



Commercial/Healthcare Exchange PA Criteria

Effective: March 1, 2008

Prior Authorization: NSAIDs

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
Diclofenac 35mg oral capsules
Meloxicam 5mg and 10 mg oral capsules
Diclofenac Potassium 25mg oral capsules
Meloxicam Oral Suspension 7.5mg/5 mL

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 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 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

Covered Uses:

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

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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

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**

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- 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 **Qmiiz 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**

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- 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.

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	Added exclusion criteria Added age restrictions: 18 years of older for all meds except Qmiiz ODT Updated age restriction for Qmiiz ODT to: 2 to 17 years of age Changed Arthrotec Criteria: removed: previous 65 years old age restriction, Added indication criteria to all products affected	All	7/17/2020

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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