Plasma Protein Therapies: Uniquely Saving Lives

Treating Rare Diseases

Plasma is the straw-colored liquid portion of blood. It contains hundreds of proteins which carry out critical functions in the human body, such as antibodies to fight diseases and clotting factors to regulate bleeding. If a person has insufficient levels of any one plasma protein, his or her body cannot carry out these vital functions, causing a variety of chronic and life-threatening medical conditions.

Plasma-derived therapies and their recombinant analogs, collectively referred to as plasma protein therapies, are unique, biologic medicines that treat plasma protein deficiencies by replacing a person's missing or functionally damaged proteins. In the United States, a disease is considered rare if it affects fewer than 200,000 individuals. Plasma protein deficiencies have very small patient populations and can be considered extremely rare.

Your blood is:

55% PLASMA

44% RED BLOOD CELLS

1% WHITE BLOOD CELLS & PLATELETS

Your plasma is:

92% WATER

7% PROTEINS

1% OTHER SOLUTIONS

Proteins in your plasma:

- IMMUNOGLOBULINS (ANTIBODIES)
- CLOTTING FACTORS
- C1 ESTERASE INHIBITOR
- ALPHA-1 PROTEINASE INHIBITOR

Patients Treated with Plasma-Derived Therapies in the U.S.

CAUSES & SYMPTOMS	U.S. PATIENTS TREATED ANNUALLY (Estimates)
PRIMARY IMMUNODEFICIENCY DISEASES • Caused by missing immunoglobins (antibodies) • Antibodies control the immune system and prevent illness • Patients are chronically ill from severe, persistent, recurrent infections	40,000
CHRONIC INFLAMMATORY DEMYELINATING POLYNEUROPATHY • Cause not certain; immune system attacks nerve coating • Messages from the brain aren't delivered to the body if nerve coating is damaged • Patients experience progressive weakness, loss of limb function, and disability	30,000
BLEEDING DISORDERS (E.G. HEMOPHILIA) • Caused by missing clotting factor protein • Clotting factors control bleeding • Patients cannot regulate bleeding • Can be fatal if bleeding occurs in brain or vital organs	30,000
HEREDITARY ANGIOEDEMA • Caused by missing C1 esterase inhibitor protein (C1-INH) • C1-INH helps regulate inflammation • Patients have edema (severe swelling) • Can be fatal if airway obstructed	5,000
ALPHA-1 ANTITRYPSIN DEFICIENCY • Caused by missing Alpha-1 Proteinase Inhibitor • Alpha-1 Proteinase Inhibitor protects the lungs • Patients have chronic emphysema and liver damage	7,500

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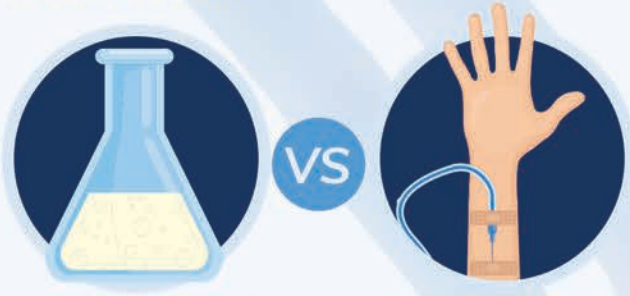
Made From Plasma

Donated Plasma is a finite starting material.

The starting material for plasma protein therapies is not an infinite resource. Rather than using synthetic or chemical ingredients, plasma protein therapies are made using human plasma. ***Plasma cannot be made in a laboratory.*** Plasma and its lifesaving proteins can only be obtained from donors who so generously give their time to donate.



PHARMACEUTICALS
Production starts with synthetic or chemical ingredients.

PLASMA PROTEINS
Production starts with a biological starting material, human plasma.

Licensure

The Food & Drug Administration (FDA) approves medicines for safety & efficacy before they can be sold in the U.S. ***Plasma protein therapies are the only medicines for which the starting material must also be licensed.*** In addition to the final products, the FDA qualifies and approves plasma before it can be used for manufacturing.

PHARMACEUTICALS
Only the final product must be approved by the FDA.

PLASMA PROTEINS
More than 47 million plasma donations as well as the final products must be qualified each year.

Plasma Collection

Plasma is collected from healthy, compensated donors through a process called plasmapheresis. Plasmapheresis removes a donor's plasma and returns the remaining blood components.

Plasma is collected at 1,200+ plasma donation centers in the U.S. After collection, the plasma donation is frozen and shipped to a state-of-the-art facility for manufacture into lifesaving plasma protein therapies.

EVERY YEAR IT TAKES APPROXIMATELY:

130: Plasma donations to treat ONE PATIENT with a PRIMARY IMMUNODEFICIENCY DISEASE.

900: Plasma donations to treat ONE PATIENT with an ALPHA-1 ANTITRYPSIN DEFICIENCY.

1200: Plasma donations to treat ONE PATIENT with HEMOPHILIA

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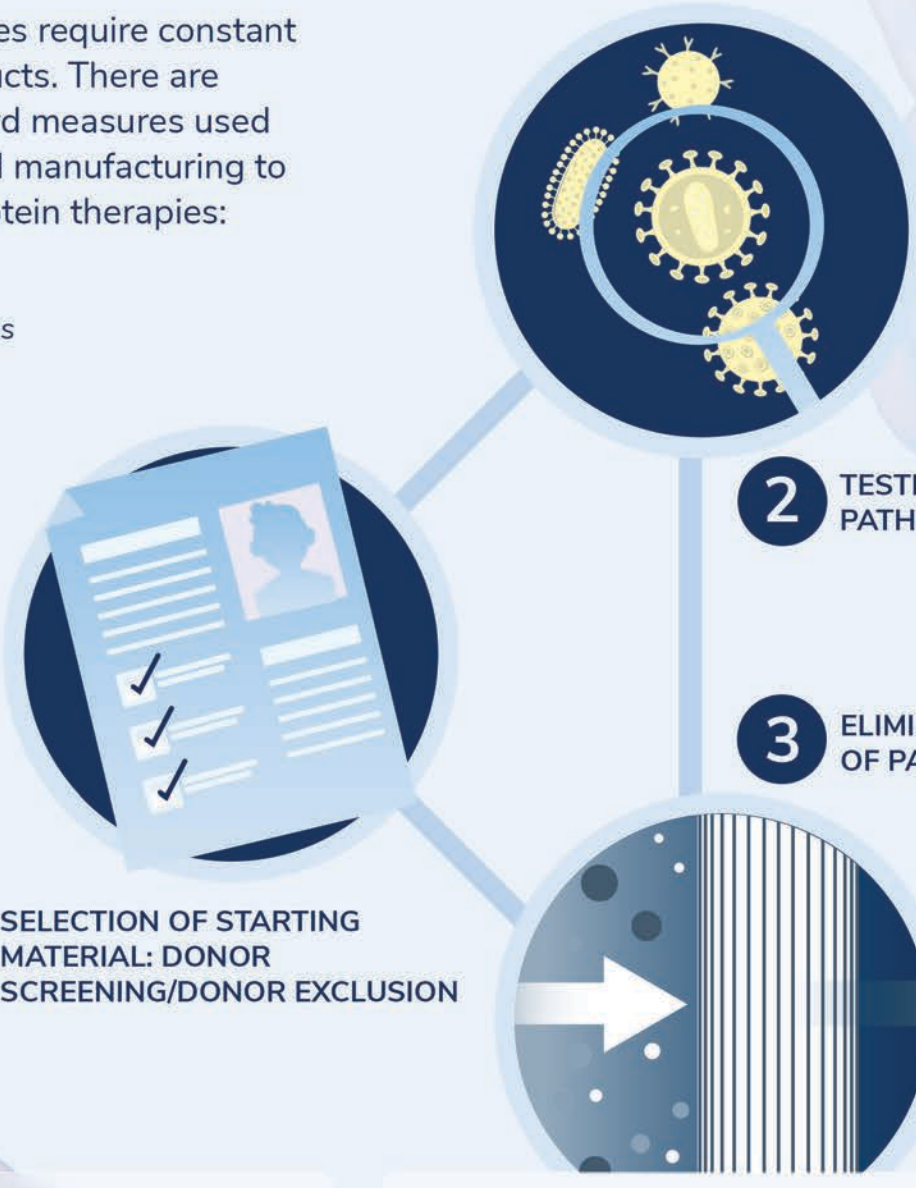
Constant Vigilance for Safe Products

Plasma protein therapies require constant vigilance for safe products. There are three types of safeguard measures used in plasma donation and manufacturing to ensure safe plasma protein therapies:

Voluntary industry standards often exceed regulatory requirements.

INTERNATIONAL QUALITY PLASMA PROGRAM

QSEAL
QUALITY STANDARDS OF EXCELLENCE, ASSURANCE & LEADERSHIP



1 SELECTION OF STARTING MATERIAL: DONOR SCREENING/DONOR EXCLUSION

2 TESTING FOR PATHOGENS

3 ELIMINATION OF PATHOGENS

Current manufacturing protocols are extremely effective against pathogens.

The industry has a record of safety from pathogens for more than 30 years.

Evolving Protocols

Unlike traditional pharmaceuticals or other biologics where standard quality assurance practices are sufficient, plasma protein therapies' safety protocols are constantly evolving due to new and emerging pathogens.

Companies must continuously perform tests to demonstrate that their viral inactivation and removal steps work on new pathogens. For instance, over the years, companies have dedicated substantial time and resources to research coronaviruses, ensuring they pose no threat to the safety of plasma protein therapies.

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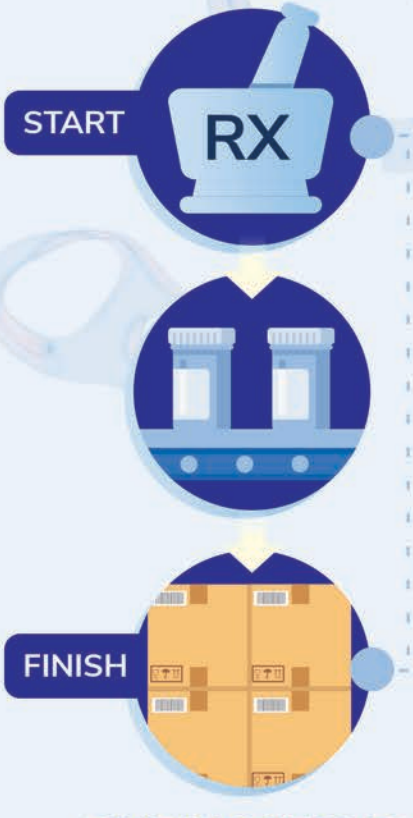
Complex Manufacturing

Complex Manufacturing of Plasma Protein Therapies

PPTs take up to **12 months** to manufacture. Companies must adhere to rigorous regulatory requirements to ensure manufacturing consistency and pathogen safety.



PHARMACEUTICALS

Costs Attributed to Manufacturing & Raw Materials*

*Average Cost of Goods Sold in 2022 for 5 leading commercial fractionators. Source: Marketing Research Bureau

PLASMA PROTEINS

Plasma Protein Therapies: Uniquely Saving Lives

Value to Patients

As different policies to slow health spending are debated, it is critical to maintain access to lifesaving treatments for rare disease patients. Although some value-based frameworks work for generic, interchangeable pharmaceuticals — a one-size-fitsall policy does not work for plasma protein therapies as these biologics are not interchangeable.

Plasma protein therapies are high-impact pharmaceuticals because they increase life expectancy, improve quality of life, and reduce life-threatening complications for individuals with plasma protein deficiencies. Plasma protein therapies provide immeasurable, lifelong benefits to the patients who use them.

"To think about having to go back long term without my IVIG infusions, I would rather not be alive. I started to receive the plasma therapy and within a couple of months from being near death...I became very vital.

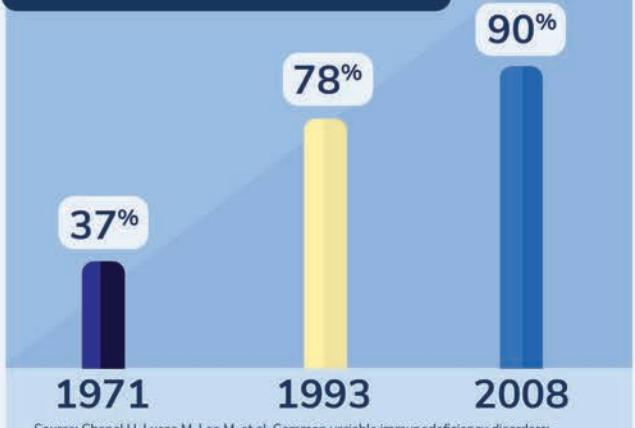
These are lifesaving therapies for which there is no alternative for many patients. To take away the plasma therapy from a PI patient such as myself — what you're doing is condemning those people to a life of sickness and possibly death."

-Terry, individual with a Primary Immunodeficiency

"Plasma protein therapies saved my children's lives, literally. The first thing that would happen if we didn't have access to them would be that we would not be able to stop bleeding inside their bodies, they would first be in a lot of pain, then they would become crippled and eventually they would die."

- Kerry, mother of sons with hemophilia

10-year survival rate of patients with **COMMON VARIABLE IMMUNE DEFICIENCY**, by year



Source: Chapel H, Lucas M, Lee M, et al. Common variable immunodeficiency disorders: division into distinct clinical phenotypes. Blood. 2008; 112(2):277–286.

Life expectancy of a patient born with **HEMOPHILIA**, by year

Source: Aledort, L. The evolution of comprehensive haemophilia care in the United States: perspectives from the frontline. Haemophilia. 2016; 22(2):676-683.

Value to the System

The economic impact of diagnosing a Primary Immunodeficiency Disease and treating an individual with immunoglobulin therapy represents an average savings of $55,882 per year.

Source: Modell, V., Quinn, J., Ginsberg, G., Gladue, R., Orange, J., & Modell, F. (2017). Modeling strategy to identify patients with primary immunodeficiency utilizing risk management and outcome measurement. Immunologic Research.

Immunoglobulin replacement therapy (IgGRT) in Common Variable Immunodeficiency Disorders yields Incremental Cost Effectiveness Ratio-estimates that are of the same magnitude as those for the–by far–more common influenza vaccination program for adults.

van Wilder P, Odnoletkova I, Mouline M, de Vries E (2021) Immunoglobulin Replacement Therapy is critical and cost-effective in increasing life expectancy and quality of life in patients suffering from Common Variable Immunodeficiency Disorders (CVID): A health-economic assessment.

Plasma Protein Therapies: Uniquely Saving Lives

Non-Interchangeable & Unique

One-size-fits-all policies are unsuitable for plasma protein therapies and endanger patient health. Each therapy is unique due to the pharmacologic and manufacturing differences that exist across different brands and patients' unique response to the treatments. Plasma protein therapies are non-interchangeable, sole-source biologics, therefore it is essential that patients have access to their medically justifiable therapy.

Expert Clinical Guidelines on Non-Interchangeability

ALPHA-1 FOUNDATION

"It is unacceptable to limit availability of augmentation therapy in any way and especially to a single product." [1]

AMERICAN ACADEMY OF NEUROLOGY.

"Given the variable nature of these diseases, individualized treatments depending on patient need and physician judgment are important." [2]

haea
US Hereditary Angioedema Association

"HAE management plans must be individualized to each patient's needs due to wide variability in HAE symptoms, response to and tolerance of various HAE medications, and numerous factors impacting clinical course and quality of life. Treatment plans should be monitored regularly and adjusted based on the needs of the patient." [3]

AAAAI
American Academy of Allergy Asthma & Immunology

"IVIG is not a generic drug and IVIG products are not interchangeable. A specific IVIG product needs to be matched to patient characteristics to insure patient safety." [4]

NATIONAL BLEEDING DISORDERS FOUNDATION
Formerly NHF

"It is critical that the bleeding disorder community has access to a diverse range of therapies and that prescriptions for specific clotting factor concentrates are respected and reimbursed." [5]

1. Alpha-1 Foundation Medical and Scientific Advisory Committee Clinical Practice Guidelines 2. American Academy of Neurology Therapeutics & Technology Assessment Subcommittee Evidence-based Guidelines
3. US HAEA Medical Advisory Board 2020 Guidelines for the Management of Hereditary Angioedema 4. American Academy of Allergy Asthma & Immunology Principle #8 5. NHF Medical and Scientific Advisory Council Recommendation #159

INDUSTRY FACILITIES*

PLASMA DONATION CENTERS

PLASMA PROTEIN THERAPEUTICS ASSOCIATION

ADMA BIOLOGICS

GRIFOLS

KEDRION BIOPHARMA

Takeda

1,200+ AND COUNTING!

There are more than 1,200 plasma donation centers in the United States.

Employment

Each plasma donation center **employs between 50–60 people.**[1]

Local Economies

On average, each plasma donation center provides more than **$4 million to the local economy.**[2]

Strength in Numbers

There are more than **75 million plasma donations annually** in the U.S.[1]

Repeat Engagement

The average donor **donates 15 times** per year.[3]

Plasma Members in the U.S.:

- ABO PLASMA
- ADMA BIOCENTERS
- B Positive Plasma LLC
- BioLife Plasma Services
- Biomat USA, Inc.
- BioTek America, LLC dba Freedom
- BPC PLASMA
- Care Plasma LLC
- CRT PLASMA
- FREEDOM PLASMA
- Grifols Bio Supplies Inc.
- Grifols Therapeutics, Inc.
- HEMARUS
- ImmunoTek BioCenters, LLC
- JOIN PARACHUTE
- Kamada Plasma LLC
- KEDPLASMA, LLC
- LFB AMERICAN PLASMA
- Octapharma Plasma Inc.
- OLGAM LIFE
- PELICAN PLASMA | LIFESHARE BLOOD
- PlasmaSource, LLC|VITALANT
- Proesis Biologics
- Southern Blood Services, Inc.
- TRUEHEALTH PLASMA

*Includes manufacturing plants, testing laboratories, research facilities, logistics and distribution centers, and corporate offices

[1]Jaworski, P. America's Plasma Contribution to the World: 2025. https://peterjaworski.substack.com/i/183058699/the-georgetown-blood-and-plasma-research-group.

[2]Industry estimates.

[3]Fransen, M, Chang, D. Who are US Source Plasma donors? Results from a preliminary analysis. (2025), Special Issue Abstracts from the American Society for Apheresis 46th Annual Meeting April 9–11, 2025. J Clin Apher, 40: e70014. https://doi.org/10.1002/jca.70014.

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Everday Medicine

Rh Incompatibility

During pregnancy, a mismatch in the type of rhesus (Rh) factor (a protein found on the surface of red blood cells), between a mother and fetus can lead to hemolytic disease of the newborn (HDN). Rh incompatibility occurs when a Rh-negative mother is carrying a Rh-positive fetus. In that case, the mother's immune system sees the red blood cells of the fetus as foreign and develops antibodies which attack them.

This can cause severe anemia in the fetus or newborn, as well as jaundice as the broken-down red blood cells produce bilirubin. The level of bilirubin in the infant's blood may range from mild to dangerously high. Plasma-derived Rh immunoglobulins (RhIg) administered during pregnancy can neutralize the fetus's Rh-positive red blood cells, preventing maternal sensitization and HDN.

Cancer

Plasma protein therapies often play a supportive role in the treatment of cancer patients. Plasma-derived immunoglobulins (IG) can be used to address treatment-related immunosuppression and reduce the risk of infections in patients undergoing chemotherapy or radiation. Additionally, plasma-derived clotting factors can help cancer patients who experience clotting disorders or increased risk of bleeding due to their cancer or related treatment.

In addition, albumin is also used as a carrying agent for some cancer medications, due to it being preferentially internalized by tumor cells. This can prolong the half-life of otherwise rapidly cleared drugs and promote their accumulation within tumors.

Liver Conditions

Plasma protein therapies such as albumin and prothrombin complex concentrates can be beneficial in managing complications associated with liver conditions. Albumin infusions help maintain fluid balance, stabilize blood pressure, and reduce the risk of abnormal swelling and fluid buildup in patients with cirrhosis.

Some liver disease patients experience an impairment in their own body's ability to produce clotting factors and can require fresh frozen plasma or plasma derived clotting factors to manage and prevent bleeding.

Organ Transplantation

Transplant recipients are at high risk of graft rejection, which occurs when the recipient's immune system attacks and begins destroying the transplanted tissue or organ. To prevent this, recipients are often given immunosuppressive medications, leaving them vulnerable to opportunistic infection. Plasma-derived immunoglobulins can bolster the immune system and minimize the risk of infections, making them an important adjunct in post-transplant care.

PLASMA PROTEIN THERAPEUTICS ASSOCIATION

Plasma Protein Therapies: Uniquely Saving Lives

Everday Medicine

Pediatric HIV

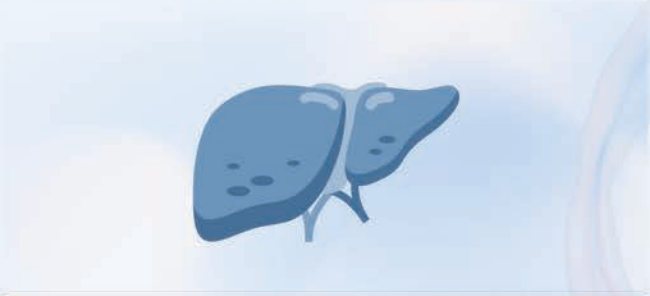
Children infected with HIV often experience immune system deficiencies that predispose them to infections. Plasma-derived immunoglobulins help provide passive immunity and boost these patients' ability to fight infections.

Burn Patients

Severe burns can lead to life-threatening complications, including fluid loss and infection. Plasma protein therapies, such as albumin, can help replenish lost fluids in burn patients. Additionally, fibrin sealants derived from plasma can help in wound healing and reduce the risk of infections.

Tetanus

The presence of antibodies and immunoglobulins in plasma equips it to neutralize harmful substances and infectious agents. In cases where individuals are bitten by animals or sustain deep cuts, there is a risk of tetanus infection, which can be life-threatening. Anti-tetanus immunoglobulin (IG) provides antibodies that protect against this infection.



Hepatitis B

A plasma protein therapy with hepatitis B antibodies, called Anti-HBV IG, can help protect people from hepatitis B virus (HBV). Anti-HBV is used as a postexposure preventative measure in individuals who are at risk of acquiring HBV, including healthcare workers and first responders treating a patient with HBV, as well as babies born to mothers

Shock and Trauma

In cases of shock and trauma, the rapid loss of blood can result in acute clotting disorders. Plasma-derived clotting factors like Factor IX may control bleeding and restore normal clotting function. Administering these factors to trauma patients can be effective in preventing excessive blood loss.

PLASMA PROTEIN THERAPEUTICS ASSOCIATION