Plasma Protein Therapeutics Association

July 27, 2015

Reference No. SASC 15029 **VIA ELECTRONIC DELIVERY**

Andrew Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Re: Medicaid and CHIP Managed Care Proposed Rule CMS-2390-P

Dear Acting Administrator Slavitt:

The Plasma Protein Therapeutics Association (PPTA) appreciates the opportunity to comment on the Medicaid and CHIP Managed Care Proposed Rule CMS-2390-P. This proposed rule seeks to improve the quality of care for beneficiaries in a cost-effective way. We recommend adding provisions to the proposed Standard Contract Requirements[1], such as a prohibition against step therapy for individuals who rely on plasma protein therapies, which will protect beneficiaries from discriminatory practices that are contrary to continuity of care, physician recommendations, and stated CMS policy.

PPTA is the standard setting and global advocacy organization that represents plasma donation centers and manufacturers of plasma-derived therapies and their recombinant analogs (collectively known as "plasma protein therapies"). Our North American members include: Baxalta, Biotest, CSL Behring, Grifols, and Kedrion Biopharma. PPTA members provide more than 75% of the plasma protein therapies used in the United States.

Plasma protein therapies are used to treat rare, life-threatening diseases, including hemophilia and other bleeding disorders, primary immune deficiencies, and Alpha-1 antitrypsin deficiency. A rare disease or disorder is one that affects fewer than 200,000 people in the United States. Plasma protein therapies are high impact, life-saving therapies that are relied on by an even smaller number of Americans. It is estimated that 28,000 individuals have hemophilia, 16,000 have a primary immune deficiency, and 6,500 have alpha-1 antitrypsin deficiency.

Each plasma protein therapy is a unique biologic to which patients respond differently. Each therapy is approved by the FDA for distinct clinical indications, and each has distinct contraindications. Treating these therapies as interchangeable directly contradicts the determinations made under FDA guidelines, which have undergone years of review.

[1] 42 C.F.R. § 438.3 (proposed).

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In the proposed rule, CMS is seeking to codify practices that will provide cost-effective, quality care that promotes continuity of care. CMS is also seeking to ensure managed care providers will not discriminate against individuals eligible to enroll[2]. CMS should include in the final rule provisions that protect the decisions of physicians who prescribe plasma protein therapies in order to protect beneficiaries from discrimination while ensuring cost-effective, quality care that promotes continuity of care.

The American Academy of Allergy, Asthma & Immunology has developed Eight Guiding Principles for Effective Use of IVIG for Patients with Primary Immunodeficiency[3]. The eighth principle states, "IVIG is not a generic drug and IVIG products are not interchangeable. A specific IVIG product needs to be matched to patient characteristics to ensure patient safety. A change of IVIG product should occur only with the active participation of the prescribing physician." This principle holds true for subcutaneous immune globulin (SCIg) therapies as well.

The Medical and Scientific Advisory Council (MASAC) is a group of expert providers and scientists that issue best practices recommendations for the treatment of bleeding disorders. MASAC Guideline #159 states, "Clotting factor therapies are neither pharmacologically nor therapeutically equivalent and vary based upon purity, half-life, recovery, method of manufacture, viral removal and inactivation processes, potential immunogenicity, and other attributes. The characteristics of each product and the resultant product choice for an individual patient require a complex decision making process with the ultimate product being agreed upon by the patient and their respective healthcare provider. It is critical that the bleeding disorders community has access to a diverse range of therapies and that prescriptions for specific clotting factor concentrates are respected and reimbursed."[4]

Despite these recommendations from experts, managed care companies occasionally implement policies that are discriminatory to patients because they interrupt continuity of care. They are also contrary to cost-effective, quality care. An example of this is step-therapy. Under a step therapy protocol, managed care companies will require a diagnosed and properly treated beneficiary to switch from a medically appropriate therapy to one that is preferred on the managed care company's formulary. It may be a therapy the beneficiary has never tried before, or a therapy that the beneficiary tried in the past with poor results. This protocol violates continuity of care by forcing a beneficiary to change from the medically appropriate therapy that was determined in consultation between the patient and the prescriber. It is also not cost-effective nor quality care because in failing on a preferred therapy a beneficiary may have adverse events that are painful for the beneficiary, and costly to the payer. This was recognized by CMS in a prior proposed rule that said step therapy poses a risk for poor health outcomes, which would result in increased costs to the Medicaid program.[5]

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[2] 42 C.F.R. § 438.3(d) (proposed).

[3] http://www.aaaai.org/Aaaai/media/MediaLibrary/PDF%20Documents/Practice%20Resources/IVIG-guiding-principles.pdf

[4] MASASC Recommendation #159 (last visited June, 2015), available at http://www.hemophilia.org/NHFWeb/MainPgs/MainNHF.aspx?menuid=57&contentid=179

[5] *See* Medicaid Program; Payment for Covered Outpatient Drugs Under Drug Rebate Agreements with Manufacturers, 60 Fed. Reg. 48442, 48454 (Sept. 19, 1995). CMS has not finalized the proposed rule.

In order to achieve the agency's mission of better care, smarter spending, and healthier people, PPTA recommends that the final rule include a standard contract requirement in proposed Section 438.3, which requires managed care companies to allow beneficiaries to continue on their medically appropriate plasma protein therapy as if the medically appropriate therapy was a product on the formulary. This "grandfathering" requirement would help ensure continuity of care for individuals with serious medical conditions. As shown above, it is consistent with the guidelines and recommendations of physicians that treat individuals who rely on plasma protein therapies.

PPTA appreciates your consideration of our concerns and welcomes the opportunity to discuss them further. Should you have any questions or require additional information please do not hesitate to contact me at: bspeir@pptaglobal.org or (443) 433-1110.

Sincerely,

Bill Speir
Senior Director, State Affairs