

## Commercial PA Criteria

*Effective: March 1, 2008*

**Prior Authorization:** NSAIDs

**Products Affected:**

Arthrotec (diclofenac sodium/misoprostol) oral tablets  
Diclofenac Potassium 25mg oral capsules  
Diclofenac 35mg oral capsules  
Dolobid 250mg oral tablet  
Dolobid 375mg oral tablet  
Meloxicam 5mg and 10 mg oral capsules  
Meloxicam Oral Suspension 7.5mg/5 mL  
Qmiiz ODT (meloxicam) orally disintegrating tablets  
Relafen DS (nabumetone)  
Tivorbex (indomethacin) oral capsules  
Tolectin Tablet 600mg  
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 2 years of age and older 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, Zipsor and Diclofenac Potassium 25mg capsules are nonsteroidal anti-inflammatory drugs indicated for treatment of mild to moderate acute pain in adults.
- Vivlodex and meloxicam oral capsules are nonsteroidal anti-inflammatory drugs indicated for management of osteoarthritis (OA) pain.
- Zorvolex and Diclofenac 35mg capsules are nonsteroidal anti-inflammatory drugs indicated for the management of mild to moderate acute pain and for the management of osteoarthritis pain.
- Meloxicam Oral Suspension is a nonsteroidal anti-inflammatory drugs indicated for the treatment of Osteoarthritis in adults, Rheumatoid Arthritis in adults, and Juvenile Rheumatoid Arthritis (JRA) Pauciarticular and Polyarticular Course, in pediatric patients 2 years of age and older
- Tolectin is a nonsteroidal anti-inflammatory drug indicated for treatment of juvenile rheumatoid arthritis (JRA) in pediatric patients  $\geq 2$  years, and relief of signs and symptoms of rheumatoid and osteoarthritis, including acute flares and the long-term management of the chronic disease.
- Dolobid is indicated for acute or long-term use for symptomatic treatment of the following: Mild to moderate pain, Osteoarthritis and Rheumatoid arthritis

**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)

**Exclusion Criteria:**

- Patients with asthma, urticaria, or allergic-type reactions after taking aspirin or other NSAIDs
- In the setting of coronary artery bypass graft (CABG) surgery

**Arthrotec:**

- Pregnancy
- Active GI bleeding

**Qmiiz ODT:**

- Patients with phenylketonuria

**Zipsor:**

- Known hypersensitivity (e.g., anaphylactic reactions and serious skin reactions) to bovine protein.
- Known hypersensitivity to diclofenac

**Required Medical Information:**

1. Diagnosis
2. Medical History
3. Previous therapies tried and failed

**Age Restrictions:**

- 18 years of age and older
- Qmiiz ODT: 2 to 17 years of age in juvenile rheumatoid arthritis
- Meloxicam Oral Suspension: 2 years of age and older in Juvenile Rheumatoid Arthritis
- Tolectin: 2 years of age and older in Juvenile Rheumatoid arthritis, 18 and older for rheumatoid/osteoarthritis
- Dolobid: ≥12 years

**Prescriber Restrictions:** None

**Coverage Duration:** 12 months

**Other Criteria:**

ConnectiCare will consider **Arthrotec** to be medically necessary in patients who meets the following:

- A. Patient has one of the following conditions:
  - i. Rheumatoid arthritis in patients at high risk of developing NSAID-induced gastric and duodenal ulcers and their complications; **OR**
  - ii. Osteoarthritis in patients at high risk of developing NSAID-induced gastric and duodenal ulcers and their complications; **AND**
- B. Patient meets at least one of the following:

- i. Arthrotec utilization on prescription history in previous 180 days; **OR**
- ii. Two non-steroidal anti-inflammatory drugs (not including over-the-counter agents and samples) within previous 180 days (based on prescription claims history); **OR**
- iii. History of therapy with proton pump inhibitor or H2 antagonist within previous 90 days; **OR**
- iv. History of 45-day supply or more of oral / Injectable corticosteroid within previous 180 days documentation required; **OR**
- v. Previous history of perforations, ulceration, or gastrointestinal bleed, or platelet or clotting disorders documentation required.

ConnectiCare will consider **Qmiiiz ODT and meloxicam 7.5mg/5mL oral suspension** to be medically necessary in patients who meet all of the following (A, B **AND** C):

- A. Patient has one of the following conditions:
  - i. Osteoarthritis
  - ii. Rheumatoid arthritis
  - iii. Juvenile rheumatoid arthritis; **AND**
- B. Patient has had an intolerance to, or treatment failure to both of the following:
  - i. Meloxicam tablets; **AND**
  - ii. An adequate trial of one other generic prescription-strength non-steroidal anti-inflammatory drug (NSAID) within the previous 180 days; **AND**
- C. Patient is unable to swallow, has dysphagia, esophagitis, or mucositis.

ConnectiCare will consider **Relafen DS** to be medically necessary in patients who meet all of the following (A **AND** B):

- A. Patient as one of the following conditions:
  - i. Osteoarthritis
  - ii. Rheumatoid arthritis: **AND**
- B. Patient has a documented intolerance to, or treatment failure to both of the following:
  - i. Generic nabumetone tablets; **AND**
  - ii. An adequate trial of one other generic prescription-strength non-steroidal anti-inflammatory drug (NSAID) within the previous 180 days

ConnectiCare will consider **Tivorbex** to be medically necessary in patients who meet all of the following (A and B):

- A. Patient is using Tivorbex for mild to moderate acute pain; **AND**
- B. Patient has had an intolerance to, or treatment failure to both of the following:
  - i. Generic indomethacin capsules; **AND**
  - ii. An adequate trial of one other generic prescription-strength non-steroidal anti-inflammatory drug (NSAID) within the previous 180 days

ConnectiCare will consider **Vivlodex and meloxicam oral capsules** to be medically necessary in patients who meet all of the following (A **AND** B):

- A. Member has the diagnosis of osteoarthritis pain; **AND**
- B. 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 will consider **Zipsor and Diclofenac potassium 25mg capsules** to be medically necessary in patients who meet all of the following (A **AND** B):

- A. Patient is using Zipsor for the relief of mild to moderate acute pain; **AND**



- B. Patient has had an intolerance to, or treatment failure to both of the following: (i **AND** ii)
  - i. generic diclofenac tablets; **AND**
  - ii. An adequate trial of one other generic prescription-strength non-steroidal anti-inflammatory drug (NSAID) within the previous 180 days

ConnectiCare will consider **Zorvolex and Diclofenac 35mg capsules** to be medically necessary in patients who meet all of the following (A and B):

- A. Patient as one of the following conditions:
  - i. mild to moderate acute pain
  - ii. osteoarthritis pain; **AND**
- B. Patient has had an intolerance to, or treatment failure to both of the following:
  - i. generic diclofenac tablets; **AND**
  - ii. An adequate trial of one other generic prescription-strength non-steroidal anti-inflammatory drug (NSAID) within the previous 180 days.

ConnectiCare will consider **Tolectin** tablets to be medically necessary in patients who meet all of the following (A **AND** B):

- A. Patient has one of the following conditions:
  - i. Osteoarthritis
  - ii. Rheumatoid arthritis
  - iii. Juvenile rheumatoid arthritis; **AND**
- B. Patient has had an intolerance to, or treatment failure to the following:
  - i. An adequate trial of one other generic prescription-strength non-steroidal anti-inflammatory drug (NSAID) within the previous 180 days

ConnectiCare will consider **Dolobid tablets** to be medically necessary in patients who meet all of the following (A and B):

- C. Patient as one of the following conditions:
  - i. Mild to moderate acute pain
  - ii. Osteoarthritis pain;
  - iii. Rheumatoid arthritis
- D. Patient has had an intolerance to, or treatment failure to both of the following:
  - iv. generic Diflunisal tablets; **AND**
  - v. An adequate trial of one other generic prescription-strength non-steroidal anti-inflammatory drug (NSAID) within the previous 180 days

#### **References:**

1. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>.
2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2017. URL: <http://www.clinicalpharmacology.com>. Updated periodically.

#### **Policy Revision history**

| Rev # | Type of Change | Summary of Change | Sections Affected | Date |
|-------|----------------|-------------------|-------------------|------|
|       |                |                   |                   |      |



|   |            |   |   |            |
|---|------------|---|---|------------|
| 1 | New Policy | New Policy  | All   | 3/1/2008   |
| 2 | Update     | <p>Added exclusion criteria</p> <p>Added age restrictions: 18 years of older for all meds except Qmiiz ODT</p> <p>Updated age restriction for Qmiiz ODT to: 2 to 17 years of age</p> <p>Changed Arthrotec Criteria: removed: previous 65 years old age restriction,</p> <p>Added indication criteria to all products affected</p> | All   | 7/17/2020  |
| 3 | Update     | Added Diclofenac 35mg capsule to products affected, medication description, and other criteria  | All   | 1/1/2021   |
| 4 | Update     | Added Meloxicam oral capsules   | Products affected, Medication descriptions, other criteria                  | 1/11/2021  |
| 5 | Update     | Added Diclofenac Potassium 25mg capsules  | Products affected, Medication descriptions, other criteria                  | 6/8/2022   |
| 6 | Update     | Add Meloxicam Oral Suspension   | Products Affected, Medication Description, Age Restrictions, Other Criteria | 8/2/2022   |
| 7 | Update     | Addition of Tolectin Tablets  | Products Affected, Medication Description, Age Restrictions, Other Criteria | 5/30/2024  |
| 8 | Update     | Addition of Dolobid 250mg oral tablet   | Products Affected, Medication Description, Age Restrictions, Other Criteria | 10/25/2024 |
| 9 | Update     | Addition of Dolobid 375mg oral tablet   | Products Affected, Medication Description, Age Restrictions, Other Criteria | 5/27/2025  |