Harvard Pilgrim Health Care | TUFTS Health Plan

Pharmacy Medical Necessity Guidelines:
NSAID Combinations

Effective: August 11, 2026

Guideline Type	☒ Prior Authorization ☐ Non-Formulary ☐ Step-Therapy ☐ Administrative

Applies to:

Commercial Products

☒ Harvard Pilgrim Health Care Commercial products; Fax: 617-673-0988

☒ Tufts Health Plan Commercial products; Fax: 617-673-0988

Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax: 617-673-0988

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Food and Drug Administration – Approved Indications

Duexis (famotidine and ibuprofen), a combination of the 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, 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.

Yosprala (aspirin and omeprazole), a combination of aspirin and omeprazole, 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.

Vimovo (naproxen and esomeprazole), a combination of naproxen and esomeprazole magnesium, is indicated in adult and adolescent patients 12 years of age and older weighing at least 38 kg, requiring naproxen for symptomatic relief of arthritis and esomeprazole magnesium to decrease the risk for developing naproxen-associated gastric ulcers.

Clinical Guideline Coverage Criteria

The plan may authorize coverage of the following NSAID combination products when the following criteria are met:

Famotidine/ibuprofen tablet (generic for Duexis)

1. Documentation that member is using this agent for relief of signs and symptoms of osteoarthritis or rheumatoid arthritis
   AND
2. Member is at risk of developing NSAID associated gastric ulcers
   AND
3. Member has tried and failed therapy with taking the individual components (famotidine and ibuprofen) concurrently, or the provider indicates clinical inappropriateness of treatment with the individual ingredients used together
   AND
4. Documentation of treatment failure or contraindication to another generic H2 antagonists (e.g., cimetidine) in combination with two different NSAIDs (e.g., naproxen, meloxicam)

Aspirin/omeprazole tablet (generic for Yosprala)

1. Documentation that medication is used for secondary prevention of cardiovascular or cerebrovascular events
   AND
2. Documentation that the member is at risk of developing aspirin associated gastric ulcers
   AND
3. Member has tried and failed concurrent therapy with aspirin and omeprazole, or the provider indicates clinical inappropriateness of treatment with the individual ingredients used together
   AND

4. Documentation of treatment failure or contraindication to two generic PPIs (e.g., esomeprazole, pantoprazole, lansoprazole) in combination with aspirin

Naproxen/esomeprazole tablet (generic for Vimovo)

1. Documentation that member is using this agent for relief of signs and symptoms of osteoarthritis, rheumatoid arthritis, or ankylosing spondylitis

AND

2. Member is at risk of developing NSAID associated gastric ulcers

AND

3. Member has tried and failed therapy with taking the individual components (naproxen and esomeprazole) concurrently, or the provider indicates clinical inappropriateness of treatment with the individual ingredients used together

AND

4. Documentation of treatment failure or contraindication to two generic PPIs (e.g., omeprazole, pantoprazole, lansoprazole) in combination with two different NSAIDs (e.g., ibuprofen, meloxicam)

Limitations

1. Duration of approval for Naproxen/esomeprazole tablet and Famotidine/ibuprofen tablet is limited to 6 months.
2. For a non-formulary medication request, please refer to the Pharmacy Medical Necessity Guidelines for Formulary Exceptions and submit a formulary exception request to the plan as indicated.

Codes

None

References

1. Duexis (famotidine and ibuprofen) [package insert]. Deerfield, IL: Horizon Therapeutics USA, Inc. November 2024.
2. Yosprala (aspirin and omeprazole) [package insert]. Allentown, PA: Genus Lifesciences Inc. November 2024.
3. Vimovo (naproxen and esomeprazole magnesium) [package insert]. Deerfield, IL: Horizon Therapeutics USA, Inc. November 2024.

Approval And Revision History

September 13, 2022: Reviewed by the Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

- August 8, 2023: No change.
- August 13, 2024: No change.
- August 12, 2025: Administrative update to add limitation statement for non-formulary medication request.
- August 11, 2026: Administrative update to remove Carelink from Medical Necessity Guideline template.

Background, Product and Disclaimer Information

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member’s benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.