Complete Summary

GUIDELINE TITLE

Guidelines of care for the management of psoriasis and psoriatic arthritis: section 2. psoriatic arthritis: overview and guidelines of care for treatment with an emphasis on the biologics.

BIBLIOGRAPHIC SOURCE(S)

Gottlieb A, Korman NJ, Gordon KB, Feldman SR, Lebwohl M, Koo JY, Van Voorhees AS, Elmets CA, Leonardi CL, Beutner KR, Bhushan R, Menter A. Guidelines of care for the management of psoriasis and psoriatic arthritis: Section 2. Psoriatic arthritis: overview and guidelines of care for treatment with an emphasis on the biologics. J Am Acad Dermatol 2008 May;58(5):851-64. [34 references] PubMed

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

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SCOPE

DISEASE/CONDITION(S)

- Psoriasis
- Psoriatic arthritis (PsA)

GUIDELINE CATEGORY

Evaluation
Management
Treatment

CLINICAL SPECIALTY

Dermatology
Family Practice
Internal Medicine
Pediatrics
Rheumatology

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

- To present guidelines on the management and treatment of psoriatic arthritis (PsA) with biologics
- To give an overview of psoriatic arthritis including its cardinal clinical features, pathogenesis, prognosis, classification, assessment tools used to evaluate psoriatic arthritis, and the approach to treatment

TARGET POPULATION

Adults and children with psoriatic arthritis (PsA)

INTERVENTIONS AND PRACTICES CONSIDERED

Evaluation/Management/Treatment

1. General interventions for psoriatic arthritis (PsA)
    - History and screening of PsA using the PsA Screening and Evaluation tool
    - Methotrexate, tumor necrosis factor (TNF) blockade, or the combination of these therapies as first-line treatment for patients with moderate to severely active PsA.
    - Nonsteroidal anti-inflammatory drugs (NSAIDs) or intra-articular injections of corticosteroids for patients with mild PsA
2. Tumor necrosis factor (TNF) inhibitors
    - Adalimumab
    - Etanercept
    - Infliximab
3. Alefacept (considered but not recommended; not FDA approved for PsA)

MAJOR OUTCOMES CONSIDERED

- Effectiveness of treatments using measures of disease activity, degree of joint involvement, quality of life, and rate of disease progression
- Adverse effects of treatment

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

A work group of recognized experts was convened to determine the audience for the guideline, define the scope of the guideline, and identify clinical questions to structure the primary issues in diagnosis and management.

An evidence-based model was used and evidence was obtained using a search of the MEDLINE database spanning the years 1990 through 2007. Only English-language publications were reviewed.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus (Committee)
Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Evidence was graded using a 3-point scale based on the quality of methodology as follows:

I. Good-quality patient-oriented evidence.
II. Limited-quality patient-oriented evidence.
III. Other evidence including consensus guidelines, opinion, or case studies.

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

The available evidence was evaluated using a unified system called the Strength of Recommendation Taxonomy developed by editors of the US family medicine and primary care journals (i.e., *American Family Physician, Family Medicine, Journal of Family Practice*, and *BMJ USA*). This strategy was supported by a decision of the Clinical Guidelines Task Force in 2005 with some minor modifications for a consistent approach to rating the strength of the evidence of scientific studies.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Clinical recommendations were developed on the best available evidence tabled in the guideline.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

A. Recommendation based on consistent and good quality patient-oriented evidence.
B. Recommendation based on inconsistent or limited quality patient-oriented evidence.
C. Recommendation based on consensus, opinion, or case studies.

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

This guideline has been developed in accordance with the American Academy of Dermatology (AAD)/AAD Association "Administrative Regulations for Evidence-based Clinical Practice Guidelines," which include the opportunity for review and comment by the entire AAD membership and final review and approval by the AAD Board of Directors.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Level of evidence grades (I-III) and strength of recommendations (A-C) are defined at the end of the "Major Recommendations" field.

General Recommendations for Psoriatic Arthritis (PsA)

Dermatologists are strongly encouraged to consider the possible concurrent diagnosis of PsA in patients presenting with psoriasis. Although a history and screening examination for PsA should be performed at every visit, there are as yet no broadly validated, user-friendly, sensitive, and specific screening tools available specifically for dermatologists to use. The development of one such instrument is in progress. The PsA Screening and Evaluation tool was developed to screen patients with psoriasis for signs and symptoms of inflammatory arthritis.

Dermatologists uncomfortable evaluating or treating patients with PsA should refer patients who they suspect may have PsA to rheumatologists.

Upon diagnosis of PsA, patients should be treated and/or referred to a rheumatologist to alleviate signs and symptoms, inhibit structural damage, and improve quality of life (QOL) parameters.

Methotrexate, tumor necrosis factor (TNF) blockade, or the combination of these therapies is considered first-line treatment for patients with moderate to severely active PsA. Although there are no prognostic indicators to identify these patients early, approximately 50% of patients with PsA may develop structural damage.

Not all patients with PsA require treatment with methotrexate or TNF blockade. Patients with mild PsA can be successfully treated with nonsteroidal anti-inflammatory drugs (NSAIDs) or intra-articular injections of corticosteroids.

General Recommendations for All Patients with PsA Who Will Be Treated with Biologics

An extensive discussion regarding general recommendations for the treatment of patients with psoriasis has been presented in Section 1 of these guidelines devoted to the use of biologics for the treatment of psoriasis. The reader is directed to this discussion in Section 1 (see the National Guideline Clearinghouse summary of American Academy of Dermatology's Section 1: Overview of Psoriasis and Guidelines of Care for the Treatment of Psoriasis with Biologics, which includes suggestions for laboratory evaluation and issues related to vaccination).

Recommendations for Adalimumab

- Indications: moderate/severe psoriatic arthritis; moderate/severe psoriasis; adult and juvenile rheumatoid arthritis (as young as 4 years); ankylosing spondylitis; and adult Crohn's disease
- Dosing: 40 mg every other week subcutaneously
- Response: ACR20* at week 12 is 58%

Recommendations for Etanercept

- Indications: moderate/severe psoriatic arthritis; moderate/severe psoriasis; adult and juvenile rheumatoid arthritis (as young as 4 years); and ankylosing spondylitis
- Dosing for Psoriatic Arthritis: 25 mg twice week or 50 mg once week given subcutaneously
- Response: ACR20* at week 12 is 59%

Recommendations for Infliximab

- Indications: moderate/severe psoriatic arthritis; severe psoriasis; adult rheumatoid arthritis; ankylosing spondylitis; and Crohn's disease (pediatric and adult)
- Dosing: 5 mg/kg given intravenously at week 0, 2, and 6, and then every 6 to 8 weeks; dose and interval of infusions may be adjusted as needed

- Response: ACR20* at week 14 is 58%

*ACR 20 = American College of Rheumatology20 scoring criteria, defined as ≥20% reduction in tender joint count, ≥20% reduction in the swollen joint count, and ≥20% reduction in 3 of 5 additional measures including patient assessment of pain, patient global assessment of disease activity, physician global assessment of disease activity, disability index of the Health Assessment Questionnaire, and acute phase reactants such as erythrocyte sedimentation rate and C-reactive protein.

Recommendation	Strength of Recommendation	Level of Evidence	References
Adalimumab	A	I	Mease et al., 2005; Gladman et al., 2007
Etanercept	A	I	Mease et al., 2000; Mease et al., 2004; Mease et al., 2006
Infliximab	A	I	Antoni et al., 2005; Kavanaugh et al., 2006

Refer to the original guideline document for general safety recommendations for patients with PsA who will be treated with TNF inhibitors.

Definitions:

Levels of Evidence

I. Good-quality patient-oriented evidence.
II. Limited-quality patient-oriented evidence.
III. Other evidence including consensus guidelines, opinion, or case studies.

Strength of Recommendations

A. Recommendation based on consistent and good quality patient-oriented evidence.
B. Recommendation based on inconsistent or limited quality patient-oriented evidence.
C. Recommendation based on consensus, opinion, or case studies.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

REFERENCES SUPPORTING THE RECOMMENDATIONS

References open in a new window

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for selected recommendations (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- Appropriate management and treatment of psoriatic arthritis
- Early diagnosis of psoriatic arthritis affords the caregiver the opportunity to improve the patient's quality of life, improve function, and slow disease progression

POTENTIAL HARMS

See the National Guideline Clearinghouse summary of the American Academy of Dermatology's Section 1: Overview of Psoriasis and Guidelines of Care for the Treatment of Psoriasis with Biologics for the adverse effects of treatment with adalimumab, etanercept, and infliximab.

CONTRAINDICATIONS

CONTRAINDICATIONS

See the National Guideline Clearinghouse summary of the American Academy of Dermatology's Section 1: Overview of Psoriasis and Guidelines of Care for the Treatment of Psoriasis with Biologics for the contraindications of treatment with adalimumab, etanercept, and infliximab.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

Adherence to these guidelines will not ensure successful treatment in every situation. Furthermore, these guidelines do not purport to establish a legal standard of care and should not be deemed inclusive of all proper methods of care nor exclusive of other methods of care reasonably directed to obtaining the same results. The ultimate judgment regarding the propriety of any specific therapy must be made by the physician and the patient in light of all the circumstances presented by the individual patient.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Gottlieb A, Korman NJ, Gordon KB, Feldman SR, Lebwohl M, Koo JY, Van Voorhees AS, Elmets CA, Leonardi CL, Beutner KR, Bhushan R, Menter A. Guidelines of care for the management of psoriasis and psoriatic arthritis: Section 2. Psoriatic arthritis: overview and guidelines of care for treatment with an emphasis on the biologics. J Am Acad Dermatol 2008 May;58(5):851-64. [34 references] PubMed

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2008 May

GUIDELINE DEVELOPER(S)

American Academy of Dermatology - Medical Specialty Society

SOURCE(S) OF FUNDING

American Academy of Dermatology operational funds and member volunteer time supported the development of this guideline.

GUIDELINE COMMITTEE

American Academy of Dermatology Work Group

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Work Group Members: Alice Gottlieb, MD, PhD, Department of Dermatology, Tufts-New England Medical Center, Tufts University School of Medicine, Boston; Neil J. Korman, MD, PhD, Murdough Family Center For Psoriasis, Department of Dermatology, University Hospitals Case Medical Center, Cleveland; Kenneth B. Gordon, MD, Division of Dermatology, Evanston Northwestern Healthcare and

Department of Dermatology, Northwestern University, Feinberg School of Medicine, Chicago; Steven R. Feldman, MD, PhD, Department of Dermatology, Wake Forest University School of Medicine, Winston-Salem; Mark Lebwohl, MD, Department of Dermatology, Mount Sinai School of Medicine, New York; John Y. M. Koo, MD, Department of Dermatology, University of California – San Francisco; Abby S. Van Voorhees, MD, Department of Dermatology, University of Pennsylvania; Craig A. Elmets, MD, University of Alabama at Birmingham; Craig L. Leonardi, MD, Department of Dermatology, Saint Louis University; Karl R. Beutner, MD, PhD, Anacor Pharmaceuticals Inc, Palo Alto; Reva Bhushan, PhD, American Academy of Dermatology, Schaumburg; Alan Menter, MD, *Chair*, Baylor University Medical Center, Dallas

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Alice Gottlieb, MD, PhD: Dr Gottlieb served as a speaker for Amgen, Inc. and Wyeth Pharmaceuticals; has current consulting/advisory board agreements with Amgen, Inc., Centocor, Inc., Wyeth Pharmaceuticals, Celgene Corp, Bristol Myers Squibb Co, Beiersdorf, Inc, Warner Chilcott, Abbott Labs, Roche, Sankyo, Medarex, Kemia, Celera, TEVA, Actelion, UCB, Novo Nordisk, Almirall, Immune Control, RxClinical, Dermipsor Ltd, Medacorp, DermiPsor, Can-Fite, and Incyte; and has received research/educational grants from Centocor, Amgen, Wyeth, Immune Control, Celgene, Pharmacare, and Incyte. All income has been paid to her employer directly.

Neil J. Korman, MD, PhD: Dr Korman has served on the Advisory Board and was investigator and speaker for Abbott Labs, Genentech, and Astellas, receiving grants and honoraria; served on the Advisory Board and was investigator for Centocor, receiving grants and residency/ fellowship program funding; and was investigator and speaker for Amgen, receiving grants and honoraria.

Kenneth B. Gordon, MD: Dr Gordon served on the Advisory Board and was consultant, investigator, and speaker for Abbott Labs, Amgen, and was a consultant and investigator for Centocor, receiving grants and honoraria; and was investigator for Genentech, receiving grants.

Steven R. Feldman, MD, PhD: Dr Feldman served on the Advisory Board and was investigator and speaker for Galderma, Stiefel, Warner Chilcott, Abbott Labs, and Astellas, receiving grants and honoraria; served on the Advisory Board for Photomedex, receiving stock options; served on the advisory board and was speaker for National Psoriasis Foundation, receiving honoraria; and was an investigator and speaker for Amgen, Centocor, and Genentech, receiving grants and honoraria.

Mark Lebwohl, MD: Dr Lebwohl served on the Advisory Board and was consultant, investigator, and speaker for Abbott Labs, Amgen, Centocor, Galderma, Genentech, and Warner Chilcott, receiving honoraria and grants; served on the Advisory Board and was consultant, investigator, and speaker for Stiefel, receiving honoraria; was consultant and investigator for Astellas, receiving grants and honoraria; was consultant for Biogen, UCB, and Isotechnika, receiving honoraria; was on the Advisory Board and was consultant and investigator for Novartis, receiving grants and honoraria; and had an "other" relationship with PharmaDerm, receiving grants and honoraria.

John Y. M. Koo, MD: Dr Koo served on the Advisory Board, was speaker, consultant, and investigator for Amgen, Abbott Labs, Astellas, Warner Chilcott, and Galderma, receiving grants and honoraria; was investigator for Genentech, receiving grants; and was on the Advisory Board and was a consultant and investigator for Teikokio receiving no compensation.

Abby S. Van Voorhees, MD: Dr Van Voorhees served on the Advisory Board, was an investigator and speaker for Amgen and Genentech, receiving grants and honoraria; was an investigator for Astellas, IDEC, and Roche receiving grants; an Advisory Board and investigator for Bristol Myers Squibb and Warner Chilcott, receiving grants and honoraria; Advisory Board and speaker for Abbott Labs and Centocor, receiving honoraria; served on the Advisory Board for Connetics, receiving honoraria; was a consultant for Incyte and Xtrac and VGX and has received honoraria from Synta for another function. Dr. Van Voorhees' spouse is an employee with Merck receiving a salary, stock, and stock options.

Craig A. Elmets, MD: Dr Elmets has served on the Advisory Board and was investigator for Amgen and Abbott Labs, receiving grants and honoraria; was consultant for Astellas, receiving honoraria; and was an investigator for Genentech and Connetics, receiving grants.

Craig L. Leonardi, MD: Dr Leonardi served on the Advisory Board and was consultant, investigator, and speaker for Abbott Labs, Amgen, Centocor, and Genentech receiving honoraria, other financial benefits, and grants for Amgen and Genentech; was speaker for Warner Chillcott, receiving honoraria; was on the Advisory Board and was an investigator for Serano, receiving honoraria and other financial benefit; was an investigator for Astellas, Biogen, Bristol Myers, Allergan, Fujisawa, CombinatorRx, and Vitae, receiving other financial benefit.

Karl R. Beutner, MD, PhD: Chair, Clinical Research Committee. Dr Beutner was an employee of Anacor, receiving salary, stock, and stock options; and had other relationships and received stocks from Dow Pharmaceutical Sciences.

Reva Bhushan, PhD: Dr Bhushan has no relevant conflicts of interest to disclose.

Alan Menter, MD: Chair, Psoriasis Work Group. Dr Menter served on the Advisory Board and was a consultant, investigator and speaker for Abbott Labs, Amgen, and Centocor, receiving grants and honoraria; served on the Advisory Board and was an investigator and consultant for Cephalon and UCB, receiving grants and honoraria; was a consultant, investigator, and speaker for Warner Chilcott and Wyeth, receiving honoraria; served on the Advisory Board and was an investigator for Galderma and Genentech, receiving grants and honoraria; was a consultant and investigator for Allergan and Astellas, receiving grants and honoraria; was an investigator for Collagenex, CombinatoRx, Dow, Ferndale, Leo, Medicis, Photocure, Pierre Fabre, 3M Pharmaceuticals, and XOMA receiving grants; and was an investigator for Connetics, receiving grants and honorarium.

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from American Academy of Dermatology Web site.

Print copies: Available from the AAD, PO Box 4014, Schaumburg, IL 60168-4014, Phone: (847) 330-0230 ext. 333; Fax: (847) 330-1120; Web site: www.aad.org.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI Institute on June 30, 2008. The information was verified by the guideline developer on July 16, 2008.

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DISCLAIMER

NGC DISCLAIMER

Readers with questions regarding guideline content are directed to contact the guideline developer.

Date Modified: 11/3/2008