

"Clustered" Prices Treat Branded Plasma Therapies as Interchangeable, Endangering Patient Health and Safety and the Continued Viability of the Therapies

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Overview

The cost-cutting "clustering" approach used by some state Medicaid programs reimburses for every branded plasma-derived and recombinant therapy (collectively "plasma therapies") in a drug category using a single maximum allowable cost (MAC) or a single reference price. However, clustering fails to acknowledge the lack of clinical and therapeutic interchangeability among the clustered therapies. This lack of recognition could lead providers to believe that they can prescribe the clustered therapies on an interchangeable basis, and using these therapies interchangeably could endanger the health and safety of patients. Further, pricing plasma therapies in a manner that disregards the investment costs and risks of developing those therapies, and disregards the labor- and capital-intensive tasks of assuring the effectiveness and safety of the therapies, could depress future investment in innovative plasma therapies and impact patient access to plasma therapies.

Background

The Plasma Protein Therapeutics Association (PPTA) is the primary advocate for the world's leading producers of plasma therapies. Plasma therapies treat unique, life-threatening diseases and disorders. Life-saving therapies produced by PPTA members include clotting factor therapies for individuals with bleeding disorders, intravenous immunoglobulins (IVIG) to treat complex diseases in persons with immune deficiencies and neurological disorders, and therapies for individuals who have alpha-1 anti-trypsin deficiency which typically manifests as adult onset Chronic Obstructive Pulmonary Disease and substantially limits life expectancy. PPTA's member companies produce 80 percent of the plasma therapies used in the United States.

While PPTA recognizes that budget pressures on state Medicaid programs are significant, total spending on all plasma therapies [primarily hemophilia clotting factor, intravenous immunoglobulins (IVIG), and Alpha-1 therapy] averages only about 1.5% of any state's Medicaid prescription drug expenditures.

In an attempt to limit the growth rate for state Medicaid drug expenditures, a few states have considered or have moved toward reimbursing all branded plasma therapies within a single drug category using a single MAC price or reference price, an approach known as clustering. In Washington State, the Medical Assistance

program has implemented an "automated" MAC price provided to the state by a national pricing service to price hemophilia clotting factors. However, the use of MAC pricing is an approach that is traditionally limited under federal and state law to generic drugs, and there are no generic hemophilia clotting factors. All drugs in the category are branded drugs.

In fact, the federal Food and Drug Administration (FDA) has approved the various clotting factor therapies for distinct clinical indications. The therapies are neither clinically nor therapeutically interchangeable. Some are intended to treat an absence of Factor VIII, while others are intended to treat an absence of Factor IX. Some treat von Willebrand's disease, while still others treat the body's resistance to Factor VIII or Factor IX. In addition, some are derived from human plasma, while others are recombinant, created from single cells.

The therapies in other plasma therapy categories are not pharmaceutically or therapeutically equivalent. Each IVIG therapy has been approved by the FDA for distinct clinical indications and each has distinct contraindications. Each has a very different shelf life, and each is prepared and administered in a distinct manner. Storage requirements vary. Sugar content varies.

In each case, different therapies require different dosages and different regimens, and may be appropriate only for specific populations or for specific individuals within those populations. Further, the effectiveness of specific therapies may vary with different populations or with specific individuals. Treating these therapies as interchangeable by using a clustering approach directly contradicts the determinations made under FDA guidelines after years of review. It encourages prescribers and patients to use them interchangeably and thereby threatens the health and safety of those patients.

Further, setting the same reimbursement level for each of these very different therapies threatens the continued economic viability of the therapies and the prospect for the development of future innovative therapies. Each has been developed with its own distinct history of research and development, requiring distinct costs and risks, and each requires continued investment to assure its continued effectiveness and safety. Reimbursement for therapies should in some manner reflect the actual costs of producing safe and effective therapies. Cluster pricing ignores this cardinal rule.

Conclusion

PPTA urges state Medicaid programs to avoid the use of clustering in reimbursement for plasma therapies. Avoiding clustering will help to assure the continued health and safety of patients, continued innovation in the plasma therapy industry, and continued patient access to crucial therapies.