



September 17, 2004

U. S. Pharmacopeia (USP)
12601 Twinbrook Parkway
Rockville, MD 20852-1790
ATTN: Ms. Lynn Lang

Submitted electronically to: lfl@usp.org

RE: **Draft Model Guidelines**

The purpose of this letter is to submit NATCO's comments on the USP's Medical Prescription Drug Benefit Draft Model Guidelines. NATCO is the society for transplant professionals who are committed to the advancement of organ and tissue donation and transplantation. NATCO's members are a diverse group of more than 2,000 transplant specialists including

- Procurement coordinators who manage the care of the donor to ensure organ viability, consult with families in their donation decision, arrange for the surgical recovery of organs and match donor organs with recipients, and
- Clinical coordinators who manage the pre-transplant evaluation process, monitor the patient's level of wellness, adjust the patient's priority listing with a national computerized tracking system and manage the care of the recipient post-transplantation.

Our membership also includes hospital development specialists, social workers, pharmacists and transplant center administrators.

We wish to thank the U.S. Pharmacopeia for allowing this opportunity to review and offer comments on the model for Medicare prescription drug plans and commend the effort your organization has put forth in developing these guidelines. However, NATCO has significant concerns that **the drug categories outlined in the guidelines are not as comprehensive as they need to be to provide adequate coverage for individuals who have received a transplant; in particular, the classes in Part D do not include immunosuppressive drugs specifically prescribed for transplant nor do they include the other drugs that are regularly used in conjunction with immunosuppressive drug therapies in treating transplant patients in the short and long term.**

While most transplant recipients receive coverage through Medicare Part B or through private insurance for the immunosuppressive drugs they must take to prevent rejection, there are a significant number of Medicare-enrolled recipients who are not eligible or who do not have insurance; therefore, they must pay for their immunosuppressive drugs out of their own pocket. As you may be aware, recipients are ineligible for Part B coverage of immunosuppressive drugs if the transplant was not paid for by the Medicare program. These individuals will be eligible for coverage of their outpatient immunosuppressive drugs through a Medicare Part D PDP, regardless of any other source of outpatient drug coverage.

The proposed “Immune Suppressants” pharmacologic class combines immunosuppressive asthma, rheumatoid arthritis, dermatologic, and cancer drugs into the same class as transplant-related immunosuppressive drugs. Under the Medicare statute, a minimum of two drugs are required per pharmacologic class. The current structure of the Model Guidelines would likely restrict transplant recipients’ access to immunosuppressive drugs. Even requiring two drugs per recommended subdivision would not guarantee access. The result could be rejection of the transplanted organ, which will result in significantly higher costs to Medicare, not to mention the impact on the recipient, who will become acutely ill or perhaps die.

To address these concerns, we recommend creating a new therapeutic category for immunosuppressive drugs, including immune stimulants, immune suppressants and other agents. While this is what many health care professionals are accustomed to seeing, it would also be flexible enough to allow PDPs to design a formulary that promotes cost effectiveness and patient access to key transplant-related immunosuppressive drugs.

We appreciate the opportunity to submit our comments on the Draft Model Guidelines. Please feel free to contact me at 212-305-0914 or dl349@columbia.edu, or Deidre Gish-Panjada, Executive Director, at 913.492.3600 x 4407, or dpanjada@goAMP.com.

Sincerely,



Dianne LaPointe-Rudow, ANP, MSN, CCTC
President

cc: Board of Directors
Deidre Gish-Panjada, MBA, Executive Director
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