

IGIV Market is Complex and Evolving

ASPE Report Title: “Analysis of Supply, Demand, and Access Issues Associated with Immune Globulin Intravenous (IGIV)”

Summary:

IGIV is a plasma product that is used to treat patients with immune system disorders. A significant percentage of IGIV use is for off-label indications. Current conditions in the IGIV industry and market are complex and rapidly evolving. The growing demand for IGIV, supply capacity issues, changes in reimbursement, and the relocation of sites of service for large numbers of patients have combined to create difficulties with access to IGIV, as observed during the study period. Subsequent to the completion of data collection for the report, anecdotal reports have emerged that the supply of IGIV has increased. Due to the complexity of the IGIV market there is no simple solution to current access and supply issues.

Major Findings:

The report concludes that the IGIV industry and market have a number of unique industry and market characteristics.

- Demand currently outstrips supply in the marketplace
- U.S. plasma availability is a bottleneck in increasing IGIV supply.
- IGIV is sold on allocation, meaning most of the product is sold at a fixed price for a fixed quantity under contracts.
- Off-label use is a significant source of demand (estimated at 50%-80%).
- There is an active secondary market in which IGIV is sold at premium prices.
- In surveys, both Medicare and non-Medicare patients have difficulties with access to IGIV.
- The majority of IGIV was sold at prices above the Medicare reimbursement rate in the first two quarters of 2006. (More recent data for the third quarter of 2006 indicate that the percentage of IVIG sales by the three largest distributors to hospitals and physicians that occurred at prices below the Medicare payment amount is increasing.)

Purpose: To develop a systematic analysis of supply, distribution, demand, and access issues associated with IGIV.

Methodology:

Eastern Research Group, an ASPE contractor, drew from published and unpublished data, discussions with stakeholders, Medicare and IMS data, and a town hall meeting for the analysis. Manufacturers and distributors did not supply any proprietary pricing data for the study. Study findings are specific to IGIV and should not be extrapolated to other biologics or drugs, or evaluation of reimbursement methodology.