

Essential Health Benefits

Issue Brief

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Summary

Beginning in 2014, individuals receiving health benefits from Medicaid and individual and small group insurance companies will receive a package of diagnostic, preventive, and therapeutic services and products defined as “essential” by the Department of Health and Human Services (HHS). The essential health benefits (EHB) package was generally outlined in the Affordable Care Act (ACA) to at least include a set of services and products within the following general categories: ambulatory patient services; emergency services; hospitalization; maternity and newborn care; mental health and substance use disorder services, including behavioral health treatment; prescription drugs; rehabilitative and rehabilitative services and devices; laboratory services; preventive and wellness services and chronic disease management; and pediatric services, including oral and vision care.

The ACA was passed to address the problems of the uninsured and underinsured in this nation. A stated goal of the ACA is to provide a health care system that provides Americans with essential health benefits. This raises the question of what are essential health benefits for individuals that rely on plasma protein therapies?

The Plasma Protein Therapeutics Association believes it is essential to provide individuals that rely on plasma protein therapies with health benefits that have been designated as essential by the highly-trained specialists that treat these individuals with rare, complex, chronic conditions. Therefore, it is important for decision-makers to require qualified health plans to provide access and payment to the providers of these services without cost-containment policies that limit an individual’s access to essential health benefits.

Background

The Plasma Protein Therapeutics Association (PPTA) represents the world’s leading manufacturers of plasma-derived and recombinant biological therapies, collectively known as plasma protein therapies and the collectors of source plasma. These critical therapies are infused or injected by more than 1 million people worldwide to treat a variety of rare, life threatening diseases and serious medical conditions. PPTA members produce in excess of 80 percent of the plasma protein therapies used in the United States today and more than 60 percent worldwide. PPTA is a global trade association that administers international, voluntary standards programs to help ensure the highest quality and safety of plasma protein therapies and the plasma collected to

manufacture them. Additionally, PPTA works in partnership with the patient community and consumer advocates to help ensure continued access to lifesaving plasma protein therapies.

Plasma protein therapies treat rare, life-threatening diseases and disorders. Lifesaving therapies produced by PPTA members include clotting factor therapies for individuals with bleeding disorders, immunoglobulins (IG) to treat complex diseases in persons with compromised immune systems 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.

Differentiation from Traditional Pharmaceuticals

Plasma protein therapies differ significantly from commonly advertised, compound based pharmaceutical products. The nature of the starting material (human plasma or derivatives of recombinant DNA) requires all plasma protein therapies to be put through a series of complex manufacturing steps, validation criteria, and constantly evolving viral inactivation processes, all intended to ensure that plasma protein therapies are safe and effective. The therapies within these classifications are distinct, sole-source products that have no generic biological equivalents.

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Section 1302(b) of the Affordable Care Act directs the Secretary of Health and Human Services (HHS) to define essential health benefits (EHB) that must be provided to beneficiaries in non-grandfathered health plans in the individual and small group markets, and Medicaid beginning in 2014. Self-insured group health plans, health insurance coverage offered in the large group market, and grandfathered health plans are not required to cover the essential health benefits.

On December 16, 2011, HHS released the Essential Health Benefits Bulletin (Bulletin) to provide information and solicit comments on the regulatory approach that the HHS proposes in the Bulletin for defining EHB under the ACA. HHS proposed four benchmark plan types for states to select in 2014 and 2015. They are:

- (1) The largest plan by enrollment in any of the three largest small group insurance products in the State's small group market;
- (2) Any of the largest three State employee health benefit plans by enrollment;

- (3) Any of the largest three national FEHBP plan options by enrollment; or
- (4) The largest insured commercial non-Medicaid Health Maintenance Organization (HMO) operating in the State.

States are permitted to select a single benchmark to serve as the standard for qualified health plans operating in their State. If a State does not exercise the option to select a benchmark health plan, HHS has proposed that the benchmark plan for that State would be the largest plan by enrollment in the largest product in the State's small group market.

The decision of HHS to leave the selection of the EHB to the states creates an opportunity for state decision-makers to shape the future of health care in their state. PPTA suggests that the decision-makers should craft their program with the needs of those with rare, chronic conditions in mind. Anyone can craft a health program to cover the healthy. The difficult part is developing a program that does not discriminate against individuals because of their age, disability, or expected length of life.

To do this, states will need to add protections and clarity to the covered services that are specified by the ACA. Section 1302(b)(1) states the EHB shall include items and services within the following 10 benefit categories: (1) ambulatory patient services, (2) emergency services (3) hospitalization, (4) maternity and newborn care, (5) mental health and substance use disorder services, including behavioral health treatment, (6) prescription drugs, (7) rehabilitative and habilitative services and devices, (8) laboratory services, (9) preventive and wellness services and chronic disease management, and (10) pediatric services, including oral and vision care.

While the ACA requires coverage for each of these categories of benefits, the law does not name the specific services that must be covered or the amount, duration, and scope of covered services. Without these specifics, there is the possibility that a plan may be a qualified health plan without meeting the needs of the individuals in the plan. This begs the question, what are essential health benefits for individuals that rely on plasma protein therapies?

Plasma protein therapies treat rare, life-threatening diseases and disorders. Lifesaving therapies produced by PPTA members include clotting factor therapies for individuals with bleeding disorders, immunoglobulins (IG) to treat complex diseases in persons with compromised immune systems 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.

Individuals that live with these life-long conditions need a coordination of health care that allows them access to specialists, access to the plasma protein therapy that is most medically appropriate for them, and access to the therapy from a qualified specialty that will provide them the plasma protein therapy in the site of infusion that has been selected by them in consultation with their physician.

Individuals that rely on plasma protein therapies require services and care from members of the medical profession who have specialized knowledge of the diagnosis, treatment and management of their disorders. Qualified health plans utilizing a provider network must provide an adequate number of in-network providers in various specialties corresponding to the EHB categories of health services. States should place safeguards in enacting legislation that will require qualified health plans to have in-network specialists trained to treat an individual's condition or allow them to seek treatment out-of-network without incurring outrageous costs.

Individuals with rare diseases must have access to the full range of medically necessary treatments appropriate for their condition. Decisions regarding which treatments are most suitable must be reserved for the physician in consultation with the individual patient. Insurance companies are increasingly attempting to take that decision away from individuals that depend on plasma protein therapies. A couple insurance companies have instituted fail first policies for patients that rely on IG. PPTA finds dangerous a policy that forces patients who are on IG to switch to another product without medical justification. Medical evidence shows that about one-third of all adverse reactions that occur with IG occur when trying a new product. PPTA considers it inappropriate to impose fail first policies plasma protein therapies because these therapies, like vaccines, are high value, high impact therapies used to treat rare conditions in very fragile populations. Such tools ultimately undermine the quality of care that patients reliant on plasma protein therapies receive.

Plasma protein therapies are not interchangeable. Individuals who rely on plasma protein therapies should have access to the full range of FDA licensed therapies from the most medically appropriate provider. Every product is unique and, because all products are all biologics, each therapy reacts differently for each patient. It is essential that the choice of product be made collaboratively with the patient and healthcare provider in order to achieve the best possible health outcome for the patient. Therefore, it is critical that individuals have access to a diverse range of therapies, and that prescriptions for specific plasma protein therapies are respected and reimbursed by qualified health plans.

Insurance companies should also leave the site of care to the medical professionals treating the patients that rely on plasma protein therapies. Individuals that rely on plasma protein therapies need life-long treatment and not episodic care, and therefore it is important to consider the site of care that works best for the patient – whether that be in the hospital, hospital out-patient, a physician's office or in the home.

Conclusion

The Affordable Care Act (ACA) was passed to address the problems of the uninsured and underinsured in this nation. A stated goal of the ACA is to provide a health care system that provides Americans with essential health benefits. The Plasma Protein

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