Duexis

Description

Duexis (ibuprofen and famotidine)

Background

Duexis is a fixed-combination product of ibuprofen and famotidine used to relieve signs and symptoms of osteoarthritis and rheumatoid arthritis and to decrease the risk of developing upper gastrointestinal ulcers. Ibuprofen is a nonsteroidal anti-inflammatory drug (NSAID) with pain relieving and fever reducing effects. Famotidine is a competitive inhibitor of histamine H$_2$-receptors that suppresses gastric acid secretion (1).

Regulatory Status

FDA-approved indication: Duexis, a combination of the NSAID ibuprofen and the histamine H$_2$-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 (1).

Duexis carries boxed warnings of both a cardiovascular and gastrointestinal risk. The non-steroidal anti-inflammatory ingredient, ibuprofen, may cause an increased risk of serious cardiovascular thrombotic events, myocardial infarction (MI), 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 a greater risk (1).

Nonsteroidal anti-inflammatory drugs (NSAIDs), including ibuprofen, cause an increased risk of serious GI adverse events, including bleeding, ulceration, and perforation of the stomach or
intestines, which can be fatal. Patients receiving Duexis who may be adversely affected by alterations in platelet function, such as those with coagulation disorders or patients receiving anticoagulants or antiplatelets, should be carefully monitored (1).

Duexis is contraindicated for the treatment of perioperative pain in the setting of coronary artery bypass graft surgery (CABG) (1).

Duexis should be avoided in patients with severe hepatic impairment or advanced renal disease due to an increased risk of renal failure or bleeding with ibuprofen. When active and clinically significant bleeding from any source occurs in patients receiving Duexis, the treatment should be withdrawn (1).

The safety and efficacy of Duexis has not been established in children younger than 18 years (1).

Related policies
Vimovo

Policy
This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Duexis may be considered medically necessary in patients 18 years and older for the relief of signs and symptoms of osteoarthritis and rheumatoid arthritis, in patients with a risk of NSAID-associated gastric ulcers and inadequate treatment response, intolerance, or contraindication to the use ibuprofen and famotidine separately or a prescription strength NSAID and H2-blocker.

Duexis may be considered investigational in patients under the age of 18 years, for acute pain or for all other indications.

Prior-Approval Requirements
Age 18 years of age or older

Diagnoses

Patient must have ONE of the following:

1. Osteoarthritis
2. Rheumatoid arthritis
AND the following:
   1. At risk for the development of NSAID-associated gastric ulcers

AND ONE of the following:
   1. Inadequate treatment response, intolerance, or contraindication to use ibuprofen and famotidine separately 
      OR
   2. Inadequate treatment response, intolerance, or contraindication to a prescription strength NSAID and H₂-blocker

Prior – Approval Renewal Requirements
Diagnoses

Patient must have ONE of the following:

   1. Osteoarthritis
   2. Rheumatoid arthritis

AND the following:
   1. At risk for the development of NSAID-associated gastric ulcers

Policy Guidelines
Pre - PA Allowance
None

Prior - Approval Limits
Quantity  270 quantity every 90 days
Duration  12 months

Prior – Approval Renewal Limits
Quantity  270 quantity every 90 days
Duration  12 months

Rationale
Summary
Duexis is a fixed-combination product of ibuprofen and famotidine used to relieve signs and symptoms of osteoarthritis and rheumatoid arthritis and to decrease the risk of developing upper gastrointestinal ulcers. Duexis carries boxed warnings of both a cardiovascular and gastrointestinal risk (1).

Prior approval is required to ensure the safe, clinically appropriate and cost effective use of Duexis while maintaining optimal therapeutic outcomes.

References

Policy History

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<th>Date</th>
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<tbody>
<tr>
<td>July 2015</td>
<td>Addition of Duexis to PA</td>
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<tr>
<td>September 2015</td>
<td>Annual review</td>
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<tr>
<td>March 2016</td>
<td>Annual review</td>
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<td>Policy number changed from 5.02.42 to 5.70.42</td>
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Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 18, 2016 and is effective April 1, 2016.

Deborah M. Smith, MD, MPH