

BREAKING DOWN ROADBLOCKS to Patient Access

THE WORLDWIDE ECONOMIC CONDITIONS

mean there is less money to spend on healthcare benefits while there is greater demand for services from individuals seeking public assistance.

As a result, all payers are looking for ways to pay for health benefits at a lower price. Cost containment policies are the tools used by payers to reduce the price of goods and services, but they can often be roadblocks to patients seeking their medically appropriate therapy.

In the United States, state Medicaid programs that provide health benefits to the poor, aged and disabled are considering numerous cost containment policies that will allow them to reduce spending. Advocacy is the answer to making sure these changes, and they are coming, do not result in limited access for patients who require plasma protein therapies.

Mandatory managed care is a common policy change that many state legislatures are considering to manage their growing expenditures because of



their increasing enrollment. Mandatory managed care is a policy where states require all Medicaid recipients to enroll in a Medicaid Health Maintenance Organization (HMO). With each patient switched from Medicaid fee-for-service to a Medicaid HMO, the states reduce their appropriation for Medicaid because the Medicaid HMOs are paid less than the expected cost of a non-managed Medicaid recipient.

Medicaid HMOs are a way for states to spend money more efficiently, while providing quality care to certain Medicaid recipients who currently don't have their care managed by anyone. The mistake for states would be taking Medicaid recipients from providers who currently manage their care well and placing them with Medicaid HMOs that don't have the experience in providing quality care for the Medicaid recipients with rare, chronic conditions such as hemophilia.

The Florida Legislature recently considered legislation that would place all Medicaid recipients in Medicaid HMOs. PPTA, working with a coalition that included the two hemophilia chapters in the state and individual manufacturers, advocated successfully to have individuals with hemophilia receive their clotting factor concentrates through the current disease management program rather than forcing them to receive their factor from vendors selected by their Medicaid HMO. This preserved their current access to all medically appropriate therapies.

The concern was that Medicaid HMOs aren't familiar with managing hemophilia like other diseases because it is a challenge to develop accurate capitation models for individuals with hemophilia. The coalition argued persuasively that Medicaid recipients with hemophilia currently have their care managed properly, just not by a Medicaid HMO. Their care is well managed through the current system, which includes a disease management program in the Florida Medicaid program that guarantees Medicaid recipients pharmaceutical care that meets most recommendations of the National Hemophilia Foundation's (NHF) Medical and Scientific Advisory Council's (MASAC).

As a result of the efforts of all involved, Medicaid recipients in Florida are ensured access to their medically appropriate clotting factor from qualified vendors.

Like the United States, Europe has known in the recent past a wave of increasingly stricter budgetary measures to counter the effects of the financial crisis, to pre-emptively contain expenditure and to contain national debts. Such measures are affecting all areas managed by the government including the healthcare sector. In the past years, restrictive measures have been seen across

Europe both in old and new Member States, including but not limited to reference pricing according to the average of the lower prices in Europe, increases in compulsory rebates for pharmaceutical companies and evaluation of product efficacy in relation to their cost.

However, these measures do not provide a solution or an adequate response to the current situation. First of all, patients need to continue receiving adequate treatment and should not carry the burden for the economic mismanagement of previous governments. Furthermore, Europe is trying to showcase its technological advancement and investment in research including in healthcare. Nevertheless, the reality is that saving measures need to be evaluated and implemented and furthermore, other innovative medicines and treatments are competing for attention and funding. So what can the industry do to obtain more favorable outcomes when introducing reimbursement requests? As discussed during the Focus meeting held in Europe earlier in July, it seems that the industry needs to be more visible and make not only government representatives but also paying bodies aware of the uniqueness of the plasma industry. This is the message that PPTA is disseminating across the Atlantic both in North America and Europe and it points out the rarity and fragility of source material, the biological nature of the products (with all the precautionary steps of viral inactivation, testing, etc), the burdens for the development and implementation of clinical trials on small populations, the fact that these products treat small patient populations with chronic, congenital, life-threatening diseases.

The plasma protein therapies industry needs to constantly educate these stakeholders to point out its differences compared to both the chemical-based pharmaceutical industry and the biotechnology industry. It needs to stress the importance for the patients to continue to have access to safe and efficient treatments.



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