October 20, 2017

Eric Hargan
Acting Secretary
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, D.C. 20201

Re: MassHealth Section 1115 Demonstration Waiver Amendment Request, Section 4 ("Waiver Request")

Dear Acting Secretary Hargan:

On behalf of the undersigned organizations representing approximately 13,500 dermatologists nationwide, who diagnose and treat more than 3,000 skin diseases, we are writing to express our strong opposition to Section 4 of the Waiver Request, which would restructure the MassHealth pharmacy benefit to create a “closed formulary.” A formulary that includes only one drug per class is an ineffective, draconian approach to reducing health care costs by creating a one–size-fits-all solution. If approved, approximately one million lives will unnecessarily be at risk, as explained below. Our members are keenly aware of the nation’s increased health care costs and their own responsibility to prescribe a treatment plan that wisely manages limited health care resources; however, a closed formulary is not the solution. Therefore, we urge policymakers from the Commonwealth of Massachusetts and the Centers for Medicare and Medicaid Services to explore alternative strategies to reduce health care costs. Patients should not be expected to bear this burden.

When developing a treatment plan for our patients, dermatologists base their recommendations and decisions on a thorough understanding of their patients’ medical history and medical needs. This knowledge enables them to identify potential contraindications and life-threatening adverse reactions, which is particularly critical for patients covered by MassHealth, many of which have multiple chronic conditions. Comorbidity often results in adverse health outcomes and complex clinical management. Requiring a patient to take a medication that the physician knows is not in the patient’s best interest and in some instances, will jeopardize the patient’s health, not only defies logic, but violates the Hippocratic oath.

The American Academy of Dermatology’s (Academy) guiding position on access to effective and affordable drugs is set forth in its Position Statement on Patient Access to Affordable Treatments:
“Physicians should have the entire compendium of pharmaceutical therapies available to them and the freedom to work with their patients to determine the appropriate course of treatment based on each patient’s unique circumstances.

“Each formulary must be developed based on scientifically valid evidence that the selected pharmaceuticals sufficiently provide the most effective therapies for any given condition and that options are available should patients not be able to utilize a given agent due to lack of response, side effects, allergy, etc.”.

A closed formulary will only exacerbate physicians’ ability to treat complicated skin diseases, such as psoriasis or pemphigus vulgaris. Forcing psoriasis patients to make consequential, potentially lengthy and disease-altering changes is a great challenge and hardship. Withdrawal of medication for psoriasis patients, particularly abrupt withdrawal, can aggravate a quiescent disease and result in psoriasis that is resistant to prior effective therapy. The consequences, which cannot be predicted for individual patients, include worsening disease, severe flares including those requiring hospitalization, therapeutic failure, antibody development and risk for greater adverse effects than those associated with current therapy. For many patients, the disease burden extends beyond physical findings; there is lost work and wages and a significant psychological impact.

Pemphigus vulgaris is a rare, auto-immune disease that causes blistering of the skin and mucous membranes. Treatment typically involves the prolonged use of steroids and immunosuppressive agents. If left untreated, the complications can be fatal. Each patient who presents with this disease is a unique challenge due to the diversity in the disease. Comorbidities, which include diabetes, hypertension, malignancies, chronic infections, among others, affect the appropriate treatment.

Additionally, the waiver request will profoundly impact patients with chronic conditions and who are stable on a drug that is no longer included in the closed formulary. Forcibly switching a patient to another drug poses significant risk to patients, possibly resulting in harmful outcomes like flaring of the disease, immunogenicity, adverse effects, and secondary nonresponse. It may also lead to the loss of effectiveness of the original medication, should the patient switch back in the future.

Lastly, this proposal unnecessarily increases the number of utilization management tools currently available for MassHealth formularies. Physicians and patients already cite difficulties accessing medications due to insurers’ use of existing utilization management tools, such as prior authorization, step therapy and tiering of formularies. Imposing a closed formulary will add to the number of patients who experience delays in accessing their prescription drugs.
As physicians, our number one priority is the health and welfare of our patients. We appreciate the opportunity to provide written comments on this important issue. Retaining physicians’ medical judgement in patients’ treatment plans is a cost-effective way to prevent health care dollars from being used on medications that are not effective. We respectfully urge you to carefully consider the ramifications of moving to a closed formulary and to reject Section 4 of the Waiver Request. Please contact Lisa Albany, Associate Director, State Policy, at LAlbany@aad.org or 202/842-3555 if you require clarification on any of the points above or would like further information.

Sincerely,

American Academy of Dermatology Association
Colorado Dermatologic Society
Georgia Society of Dermatology & Dermatologic Surgery
Idaho Dermatologic Society
Indiana Academy of Dermatology
Iowa Dermatological Society
Maryland Dermatologic Society
Massachusetts Academy of Dermatology
Mississippi Dermatological Society
Dermatological Society of New Jersey
Ohio Dermatological Association
Pennsylvania Academy of Dermatology and Dermatologic Surgery
Rhode Island Dermatology Society
Washington D.C. Dermatological Society

Enclosure

cc: The Honorable Charles D. Baker
A dermatologist is a licensed medical doctor and the only residency-trained physician fully educated in the science of cutaneous medicine, which includes the medical and surgical conditions of the skin, hair, nails, and mucous membranes. Dermatologists diagnose and treat more than 3,000 different diseases.

Dermatologists’ post-medical school training and education consists of a one-year internship in internal medicine with a subsequent three-year residency program comprised of extensive training in medical dermatology and skin surgery. After residency, many dermatologists seek fellowship training in one of several sub-specialties, including procedural dermatology, Mohs surgery, dermatopathology, pediatric dermatology, aesthetic dermatology, and cutaneous oncology. Upon training and exam completion, dermatologists are board certified through the American Board of Dermatology, one of 24 medical specialty boards that make up the American Board of Medical Specialties.

Dermatologists in the United States practice in every type of medical practice setting. However, the vast majority of dermatologists are in solo practice or in small group practices consisting of 10 clinicians or fewer.

92 percent of dermatologists in the United States are members of the American Academy of Dermatology Association (Academy), the largest representative dermatology group in the United States. The Academy and its members are dedicated to promoting leadership in dermatology and excellence in patient care through education, research and advocacy. To better guide dermatology’s position in the changing health care system, the Academy engaged in research to look at the effects of skin disease on patients in the United States, and to provide an up-to-date analysis of the burden of skin disease that reflects recent changes in the practice of medicine. The Academy’s 2016 Burden of Skin Disease report was published in early 2017.

Dermatologists treat a wide array of conditions and provide essential, lifesaving care to patients.

- The American Academy of Dermatology’s 2016 Burden of Skin Disease report analyzed 24 skin disease categories using data from 2013 medical claims.
- The scope of dermatology is far more than skin deep—common skin diseases such as eczema and psoriasis have been associated with other medical conditions, such as heart disease and diabetes.
  - Rosacea and Alzheimer’s disease may share common disease processes.
  - There is a correlation between psoriasis, diabetes, and excess weight, perhaps due to a common genetic cause.
  - Patients with eczema are at heightened risk of cardiovascular disease, obesity, asthma, food allergies, and hay fever.
- Half of skin disease categories analyzed were associated with mortality.
  - Life expectancy decreased by 5 years for those with fatal skin diseases.
- Skin cancers make up 60 percent of skin-related deaths; yet skin cancer is one of the most preventable skin diseases.

Prevalence of skin disease is high, and is likely to increase as the population ages.

- One in four Americans sought treatment for at least one skin disease in 2013; the average person was treated for 1.6 skin diseases.
- Nearly 50 percent of Americans over age 65 have skin disease, with an average of 2.2 skin diseases each.
- According to the Burden of Skin Disease report, there were more skin disease claims across the U.S. population in 2013 than cardiovascular disease, diabetes, or end stage renal disease.
IMPACT. (Effects of skin disease are far-reaching)

Skin diseases present a significant burden on Americans, their families, and employers.

- Patients and caregivers with skin disease suffered $11 billion in lost productivity. This does not include additional time with at-home care and treatments, which were not evaluated.

- $75 billion was spent on skin disease in 2013. The majority of this was for treatment costs, including:
  - $46 billion for health care provider medical care;
  - $15 billion for prescription drugs; and
  - $10 billion for over-the-counter skin treatment products.

- Nearly 25 percent of the population ages 0-17 had a diagnosed skin disease, creating a burden on families.

TEAM. (We embrace a team-based approach to care)

Dermatologists are eager to be ‘team players’ with their fellow clinicians, coordinating with other disciplines to treat ‘the whole patient.’

- Dermatologists are critical members of the health care team.

- Greater access to dermatology care is needed. An estimated 20,000 dermatology clinicians were needed to treat skin disease in 2013. There are only 10,000 board-certified dermatologists in the country.

- Two thirds of patients with skin diseases are treated by non-dermatologists, which can lead to disparities in the quality of care provided.

- Dermatologists are rapidly embracing innovative approaches to increase access to dermatologists’ knowledge and professional expertise, including telemedicine, physician extenders, expanded hours, learning collaboratives, and more.

- When dermatologists work with other physicians—whether primary care physicians, pediatricians, or other specialists—benefits can include improved patient outcomes and lowered health care costs.

- In an era of team-based care and payments that reward collaboration, dermatologists recognize the importance of these partnerships with our physician colleagues.

PREVENTION. (More prevention research is needed)

Prevention and early detection are key to reducing morbidity and mortality rates from preventable skin diseases.

- More research to study the impact of screenings and public education on skin disease is necessary.

- Physician electronic health records (EHRs) must be interoperable with clinical data registries.
  - Further data collection on outcomes by clinical data registries like the Academy’s DataDerm are key to understanding how dermatologists’ work alleviates the burden of skin disease for our patients.

- Exposure to ultraviolet radiation—from the sun and indoor tanning beds—is the most preventable risk factor for all skin cancers, including melanoma, the deadliest form of skin cancer.
  - Indoor tanning may cause upwards of 400,000 cases of skin cancer in the U.S. each year.