Reference number(s)
2730-A

Prior Authorization Criteria
Duexis-Vimovo

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Duexis	ibuprofen/famotidine
Vimovo	naproxen/esomeprazole

Indications

FDA-approved Indications

Duexis

Duexis, 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. Controlled trials do not extend beyond 6 months.

Vimovo

Vimovo, 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.

The naproxen component of Vimovo is indicated for relief of signs and symptoms of:

- osteoarthritis, rheumatoid arthritis, and ankylosing spondylitis in adults.

- juvenile idiopathic arthritis (JIA) in adolescent patients.

The esomeprazole magnesium component of Vimovo is indicated to decrease the risk of developing naproxen-associated gastric ulcers.

Limitations of Use:

- Do not substitute Vimovo with the single-ingredient products of naproxen and esomeprazole magnesium.
- 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.

Coverage Criteria

Ankylosing Spondylitis, Juvenile Idiopathic Arthritis

Authorization may be granted when the requested drug is being prescribed for the treatment of ankylosing spondylitis or juvenile idiopathic arthritis when ALL of the following criteria are met:

- The request is for Vimovo (naproxen/esomeprazole).
- The patient tried a non-steroidal anti-inflammatory drug (NSAID) taken with separate 30 day trials of THREE different acid blockers from ANY of the following classes: H2-receptor antagonist (H2RA), proton pump inhibitor (PPI). [ACTION REQUIRED: Documentation is required for approval.]
- The patient has tried the two individual components of the requested drug taken together for a minimum of 30 days [i.e., (ibuprofen plus famotidine) or (naproxen plus esomeprazole)].

Osteoarthritis, Rheumatoid Arthritis

Authorization may be granted when the requested drug is being prescribed for the treatment of osteoarthritis or rheumatoid arthritis to decrease the risk of developing gastrointestinal ulcers when ALL of the following criteria are met:

- The patient tried a non-steroidal anti-inflammatory drug (NSAID) taken with separate 30 day trials of THREE different acid blockers from ANY of the following classes: H2-receptor antagonist (H2RA), proton pump inhibitor (PPI). [ACTION REQUIRED: Documentation is required for approval.]
- The patient has tried the two individual components of the requested drug taken together for a minimum of 30 days [i.e., (ibuprofen plus famotidine) or (naproxen plus esomeprazole)].

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Duration of Approval (DOA)

- 2730-A: DOA: 12 months

References

1. Duexis [package insert]. Deerfield, IL: Horizon Medicines LLC; November 2024.
2. Vimovo [package insert]. Deerfield, IL: Horizon Medicines LLC; November 2024.
3. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2025. https://online.lexi.com. Accessed February 05, 2025.
4. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: https://www.micromedexsolutions.com/ (cited: 02/05/2025).
5. Lanza FL, Chan FKL, Quigley EM, et al. Guidelines for Prevention of NSAID-Related Ulcer Complications. Am J Gastroenterol 2009; 104:728-738.

Document History

Written by: UM Development (ME)

Date Written: 09/2018

Revised: (CF) 09/2019 (no clinical changes), (ME) 09/2020 (documentation requirement added), 01/2021 (no clinical changes); (PM) 02/2022 (no clinical changes); (DRS) 06/2022 (created new Ref# for BOG Strategy for Brand only Duexis), (VLS) 03/2023 (no clinical changes); (KEJ) 03/2024 (removed BOG due to retirement, updated document title), 03/2024 (annual review – no clinical changes); (NSS) 02/2025 (no clinical changes)

Reviewed: Medical Affairs: (AN) 10/2018; (CHART) 9/26/2019, (CHART) 9/24/20, (CHART) 01/28/2021, 02/03/2022, 06/30/2022, 03/28/2024, 03/27/2025

External Review: 12/2018, 12/2019, 12/2020, 06/2021, 08/2022 (FYI), 06/2023, 03/2024 (FYI), 06/2024, 06/2025

CRITERIA FOR APPROVAL

1 Which drug is being requested? Please check the drug being requested.

[] Duexis (If checked, go to 3)

[] Vimovo (If checked, go to 2)

2	Is Vimovo (naproxen/esomeprazole) being prescribed for the treatment of ankylosing spondylitis or juvenile idiopathic arthritis and to decrease the risk of developing gastrointestinal ulcers? [If Yes, then go to 4. If No, then go to 3.]	Yes	No
3	Is the requested drug being prescribed for the treatment of osteoarthritis or rheumatoid arthritis and to decrease the risk of developing gastrointestinal ulcers? [If Yes, then go to 4. If No, then no further questions.]	Yes	No
4	Has the patient tried a non-steroidal anti-inflammatory drug (NSAID) taken with separate 30 day trials of THREE different acid blockers from ANY of the following classes: A) H2-receptor antagonist (H2RA), B) proton pump inhibitor (PPI)? ACTION REQUIRED: If yes, then documentation is required for approval. Document the drug names (one NSAID and three acid blockers): _____ [If Yes, then go to 5. If No, then no further questions.]	Yes	No
5	Has documentation of the patient's previous drug trials, including the drug names (one NSAID and three acid blockers) been submitted to CVS Health? [If Yes, then go to 6. If No, then no further questions.]	Yes	No
6	Has the patient tried the two individual components of the requested drug taken together for a minimum of 30 days [i.e., (ibuprofen plus famotidine) or (naproxen plus esomeprazole)]? [No further questions]	Yes	No

Mapping Instructions			
	Yes	**No**	**DENIAL REASONS**
1.	1=3 ;2=2		
2.	Go to 4	Go to 3	
3.	Go to 4	Deny	Your plan only covers this drug when it is used for certain health conditions. Covered uses are to lower the risk of developing gastrointestinal ulcers when you have osteoarthritis or rheumatoid

			arthritis, or the request is for Vimovo (naproxen/esomeprazole), and you have ankylosing spondylitis or juvenile idiopathic arthritis. Your plan does not cover this drug for your health condition that your doctor told us you have. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Diagnosis]
4.	Go to 5	Deny	Your plan only covers this drug if you have tried a non-steroidal anti-inflammatory (NSAID) drug taken with three different acid blockers for 30 days each and they did not work well for you. We have denied your request because you have not tried it. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Step therapy - NSAID with three acid blockers]
5.	Go to 6	Deny	Your plan only covers this drug when records with your previous drug trials are sent to us. Your records must be provided and must show what your doctor tells us. We denied your request because we did not receive your records. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Documentation]
6.	Approve, 12 Months	Deny	Your plan only covers this drug if you have tried the individual drugs (ibuprofen plus famotidine) or (naproxen plus esomeprazole) together for 30 days and it did not work well for you. We have denied your request because you have not tried it. We reviewed

			the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Step therapy - individual components]