

USP Issues Final Model Formulary Guidelines

BY MARY ELLEN SCHNEIDER
Senior Writer

The standard-setting group U.S. Pharmacopeia has established 146 unique therapeutic categories and pharmacologic classes to guide the establishment of formularies under the new Medicare Part D prescription drug benefit.

The model guidelines created by USP will serve as a voluntary framework for health plans and prescription drug plans as

they create drug plan formularies for Medicare, as established by the Medicare Modernization Act of 2003.

"The model guidelines are not a formulary," Roger L. Williams, M.D., USP executive vice president and CEO and chair of the group's Model Guidelines Expert Committee, said in a press teleconference.

In addition to the categories and classes created by USP, the group also created a separate listing of formulary key drug types to help the Centers for Medicare and

Medicaid Services assess the comprehensiveness of proposed formularies.

Under proposed Medicare regulations, plans that follow the model guidelines would need to offer at least two drugs in each therapeutic category and pharmacologic class. USP has also recommended that CMS require plans to offer at least one drug from the list of formulary key drug types or have a clinical or scientific rationale for excluding the drugs.

CMS officials will use the guidelines to

help evaluate proposed formularies.

The USP issued draft guidelines last August that were criticized by physician groups and patient advocates as leaving too many critical drugs in a third category, where coverage would not be required.

The final guidelines include a new therapeutic category for inflammatory bowel disease agents and a new pharmacologic class for proton pump inhibitors. Other changes to the model guidelines include additional antimental drugs and expanded dermatologic agents.

Dr. Williams said he hopes all parties will see this as "workable compromise."

The American Academy of Dermatology had raised concerns last year that the draft guidelines did not adequately cover combination therapies for chronic conditions such as psoriasis and psoriatic arthritis, for example. At press time, the group was still reviewing the final guidelines.

The American College of Rheumatology (ACR) applauded USP's efforts in

The AAD had raised concerns that the draft guidelines did not adequately cover combination therapies for conditions such as psoriasis and psoriatic arthritis.

putting together the model guidelines and called it a good place to start. But much will depend upon how CMS decides to use the guidelines, said Pam Ferraro, a regulatory analyst for ACR.

Many of the drugs of interest to rheumatologists, such as tumor necrosis factor inhibitors, were not included as either therapeutic categories or pharmacologic classes but were part of USP's list of formulary key drug types. ACR officials want to see drug plans cover the medications in this third category and make them available at affordable prices, Ms. Ferraro said.

The National Mental Health Association (NMHA) warned that the USP guidelines ignored recommendations from the mental health field not to group older medications with newer therapies. Since these medications are lumped together, health plans could choose to cover only the older, less expensive drugs. But NMHA president and CEO Michael M. Faenza said that his group is encouraged that CMS plans to consider widely accepted treatment guidelines for mental health when reviewing formularies.

But America's Health Insurance Plans (AHIP) praised the USP's final document. "The final model continues to provide needed flexibility by not expanding the number of categories and classes previously proposed," said Karen Ignagni, AHIP president and CEO. "The direction that CMS is clearly taking supports the building of effective private plan strategies to make the Part D benefit clinically appropriate and affordable for Medicare beneficiaries."

Officials at the Pharmaceutical Research and Manufacturers of America, which has supported access to a broad array of treatments, were still reviewing the document at press time.

29th Annual
Hawaii Dermatology Seminar™
A CONTINUING MEDICAL EDUCATION CONFERENCE

MARCH 17 - 25, 2005

GRAND WAILEA RESORT
Wailea, Maui, HI

Recognized as the premier medical education meeting delivering the latest developments in all areas of dermatology to improve patient care.

FEATURING

- ALA Photodynamic Therapy
- The Use of Active Naturals in Dermatology
- A New Approach For Volumetric Restoration
- Topical Anesthesia Made Fast, Neat & Easy
- Investigating Selective T-Cell Targeting in Psoriasis: Optimizing Outcomes in Clinical Practice
- Evolving Options in Anti-Inflammatory Therapy: The Role of Retinoids
- Contemporary and Creative Treatment Approaches for Acne, Psoriasis and Other Inflammatory Dermatosis
- Treatment of Subclinical Cutaneous Neoplasia
- Experience with Anti-TNF Therapies in Psoriatic Diseases
- Update on Appearance: Enhancing Agents
- Selecting a Daily Skin Care Regimen for Today's Female Patients: Clinical and Cosmetic Considerations
- Actinic Keratosis
- Anti-TNFs for PsA and Psoriasis - What's New in 2005
- Therapeutic Advances in the Treatment of Acne
- Management of a Chronic Disease: A Proactive Approach to the Treatment of Eczema
- Long-term Therapy for Psoriasis: What Does the Future Hold?
- Retinaldehyde: A Breakthrough Program in Skin Rejuvenation
- Maximizing the Performance of Your Acne Therapy
- Excellence in Adjunctive Therapy
- Anti-TNF Therapies in the Treatment of Dermatologic Diseases
- Advances in Hyperkeratotic Skin Disorders
- Maximizing Results in the Treatment of Acne and Facial Photodamage
- Latex Allergy Update
- Acne and Isotretinoin



FOUNDING DIRECTORS

- Howard I. Maibach, M.D.**
University of California, San Francisco
- Henry H. Roenigk, Jr., M.D.**
Arizona Advanced Dermatology, Phoenix

DIRECTOR OF MEETINGS

- Randall K. Roenigk, M.D.**
Mayo Clinic, Rochester

SCIENTIFIC ADVISORY BOARD

- Terry L. Barrett, M.D.***
Johns Hopkins University
- Steven C. Bernstein, M.D.***
University of Montreal
- Ilona J. Frieden, M.D.***
University of California, San Francisco
- David J. Goldberg, M.D., J.D.***
Mount Sinai School of Medicine
- Kenneth E. Greer, M.D.***
University of Virginia
- Francisco A. Kerdel, M.D.**
University of Miami, School of Medicine
- Sigrid A. Muller, M.D.**
Las Vegas Skin & Cancer Clinics
- R. Steven Padilla, M.D.**
University of New Mexico
- James M. Spencer, M.D.**
Mount Sinai School of Medicine
- Christopher B. Zachary, M.D.**
University of California, San Francisco

* indicates member of Hawaii Dermatology Seminar Planning Committee

Hawaii Dermatology Seminar is recognized by the American Academy of Dermatology for 34 hours of AAD Category 1 CME credit and may be used toward the AAD Continuing Medical Education Award.

THIS CME SEMINAR IS SUPPORTED IN PART BY EDUCATIONAL GRANTS FROM:

- 3M Pharmaceuticals
Abbott Immunology
Allerderm Laboratories
Allergan, Inc.
Amgen, Inc.
Biogen Idec
Bioglan Pharmaceuticals Company
Centocor
CollaGenex Pharmaceuticals, Inc.
Connetics Corporation
Dermik Aesthetics
DUSA Pharmaceuticals
Ferdale Laboratories, Inc.
Fujisawa Healthcare, Inc.
Galderma Laboratories, L.P.
Genentech, Inc.
Healthpoint Dermatology
Johnson & Johnson
Consumer Products Company
La Roche-Posay
Ligand Pharmaceuticals Incorporated
Medicis Aesthetics
Novartis Pharmaceuticals
OrthoNeutrogena
Pierre Fabre Dermo-Cosmetiques USA
Ranbaxy USA
SkinMedica
Stiefel Laboratories
Thermage, Inc.
Unilever Home & Personal Care, USA
Upsher-Smith Laboratories, Inc.



SKIN DISEASE
EDUCATION FOUNDATION™
AN ELSEVIER COMPANY

For more information or to register for the 29th ANNUAL HAWAII DERMATOLOGY SEMINAR, visit www.sdefderm.com or call 312/988-7700.