

WORKING FOR PATIENT ACCESS TO BLOOD CLOTTING FACTOR

BY BILL SPEIR

THE UNITED STATES OF AMERICA provides health care services to low-income individuals through its Medicaid program. The administration of the Medicaid program is a partnership between the federal government and the states.

Basically, the federal government establishes minimum requirements, and the individual states design their program as they see fit, as long as a state program meets the approval of the federal government's Centers for Medicare and Medicaid Services (CMS).

Patient access is always a concern for Medicaid recipients because Medicaid reimbursement is low when compared to private insurance and Medicare. And since providers are not required to participate in Medicaid, finding providers willing to take the low reimbursement is always a concern for Medicaid recipients.

Many individuals with bleeding disorders are Medicaid recipients. Access to blood clotting factor, a plasma protein therapy, is always a concern and any changes to Medicaid reimbursement could result in access problems for those that rely on blood clotting factor for their quality of life.

Since the 1960's, the benchmark for the Medicaid pharmacy reimbursement estimated acquisition cost has been the Average Wholesale Price (AWP), a value based on manufacturer-reported information and compiled by commercial drug pricing compendia. The decision of First DataBank, a major drug pricing compendia to cease publication of AWP in September, 2011 as part of a court settlement was the impetus for state Medicaid programs to find a new benchmark.

In June of 2010, a white paper was developed by The American Medicaid Pharmacy Administrators Association that recommends a change in Medicaid pharmacy reimbursement methodology from AWP to average actual acquisition cost (AAC). The white paper does not address the other piece of outpatient pharmacy reimbursement, a dispensing fee, but it is critical to patient access that the dispensing fee adequately reflects the true cost of dispensing blood clotting factors. If the dispensing fee is established without consideration of the challenges faced in dispensing blood clotting factors, this could result in serious patient access issues.

Key decision-makers are struggling with how to develop an appropriate dispensing fee because some lack the knowledge of how blood clotting factors are delivered and the services necessary for that delivery and medically appropriate administration.

In addition to this change, state Medicaid agencies are under tremendous pressure to control costs given the state budget deficits are at historic levels. Because of the high per recipient cost of Medicaid enrollees with hemophilia, blood clotting factor has been under great scrutiny by Medicaid pharmacy directors in the last few years.

As Medicaid pharmacy directors implement the new Medicaid pharmacy methodology and develop new cost containment strategies, there is a potential that individuals with hemophilia will lose access to their medically appropriate blood clotting factor and specialty pharmacy provider.

To ensure patient access to their medically appropriate therapy and pharmacy provider, PPTA organized the State Patient Access Coalition (SPAC) which represents the world's leading manufacturers of clotting factor and the nation's leading distributors of clotting factor. Clotting factor therapies are vital for individuals with bleeding disorders, including hemophilia and von Willebrand Disease.

Current SPAC Members

Accredo Health Group, Inc.	Curascript, Inc.
Baxter Healthcare Corp.	CVS Caremark
Bayer Healthcare	Grifols USA
Biogen Idec	Novo Nordisk
Cangene Corporation	Pfizer
CSL Behring	Walgreens

The SPAC's goal is to educate decision makers in CMS, state Medicaid agencies, and state legislatures on the need for open access to all blood clotting factors. As part of this education, SPAC has developed Patient Access Principles that urges decision-makers to consider the National Hemophilia Foundation's Medical and Scientific Advisory Council (MASAC) Recommendations 188 and



159 when implementing Medicaid policies that impact patient access to clotting factor.

The SPAC will also respond to threats to patient access to blood clotting factor when they arise. Two examples of this are the developments in New York and Washington.

New York has announced it will switch the reimbursement for blood clotting factor to Average Acquisition Cost starting in November of 2011. The SPAC, working with other specialty pharmacies that provide clotting factors and the National Hemophilia Foundation, developed dispensing fee data points for New York Medicaid to consider when developing the dispensing fee that would be paid to specialty pharmacies that provide blood clotting factor to New York Medicaid recipients.

The State of Washington put out a request for external review of a policy that has not yet been formerly proposed according to state rulemaking procedures. The policy would require all individuals that receive health care through public assistance programs, including Medicaid, to have their blood clotting factor supplied by a hemophilia treatment center that is a covered entity under the federal 340B program.

The SPAC responded to the state's request for comment by pointing out we oppose this policy since it limits patient access to qualified blood clotting factor providers which is contrary to MASAC recommendations and federal rules that govern the 340B program. 

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