



Complete Summary

GUIDELINE TITLE

Guidelines of care for the management of psoriasis and psoriatic arthritis: section 1. overview of psoriasis and guidelines of care for the treatment of psoriasis with biologics.

BIBLIOGRAPHIC SOURCE(S)

Menter A, Gottlieb A, Feldman SR, Van Voorhees AS, Leonardi CL, Gordon KB, Lebwohl M, Koo JY, Elmets CA, Korman NJ, Beutner KR, Bhushan R. Guidelines of care for the management of psoriasis and psoriatic arthritis: Section 1. Overview of psoriasis and guidelines of care for the treatment of psoriasis with biologics. J Am Acad Dermatol 2008 May;58(5):826-50. [177 references] <u>PubMed</u>

GUIDELINE STATUS

This is the current release of the guideline.

**** REGULATORY ALERT ****

FDA WARNING/REGULATORY ALERT

Note from the National Guideline Clearinghouse: This guideline references drug(s) for which important revised regulatory and/or warning information has been released.

• October 17, 2008, Raptiva (efalizumab): The U.S. Food and Drug Administration (FDA) notified healthcare professionals of extensive labeling changes, including a Boxed Warning, to highlight the risks of life-threatening infections, including bacterial sepsis, viral meningitis, invasive fungal disease, progressive multifocal leukoencephalopathy and other opportunistic infections with the use of Raptiva. In addition, the prescribing information will be updated to describe a potential risk for the permanent suppression of the immune system with repeat administration of Raptiva in children. Raptiva is not approved for children under 18 years of age.

COMPLETE SUMMARY CONTENT

** REGULATORY ALERT ** SCOPE METHODOLOGY - including Rating Scheme and Cost Analysis RECOMMENDATIONS EVIDENCE SUPPORTING THE RECOMMENDATIONS BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS CONTRAINDICATIONS QUALIFYING STATEMENTS IMPLEMENTATION OF THE GUIDELINE INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES IDENTIFYING INFORMATION AND AVAILABILITY DISCLAIMER

SCOPE

DISEASE/CONDITION(S)

- Psoriasis (adult and childhood)
- Psoriatic arthritis (PsA)

Note: Guideline developers did not include less common subtypes of psoriasis, such as guttate, pustular, inverse, and erythrodermic.

GUIDELINE CATEGORY

Diagnosis 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 adult and childhood psoriasis and psoriatic arthritis
- To present an overview of classification, comorbidities, and assessment tools and cover biologic treatments for psoriasis

TARGET POPULATION

Children and adults with psoriasis and psoriatic arthritis

INTERVENTIONS AND PRACTICES CONSIDERED

Evaluation/Management/Treatment

- 1. Classification of psoriasis
- 2. Evaluation of comorbidities
- 3. Evaluation of psoriasis treatment using assessment tools (The Psoriasis Area and Severity Index [PASI]; the Physicians Global Assessment [PGA] and target plaque scores together with percent of body surface area [BSA] involvement)
- 4. Topical therapies
- 5. Ultraviolet (UV) light therapies, including narrowband (NB) and broadband UVB, psoralen plus ultraviolet A (PUVA), and sunlight
- 6. Systemic agents, including methotrexate, cyclosporine (CyA), oral retinoids
- 7. Biologic therapies
 - Therapies that target pathogenic T cells, including alefacept and efalizumab
 - Tumor necrosis factor (TNF) inhibitors, including adalimumab, etanercept, infliximab

MAJOR OUTCOMES CONSIDERED

- Sensitivity, specificity and utility of assessment tools
- Safety and efficacy of treatments
- 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 psoriasis experts was convened to determine the audience and scope of the guideline, and identify clinical questions to structure the primary issues in diagnosis and management. Work group members completed a disclosure of commercial support.

An evidence-based model was used and evidence was obtained using a search of the MEDLINE database spanning the years 1990 through 2007. Only Englishlanguage 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

Review of Published Meta-Analyses 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 *British Medical Journal 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

These guidelines have been developed in accordance with the American Academy of Dermatology (AAD)/American Academy of Dermatology 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 the Treatment of Psoriasis

Topical treatments are appropriate for patients who are candidates for localized therapy but may not be practical as monotherapy for most patients who are candidates for systemic and/or phototherapy (Pariser et al., 2007), where traditional systemic treatments, including methotrexate, cyclosporine (CyA), narrowband (NB) and broadband ultraviolet light B (UVB), psoralen plus ultraviolet A (PUVA), oral retinoids, and the newer biologic agents are prescribed.

- 1. UVB is safe, effective, and cost-effective. NB UVB is more effective than broadband UVB. Up to 20 to 25 NB UVB treatments, given 2 to 3 times a week, are usually required for significant improvement. Treatment can be offered in the office or at home; home UVB reduces the inconvenience of patients having to travel a long distance for treatment. Other forms of UV exposure, including sun exposure, may offer benefit in select patients.
- 2. PUVA therapy is very effective in the majority of patients, with potential for long remissions. However, long-term PUVA treatment in Caucasians is associated with an increased risk of squamous cell carcinoma and possibly malignant melanoma. PUVA induces photoaging and other skin changes including lentigines. Ingestion of psoralen may also produce nausea. Oral psoralen is contraindicated in pregnancy. NB-UVB therapy avoids some of the adverse side effects of PUVA, while being slightly less effective than PUVA.
- 3. Methotrexate, although effective in the majority of patients, has the potential for hepatotoxicity and is contraindicated in the following clinical scenarios: pregnancy; individuals with renal impairment, hepatitis, or cirrhosis; alcoholics; unreliable patients; and patients with leukemia or thrombocytopenia. In addition, drug interactions are common. Methotrexate is an immunosuppressive agent. In patients treated with methotrexate, drug interactions are common with resultant bone-marrow suppression a concern. Methotrexate may induce pneumonitis. Methotrexate is a teratogen, an abortifacient, and decreases sperm count. Prior guidelines suggest a liver biopsy after 1.5-g cumulative dose (Roenigk et al., 1988).
- 4. CyA, another immunosuppressive medication, works rapidly and is effective in the majority of patients. However, impaired renal function, hypertension, concerns about lymphoma, and a potential increase in cutaneous malignancies are known adverse effects after long-term treatment with CyA. CyA is thus best used interventionally in short-term courses of 3 to 4 months. There are also numerous potential drug interactions with CyA. Guidelines

exist for reducing the CyA dose in patients who develop hypertension or elevations in creatinine.

- 5. Acitretin is an effective systemic agent for the treatment of psoriasis that is not immunosuppressive. Because it is teratogenic and should not be used in women who are pregnant, breast-feeding, or may become pregnant within 3 years of discontinuing acitretin, its use is substantially limited in female patients of childbearing potential. Mucocutaneous side effects are frequent. Dyslipidemia may also ensue and require dose reduction or treatment with lipid-lowering agents. Hepatotoxicity rarely arises during therapy. Acitretin is frequently used in combination therapy with UVB or PUVA.
- 6. Biologic agents are proteins that can be extracted from animal tissue or produced by recombinant deoxyribonucleic acid (DNA) technology and possess pharmacologic activity. Five biologic agents are currently Food and Drug Administration (FDA) approved for psoriasis. Their safety and efficacy are discussed in detail in the original guideline document.

Treatment of Psoriasis with Biologics

Refer to the original guideline document for general recommendations for all patients who will be treated with biologics including T-cell inhibitors and tumor necrosis factor (TNF) inhibitors.

Biologics that Target Pathogenic T Cells

Recommendations for Alefacept

- **Indication**: moderate to severe psoriasis
- **Dosing**: 15 mg every week given as an intramuscular injection for 12 weeks, with a 12-week follow-up nontreatment period
- **Short-term Results**: 21% of patients achieved a 75% improvement in the Psoriasis Area and Severity Index (PASI-75) at week 14
- Long-term Results:
 - Associated with long remissions in a subset of responders
 - Prior response to alefacept is a likely marker of future treatment response; thus, patients responding to the first course of therapy may be treated long-term with repeated 12-week courses of alefacept -- at a minimum of 24-week intervals
- **Toxicity**: excellent safety profile in clinical trials
- Baseline Monitoring: CD4 count
- **Ongoing Monitoring**: biweekly CD4 count required; hold dose for counts <250
- Pregnancy Category: B
- Contraindications: human immunodeficiency virus (HIV) infection

Recommendations for Efalizumab

- **Indication**: moderate to severe psoriasis
- **Dosing**: 0.7 mg/kg first dose followed by 1.0 mg/kg/week subcutaneously
- **Short-term Response**: 27% of patients achieve a 75% improvement in the Psoriasis Area and Severity Index score (PASI-75) at 3 months)
- **Long-term Response**: 44% to 50% of patients achieved and maintained a PASI-75 response in a 3-year open-label study that only enrolled responders

- Toxicities:
 - Flu-like symptoms frequently occur initially and generally disappear after the third week of treatment
 - Thrombocytopenia, hemolytic anemia, pancytopenia, and peripheral demyelination have all been reported
- Other Issues:
 - Small percentage of patients may develop rebound or flare
 - Do not discontinue treatment abruptly unless essential
 - Not effective in psoriatic arthritis; flares and new-onset psoriatic arthritis have been reported in a subset of patients
- **Baseline Monitoring**: complete blood count (CBC)
- Ongoing Monitoring:
 - CBCs monthly for the first 3 months and at periodic intervals thereafter
 - Liver function test (LFT) and a periodic history and physical examination are recommended while on treatment
- Pregnancy Category: C

Table: The Strength of Recommendations for the Treatment of PsoriasisUsing Biologics That Target Pathogenic T Cells

Recommendation	Strength of Recommendation	Level of Evidence	References
Alefacept	A	I	Gordon et al., "Treatment of psoriasis," 2003; Krueger & Ellis, 2003; Ellis & Krueger, 2001; Finlay, Salek, & Haney, 2003; Gottlieb, Boehncke, & Darif, 2005; Krueger, 2003; Krueger et al., 2002; Lebwohl et al., "An international," 2003; Menter et al., 2006
Efalizumab	A	Ι	Ortonne et al., 2005; Dubertret et al., 2006; Lebwohl et al., "A novel," 2003; Leonardi et al., 2005; Gordon et al., Efalizumab for patients," 2003; Gottlieb et al., "Extended efalizumab therapy," 2004; Gottlieb et al., "Long-term continuous efalizumab therapy," 2006; Menter et al., 2005; Menter et al., 2006; Papp et al., "Safety of efalizumab in adults," 2006; Papp et al., 2005; Papp et al., "Efalizumab retreatment,"

Recommendation	Strength of Recommendation	Level of Evidence	References
			2006; Pariser et al., 2005; Leonardi et al., 2007

General Recommendations for Tumor Necrosis Factor (TNF) Inhibitors

- Anti-TNF agents are contraindicated in patients with active, serious infections
- Tuberculosis testing (purified protein derivation [PPD]) should be performed on all patients who will be treated with TNF inhibitors as there are reports of tuberculosis reactivation in patients treated with this class of drug. (Desai & Furst, 2006)
- Do not use with live vaccines; biologically inactive or recombinant vaccines may be considered, although the immune response of these vaccines could be compromised
- Because there is an association between anti-TNF therapy and demyelinating diseases (i.e., multiple sclerosis [MS]), TNF inhibitors should not be used in patients with MS or other demyelinating diseases; first-degree relatives of patients with MS have an increased risk of developing MS, with a sibling relative risk of between 18 and 36, evidence strongly suggesting that TNF inhibitors should not be used in first-degree relatives of patients with MS.
- Because there have been reports of new onset and worsening of congestive heart failure (CHF) in patients treated with TNF inhibitors, caution should be used when considering TNF inhibitor use in patients with CHF; it is recommended that patients with New York Heart Association class III or IV CHF avoid all use of TNF inhibitors and patients with class I or II CHF undergo echocardiogram testing; if the ejection fraction of these patients is <50%, then TNF inhibitor treatment should potentially be avoided. (Desai & Furst, 2006)
- Hepatitis B reactivation after treatment with TNF inhibitors has been reported; in the appropriate clinical setting, patients should be screened for hepatitis B infection.

Recommendations for Adalimumab

- **Indications**: moderate to severe psoriatic arthritis, moderate to severe psoriasis, adult and juvenile rheumatoid arthritis (as young as age 4 years), ankylosing spondylitis, and Crohn's disease
- **Dosing for Psoriasis**: 80 mg the first week, 40 mg the second week, followed by 40 mg every other week given subcutaneously
- Short-term Results: 80% of patients achieve PASI-75 at 12 week
- **Long-term Results**: 68% of patients achieve 75% improvement in the Psoriasis Area and Severity Index score (PASI-75) at 60 weeks
 - Small percentage of patients lose efficacy with continued use
- Toxicities:
 - Moderately painful injection site reactions are noted
 - Rare reports of serious infections (i.e., tuberculosis and opportunistic infections) and malignancies
 - There are rare reports of drug-induced, reversible side effects including lupus without renal or central nervous system (CNS)

complications, cytopenia, multiple sclerosis (MS), and exacerbation of and new onset of congestive heart failure (CHF)

- Baseline Monitoring:
 - Purified protein derivation (PPD) is required
 - Liver function test (LFT), complete blood count (CBC), and hepatitis profile

Ongoing Monitoring:

Periodic history and physical examination are recommended while on treatment

Consider a yearly PPD, and periodic CBC and LFT

• Pregnancy Category: B

Recommendations for Etanercept

- **Indications**: moderate to severe psoriasis, moderate to severe psoriatic arthritis, adult and juvenile rheumatoid arthritis (as young as 4 years), and ankylosing spondylitis
- **Dosing**: 50 mg twice/week given subcutaneously for 3 months followed by 50 mg once/week
- **Short-term Results**: 49% of patients given 50 mg twice/week achieved a PASI-75 at 12 weeks; 34% of patients given 25 mg twice/week achieved a PASI-75 at 12 weeks
- **Step-down Results**: 54% of patients whose dose was decreased from 50 mg twice/week to 25 mg twice/week achieved a PASI-75 at 24 weeks; 45% of patients whose dose remained at 25 mg twice/week achieved a PASI-75 at 24 weeks
- Toxicities:
 - Mildly pruritic injection site reactions may occur
 - Rare cases of serious infections (i.e., tuberculosis) and malignancies
 - There are also rare cases of drug-induced, reversible side effects including lupus without renal or central nervous system (CNS) complications, cytopenia, multiple sclerosis (MS), and exacerbation and new onset of congestive heart failure (CHF)

• Baseline Monitoring:

- Purified Protein Derivation (PPD) is required
- Liver function test (LFT) and complete blood count (CBC)
- Ongoing Monitoring:
 - Periodic history and physical examination are recommended while on treatment
 - Consider yearly PPD, and periodic CBC and LFT
- Pregnancy Category: B
- Contraindications: sepsis

Recommendations for Infliximab

• **Indications**: severe psoriasis, moderate to severe psoriatic arthritis, adult rheumatoid arthritis, ankylosing spondylitis, ulcerative colitis, and Crohn's disease

- **Dosing**: 5 mg/kg dose infusion schedule at week 0, 2, and 6 and then every 6 to 8 weeks; dose and interval of infusions may be adjusted as needed
- **Short-term Response**: 80% of patients achieved a PASI-75 at week 10, 50% PASI improvement noted by week 2
- Long-term Response: 61% of patients achieved a PASI-75 at week 50
- Toxicities:
 - Infusion reactions and serum sickness can occur -- more commonly in patients who have developed antibodies
 - The incidence of infusion reactions may be reduced by concurrent administration of methotrexate
 - Rare cases of serious infections (i.e., tuberculosis) and malignancies including hepatosplenic T-cell lymphoma (in children); there are rare reports of drug-induced, reversible side effects including lupus without renal or central nervous system (CNS) complications, cytopenia, multiple sclerosis (MS), and exacerbation of and new onset of congestive heart failure (CHF)

Baseline Monitoring:

- Purified Protein Derivation (PPD) is required
- Liver function test (LFT), complete blood count (CBC), and hepatitis profile
- Ongoing Monitoring:
 - Periodic history and physical examination are recommended while on treatment
 - Consider a yearly PPD, and periodic CBC and LFT
- Pregnancy Category: B
- **Contraindications**: infliximab at doses >5 mg/kg should not be given to patients with New York Heart Association functional class III or IV CHF

Table: The Strength of Recommendations for the Treatment of PsoriasisUsing Tumor Necrosis Factor Inhibitors

Recommendation	Strength of Recommendation	Level of Evidence	References
Adalimumab	A	I	Gordon et al., "Clinical response," 2006; Menter et al., 2008; Patel & Gordon, 2004; Gordon, 2007
Etanercept	A	I	Tyring et al., 2006; Gottlieb et al., "A randomized trial of etanercept," 2003; Gordon et al., "Efficacy of etanercept, " 2006; Gottlieb et al., "Etanercept monotherapy,' 2006; Krueger et al., 2005; Moore et al., 2007; Leonardi et al., 2003; Papp et al., 2005; Paller et al., 2008

Recommendation	Strength of Recommendation	Level of Evidence	References
Infliximab	A	I	Menter et al., 2007; Gottlieb et al., "Pharmacodynamic and pharmacokinetic response," 2003; Chaudhari et al., 2001; Feldman et al., 2005; Gottlieb et al., "Infliximab monotherapy," 2003; Gottlieb et al., "Infliximab induction, " 2004; Antoni et al., 2005; Reich et al., 2005

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)

A decision tree for the treatment of psoriasis with or without psoriatic arthritis is provided in the original guideline document.

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").

POTENTIAL BENEFITS

Appropriate management of psoriasis and psoriatic arthritis

POTENTIAL HARMS

Adverse Effects of Treatment

- *Psoralen Plus Ultraviolet A (PUVA)*. Long-term PUVA treatment in Caucasians is associated with an increased risk of squamous cell carcinoma and possibly malignant melanoma. PUVA induces photoaging and other skin changes including lentigines. Ingestion of psoralen may also produce nausea.
- Methotrexate has the potential for hepatotoxicity. In addition, drug interactions are common. Methotrexate is an immunosuppressive agent. In patients treated with methotrexate, drug interactions are common with resultant bone-marrow suppression a concern. Methotrexate may induce pneumonitis. Methotrexate is a teratogen, an abortifacient, and decreases sperm count.
- *Cyclosporine (CyA)*. Known adverse effects after long-term treatment include impaired renal function, hypertension, concerns about lymphoma, and a potential increase in cutaneous malignancies. There are also numerous potential drug interactions with CyA.
- *Acitretin* is a teratogenic. Mucocutaneous side effects are frequent. Dyslipidemia may also ensue and require dose reduction or treatment with lipid-lowering agents. Hepatotoxicity rarely arises during therapy.
- Adalimumab: Moderately painful injection site reactions are noted. There are rare reports of serious infections (i.e., tuberculosis and opportunistic infections) and malignancies, drug-induced, reversible side effects including lupus without renal or central nervous system (CNS) complications, cytopenia, multiple sclerosis (MS), and exacerbation of and new onset of congestive heart failure (CHF).
- *Etanercept*. Mildly pruritic injection site reactions may occur. There have been rare cases of serious infections (i.e., tuberculosis) and malignancies, and cases of drug-induced, reversible side effects including lupus without renal or CNS complications, cytopenia, MS, and exacerbation and new onset of CHF.
- Infliximab. Infusion reactions and serum sickness can occur more commonly in patients who have developed antibodies. There have been rare cases of serious infections (i.e., tuberculosis) and malignancies including hepatosplenic T-cell lymphoma (in children). There have also been rare reports of druginduced, reversible side effects including lupus without renal or CNS complications, cytopenia, MS, and exacerbation of and new onset of CHF.

See the original guideline document for detailed discussions concerning general and specific safety issues of the tumor necrosis factor (TNF) inhibitors.

CONTRAINDICATIONS

CONTRAINDICATIONS

- Oral psoralen is contraindicated in pregnancy.
- *Methotrexate* is contraindicated in the following clinical scenarios: pregnancy; individuals with renal impairment, hepatitis, or cirrhosis; alcoholics; unreliable patients; and patients with leukemia or thrombocytopenia.
- Treatment with biologics (e.g., anti-TNF agents) is contraindicated in patients with active, serious infections. If patients develop serious infections (usually defined as an infection that requires antibiotic therapy) while being treated with a biologic agent, it is prudent to hold the biologic until the infection has resolved.
- *Acitretin* is contraindicated in women who are pregnant, breast-feeding, or may become pregnant within 3 years of discontinuing acitretin.
- Alefacept therapy is not indicated for patients with a CD4 T-lymphocyte count below normal or in those who are infected with human immunodeficiency virus (HIV) because of the potential for acceleration of disease progression as a result of CD4 T-lymphocyte count reduction induced by alefacept. Caution should be exercised in patients who are at risk for or have a history of malignancy or infection, especially clinically significant infections.
- *Etanercept* is contraindicated in sepsis.
- Infliximab at doses >5 mg/kg should not be given to patients with New York Heart Association functional class III or IV CHF.

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.

IMPLEMENTATION TOOLS

Clinical Algorithm

For information about <u>availability</u>, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness

IOM DOMAIN

Effectiveness Safety

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Menter A, Gottlieb A, Feldman SR, Van Voorhees AS, Leonardi CL, Gordon KB, Lebwohl M, Koo JY, Elmets CA, Korman NJ, Beutner KR, Bhushan R. Guidelines of care for the management of psoriasis and psoriatic arthritis: Section 1. Overview of psoriasis and guidelines of care for the treatment of psoriasis with biologics. J Am Acad Dermatol 2008 May;58(5):826-50. [177 references] <u>PubMed</u>

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: Alan Menter, MD, *Chair*, Baylor University Medical Center, Dallas; Alice Gottlieb, MD, PhD, Department of Dermatology, Tufts-New England Medical Center, Tufts University School of Medicine, Boston; Steven R. Feldman, MD, PhD, Department of Dermatology, Wake Forest University School of Medicine, Winston-Salem; Abby S. Van Voorhees, MD, Department of Dermatology, University of Pennsylvania; Craig L. Leonardi, MD, Saint Louis University; Kenneth B. Gordon, MD, Division of Dermatology, Evanston Northwestern Healthcare and Department of Dermatology, Northwestern University, Fienberg School of Medicine, Chicago; 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; Craig A. Elmets, MD, Department of Dermatology, University of Alabama at Birmingham; Neil J. Korman, MD, PhD, Murdough Family Center For Psoriasis, Department of Dermatology, University Hospitals Case Medical Center, Cleveland; Karl R. Beutner, MD, PhD, Anacor Pharmaceuticals Inc, Palo Alto; Reva Bhushan, PhD, American Academy of Dermatology, Schaumburg

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

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; as 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.

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, Incyte; and has received research/educational grants from Centocor, Amgen, Wyeth, Immune Control, Celgene, Pharmacare, Incyte. All income has been paid to her employer directly.

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.

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; investigator for Astellas, IDEC and Roche, receiving grants; Advisory Board and investigator for Birstol Myers Squibb and Warner Chilcott, receiving grants and honoraria; Advisory Board and was speaker for Abbott Labs and Centocor, receiving honoraria; served on the Advisory Board for Connetics, receiving honoraria; was 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 L. Leonardi, MD: Dr Leonardi served on the Advisory Board and was consultant, investigator, and speaker for Abbott Labs, Amgen, Centocor, Genentech, receiving honoraria, other financial benefit, and grants for Amgen and

Genentech; was speaker for Warner Chillcott receiving honoraria; was on the Advisory Board and was investigator for Serano receiving honoraria and other financial benefit; was investigator for Astellas, Biogen, Bristol Myers, Allergun, Fujisawa, CombinatorRx, and Vitae receiving other financial benefit.

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

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 an Advisory Board consultant and investigator for Teikokio, receiving compensation.

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.

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.

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 stock from Dow Pharmaceutical Sciences.

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GUIDELINE STATUS

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AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

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