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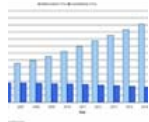


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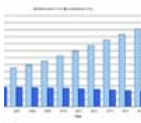
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Reimbursement Changes to Drive U.S. Market for Vascular Access Devices

DATE: 18 Jan 2010

iData Research reveals how changes in Medicare and Medicaid encouraged medical professionals and healthcare facilities to adopt the use of antimicrobial devices...



By Dr. Kamran Zamanian & Imelda Nurwisah, B.Sc



In 2009, the U.S. market for **vascular access devices** and accessories exceeded \$3 billion, a 5.4% increase over the previous year. This rapid increase was due, in part, to changes to **Medicare** and **Medicaid** stating that infections acquired during a patient's hospital stay would no longer be reimbursed. This change encouraged medical professionals and healthcare facilities to adopt the use of **antimicrobial devices** that prevent micro-organisms from growing, particularly when performing vascular access procedures. The higher average selling prices (ASPs) associated with antimicrobial devices and more complex kits containing full body drapes will continue to drive the overall vascular access devices and accessories market.

About Vascular Access

Vascular access devices are used to gain access to a patient's bloodstream by way of the veins. The devices deliver a wide range of treatments including fluid infusion, blood draws, parenteral nutrition, antibiotics, chemotherapy and dialysis, and in 2009, *approximately 90% of hospitalized patients in the U.S. received vascular access treatment during their stay.* Vascular access devices that saw the highest rates of conversion to antimicrobials include central venous catheters (CVCs), dialysis catheters, peripherally inserted central catheters (PICCs) and needleless connectors. The high adoption rate of premium antimicrobial devices has translated to growth in each of these market segments and therefore to the overall vascular access market.

Changes to Medicare and Medicaid Reimbursement

The push to reduce **catheter-related bloodstream infections** (CRBSIs) was reinforced by reimbursement changes to **Medicare** and **Medicaid** in October 2008. These changes state that treatments for vascular access-related infections acquired during a patient's hospitalization would no longer be reimbursed, as these infections are preventable. The cost of treating CRBSIs ranges from \$3,700 to \$29,000, and as a result, a healthcare facility's initial investment in preventative devices would offset the financial burden that a CRBSI would present.

Antimicrobial CVCs Outgrow Conventional CVCs

CVCs are highly susceptible to infection because the devices provide a direct route to the bloodstream through the large internal jugular, subclavian and femoral veins; therefore, the market for CVCs has been highly impacted by the changes in **Medicare** and **Medicaid**. In 2009, the antimicrobial CVC

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market was over double the value of the conventional CVC market due to growth in units sold and higher ASPs associated with antimicrobial devices and more complex kits. In addition, antimicrobial CVCs are the fastest growing segment of the total CVC market.

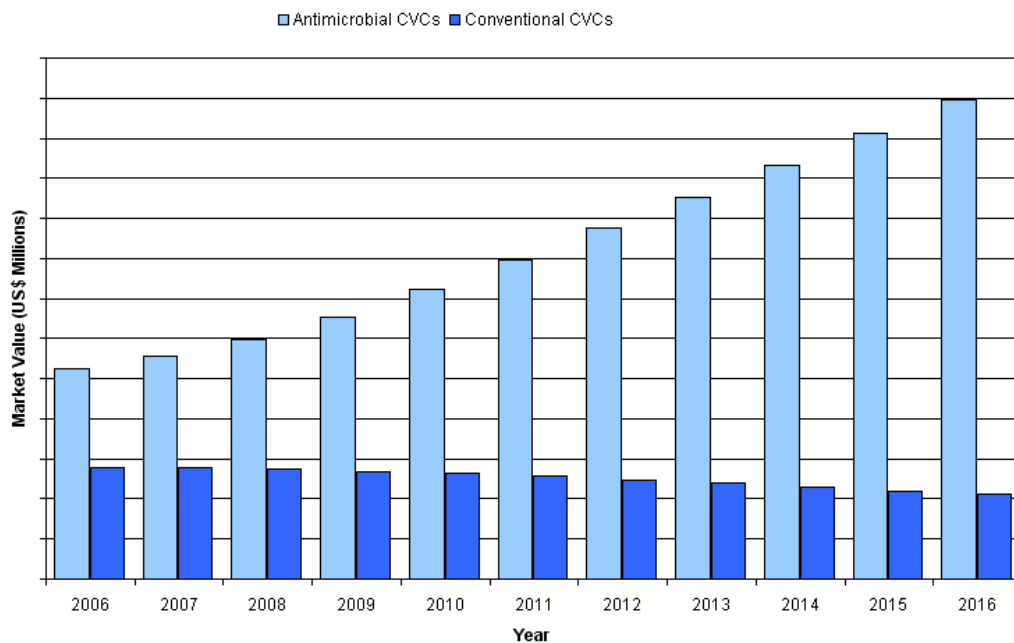
The CVC market is also driven by the demand for more complete **CVC kits** that include maximum barrier drapes, manufactured catheter securement devices (MCSDs) and the antimicrobial agent, **chlorhexidine**. These infection prevention features are priced at a considerable premium. However, the more complex kits were highly adopted by surgeons following the reimbursement changes to Medicare and Medicaid.

Chart 1-1: CVC Market by Type, U.S., 2006 – 2016

will be held November 2–4, 2009 in Vienna, Austria

Oppenheimer 20th Annual Healthcare Conference

The conference will be held November 3-4, 2009 at the Waldorf Astoria in New York City



Source: iData Research Inc.

Antimicrobial Dialysis Catheters to Experience Rapid Growth

In 2009, 3.8% of all **dialysis catheters** placed were antimicrobial. While the market for antimicrobial dialysis catheters is still relatively small as compared to CVCs, growth of the antimicrobial dialysis catheter market is expected to outpace the market for antimicrobial CVCs by 2016.

Dialysis catheters are used to facilitate dialysis for patients whose kidneys are not functioning properly, especially those diagnosed with **End Stage Renal Disease (ESRD)**. As of 2009, antimicrobial dialysis catheters with extraluminal coatings of silver and heparin were the only ones available; however, demand for dialysis catheters with intraluminal antimicrobial properties will drive the market in the future. While antimicrobial dialysis catheters are sold at a premium of \$100 or more over conventional dialysis catheters, healthcare facilities are considering the devices as a worthwhile investment relative to the costs associated with CRBSIs.

CRBSI Reimbursement Changes to Drive Market for Antimicrobial PICCs

PICCs have an average infection rate of 1.6 per 1,000 catheter indwelling days. While this rate is significantly lower than that of CVCs, Medicare and Medicaid reimbursement changes have encouraged hospitals to consider the increased use of antimicrobial PICCs. PICCs are commonly used to deliver chemotherapy and antibiotics as well as for drawing blood. In addition, antimicrobial PICCs are used extensively on immunocompromised patients.

Cook Medical's Spectrum® antimicrobial PICC was

introduced in 2009 and is the first of its kind in the market. The product uses the same monocycline and rifampin coating technology used in Cook Medical's antimicrobial CVCs. Although antimicrobial PICCs are sold at a premium over conventional devices, clinical results showing even a moderately reduced infection rate will be enough for antimicrobial PICCs to establish themselves in the market. Antimicrobial PICCs are still in the early stages of market entry; however, ongoing technological advancements and premium ASPs will drive the overall market for PICCs.

ASP for Antimicrobial Needleless Connectors to Decline

Antimicrobial **needleless connectors** are a relatively new addition to the market and represented only 0.02% of all needleless connectors placed in 2009. However, as a result of the reimbursement changes to **Medicare** and **Medicaid**, the market for antimicrobial needleless connectors is expected to grow rapidly. To claim antimicrobial status, products must kill at least 99.99% of six common pathogens that cause CRBSIs, and as of 2009, only two antimicrobial needleless connectors were available with such properties.

The price premium and lack of long term **clinical studies** have limited sales of antimicrobial needleless connectors; however, the ASP of antimicrobial products is decreasing and will continue to decrease in order to encourage greater usage. In addition, since needleless connectors are found in infusion sets and at the terminus of all **PICCs, CVCs** and **peripheral intravenous catheters** (PIVCs), the increased adoption rate of antimicrobial devices in those segments will further drive the market for antimicrobial needleless connectors.

Conclusion

Since the reimbursement changes to **Medicare** and **Medicaid** took place in late 2008, the use of antimicrobial devices has **increased substantially** in the vascular access devices and accessories market. As healthcare facilities become more aware of **antimicrobial devices** and the benefits that these products have in preventing CRBSIs, the ASP and revenue for the vascular access devices and accessories market will see considerable growth.

Additional Information is Available

The information contained in this article is taken from a detailed and comprehensive report published by **iData Research** (www.idataresearch.net) on the "U.S. Market for Vascular Access Devices and Accessories 2010," which is available for purchase from iData Research. iData Research is an international market research and consulting firm focused on providing market intelligence for the medical device, dental and pharmaceutical industries. For a free synopsis of the above report, please contact iData Research at: vascular@idataresearch.net or +1-866-964-3292