

Specifications for Effective Health Care (EHC) Clinician Research Summary

Page Size: 8.5 x 11 inches

Margins: 1/2 of an inch on all four sides (.5 inches)

Ink colors: *Clinician Research Summary:* Use Pantone 295 (blue) for banner and headings. Use Pantone 370 (green) for bullets, rules, and other accents. Make body text black.

In special cases, where a full-color figure is required to convey essential information, use a 5-color treatment as follows: equivalents of full process color plus the primary Pantone color.

Bleed: No bleed.

Sample product



Clinician Research Summary
Muscle, Bone, and Joint Conditions
Arthritis

Drug Therapy for Psoriatic Arthritis in Adults: Comparative Effectiveness
Research Focus for Clinicians

In response to a request from the public to AHRQ concerning the expanding use of DMARDs in treatment of inflammatory arthritis, a systematic review was undertaken to review the effectiveness and safety of the DMARDs, both oral and biologic, used to treat psoriatic arthritis (PsA). The review does not cover dermatological treatments specifically targeted to PsA skin disease. This summary is based on a systematic review that included 16 studies published before January 2011. The full report, listing all studies, is available at www.effectivehealthcare.ahrq.gov/dmardpsa.cfm. This summary, based on the full report of research evidence, is provided to clinicians to inform discussions of options with patients and to assist in decisionmaking along with consideration of a patient's values and preferences. However, reviews of evidence should not be construed to represent clinical recommendations or guidelines.

Background
PsA is one of the most disabling presentations of inflammatory arthritis. In addition to the characteristic pain, inflammation, joint damage, and loss of function that worsen over time, this form of arthritis is associated with the skin disease psoriasis. Along with the skin condition, PsA presents with small-joint polyarthritis and/or axial arthritis that involves the spinal, sacroiliac, and large joints. The prevalence of arthritis in the population of patients with psoriasis varies from 6 to 12 percent. In the general population, the prevalence is 0.3 to 1.0 percent, and it appears most often between 30 to 50 years of age.* Treatment of PsA is aimed at controlling pain and inflammation, usually starting with NSAIDs. With disease-modifying anti-rheumatic drugs (DMARDs) as treatment options, slowing or blocking progression of the disease may be possible. The oral DMARDs, particularly methotrexate (MTX), are widely used in treatment strategies for PsA, although their targets are not well defined. The biologic DMARDs approved by the U.S. Food and Drug Administration (FDA) for marketing as PsA treatment target tumor necrosis factor-alpha (TNF- α) signaling. A synthesis of the clinical evidence from studies of DMARDs used to treat PsA is needed to support decisionmaking that balances the benefits of controlling progressive disease against the risks of adverse effects.

Conclusion
Clinical study evidence about DMARDs as PsA treatment is limited. Low- to moderate-strength evidence indicates that anti-TNF- α biologic DMARDs improve psoriatic arthritis, assessed by multiple rating indices. Oral DMARDs may also be beneficial. However, sparse evidence from head-to-head comparisons (both within and between classes) does not permit conclusions about which DMARDs and treatment strategies are superior for minimizing joint damage and optimizing quality of life. Other than the reported infection risks associated with the TNF- α inhibitors, the evidence about adverse events associated with treatment of PsA using DMARDs of either class is insufficient to inform decisionmaking.



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Table 1. Effects of Anti-TNF- α Biologic DMARDs on PsA Outcomes
The range of the effect sizes from individual studies (difference between drug and placebo) are shown.

Biologic DMARDs	Improvement in Disease Activity	Functional Capacity (Mean Improvement)	HRQL (Mean Improvement)
	Percentage Achieving ACR20*	HAQ; MCID \geq 0.22*	SF-36 PCS; MCID = 2.2 to 4.7*
Adalimumab	39 to 57 ●●○	0.2 to 0.3 ●●○	2.9 to 7.9 ●○○
Etanercept	59 to 65 ●●○	0.5 to 1.1 ●●○	8.6 ●○○
Golimumab	45 to 51 ●○○	0.34 to 0.4 ●○○	5.9 to 7.2 ●○○
Infliximab	58 to 62 ●●○	0.4 to 0.6 ●●○	6.4 to 8 ●○○

*The range of results from studies, from lowest to highest.
ACR20 = American College of Rheumatology 20 percent improvement from baseline to end point; DMARDs = disease-modifying anti-rheumatic drugs; HAQ = Health Assessment Questionnaire; HRQL = health-related quality of life; MCID = minimum clinically important difference; PCS = physical component score; SF-36 = Medical Outcomes Study Short Form 36

Adverse Effects

- TNF- α inhibitors are generally associated with increased risk of infections. The FDA has warned that cancer risk may be elevated with their use, but the actual risk to patients with PsA is not known.
- Some adverse effects have been reported with the use of DMARDs to treat PsA, when compared with placebo.
- Rates of injection site reactions are increased with adalimumab and etanercept. ●○○
- Etanercept has a lower risk of discontinuation due to adverse events when compared with infliximab. ●○○
- Adding MTX to treatment with etanercept reduced the rate of withdrawals from treatment. ●○○

Gaps in Knowledge

- Randomized controlled trials that examine DMARD effectiveness for treating PsA in head-to-head comparisons are needed.
- Studies that investigate combination therapies and specific treatment strategies are needed.
- Outcomes evaluated in future studies should include axial disease, enthesitis, and dactylitis along with joint counts and should specify the pattern of joint involvement in study patients.
- There are no data about how effectiveness and safety are modified by patient characteristics, subpopulations, and use in typical clinical settings.
- The evidence about the harms, tolerability, adverse effects, and adherence to treatment in studies of DMARD treatment for PsA is very limited and is insufficient to permit conclusions about specific risks for patients with PsA.

What to Discuss With Your Patients

- The role of DMARDs for reducing symptoms and improving disease control
- The limited research about the potential benefits and adverse effects of DMARDs for treating PsA
- Patient and caregiver preferences and values regarding treatment

Resource for Patients
Medicines for Psoriatic Arthritis, A Review of the Research for Adults is a free companion to this clinician research summary. It covers:

- A description of PsA
- The types of DMARDs that are used
- The evidence about the short- and long-term benefits and adverse effects associated with DMARDs used for patients with PsA
- Costs related to biologic and nonbiologic DMARDs

Ordering Information
For electronic copies of *Medicines for Psoriatic Arthritis, A Review of the Research for Adults*, this clinician research summary, and the full systematic review, visit www.effectivehealthcare.ahrq.gov/dmardpsa.cfm. To order free print copies, call the AHRQ Publications Clearinghouse at 800-358-9295.

Source
The information in this summary is based on *Drug Therapy for Psoriatic Arthritis in Adults: Update of a 2007 Report, Comparative Effectiveness Review No. 54*, prepared by the RTI International—University of North Carolina Evidence-based Practice Center under Contract No. HHS-290-2007-10056-1 for the Agency for Healthcare Research and Quality, April 2012. Available at www.effectivehealthcare.ahrq.gov/dmardpsa.cfm. This summary was prepared by the John M. Eisenberg Center for Clinical Decisions and Communications Science at Baylor College of Medicine, Houston, TX.



AHRQ Pub. No. 12(13):EHC2024-3
November 2012

Specifications for Effective Health Care (EHC) Clinician Research Summary

Design Elements: *EHC banner:* The EHC banner with rounded corners should be used at the top of page 1. The banner includes the topic name and subject area. The banner should be flush with the top, left, and right margins at 1/2 inch. The banner must not be stretched, cropped, or modified in any way. The banner should be Pantone 295 (blue) with white lettering.

Sample banner



Charts and tables: Charts and tables should be in shaded boxes with rounded corners. See page 1 for sample charts.

Photos: The only photos used are images of the corresponding EHC consumer booklet front cover. The cover prints as a gray-scale image.

Columns: After the introductory text, which spans the page width, text will appear in two columns. The only exception to this are the “Source” and “For More Information” pages which may be one column depending on fit and design. Charts, figures, and other visuals may be one or two columns as required for best layout.

Page numbers: Page numbers should appear on each page, except for the first page, in a size equal to the body text. Page numbers are not needed if the summary is front and back only.

Specifications for Effective Health Care (EHC) Clinician Research Summary

Fonts: Use the fonts below. Due to their complexity, charts and graphs can have text smaller than 11-point, but no smaller than 8 point.

Title: 20-point Myriad Pro Bold.

Body text: 11-point Minion Pro with 13-point leading.

Level 1 heads: 14-point Myriad Pro Bold.

Level 2 heads: 11-point Myriad Pro Bold.

Level 3 heads: 11-point Myriad Pro Italic.

Run-in heads: 11-point Minion Pro Bold.

Bullets: Square.

Hyphenation: Should be turned off.

Sample fonts and sizes

Sample Title is 20-point Myriad Pro Bold

Head Level 1 is 14-point Myriad Pro Bold

Head Level 2 is 11-point Myriad Pro Bold

Head Level 3 is 11-point Myriad Pro Italic

Body text is 11-point Minion Pro with 13-point leading. It should be flush left, ragged right, with no hyphenation.

■ This is a sample of bulleted text with a square bullet. It should be flush left, ragged right, with no hyphenation. The text size is 11-point Minion Pro with 13-point leading.

Run-in heads. This is a sample of a run-in head. The run-in head is 11-point Minion Pro Bold.

Specifications for Effective Health Care (EHC) Clinician Research Summary

Branding: HHS and AHRQ branding logos must be placed at the bottom of the front cover (see below). The HHS/AHRQ logos must not be stretched, cropped, or modified in any way. The branding logo should fit proportionally with the design elements on the front cover. Use PMS 295 (blue) or black for color. See sample below.

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Back cover logo



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