



## Commercial/Healthcare Exchange PA Criteria

*Effective: March, 2008*

### **Prior Authorization:**

Arthrotec (diclofenac sodium/misoprostol)  
Qmiiz ODT (meloxicam)  
Relafen DS (nabumetone)  
Tivorbex (indomethacin)  
Vivlodex (meloxicam)  
Zipsor (diclofenac potassium liquid-filled capsules)  
Zorvolex (diclofenac capsules)

### **Products Affected:**

Arthrotec (diclofenac sodium/misoprostol) oral tablets  
Qmiiz ODT (meloxicam) orally disintegrating tablets  
Relafen DS (nabumetone)  
Tivorbex (indomethacin) oral capsules  
Vivlodex (meloxicam) oral capsules  
Zipsor (diclofenac potassium liquid-filled capsules)  
Zorvolex (diclofenac) oral capsules

### **Medication Description:**

- Arthrotec is a combination nonsteroidal anti-inflammatory and prostaglandin E1 analog drug indicated for the treatment of signs and symptoms of osteoarthritis (OA) or rheumatoid arthritis (RA) in patients at high risk of developing NSAID-induced gastric and duodenal ulcers and their complications.
- Qmiiz ODT is a nonsteroidal anti-inflammatory drug indicated for the treatment of Osteoarthritis in adults, Rheumatoid Arthritis in adults, and Juvenile Rheumatoid Arthritis (JRA) Pauciarticular and Polyarticular Course, in pediatric patients who weigh greater than or equal to 60 kg.
- Relafen DS is a nonsteroidal anti-inflammatory drug indicated for relief of signs and symptoms of osteoarthritis and rheumatoid arthritis.
- Tivorbex and Zipsor are both nonsteroidal anti-inflammatory drugs indicated for treatment of mild to moderate acute pain in adults.
- Vivlodex is a nonsteroidal anti-inflammatory drug indicated for management of osteoarthritis (OA) pain.

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- Zorvolex is a nonsteroidal anti-inflammatory drug indicated for the management of mild to moderate acute pain and for the management of osteoarthritis pain.

**Covered Uses:**

1. Mild to moderate acute pain in adults
2. Osteoarthritis (OA) in adults
3. Rheumatoid arthritis (RA) in adults
4. Juvenile Rheumatoid Arthritis (JRA)

**Age Restrictions:**

Arthrotec: age 65 and older

**Prescriber Restrictions:** N/A

**Other Criteria:**

ConnectiCare will consider **Arthrotec** to be medically necessary in patients who meet at least one of the following:

- A. Arthrotec utilization on prescription history in previous 180 days; **OR**
- B. Member is 65 years of age or older; **OR**
- C. Two non-steroidal anti-inflammatory drugs (not including over-the-counter agents and samples) within previous 180 days (based on prescription claims history); **OR**
- D. History of therapy with proton pump inhibitor or H2 antagonist within previous 90 days; **OR**
- E. History of 45 day supply or more of oral / Injectable corticosteroid within previous 180 days documentation required; **OR**
- F. Previous history of perforations, ulceration, or gastrointestinal bleed, or platelet or clotting disorders documentation required.

ConnectiCare will consider **Qmiiz ODT** to be medically necessary in patients who meet the following criteria (A and B):

- A. Patient has had an intolerance to, or treatment failure to both of the following:
  - i. Meloxicam tablets; **AND**
  - ii. A prescription-strength non-steroidal anti-inflammatory drug (NSAID)
- B. Patient is unable to swallow, has dysphagia, esophagitis, or mucositis.

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ConnectiCare considers Relafen DS to be medically necessary when the following criteria are met (A and B):

- A. Patient has a documented intolerance to, or treatment failure of an adequate trial of generic nabumetone tablets;  
**AND**
- B. Patient has a documented intolerance to, or treatment failure of an adequate trial of one other generic prescription strength non-steroidal anti-inflammatory drugs (NSAID) within previous 180 days

ConnectiCare considers **Tivorbex** medically necessary when the following criteria is met (A and B):

- A. Patient has a documented intolerance to, or treatment failure of an adequate trial of generic indomethacin tablets;  
**AND**
- B. Patient has a documented intolerance to, or treatment failure of an adequate trial of one other generic prescription strength non-steroidal anti-inflammatory drugs (NSAID) within previous 180 days

ConnectiCare will consider **Vivlodex** to be medically necessary in patients who meet the following criteria:

- A. Patient has had an intolerance to, or treatment failure to both of the following:
  - i. Meloxicam tablets; **AND**
  - ii. A prescription-strength non-steroidal anti-inflammatory drug (NSAID)

ConnectiCare considers **Zipsor and Zorvolex** medically necessary when the following criteria are met (A and B):

- A. Patient has a documented intolerance to, or treatment failure of an adequate trial of generic diclofenac tablets;  
**AND**
- B. Patient has a documented intolerance to, or treatment failure of an adequate trial of one other generic prescription strength non-steroidal anti-inflammatory drugs (NSAID) within previous 180 days.

**References:**

1. Qmiiz ODT [prescribing information]. Lake Forest, IL: TerSera Therapeutics LLC; October 2018.
2. Tivorbex [prescribing information]. Philadelphia, PA: Iroko Pharmaceuticals, Inc; May 2016.
3. Zipsor [prescribing information]. Newport, KY: Xanodyne Pharmaceuticals, Inc; October 2016.
4. Zorvolex [prescribing information]. Philadelphia, PA: Iroko Pharmaceuticals, Inc; May 2016.
5. Arthrotec [prescribing information]. New York, NY: Pfizer Inc; May 2016.
6. Vivlodex [prescribing information]. Philadelphia, PA: Iroko Pharmaceuticals, Inc; October 2015.

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7. Facts and Comparisons Online

**Policy Revision history**

<b>Rev #</b>	<b>Type of Change</b>	<b>Summary of Change</b>	<b>Sections Affected</b>	<b>Date</b>
1	New Policy	New Policy	All	03/2008
2	CCI P&T Review History	3/08, 6/08, 9/09, 9/10, 12/11, 10/12, 10/13, 2/14, 10/14, 11/15, 2/16, 11/16, 11/17, 11/18	All	
3	CCI Revision Record	5/14, 6/14, 9/15, 11/16	All	
4	Update	Added Qmiiz ODT Updated Vivlodex indications Added Vivlodex package insert Updated Template	All	03/25/2019
5	Update	Added Relafen DS	All	11/8/2019

