



Preferred Drug List

NEW DRUG REVIEW

Proprietary Name: Simponi™

Common Name: Golimumab

PDL Category: Rheumatoid Arthritis- Biologicals

<u>Comparable Products</u>	<u>Preferred Drug List Status</u>
Enbrel®	Preferred
Humira®	Preferred

Summary

Indications and Usage: Moderately to severely active Rheumatoid Arthritis (RA) in adults, in combination with methotrexate. Active Psoriatic Arthritis (PsA) in adults, alone or in combination with methotrexate. Active Ankylosing Spondylitis (AS) in adults. ¹

Mechanism of Action: Binds to excess TNF-alpha which inhibits inflammation to bones, cartilage, and tissue. ¹

Dosage Forms: Injection: 50mg/0.5ml in a prefilled syringe or autoinjector

Recommended Dosage: 50mg by subcutaneous injection once monthly for all indications. ¹

Common Adverse Drug Reactions: Upper respiratory tract infection, nasopharyngitis. ¹

Contraindications: None¹

Manufacturer: Centocor Ortho Biotech Inc.

Analysis: Simponi™ is a new TNF-a inhibitor indicated for the treatment of RA, PsA, and AS in adults. It is the first TNF-a inhibitor to offer a once-monthly treatment option. In the trials used to gain FDA approval, Simponi™ was only compared to placebo. Although Simponi™ appears to be effective for the indicated diagnoses, no clinical trials are available comparing it with other TNF-a inhibitors currently available. Preferred alternatives appear on the Preferred Drug List, which have similar clinical efficacy and are more cost effective. Therefore, it is recommended that Simponi™ be added to the Preferred Drug List as a non-preferred drug with conditions.

IME Recommendation:

<input type="checkbox"/> Preferred Drug	<input type="checkbox"/> Recommended Drug
<input type="checkbox"/> Non-Preferred Drug	<input type="checkbox"/> Non-Recommended Drug
<input checked="" type="checkbox"/> Non-Preferred Drug with Conditions	

1. Simponi™ [package insert]. Horsham, PA: Centocor Ortho Biotech, Inc.; 2009.