

Oregon Health Resources Commission



Targeted Immune Modulators

Subcommittee Report

Update #1, April 2007

TIMs Subcommittee Report of March 2006.
All revisions are highlighted.

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Overview

The 2001 session of the Oregon Legislature passed Senate Bill 819, authorizing the creation of a Practitioner-managed Prescription Drug Plan (PMPDP). The statute specifically directs the Health Resources Commission to advise the Department of Human Services on this Plan.

In the winter of 2003 the Oregon Health Resources Commission (HRC) appointed a subcommittee to perform an evidence-based review of the use of Targeted Immune Modulator drugs. Members of the subcommittee consisted of physicians, an RPh, and other health care professionals. The subcommittee had four meetings. All meetings were held in public with appropriate notice provided.

Subcommittee members worked with the Center for Evidence-based Policy (Center) and the Oregon Health and Science University's (OHSU) Evidence-based Practice Center (EPC) to develop and finalize key questions for drug class review, specifying patient populations, medications to be studied and outcome measures for analysis, considering both efficacy and safety. Evidence was specifically sought for subgroups of patients based on race, ethnicity and age, demographics, other medications and co-morbidities.

Using standardized methods, the RTI-UNC Evidence-based Practice Center of North Carolina reviewed systematic databases, the medical literature and dossiers submitted by pharmaceutical manufacturers. Inclusion and exclusion criteria were applied to titles and abstracts, and each study was assessed for quality according to predetermined criteria.

The RTI-UNC EPC's report, "Drug Class Review on Targeted Immune Modulators" was completed in November 2005 and circulated to subcommittee members and posted on the web. The subcommittee met on January 18, 2006 to review the document and by consensus agreed to adopt the EPC report. Time was allotted for public comment, questions and testimony. Further meetings were held on February 13, 2006 and March 8, 2006. This draft report was accepted by the HRC full commission on March 17, 2006.

In January, 2007 the RTI-UNC EPC updated their report "Drug Class Review on Targeted Immune Modulators" and it was accepted by the TIMs subcommittee on January 24, 2007. This report does not recite or characterize all the evidence that was discussed by the OHSU EPC, the RTI-UNC EPC, the TIM Subcommittee or the Health Resources Commission. This report is not a substitute for any of the information provided during the subcommittee process, and readers are encouraged to review the source materials. This report is prepared to facilitate the Health Resources Commission in providing recommendations to the Department of Human Services.

The Standing Update Committee of the Health Resources Commission, working together with the EPCs, Center, OMAP, and the Oregon State University College of Pharmacy, will monitor medical evidence for new developments in this drug class. At least once per year new pharmaceuticals will be reviewed and if appropriate, a recommendation for inclusion in the PMPDP will be made. For pharmaceuticals on the plan, significant new evidence will be assessed and Food and Drug Administration (FDA) changes in indications and safety recommendations will be evaluated. The TIM report will be updated if indicated. Substantive changes will be brought to the attention of the Health Resources Commission, who may choose to approve the report, or reconvene at least two original members of the TIM Subcommittee to be added to the Standing Update Committee.

The full RTI-UNC Evidence-based Practice Center's draft report, *Drug Class Review on Targeted Immune Modulators*, is available on the Office for Oregon Health Policy & Research, Practitioner-Managed Prescription Drug Plan website: http://egov.oregon.gov/DAS/OHPPR/ORRX/HRC/evidence_based_reports.shtml

Information regarding the Oregon Health Resources Commission and its subcommittee policy and process can be found on the Office for Oregon Health Policy & Research website: <http://egov.oregon.gov/DAS/OHPPR/ORRX/HRC/process.shtml>

You may request more information including copies of the draft report, minutes and tapes of subcommittee meetings, from:

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Information dossiers submitted by pharmaceutical manufacturers are available upon request from the OHSU Center for Evidence-based Policy by contacting:

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Critical Policy:

- Senate Bill 819
 - “The Department of Human Services shall adopt a Practitioner-managed Prescription Drug Plan for the Oregon Health Plan. The purpose of the plan is to ensure that enrollees of the Oregon Health Plan receive the most effective prescription drug available at the best possible price.”
- Health Resources Commission
 - “Clinical outcomes are the most important indicators of comparative effectiveness”;
 - “If evidence is insufficient to answer a question, neither a positive nor a negative association can be assumed.”

Clinical Overview

Targeted Immune Modulators are used in the treatment of certain types of immunologic and inflammatory diseases, including rheumatoid arthritis (RA), juvenile rheumatoid arthritis (JRA), ankylosing spondylitis (AS), psoriatic arthritis (PsA), plaque psoriasis, Crohn’s disease, and ulcerative colitis.

Rheumatoid Arthritis (RA)

RA is an autoimmune disease that affects 1% of the population. Genetic susceptibility factors have been described in this disease characterized by inflammation of the synovial tissues with progressive erosion of bone, leading to mal-alignment of the effected joints that can produce disability. Constitutional symptoms are common before the onset of joint swelling and pain. Treatment is aimed at controlling pain and inflammation with slowing or prevention of joint destruction. In patients with persistent disease despite aggressive management, biologic agents such as a TIM, often in combination with - (MTX) are considered the standard of care.

Juvenile Rheumatoid Arthritis (JRA)

JRA is a form of arthritis that occurs for at least 6 weeks in a child <16. It is a systemic disease with variable presentation and three established subtypes: pauciarticular (<5 joints), polyarticular (≥5 joints) and systemic (arthritis with fever and a rash.). The goals of treatment are similar to RA, but steroids are avoided because of adverse effects on bone growth. Oral disease-modifying anti-rheumatic drugs (DMARDs) especially methotrexate (MTX) are used next. When the disease is resistant to oral therapies, biological agents are indicated.

Ankylosing Spondylitis (AS)

AS is a chronic inflammatory arthritis with prominent involvement of the axial skeleton. Peripheral joint disease may be destructive in some cases. Men in their early 20s are the subgroup primarily affected. The sacroiliac joints are usually the first joints involved leading to later enthesitis (inflammation of the insertion of ligaments and tendons on bones.) Over time patients with AS develop progressive fusion of the spine with resultant deformity and disability. As TNF has been implicated in the pathophysiology of AS, biologic agents targeting TNF have become a standard treatment approach.

Psoriatic Arthritis (PsA)

PsA is a chronic inflammatory arthritis associated with psoriasis, and usually post-dates the onset of the skin lesions. The etiology and pathogenesis of psoriasis and PsA are incompletely understood, but genetic, immunologic and environmental factors are all likely to play a role. NSAIDs, DMARDs and biologics are used to treat PsA. NSAIDs are useful for symptomatic treatment only. DMARDs and biologics are indicated with progressive disease or joint destruction. It is important to consider the early use of DMARDs and biologics to slow the progression of joint damage and disability.

Plaque Psoriasis.

Psoriasis is a chronically recurring, debilitating inflammatory disease that affects the skin and nails. It is characterized by erythematous scaly skin lesions and ranges in severity from mild to severe that may interfere significantly with quality of life. The severity of plaque psoriasis is most commonly classified based on percentage of body surface area (BSA) involved. Severe psoriasis is generally defined as more than 10% BSA affected. The pathogenesis is unclear but it is thought to be due to an over-production of pro-inflammatory cytokines. In particular, TNF levels are increased in psoriatic lesions compared with healthy skin. The goal of plaque psoriasis treatment is to decrease the percentage of body surface involved and improve quality of life

Crohn's Disease

Crohn's disease is inflammation involving the full thickness of the bowel wall that may occur at any point. Fistulizing disease is a serious complication due to an abnormal communication between the gut and the skin or other internal organs. Treatment is aimed at controlling the inflammation and preventing complications. If symptoms persist despite steroids, immunomodulatory agents are instituted. However, patients with unremitting disease (especially with fistulas) may warrant the use of a biological agent to avoid surgery.

Ulcerative Colitis (UC)

UC is a chronic inflammatory bowel disease (IBD) that is characterized by mucosal ulceration, rectal bleeding, diarrhea, and abdominal pain limited to the colon and rectal areas, as compared to Crohn's disease which causes a deeper inflammation within the intestinal wall and can occur in other parts of the digestive tract, including small bowel, mouth, esophagus, and stomach.

Definition of Targeted Immune Modulator Drugs

Targeted Immune Modulators (TIMs) – commonly referred to as biological response modifiers or simply biologics – are relatively new categories of medication used in the treatment of certain types of immunologic and inflammatory diseases. The FDA approved the first of the biologics in 1998. TIMs work by selectively blocking mechanisms involved in the inflammatory and immune response. Tumor necrosis factor (TNF) inhibitors block specific pro-inflammatory mediators known as cytokines.

Adalimumab, etanercept and infliximab produce their primary effect by blocking TNF- α from interacting with cell surface TNF receptors. Adalimumab is a fully human monoclonal antibody that binds specifically to TNF- α , blocking its interaction with both the p55 and p75 cell surface TNF receptor. Etanercept is a dimeric form of the p75 TNF- α receptor linked to the Fc portion of human immunoglobulin G1 (IgG1). It exerts its action by binding circulating TNF and preventing it from interacting with a cell surface receptor. Infliximab is a chimeric (mouse/human) anti-TNF- α antibody that binds both the circulating and trans-membrane forms of TNF- α , thereby preventing binding with the receptor.

Interleukin-1 (IL-1), another naturally occurring cytokine, has both immune and pro-inflammatory actions. Anakinra is a human recombinant protein that competitively blocks the IL-1 receptor, thus blocking various inflammatory and immunological responses.

The immunosuppressant agents, alefacept and efalizumab, produce their immune response by interfering with T-lymphocyte activation. Alefacept is a dimeric fusion protein that consists of the extracellular CD2-binding portion of the human leukocyte function antigen (LFA-3) and the Fc portion of human IgG1. Efalizumab is a recombinant humanized IgG1 monoclonal antibody that binds to human CD11a and inhibits the binding of LFA-1 to intercellular adhesion molecule-1 (ICAM-1). Abatacept (Orencia) and rituxamab (Rituxan) have been approved by the FDA after the closure of the data abstraction for the RTI-UNC Evidence-based Practice Center's draft report, *Drug Class Review on Targeted Immune Modulators*.

Table 1: Targeted Immune Modulators

Generic Name	US Trade Name	Manufacturer	Route	Half-life	Onset of Action	Mechanism of Action	Labeled Uses
Infliximab	Remicade®	Centocor	Intravenous	9.8 days	2-14 days	TNF inhibitor	- RA - Crohn's Disease - PsA - AS - Ulcerative colitis
Etanercept	Enbrel®	Amgen Wyeth Immunex	Subcutaneous	4.8 days	1-28 days	TNF inhibitor	- RA - JRA - PsA - AS - Plaque Psoriasis
Adalimumab	Humira®	Abbott	Subcutaneous	10-18 days	1-14 days	TNF inhibitor	- RA - PsA
Anakinra	Kineret®	Amgen	Subcutaneous	7-8 hours	7-21 days	IL-1 receptor antagonist	- RA
Efalizumab	Raptiva®	Genentech	Subcutaneous	6.2 days	14 days	CD11a inhibitor	- Plaque Psoriasis
Alefacept	Amevive®	Biogen	Intramuscular	11-12 days	30-60 days	CD2 antagonist	- Plaque Psoriasis

Table 2: FDA Recommended Dosage and Administration

Generic Name	Brand Name	Indication	FDA Recommended Dosage and Administration
Infliximab	Remicade®	RA	3 mg/kg intravenous infusion at 0, 2, and 6 weeks followed by maintenance every 8 weeks thereafter; may increase to maximum of 10 mg/kg every 4 weeks
		Crohn's Disease	5 mg/kg intravenous infusion at 0, 2, and 6 weeks followed by maintenance every 8 weeks thereafter; may increase to 10 mg/kg
		PsA	5 mg/kg intravenous infusion at 0, 2, and 6 weeks followed by maintenance every 8 weeks thereafter
		AS	5 mg/kg intravenous infusion at 0, 2, and 6 weeks followed by maintenance every 6 weeks thereafter
		Active ulcerative colitis	5 mg/kg induction regimen at 0, 2, and 6 weeks followed by a maintenance regimen of 5 mg/kg every 8 weeks thereafter.
Etanercept	Enbrel®	RA PsA AS	25 mg twice weekly as subcutaneous injections or 50 once weekly as subcutaneous injection
		JRA (patients 4-17 years)	0.8 mg/kg per week (maximum 50 mg per week) given as one or two subcutaneous injections
		Plaque Psoriasis	50 mg given twice weekly (administered 3 or 4 days apart) as a subcutaneous injection for 3 months, followed by 50 mg weekly
Adalimumab	Humira®	RA	40 mg every other week as subcutaneous injection; may increase to 40 mg per week
		PsA	40 mg every other week as subcutaneous injection
Anakinra	Kineret®	RA	100 mg daily as subcutaneous injection; dose should be decreased to 100 mg every other day in renal insufficiency
Efalizumab	Raptiva®	Plaque Psoriasis	Initial 0.7 mg/kg subcutaneous injection followed by weekly doses of 1 mg/kg (not to exceed total of 200 mg)
Alefacept	Amevive®	Plaque Psoriasis	15 mg given once weekly as an intramuscular injection. Treatment should be continued for 12 weeks; re-treatment with an additional 12 week course may be initiated provided that CD4+ T lymphocytes counts are < 250 cells/μL and a 12-week interval has passed since the end of the initial treatment cycle

Quality of the Evidence

For quality of evidence the TIM Subcommittee took into account the number of studies, the total number of patients in each study, the length of the study period, and the end points of the studies. Statistical significance was an important consideration. The subcommittee utilized the EPC's ratings of "good, fair or poor" for grading the body of evidence. Overall quality ratings for an individual study were based on the internal and external validity of the trial.

Internal validity of each trial was based on:

- 1) Methods used for randomization
- 2) Allocation concealment and blinding
- 3) Similarity of compared groups at baseline and maintenance of comparable groups
- 4) Adequate reporting of dropouts, attrition, and crossover
- 5) Loss to follow-up
- 6) Use of intention-to-treat analysis

External validity of trials was assessed based on:

- 1) Adequate description of the study population
- 2) Similarity of patients to other populations to whom the intervention would be applied
- 3) Control group receiving comparable treatment
- 4) Funding source that might affect publication bias.

Weighing the Evidence

A particular randomized trial might receive two different ratings: one for efficacy and another for adverse events. The overall strength of evidence for a particular key question reflects the quality, consistency and power of the body of evidence relevant to that question.

Clinical Assessment Scales

Rheumatoid Arthritis Response Measures

ACR 20/50/70 – American College of Rheumatology % improvement in tender and swollen joint counts and at least three of the following:

- Patient's assessment of pain
- Patient's global assessment
- Patient's assessment of disability
- Acute phase reactant (CRP)

New Findings, January 2007

- Since the last report abatacept and rituximab have been added.
- The FDA has approved adalimumab for Psoriatic Arthritis and Crohn's disease.
- Using the same search strategy that was used in the original TIMs report, the EPC found 45 that met criteria and were included in this review. Of these 14 were new placebo-controlled trials, 1 meta-analysis, 3 head-to-head observational studies, and 25 other observational studies. .
- For RA:

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- Three head-to-head prospective cohort studies compared etanercept to infliximab.
 - One head-to-head retrospective cohort study on radiological outcomes comparing etanercept in.
 - For PA:
 - Two new placebo-controlled trials on alefacept and adalimumab
 - For Crohn's Disease:
 - One new RCT on adalimumab
 - For Plaque Psoriasis:
 - 12 placebo controlled trials (2 on alefacept, 4 on efalizumab, 4 on etanercept, and 2 on infliximab.)

Key Questions

Key Question 1

How do included drugs compare in their efficacy for alleviating symptoms and stabilizing the disease in patients with:

1a. Rheumatoid arthritis?

There are no head-to-head studies. Adjusted indirect comparisons indicate that adalimumab, etanercept and infliximab plus MTX are more efficacious than anakinra for ACR20 and ACR50. Infliximab, in combination with MTX, appears to be similarly effective compared to monotherapy with either etanercept or adalimumab. There was no synergistic effect of etanercept and anakinra treatment for efficacy, and there was a higher adverse events rate for the combination.

In summary, there was no demonstrable clinically important difference between adalimumab, etanercept, or infliximab plus MTX, for efficacy. Indirect comparative evidence suggests that adalimumab, etanercept, or infliximab plus MTX, are probably superior to anakinra. Adalimumab, anakinra, etanercept, or infliximab plus MTX are all superior to placebo.

1b. Juvenile rheumatoid arthritis?

There was no direct comparative evidence. Evidence is limited to one placebo-controlled trial that indicates general efficacy of etanercept. Etanercept has FDA approval for use in JRA based on this one placebo-controlled trial. There is no acceptable evidence on infliximab since the one published trial was uncontrolled and thus fatally flawed.

1c Ankylosing spondylitis?

There was no direct comparative evidence and the evidence was insufficient for adjusted indirect comparisons. Good to fair evidence from 5 placebo-controlled trials revealed that etanercept and infliximab are significantly more efficacious than placebo. There was no evidence on adalimumab and anakinra.

In patients with ankylosing spondylitis there was no demonstrable clinical difference between etanercept and infliximab for efficacy.

1d. Psoriatic arthritis?

There was no direct comparative evidence and the evidence was insufficient for adjusted indirect comparisons. Fair evidence from 3 placebo-controlled trials revealed etanercept and infliximab are significantly more efficacious than placebo. There was no evidence on adalimumab and anakinra.

1e. Plaque psoriasis?

Studies in general enrolled patients who had a history of plaque psoriasis for more than 6 months, with more than 10 percent of body area involved. The FDA approves alefacept, efalizumab, etanercept and infliximab for plaque psoriasis. Overall the evidence of the comparative effectiveness of TIMs for the treatment of plaque psoriasis is poor. No evidence directly comparing the efficacy and safety of one TIM to another could be found, and evidence was insufficient to make indirect comparisons. Fair to good evidence exists on the general efficacy of alefacept, etanercept, efalizumab and infliximab for the treatment of plaque psoriasis.

1f. Crohn's disease?

There was no direct comparative evidence and the evidence was insufficient for adjusted indirect comparisons. However, there was good to fair evidence from 6 placebo-controlled trials that infliximab is significantly more efficacious for initial and maintenance therapy than placebo. In addition infliximab is more efficacious than placebo in fistulizing Crohn's disease.

A single trial showed that etanercept did not show general efficacy for the treatment of Crohn's disease. There was no evidence on adalimumab and anakinra.

1g. Ulcerative colitis?

Infliximab is the only drug currently approved by the FDA for the treatment of ulcerative colitis. Overall, the evidence of the comparative effectiveness of TIMS for the treatment of UC is poor. Fair evidence from three RCTs exists that

infliximab is significantly more efficacious than placebo for the treatment of active UC. Treatment effects are large across studies.

Key Question 1 Consensus

The TIM Subcommittee agrees by consensus that:

1. *If one biological agent doesn't work, then consideration of another should not be restricted by the preferred drug list.*
 - 1a. *In patients with RA there was no demonstrable clinical difference between abatacept, adalimumab, etanercept, or infliximab plus MTX or for rituximab for efficacy. Adalimumab, etanercept or infliximab plus methotrexate were superior to anakinra using indirect comparative evidence. Adalimumab, anakinra, efalizumab, etanercept, and infliximab are all superior to placebo in efficacy.*
 - 1b. *In patients with JRA there is so little evidence available other than one placebo-controlled efficacy trial for etanercept, that no comparisons amongst TIMs can be made.*
 - 1c. *In patients with AS there was no demonstrable clinical difference between adalimumab, etanercept and infliximab for efficacy, while all are superior to placebo.*
 - 1d. *In patients with PsA there was no demonstrable clinical difference between adalimumab, etanercept and infliximab for efficacy. All three are superior to placebo.*
 - 1e. *In patients with plaque psoriasis alefacept, efalizumab, etanercept, and infliximab had significantly greater Psoriasis and Severity Index (PASI) response and improvements in quality of life for TIMs than placebo. There are no head-to-head RCT comparing one TIM with another.*
 - 1f. *In patients with Crohn's disease only infliximab has been proven to be efficacious compared to placebo for initial therapy, maintenance, and the treatment of fistulas, whereas etanercept has not.*
 - 1g. *In patients with UC only infliximab has been proven to be efficacious compared to placebo for moderate to severe UC refractive to conventional treatment.*

Key Question 2

What are the comparative incidence and severity of complications of the included drugs?

The only direct comparison did not indicate any differences in adverse events between etanercept and infliximab. Overall no substantial differences in tolerability to the administration of these drugs appear to exist among TIMs.

Rare, but severe adverse events are of equal concern for all TIMs. However, assessment of potentially fatal adverse events is severely limited by a lack of long-term studies adequately powered to discover them.

- Heart failure
- Serious infections (TB)
- Lymphoma
- Autoimmunity (drug-induced lupus)
- Neutropenia
- Demyelinating diseases

Key Question 2 Consensus

The TIM Subcommittee agrees by consensus that:

- *Overall there is no significant difference in tolerability so far as the administration of these drugs. In some cases the route of administration is a factor for adverse drug events.*
- *Rare adverse events are of equal concern for all TIMs; however, assessment of these events is severely limited by a lack of adequately powered long-term studies.*
 - *Heart failure*
 - *Serious infections (e.g. tuberculosis)*
 - *Autoimmunity*
 - *Lymphoma*
 - *Neutropenia*
 - *Demyelinating disease*

Key Question 3

Do the included drugs differ in efficacy or adverse events in different age, sex, or ethnic groups, or in patients taking other commonly prescribed drugs?

No controlled trials compared the efficacy of TIMs in a subgroup to the efficacy in the general population. Other evidence is insufficient to draw firm conclusions about subgroups (age, race, or sex) compared to another.

Good indirect evidence exists that anti-TNF drugs can worsen congestive heart failure. There was no evidence for HF with anakinra.

Insufficient evidence exists to draw firm conclusions about the effect of TIMs in patients taking other commonly prescribed drugs.

Key Question 3 Consensus

The TIMs Subcommittee agrees by consensus that:

- *No study was specifically designed to evaluate the effect of adalimumab, alefacept, anakinra, efalizumab, etanercept, infliximab and in one subgroup of patients compared to another.*

Conclusion

It is the decision of the TIMs Subcommittee that:

- *Based on clinical practice, there is individual variability of the effectiveness and safety of these drugs that may require sequential treatment with another TIM if the first TIM proves intolerable or ineffective. Therefore the full range of these drugs should remain available for diseases in which they have proven efficacy unless comparative evidence-based studies prove otherwise.*
- *In patients with RA, indirect comparative evidence suggests that etanercept, infliximab and adalimumab have similar efficacy, but each are more effective than anakinra.*
- *In patients with JRA, only etanercept has been demonstrated to be effective.*
- *In patients with AS or PsA, indirect comparative evidence has shown that etanercept and infliximab have similar efficacy.*
- *In patients with psoriasis alefacept, efalizumab, etanercept, and infliximab had significantly greater improvement than placebo.*
- *In patients with Crohn's disease, only infliximab compared to placebo has been proven to be efficacious for initial therapy, maintenance, and the treatment of fistulas, whereas etanercept has not.*
- *In patients with UC only infliximab has been proven to be efficacious compared to placebo.*
- *Because of the rapidly evolving research with TIMs, it will be important to update this report in a timely fashion.*

James MacKay, MD

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Health Resources Commission

The State of Oregon's Health Resources Commission is a volunteer commission appointed by the Governor. The Health Resources Commission provides a public forum for discussion and development of consensus regarding significant emerging issues related to medical technology. Created by statute in 1991, it consists of four physicians experienced in health research and the evaluation of medical technologies and clinical outcomes; one representative of hospitals; one insurance industry representative; one business representative; one representative of labor organizations; one consumer representative; two pharmacists. All Health Resources Commissioners are selected with conflict of interest guidelines in mind. Any minor conflict of interest is disclosed.

The Commission is charged with conducting medical assessment of selected technologies, including prescription drugs. The commission may use advisory committees or subcommittees, the members to be appointed by the chairperson of the commission subject to approval by a majority of the commission. The appointees have the appropriate expertise to develop a medical technology assessment. Subcommittee meetings and deliberations are public, where public testimony is encouraged. Subcommittee recommendations are presented to the Health Resources Commission in a public forum. The Commission gives strong consideration to the recommendations of the advisory subcommittee meetings and public testimony in developing its final reports.