

# SAMPLE

## Letter to State Medicaid Directors for Clotting Factors

***[The following letter is intended to be illustrative only. Correspondents should phrase the letter in a manner appropriate to their own circumstances.]***

DATE

[ NAME ]  
[Street Address]  
[City, State, Zip]

RE: Plasma-Derived and Recombinant Analog Therapies

Dear [ NAME ]:

Plasma-derived and recombinant analog therapies ("plasma therapies") treat unique life-threatening diseases, medical conditions, and disorders, such as hemophilia, immune system deficiencies, hepatitis, Alpha-1, as well as burns and shock. I am writing to acquaint you with these therapies and to ask that you not subject plasma therapies to prior authorization under your state's Medicaid program, but instead include them on the Medicaid program preferred drug list (PDL).

I am the [mother/father] of a [son/daughter] with [a blood clotting disorder/Alpha-1/immune deficiency disorder]. I know that recent 15 percent annual increases in Medicaid prescription drug expenditures are driving total Medicaid costs higher and that, as a result, your program is considering [creating/enhancing] prior authorization procedures and creating a preferred drug list (PDL). I believe that it would be inappropriate to subject the prescription of plasma therapies to prior authorization.

State Medicaid spending on plasma therapies does not drive Medicaid program expenditures. Subjecting plasma therapies to prior authorization could compromise the timely access of Medicaid recipients to crucial treatments, while doing little to reduce overall Medicaid expenditures. The nature of plasma therapies is such that those therapies should be automatically placed on any PDL developed by the state Medicaid program.

Plasma therapies are different from the commonly advertised, compound-based pharmaceutical products, which are the target of Medicaid cost-cutting efforts. These therapies are not pills, syrups, sprays, lotions, or inhalants; they are administered through infusion. They are designed to treat highly unique, chronic diseases. They require a series of complex manufacturing steps, validation criteria, and constantly evolving viral inactivation processes to ensure safety and efficacy. In addition, for the most part, these plasma therapies are distinct, sole source pharmaceuticals that have no generic equivalents that could be substituted under a prior authorization program.

The diseases, conditions, and disorders that plasma therapies treat include the following:

- **Blood Clotting Disorders (Hemophilia):** More than 17,000 people in the United States with hemophilia have inherited a missing or low supply of the genetic factors needed for normal blood clotting. Not only may hemophiliacs experience bleeding after dental work, surgery, or trauma, they may experience bleeding in their joints or internal bleeding with no trauma or injury, and without apparent cause. Treatment to prevent this spontaneous bleeding typically requires the infusion of blood-clotting factor one to three times a week. Patients who rely on anti-hemophilic factor products need their therapies in an expedited fashion. A delay in a patient receiving his or her clotting factor product could cause long-term medical complications. Bleeds into joints can cause permanent damage and crippling, especially in children. A delay may even prove to be fatal if the patient is suffering from an intracranial or gastrointestinal bleed.
- **Immune Deficiency Disorders:** Immune deficiency diseases are disorders in which the immune system fails to properly recognize and react to invading microorganisms, leading to life-threatening or fatal infections. Primary immune deficiency diseases are a group of 50 diseases caused by intrinsic defects at the cellular or tissue level. Intravenous immune globulin (IGIV) is a solution of immunoglobulin that contains antibodies normally present in human blood. The solution is prepared from pools of serum collected from large numbers of donors and extensively processed to ensure patient safety. IGIV is the only effective treatment for primary immunodeficiency disease, and it has been proven clinically beneficial in the treatment of secondary immune deficiency diseases, such as chronic lymphocytic leukemia and HIV infection, and in bone marrow transplantation.
- **Alpha-1-Antitrypsin Deficiency (AAT):** Alpha-1-Antitrypsin deficiency is one of the most potentially lethal hereditary disorders. It is the leading cause of pediatric liver transplants and causes chronic obstructive pulmonary disease, with a high frequency of emphysema in adults. AAT inhibits the destructive enzymes - protease - that cause damage to the liver and to the lungs. The only known treatment for this disorder, AAT is infused on a weekly basis, after being purified from pooled human plasma and processed to reduce the potential for the transmission of infectious agents. It is crucial as a matter of public policy that individuals threatened by the unique, life-threatening diseases that plasma therapies treat not be denied timely access to the treatments they need. A patient with intracranial bleeding who is in need of a blood clotting therapy cannot wait the 24 hours that prior authorization could take to pre-approve his or her therapy.

## Conclusion

Plasma therapies clearly represent the type of therapy which pharmacy and therapeutics committees should add to Medicaid PDLs. They are safe and effective, and they have no generic equivalents. Further, they have had little or no impact on the overall escalation in Medicaid drug spending. Denying immediate access to these therapies could result in greater expense to the state Medicaid program when hospitalization or skilled nursing care becomes necessary. I ask that you not subject these important life-saving therapies to prior authorization procedures.

Sincerely,