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Commentary
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EHL (Extended Half-Life) Products, What Are They Really Costing?

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Commentary

The advent of biotechnology has substantially advanced the field of hemophilia from the days when treatment options largely consisted of fresh frozen plasma and cryoprecipitate.

The HIV and hepatitis C viral epidemics led to innovations that made safer plasma and recombinant products. The ability to perform self-infusion and home care has changed life styles, prophylaxis, and the orthopedic outcomes of this disease. The recent introduction of EHL (extended half-life) blood-clotting factor agents for patients with Factor VIII (FVIII) and Factor IX (FIX) deficiencies originated with the goal of reducing the frequency and number of infusions required for even higher trough levels and achievement of equivalent or greater outcomes. It was projected that the costs per annum would not be substantially different from the patient's previous regimen (prior to switching to an EHL product) as fewer treatments would be necessary.

Using a data base from AETNA insurance company to track patients throughout the United States with hemophilia, records kept on each patient include treatment regimen, factor product, factor price, product acquisition, and how much is paid (not billed) for each international unit (IU). Annualized costs were calculated from the patient's regimen before the switch and the current regimen. Only patients on prophylaxis were included in the analysis as annual use could not be predicted for on demand patients. The costs were based on the regimen their physician chose to use, the 340 price charged by the delivery program (there is no maximum), and what the buyer paid for the product. The data collection for AETNA does not include outcome data, rationale for regimen choice, trough levels (desired or achieved), bleeding episodes or quality of life data.

Twenty-one patients were identified who made a switch from a recombinant FVIII product (16 patients) or FIX product (5 patients) to an EHL product. Most of the patients were switched to either Eloctate or Aprolix and paid the 340B price charged by the supplier. The time on the new EHL product ranged from 6 months to a year. Only 1/5 (20%) of the FIX patients and 4/16 (25%) of the FVIII patients had lower annual costs when switched to an EHL product. Thus, 75% to 80% of patients experienced incremental costs. Only one FIX patient remained on the same treatment regimen post switch, while the rest (5/6, 83%) including the one case with lower annual costs were able to decrease the interval between infusions. Three of the four FVIII patients with lower annual costs (75%) decreased their treatment regimen and one (25%) increased the frequency of infusions. Of the remaining 12/16 FVIII patients who experienced incremental costs, only 1 patient increased their regimen, while the remainder (11/12, 92%) actually decreased their treatment frequency.

The bulk of prices paid by AETNA were based on 340B prices, and some were on ARX (AETNAS own pharmacy) prices. The charges paid for FIX before switching ranged from $0.81/IU to $1.41/IU with a median $0.98/IU. Post FIX switch, the range was $2.21/IU to $4.11/IU with a median $2.62/IU. The range for FVIII pre switch charges paid was $0.97/IU to $2.06/IU with a median $1.01/IU. Post FVIII switch, the range was $1.19/IU to $2.56/IU with a median $1.65/IU. The patient's body weight was held constant as a factor in the cost calculation. The average annualized cost per patients in US dollars (USD) pre and post switching to an EHL product is shown in Table 1.

In a changing health care reimbursement environment, it is important to document the fiscal impact of these new EHL biologics. The AETNA database does not include data as to the patient-doctor decision regarding the regimens that were selected (i.e. interval, trough level, or pharmacokinetic levels of a given patient). Additionally patient outcomes, bleeding episodes, joint pathology, CNS bleeds, and quality of life are not documented and medical improvement cannot be assessed.

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Table 1: Average annualized cost per patient in USD (n=21 patients).

	Pre Switch		Post Switch		% Change
	Mean	Median	Mean	Median	
VIII	$415,512	$302,640	$697,351	$681,227	+67.8%
IX	$230,021	$234,416	$628,595	$761,682	+173.3%

Although there is a deficiency in the data presented, the goal of this was to show what the actual, not theoretical, costs to the insurance industry were by switching to an EHL product. It is, however, very important to note that most patients have incurred substantially higher costs after the switch was made. This is true in many cases despite fewer infusions. Currently some insurers have decided not to cover EHL products based on their assumption that costs would rise. This commentary provides the first hard data on actual costs to the insurer for these 21 patients.

It behooves the treating community to justify these incremental costs of EHL utilization and show that patient outcomes are better using them. If this is true, it must be documented and a cost/benefit analysis performed.

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