



Virginia Medicaid DUR Quarterly Newsletter

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Welcome

DMAS is pleased to present the first edition of the quarterly Drug Utilization Review (DUR) newsletter which will be published after each DUR Board meeting. Each newsletter will include topics discussed at the Board meetings such as trend analysis and service authorization requirements for new drugs. We will also include the latest drug and treatment related topics that are occurring on the national level.

New Class of Cholesterol Lowering Agents - PCSK9 Inhibitors

On July 24, 2014, the FDA announced approval of the first proprotein convertase subtilisin-kexin type 9 (PCSK9) inhibitor, alirocumab (Praluent™).¹ The approval of the second PCSK9 inhibitor, evolocumab (Repatha™) is expected in early August. By inhibiting PCSK9, these agents cause an increased number of low-density lipoprotein (LDL) receptors in hepatocytes, and therefore a decreased amount of LDL circulating in the bloodstream. Although statins have been first line therapy for lowering cholesterol for the last 20-30 years, there is still a need for alternative treatment options. Approximately 15% of patients with elevated LDL cholesterol are either statin-intolerant, not at LDL treatment goals with statins, or have familial hypercholesterolemia. In clinical trials, PCSK9 inhibitors have shown rates of LDL lowering of greater than or equal to 60%. In one trial, patients treated with evolocumab for one year had an average LDL of 48mg/dL ("healthy" LDL being classified as less than 100mg/dL), the lowest LDL ever seen in an experimental arm of a lipid-lowering trial.

The FDA review and approval of the first PCSK9 inhibitor has garnered a great deal of attention from the media, and rightfully so. The potential of reducing LDL levels at such a robust rate holds significant promise for treating a population that clearly needs a new treatment alternative. This promise, however, does not come without a significant price tag. While the specific cost for these agents is not known yet, it has been estimated to be between \$7,000 - \$12,000 per patient per year. Statins, available generically for most agents, can be obtained for less than \$10 per month. Knowing this, it will be important for pharmacy programs to ensure that this class is being used judiciously for the population it is intended to treat.

CONTACT INFORMATION

Virginia Department of Medical Assistance
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DUR BOARD MEETINGS

August 20, 2015

November 12, 2015

P&T COMMITTEE MEETINGS

October 15, 2015

EDITORIAL STAFF

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1. FDA approves Praluent to treat certain patients with high cholesterol. . U.S. Food and Drug Administration. July 24, 2015. Available at <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm455883.htm>

New Cystic Fibrosis Therapy

In July 2015, the FDA approved Orkambi™, the first drug for cystic fibrosis (CF) that targets the root cause of the disease in people who have a specific genetic mutation. Orkambi is a combination of lumacaftor and ivacaftor, a cystic fibrosis transmembrane conductance regulator (CFTR) potentiator, indicated for the treatment of cystic fibrosis (CF) in patients age 12 years and older who are homozygous for the *F508del* mutation in the *CFTR* gene. Patients with two copies of the *F508del* mutation are easily identified by a simple genetic test.

Cystic fibrosis affects about 30,000 people in the United States. The *F508del* mutation is the most common cause of CF. Individuals with two copies of this mutation account for approximately one half of all CF cases. The first CF breakthrough drug, Kalydeco (ivacaftor) targets different CFTR mutations which comprise only 4% of CF cases.²

Orkambi will not be cheap. The manufacturer, Vertex, has priced it at roughly \$259,000 annually per patient. However, some of this cost may offset by the decrease in the number of extensive breathing treatments and respiratory infections that patients normally have to endure. Orkambi dramatically improves lung function and guards against future lung damage.

2. FDA approves new treatment for cystic fibrosis. U.S. Food and Drug Administration. July 2, 2015. Available at <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm453565.htm>

August DUR Board Summary

The Board reviewed seventeen new drugs and approved service authorization (SA) criteria on the drugs listed below.

The next DUR Board meeting is scheduled for November 12, 2015.

The minutes from the August meeting can be found at http://www.dmas.virginia.gov/Content_pgs/pharm-durb.aspx.

New Clinical Service Authorizations - effective date October 1, 2015

Brand Name	Generic Name	Indication
Esbriet	pirfenidone	idiopathic pulmonary fibrosis
Ofev	nintedanib	idiopathic pulmonary fibrosis
Lynparza	olaparib	ovarian cancer
Soolantra	ivermectin	rosacea
Farydak	panobinostat	multiple myeloma
Ibrance	palbociclib	breast cancer
Lenvima	lenvatinib	thyroid cancer
Jadenu	deferasirox	iron overload
Natpara	parathyroid hormone	hypoparathyroidism
Orkambi	ivacaftor/lumacaftor	cystic fibrosis
Saxenda	liraglutide	weight loss

The SA Request Fax Forms can be found at <https://www.virginiamedicaidpharmacyservices.com/asp/authorizations.asp>.