

Clinical Pharmacy Program Guidelines for Duexis and Vimovo

Program	Prior Authorization
Medication	Duexis (ibuprofen/famotidine) tablets Vimovo (naproxen/esomeprazole) delayed-release tablets
Markets in Scope	Arizona, California, Florida-CHIP, Hawaii, Maryland, Nevada, New Jersey, New York, New York EPP, Ohio, Pennsylvania, Rhode Island
Issue Date	4/2019
Pharmacy and Therapeutics Approval Date	4/2019
Effective Date	6/2019

1. Background:

Duexis, a combination of a nonsteroidal anti-inflammatory drug (NSAID) ibuprofen and the histamine H₂-receptor antagonist famotidine, is indicated for the relief of signs and symptoms of rheumatoid arthritis and osteoarthritis and to decrease the risk of developing upper gastrointestinal ulcers.

Vimovo, a combination of an NSAID naproxen and the proton pump inhibitor (PPI) esomeprazole magnesium, is indicated for symptomatic relief of arthritis and to decrease the risk of developing naproxen associated gastric ulcers.

2. Coverage Criteria:

<p>A. Duexis will be approved based on <u>all</u> of the following criteria:</p> <ol style="list-style-type: none"> 1. <u>One</u> of the following risk factors for NSAID-induced adverse GI events: <ol style="list-style-type: none"> a. Patient is greater than or equal to 65 years of age b. Prior history of peptic, gastric, or duodenal ulcer c. History of NSAID-related ulcer d. History of clinically significant GI bleeding e. Untreated or active <i>H. Pylori</i> gastritis f. Concurrent use of oral corticosteroids (eg, prednisone, prednisolone, dexamethasone) g. Concurrent use of anticoagulants (eg, warfarin, heparin) h. Concurrent use of antiplatelets (eg, aspirin including low-dose, clopidogrel)
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-AND-

2. Documentation of history of failure, contraindication, or intolerance to **three** combinations of preferred NSAIDS taken with preferred H2-receptor antagonists. (Provide name and date preferred products were tried)

-AND-

3. Physician has provided rationale for needing to use fixed-dose combination therapy with Duexis instead of taking individual products in combination.

Authorization will be issued for 12 months.

B. Vimovo will be approved based on all of the following criteria:

1. **One** of the following risk factors for NSAID-induced adverse GI events:
 - a. Patient is greater than or equal to 65 years of age
 - b. Prior history of peptic, gastric, or duodenal ulcer
 - c. History of NSAID-related ulcer
 - d. History of clinically significant GI bleeding
 - e. Untreated or active *H. Pylori* gastritis
 - f. Concurrent use of oral corticosteroids (eg, prednisone, prednisolone, dexamethasone)
 - g. Concurrent use of anticoagulants (eg, warfarin, heparin)
 - h. Concurrent use of antiplatelets (eg, aspirin including low-dose, clopidogrel)

-AND-

2. Documentation of history of failure, contraindication, or intolerance to **three** combinations of preferred NSAIDS taken with preferred proton pump inhibitors. (Provide name and date preferred products were tried)

-AND-

3. Physician has provided rationale for needing to use fixed-dose combination therapy with Vimovo instead of taking individual products in combination.

Authorization will be issued for 12 months.

3. References:

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1. Duexis package insert. Horizon Pharma USA, Inc.; Lake Forest, IL. June 2017.
2. Vimovo package insert. Horizon Pharma USA, Inc.; Lake Forest, IL. June 2018.
3. Lanza FL, Chan FK, Quigley EM, et al. Guidelines for prevention of NSAID-related ulcer complications. *Am J Gastroenterol.* 2009; 104(3):728-38.

Program	Prior Authorization- Duexis and Vimovo
Change Control	
Date	Change
4/2019	New policy