PROPOSALS TO

LOWER DRUG SPENDING:

What could they mean for patient access to PPTs?

BY TOM LILBURN, SENIOR DIRECTOR, GOVERNMENT RELATIONS, PPTA
BRENNA RAINES, ASSISTANT DIRECTOR, GLOBAL HEALTH POLICY, PPTA

Government spending on Centers for Medicare & Medicaid Services (CMS) programs (Medicaid, Children's Health Insurance Program, and Medicare) accounts for 37 percent of the total national health expenditure and 41 percent of the total prescription drug expenditure in the United States.[1] Some projections estimate these percentages will increase over the next decade as a result of enrollment growth due to the aging population, changes in projected income growth, and changes in program eligibility. In addition to this trend, all payers are grappling with how to budget for new high-cost, curative therapies. Often the solution for public payers is to propose laws or regulations that will curb prescription drug spending by reducing choice and utilization.

Much of the rhetoric about government spending on prescription drugs at the federal and state level surrounds a perceived lack of competition and/or negotiation. Accordingly, many proposed solutions exemplify increased competition and/or negotiation. For example, a recent federal proposal[2] would introduce third-party vendors to negotiate prices with pharmaceutical manufacturers and sell them to providers. However, the proposal does not require vendors to make all therapies available, nor does it mandate that physicians must contract with enough vendors to make all therapies available. A failed state proposal[3] would have established a closed formulary, meaning individuals would not have access to all therapies. Rather, manufacturers would have to compete for approval by the state.

These and other proposals attempt to assuage access concerns by saying therapies may be available after prior authorization or step therapy/fail first. These utilization

management techniques may be suitable for generics and interchangeable biologics, but they are not appropriate for non-interchangeable sole source biologics, such as plasma protein therapies. Access to all therapies is better achieved by having multiple competing manufacturers and products, a position affirmed by CMS Administrator Seema Verma who has stated: "This is yet another call to action for CMS to increase market competition and consumer choice within our programs to help control costs and ensure that our programs are available for future generations." [4]

Several patient advocacy organizations have conducted research projects to determine the effects of insurance issues on access to plasma protein therapies for individuals in their communities. Findings from the Hemophilia Federation of America's Project CALLS[5] show that approximately half of the patients who experience a coverage issue due to utilization management delay care. A recent survey from the Immune Deficiency Foundation finds that the primary reason individuals skip treatment is due to problems with health insurance.[6] Delays in care for individuals who use plasma protein therapies can exacerbate medical issues and lead to more expensive hospitalizations and negative health outcomes.

These restrictions also ignore expert clinical recommendations that require access to all available brands to ensure quality care and positive health outcomes. Each plasma protein therapy is approved by the U.S. Food & Drug Administration for distinct clinical indications, and each individual responds to a plasma protein therapy differently. Approximately one-third of patients receiving plasma protein therapies will experience intolerance to a particular product, as plasma protein therapies are not broadly interchangeable. Physicians with expertise in plasma protein deficiencies must have the ability to select the most medically appropriate therapy for patients in their care. In its responses to such proposals, PPTA has urged policymakers to respect the expert medical guidelines put forth by stakeholder groups:

- ***"It is unacceptable to limit availability of augmentation therapy in any way and especially to a single product."***
  — Alpha-1 Foundation Medical and Scientific Advisory Committee Clinical Practice Guidelines
- ***"IVIG is not a generic drug and IVIG products are not interchangeable. A specific IVIG product needs to be matched to patient characteristics to insure patient safety."*** — American Academy of Allergy Asthma & Immunology Principle #8
- ***"Given the variable nature of these diseases, individualized treatments depending on patient need and physician judgment are important."*** — American Academy of Neurology Therapeutics & Technology Assessment Subcommittee Evidence-based Guidelines
- ***"Because not all patients respond the same to each medication, it is the responsibility of the coordinating expert physician to work with each patient to define the optimal medication(s) for that particular patient."*** — U.S. Hereditary Angioedema Association Medical Advisory Board Recommendations
- ***"It is critical that the bleeding disorder community has access to a diverse range of therapies and that prescriptions for specific clotting factor concentrates are respected and reimbursed."***
  — National Hemophilia Foundation Medical and Scientific Advisory Council Recommendation #159

PPTA's mission is to promote the availability of and access to safe and effective plasma protein therapeutics for all patients in the world. PPTA, its members, and stakeholders all advocate for access to providers, sites of care, and all brands of plasma protein therapies. As new proposals emerge, the Association will continue to emphasize the unique nature and value of plasma protein therapies. •

References:
1. CMS National Health Expenditures 2017; CMS National Health Expenditure Projections 2017 – 2026
2. CMS-5528-ANPRM
3. MassHealth Section 1115 Demonstration Amendment Request proposed July 20, 2017 https://www.cms.gov/newsroom/press-releases/cms-office-actuary-releases-2017-2026-projections-national-health-expenditures
4. The Hemophilia Federation of America Project CALLS (Creating Alternatives to Limiting and Lacking Services)
5. The Immune Deficiency Foundation National Health Insurance Surveys, 2014 - 2016

UTILIZATION MANAGEMENT

is a technique that insurers/payers use to control the products or services beneficiaries access. In terms of medicines: **prior authorization** is when beneficiaries must get approval from the insurer/payer before they can access their prescribed therapy. **Step therapy or fail first policies** require beneficiaries to try and fail on another product before being able to access their prescribed therapy. These requirements are often a form of non-medical switching or cost-motivated treatment changes and are generally opposed by PPTA, its member companies, and stakeholders.