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Indiana Medicaid Therapeutics Committee **Therapeutic Class Review Summary**

Therapeutic Class:

Non-Steroidal Anti-Inflammatory Drug (NSAID) and Prostaglandin Combination Product

Overview:

Diclofenac/misoprostol (Arthrotec[®]) is a combination agent indicated for treatment of the signs and symptoms of osteoarthritis or rheumatoid arthritis in patients at high risk of developing NSAID-induced gastric and duodenal ulcers and their complications. Diclofenac is a non-steroidal anti-inflammatory agent with actions against COX-1 and COX-2, and is paired with misoprostol due to its mucosal protectant effect. The addition of misoprostol allows for safer use of the non-steroidal with regards to upper gastrointestinal erosion and ulceration.

Arthrotec[®] is available as diclofenac/misoprostol in 50mg/200mcg and 75mg/200mcg tablets for TID-QID dosing. Twice-daily dosing is a consideration when intolerance occurs. Common adverse events are gastrointestinal related and include abdominal pain, diarrhea, dyspepsia, nausea, and flatulence. Drug-interactions should also be considered. Special consideration of this medication should be used in women of child-bearing potential and in those with cardiovascular risk factors.

Generic Name	Brand Name	Manufacturer
Diclofenac / Misoprostol	Arthrotec [®]	Pfizer Pharmaceuticals, Inc.

Summary:

Diclofenac/misoprostol (Arthrotec[®]), a NSAID-prostaglandin combination agent, is an effective treatment option for patients with osteoarthritis or rheumatoid arthritis who are at high risk for developing NSAID-induced gastric and duodenal ulcers and their complications. While the black box warnings for this product are extensive, some of the warnings are similar to those listed for other traditional NSAID agents. The primary difference is its category X rating in pregnancy due to the misoprostol component. Diclofenac/misoprostol is well tolerated with most adverse events being gastrointestinal related.