

Industry Spotlight

Fresenius' New Partnerships

Fresenius Medical Care North America (FMCNA), a division of Fresenius Medical Care, has been busy forming partnerships with national insurers. FMCNA announced a partnership in March 2017 with Humana Inc. with plans for a new program to improve care and health outcomes for Humana's members with end stage renal disease (ESRD). In February 2017, FMCNA announced a partnership with Cigna in a national program to lower the cost and improve quality of care for people with ESRD who are undergoing dialysis.

Under the program with Humana, FMCNA will implement its proprietary care coordination model. Each patient will be supported by a collaborative team of local nephrologists and clinicians working in partnership with the Care Navigation Unit (CNU), FMCNA's group of specialized nurses and service coordinators who provide 24/7 care coordination services. By focusing on the physical and emotional needs of each patient, the CNU aims to foresee issues before they arise and to help patients, their families, and their providers respond as conditions change.

"Through this partnership, we will positively impact the overall medical care of Humana's ESRD members who receive treatment within our dialysis centers, and it's our responsibility to ensure they can access the care they need, when they need it," said William McKinney, president of FMCNA's Integrated Care Group.

In the new Cigna partnership, FMCNA will continue to be paid for the kidney dialysis services it provides to its Cigna patients, while its affiliate, Fresenius Health Partners, will assume separate responsibility for providing management of medical costs and improving patient outcomes.

Implementing its proprietary care coordination model for this purpose, FMCNA may be eligible for additional reimbursement if it achieves such goals, the company noted in an announcement. The dialysis clinics must maintain or improve their star ratings within parameters set by the Centers for Medicare & Medicaid Services (CMS) in its Dialysis Facility Compare (DFC) quality rating. Cigna will evaluate outcomes for a number of quality measures that correlate directly to the total cost of care and overall patient experience.

One of the program's goals is to reduce emergency room use and hospital admission for dialysis by keeping patients healthier and providing them with additional access to dialysis at Fresenius Kidney Care outpatient facilities as needed, Fresenius announced. ●

Kidney Cancer Developments

The National Institute for Health and Care Excellence (NICE), has approved everolimus (brand name Afinitor, manufactured by Novartis) for routine use as a regular National Health Service (NHS) treatment option for patients with advanced renal cell carcinoma (RCC). NICE provides evidence-based guidelines on health care for the NHS and other medical organizations in England.

Previously, the drug was available only to NHS patients if they applied through the Cancer Drugs Fund (CDF). However, NICE reappraised the drug and assessed the cost and clinical effectiveness. As part of the reappraisal, Novartis Pharmaceuticals submitted a further discount to the cost of everolimus.

NICE originally published guidance not recommending everolimus as a standard NHS offering in April 2011, because it was deemed not to have sufficient benefits to justify its cost. It was then made available through the Cancer Drugs Fund.

A different fate met rocupuldencel-T, which was in a Phase 3 trial as a personalized cancer vaccine for metastatic renal cell carcinoma, wrote SeekingAlpha.com, an



investment news website. Argos Therapeutics, based in Durham, NC, progressed in its new drug development to the Phase 3 ADAPT Trial, but was unable to show significant benefit in patient survival for its drug. An Independent Data Monitoring Committee reviewed data from earlier trials that showed the drug warranted moving to a Phase 3 trial.

After the trial results emerged, Argos announced it would cut more than a third of its employees, the *Durham Herald-Sun* wrote. ●

Nephros' New Filter Approved

The US Food and Drug Administration (FDA) has approved a new filter from Nephros (River Edge, NJ).

In early March 2017, Nephros received 510(k) clearance to market its EndoPur™ Endotoxin 10-Inch Filter.

The filter is designed to provide hemodialysis-quality water to dialysis machines. It fits into existing filter cartridge housings of the reverse osmosis (RO) water systems that provide dialysis clinics with high volumes of ultrapure water. The EndoPur™ has an endotoxin barrier with the smallest pore size on the market, the company announced.

"With the FDA clearance of the EndoPur, we have achieved a significant milestone in the expansion of our dialysis water filter portfolio," said Daron Evans, president and CEO of Nephros. "We now can provide our industry-leading 5-nanometer pore-size endotoxin protection to all dialysis clinic RO systems. We expect to begin selling the

EndoPur to customers in the second quarter of 2017."

The filter can be used in large clinic-based, and small, portable machine scenarios.

Nephros' primary objectives in the second half of 2016 were to support the commercial launch of the S100 Point-of-Use filters and to complete the regulatory process for the 10-inch filter platform. The company also focused efforts on launching its hemodiafiltration treatment at a dialysis clinic managed by Vanderbilt University, according to a corporate update announcement.

Nephros expected total revenue for fourth quarter 2016 to exceed \$740,000 and predicts it will be cash flow positive by the end of the second quarter of 2017, as its 10-inch cartridge product line becomes available. Nephros ultrafilters are used by dialysis centers to assist in the added removal of biological contaminants from water and bicarbonate concentrate in hemodialysis machines. ●

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