depends upon the product, the condition being treated, and the target population for the product.

Ibuprofen/ famotidine (Duexis®) is an FDC containing 800mg of ibuprofen, a non-steroidal anti-inflammatory drug (NSAID), and 26.6 mg of famotidine, a histamine H₂-receptor antagonist (H₂RA). It is indicated for the relief of signs and symptoms of rheumatoid arthritis and osteoarthritis and to decrease the risk of developing upper gastrointestinal ulcers, which in the clinical trials was defined as a gastric and/or duodenal ulcer, in patients who are taking ibuprofen for those indications. The clinical trials primarily enrolled patients less than 65 years of age without a prior history of gastrointestinal ulcer. Controlled studies do not extend beyond 6 months.

Naproxen/ esomeprazole (Vimovo®) is an FDC containing 375mg or 500mg of naproxen, an NSAID, and 20mg of esomeprazole, a proton pump inhibitor (PPI). It is indicated for the relief of signs and symptoms of osteoarthritis, rheumatoid arthritis and ankylosing spondylitis and to decrease the risk of developing gastric ulcers in patients at risk of developing NSAID-associated gastric ulcers. Naproxen/ esomeprazole (Vimovo®) is not recommended for initial treatment of acute pain because the absorption of naproxen is delayed compared to absorption from other naproxen-containing products. Controlled studies do not extend beyond 6 months.

Aspirin/ omeprazole (Yosprala®) is an FDC containing 81mg or 325mg of aspirin, an antiplatelet and 40mg of omeprazole, a PPI. It is indicated for patients who require aspirin for secondary prevention of cardiovascular and cerebrovascular events and who are at risk of developing aspirin associated gastric ulcers. Controlled studies do not extend beyond 6 months.

These FDCs offer no clinical advantage over the individual components. There are several formulary alternatives available.
**Metformin modified extended release (Glumetza®)**

Metformin is a biguanide that improves glucose tolerance in patients with type 2 diabetes mellitus (T2DM), lowering basal and postprandial plasma glucose. Metformin decreases hepatic glucose production, decreases intestinal absorption of glucose, and improves insulin sensitivity by increasing peripheral glucose uptake and utilization. Metformin does not produce hypoglycemia in patients with T2DM or in healthy subjects except in special circumstances and does not cause hyperinsulinemia. With metformin therapy, insulin secretion remains unchanged, while fasting insulin levels and day-long plasma insulin response may actually decrease.

**Omeprazole/ sodium bicarbonate (Zegerid®)**

Proton Pump Inhibitors (PPIs) suppress gastric acid secretion by inhibiting hydrogen-potassium adenosinetriphosphatase (H⁺/K⁺ ATPase) on the surface of parietal cells, the final step in acid secretion. PPIs are the most potent gastric acid suppression agents and are most effective when the parietal cells are stimulated to produce acid post-prandially.

PPIs are useful in treating peptic ulcer disease (including prevention and treatment of NSAID induced gastric ulcers), gastroesophageal reflux disease (GERD) with and without esophageal erosions, hypersecretory diseases, and helicobacter pylori infections (as part of an antibiotic containing regimen).

**Fluocinonide 0.1% cream (Vanos®)** is a super high potency topical corticosteroid indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid responsive dermatoses in patients 12 years of age or older.

**Policy:**

**Ibuprofen/ famotidine (Duexis®), naproxen/ esomeprazole (Vimovo®), or aspirin/ omeprazole (Yosprala)** is approved when there is an inadequate response or inability to tolerate a TWO week trial of BOTH of the following:

1. Concurrent administration of each of the components of the requested product; and
2. At least FOUR generic alternatives (when available) of each of the individual components of the requested product

<table>
<thead>
<tr>
<th>Drug</th>
<th>Components</th>
<th>Generic alternative(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Duexis®</td>
<td>ibuprofen</td>
<td>Eg celecoxib, diclofenac, etodolac, meloxicam, naproxen</td>
</tr>
<tr>
<td></td>
<td>famotidine</td>
<td>Eg Cimetidine, nizatidine, ranitidine</td>
</tr>
<tr>
<td>Vimovo®</td>
<td>naproxen</td>
<td>Eg celecoxib, diclofenac, etodolac, ibuprofen, meloxicam</td>
</tr>
<tr>
<td></td>
<td>esomeprazole</td>
<td>Eg pantoprazole, omeprazole, rabeprazole</td>
</tr>
<tr>
<td>Yosprala®</td>
<td>aspirin</td>
<td>NA</td>
</tr>
<tr>
<td></td>
<td>omeprazole</td>
<td>Eg pantoprazole, rabeprazole, lansoprazole</td>
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</table>

**Metformin modified extended release (Glumetza®)** is approved when there is inadequate response or inability to tolerate BOTH of the following:

A. Two generic forms of extended release metformin; and
B. Glucophage XR

**Omeprazole/sodium bicarbonate 40mg-1.1g (Zegerid®)** capsules are approved when there is documentation of BOTH of the following:

A. An FDA or compendia approved indication; and
B. Inadequate response to a two-week trial or inability to tolerate THREE of the following generic proton pump inhibitors:

1. omeprazole
2. lansoprazole
3. pantoprazole
4. rabeprazole

Quantity limit: 2 capsules per day; 60 capsules per 30 days

Zegerid® increased quantity limits are approved when ONE of the following is met:

A. Pathological hypersecretory condition including Zollinger-Ellison syndrome; or
B. Barrett's esophagus; or
C. Upper gastrointestinal bleed (gastric or duodenal); or
D. Failure of once daily proton pump inhibitor therapy with ONE of the following:
   1. Gastroesophageal reflux disease (GERD) with nocturnal symptoms
   2. GERD or erosive esophagitis for member less than 11 years old
   3. Laryngopharyngeal reflux
   4. Treatment for the eradication of H pylori with triple therapy (duration of therapy will be limited to 14 days)

Fluocinonide 0.1% cream (Vanos®) is approved when documentation is provided of ALL of the following:

A. Diagnosis of the relief of inflammatory and pruritic manifestations of corticosteroid response dermatoses
B. Age 12 years or older
C. Documentation of an inadequate response or inability to tolerate THREE class-1 superpotent topical steroids (e.g clobetasol propionate, augmented betamethasone, halobetasol)

****Applies to AmeriHealth Insurance Company of New Jersey and AmeriHealth HMO Inc (New Jersey)****

Black Box Warning as shown in the drug Prescribing Information:

NSAIDs (ibuprofen, naproxen)

Cardiovascular Risk: NSAIDs may cause an increased risk of serious cardiovascular thrombotic events, myocardial infarction, and stroke, which can be fatal. This risk may increase with duration of use. Patients with cardiovascular disease or risk factors for cardiovascular disease may be at greater risk.

NSAIDs are contraindicated for treatment of perioperative pain in the setting of coronary artery bypass graft (CABG) surgery.

Gastrointestinal Risk: NSAIDs cause an increased risk of serious gastrointestinal adverse reactions including bleeding, ulceration, and perforation of the stomach or intestines, which can be fatal. These reactions can occur at any time during use and without warning symptoms. Elderly patients are at greater risk for serious gastrointestinal events.

Metformin (Glumetza®)

Lactic acidosis is a rare, but serious, complication that can occur because of metformin accumulation. The risk increases with conditions such as renal impairment, sepsis, dehydration, excess alcohol intake, hepatic impairment, and acute congestive heart failure.

The onset is often subtle, accompanied only by nonspecific symptoms such as malaise, myalgias, respiratory distress, increasing somnolence, and nonspecific abdominal distress.

Laboratory abnormalities include low pH, increased anion gap, and elevated blood lactate. If acidosis is suspected, discontinue metformin containing agent and immediately hospitalize the patient.
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 prescription drug 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:


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>
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<tbody>
<tr>
<td>Duexis®</td>
<td>Ibuprofen/ famotidine</td>
</tr>
<tr>
<td>Vimovo®</td>
<td>Naproxen/ esomeprazole</td>
</tr>
<tr>
<td>Yosprala®</td>
<td>Aspirin/ omeprazole</td>
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<tr>
<td>Glumetza®</td>
<td>Metformin, modified extended release</td>
</tr>
<tr>
<td>Zegerid® caps</td>
<td>Omeprazole/ sodium bicarbonate</td>
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### Cross References:
Off-Label Use policy Rx.01.33

<table>
<thead>
<tr>
<th>Policy Version Number:</th>
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<tbody>
<tr>
<td>P&amp;T Approval Date:</td>
<td>October 10, 2019</td>
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<tr>
<td>Policy Effective Date:</td>
<td>January 1, 2020</td>
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<tr>
<td>Next Required Review Date:</td>
<td>October 10, 2020</td>
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The Policy Bulletins on this web site were developed to assist the Company in administering the provisions of the respective benefit programs, and do not constitute a contract. If you have coverage through the Company, please refer to your specific benefit program for the terms, conditions, limitations and exclusions of your coverage. Company does not provide health care services, medical advice or treatment, or guarantee the outcome or results of any medical services/treatments. The facility and professional providers are responsible for providing medical advice and treatment. Facility and professional providers are independent contractors and are not employees or agents of the Company. If you have a specific medical condition, please consult with your doctor. The Company reserves the right at any time to change or update its Policy Bulletins.