PPTA Plasma Protein Therapeutics Association — Stakeholder Report

June 2011
Vol. 9, Issue 2

Many thanks to all of the stakeholders who attended the second meeting of the year focused nearly exclusively on federal issues. With the implementation of health reform well underway, this mid-year Stakeholder Meeting was an excellent way to discuss how new provisions may affect access to lifesaving plasma protein therapies and to discuss needs and concerns of the community as implementation unfolds.

After a welcome and brief antitrust statement, the meeting began first with an overview from consumer groups representatives to provide a common understanding of what comprises each patient community and how those patients are currently being covered with health insurance. Please see the following presentations to learn more about the statistics provided.

- Primary Immune Deficiencies
- Bleeding Disorders
- Alpha-1 Antitrypsin Deficiency
- GBS and CIDP

Two members of the PPTA staff from the Brussels office, Charles Waller, vice president, Europe and Siada El Ramly, director of Public Affairs, Europe, presented information about how orphan drugs including plasma protein therapies are characterized in the European Union (EU) and in members states. The rules regarding prevalence and reimbursement are slightly different, but moreover, the EU is seeing more and more manufacturers representing their companies as orphan drug producers, diluting the space and making it increasingly difficult to ensure that laws and regulations that protect patient access to plasma protein therapies. For more information about this presentation, go here.

Essential Benefits was the first issue discussed on the agenda and includes a federal and state component. PPTA's State Affairs Director Bill Speir provided context for how the Essential Benefits package may take shape on the federal level, praised consumer group input into this important provisions and discussed with the group at large the timetable for regulations - late 2011 - and how this may affect implementation of state health insurance exchanges. To view presentation slides, go here.

Jim Romano with Patient Services, Inc. (PSi) provided an overview of comparative effectiveness research (CER) and how it has evolved over the years. The group discussed how CER may affect the patient community, the continuing lack of organization and clear agenda of the Patient-Centered Outcomes Research Institute (PCORI) board and how, until there is some clarity of direction, we will not know how the Rare Disease Panels that were included in the final health reform law will take shape. For more information, please view Jim's presentation.

PPTA consultant Stuart Langbein with Hogan Lovells talked with Stakeholders about Least Costly Alternative (LCA) policy, its genesis out of Medicare policy and how it may be used moving forward. He discussed how primarily LCA has been used for Durable Medical Equipment (DME), recent court challenges

when LCA has been applied to two particular drugs and how the court decision may influence the use of LCA in the future. See Stuart's presentation here.

Jay Greissing, PPTA's senior director of Federal Affairs, provided background about the Orphan Drug Act (ODA) passed in to law in 1983. This significant legislation paved the way for numerous drugs and therapies to come to market to treat rare diseases and conditions. The benefits to receiving orphan drug status were discussed as well as the potential for future expansions to the existing law. The ODA also was discussed in the context of the annual pharmaceutical fee that was enacted as part of the health reform law and the current language of the orphan drug exclusion. Expanding on the current orphan drug exclusion from the annual fee is part of the Association's advocacy agenda in order to further protect innovation and access to lifesaving plasma protein therapies. For more information, please view Jay's presentation.

The Stakeholders collectively discussed many of the major achievements of the plasma protein therapy users community over the years including:

- Differentiation of IVIg - "Brand specific" and also lyophilized vs. liquid;
- Exemption from Competitive Acquisition Program (CAP) that is part of the 2003 Medicare Modernization Act (MMA);
- Elimination of lifetime caps in health reform passed in 2010; and many more.

Further, the composition of the Essential Benefits package was identified by the patient communities as a key concern in the near term. The A-PLUS has provided recommendations to the Institute of Medicine (IOM) on what the users of plasma protein therapies need in an Essential Benefits package. The composition of that package and subsequent impact on the patient community remains to been determined and will continue to be monitored.

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