24. Economic and Cost-Effectiveness Evaluation

Archive Note: Data on Forms #266, #267, #268, 610 indicated below were not collected.

24.1 Possible Impacts on Costs and Effectiveness for Hemodialysis Patient Care

Although 6 hemodialysis sessions per week will cost more than 3 sessions per week, it is not clear how more frequent hemodialysis will affect the total costs of caring for a hemodialysis patient. One of the hopes is that patients dialyzed more frequently may have fewer hospitalizations and need fewer injectable medicines. This could save money for Medicare and patients, but may also adversely affect hemodialysis center finances. It is possible that patients dialyzed 6 times weekly may have more access problems than those whose access is entered only 3 times weekly. But the reverse could also happen. CMS needs to understand the impact of frequent hemodialysis on total Medicare costs, in order to make good policy decisions about how to pay for more frequent hemodialysis, if it proves to be more effective than conventional hemodialysis.

The initial time horizon will be the 5-year study period, but will also be extended to 10 years using Markov modeling approach to measure the long-term cost-effectiveness difference between the frequent and the standard hemodialysis. It is possible that frequent hemodialysis will be more effective, but also more expensive, than standard hemodialysis. In this case, we will have to estimate its cost-effectiveness in a standard way, by calculating incremental cost per quality adjusted life years (QALYs) saved. The quality of life data (utility), which is the effectiveness component of the cost-effectiveness analysis (economic evaluation), will be collected using Health Utility Index, Mark 3 (HUI3) (Form #223). The following description focuses mainly on the cost component of the evaluation.

24.2 Cost Analysis

In practice, we will be able to look only at the major costs from the payer (especially Medicare) and the provider perspectives. With respect to costs to the patient, we will be looking at the cost of home modifications for nocturnal hemodialysis, and also the out-of-pocket cost by the patients for CMS-covered services and prescription medications, which will be included in the claims data. Our ultimate goal will be to simulate the long-term costs to the Medicare program, if frequent hemodialysis were to be adopted by many centers, not those just participating in the trial. The major components of costs we will collect data on under the trial include:

Costs related directly to hemodialysis treatment by a facility:

- Hemodialysis costs – 40% of Medicare costs
- For home hemodialysis: Training vs. Maintenance
- Injectable medicines
- Costs of maintaining hemodialysis access

Other health care costs:

- Hospitalizations – 40% of Medicare costs
- Outpatient visits and procedures
- Oral medicines
- Home care by professionals or by family
- Travel to and from hemodialysis sessions

The last four parts of other health care costs (outpatient visits and procedures, oral medicines, home care by professionals or by family, and travel to and from hemodialysis sessions) will not be focused due to the expense of data collection itself. In the meantime, these costs will only comprise a very small fraction of the total costs. Wasting a large amount of resources to collect minute cost information is not worthwhile. Nonetheless, the estimate of these costs will be factored in for final analysis through imputation technique and sensitivity analysis. In particular, use of oral phosphate binder medications (Form #205) and the number of blood pressure medications will be collected. The drug claims data for a subset of Medicare beneficiaries in the trial will still be collected from CMS and the oral medication cost of these patients will be examined.

For most economic estimates, we need to understand the *payments* that will be made for medical care. Payments for specific services will be estimated in terms of standard Medicare payments for these services, irrespective of what insurance the study patients have (Medicare, private, HMO, Canadian). There is a specific need to understand the actual *costs* of performing standard and frequent hemodialysis. Therefore we need to estimate these costs, and not just the current Medicare payments for hemodialysis. For Canadian patients in particular, social insurance number, Ontario health insurance number, or British Columbia health insurance number is needed to link to the administrative data for hospitalizations.

24.3 Approach to Estimating Cost of Hemodialysis Itself

Equipment and supplies: A detailed list of equipment needed per station and an amortization schedule for capital equipment will be constructed and agreed to by hemodialysis administrators. A detailed list of supplies needed per hemodialysis session will be circulated to dialysis administrators for their comments. Use of the common GSA price list will permit us to estimate costs independent of local variations in costs and different contractual relationships among the providers. (Form #266, #267, #268)

Professional time: We will perform initial estimates of the range of professional time needed per standard hemodialysis from Medicare dialysis center cost reports as: professional FTEs (by type) / # dialysis sessions. Within the study, we will estimate the difference in professional time needed to do standard and frequent in-center hemodialysis by collecting facility-level data on a form very similar to the Medicare cost report (Form # 268). These data will be collected at two intervals during the study: early, when there will be few frequent hemodialysis sessions at any given center and during the height of the study when there are a peak number of patients on frequent hemodialysis. Professional time will be converted to cost using standard salary scales for the types of

personnel involved, again making estimates independent of geographical and other similar issues. An important issue will be to determine the variation in professional time per session, and number of patients served per hemodialysis station, from one type of dialysis center setting to another: large urban dialysis center, small rural dialysis center, numbers of standard and frequent hemodialysis patients. (Form #268, #610)

Overhead: Hemodialysis unit overhead as a proportion of a standard hemodialysis session costs will be estimated from current overhead rates from the Medicare dialysis center cost reports: Administrative salaries, space, heating, waste disposal, etc. Total estimated hemodialysis costs per session: (standard and frequent) will be reviewed iteratively with the dialysis unit administrators and CMS until there is agreement that the estimates accurately account for total costs, and no large "miscellaneous" category remains.

24.4 Home Hemodialysis

Medicare presently pays separately for the period of home hemodialysis training, and then for the maintenance hemodialysis once patients are home. The costs for personnel to train new home patients and support established home patients are not well understood. We also do not have a good understanding to the costs for home modifications needed to permit home hemodialysis. Therefore, we need to estimate these costs directly in the centers involved in the Nocturnal Hemodialysis Protocol.

Professional time: Dialysis center nurses and technicians involved in home hemodialysis training and support of patients at home will be asked to track time spent in each of two one week periods that they spend on (Form #610):

- Hands-on home hemodialysis training with patients;
- Support of established home hemodialysis patients;
- Management of other in-center patients;
- Other time not attributable to care of a specific patient (CME, administrative, etc.).

The study coordinators will be asked to complete a form listing costs of home modifications needed to permit home hemodialysis (Form #260). The entries on the form should be based on copies of actual invoices or bills if possible. The home modification costs should be listed irrespective of who pays for them (the center, the patient, assistance programs, voluntary agencies such as NKF, etc.)

24.5 Payments for Injectable Medicines

Medicare pays for injectable medicines administered in the course of hemodialysis (epoetin, iron, vitamin D analogues) based on:

- The specific medicine,
- Dose,
- Number of doses in monthly billing cycle.

One hypothesis is that frequent hemodialysis will reduce the need for these injectables, which will impact total costs. These data are needed both for the cost analysis and for the clinical analysis. (Form #203, #204, #205)

24.6 Payments for Access Procedures

Study coordinators are asked to report all access procedures and to classify them into one of a small number of procedure types (Form #271, #276, #277, #278). We will capture from Medicare billing records the actual Medicare payments for access procedures on Medicare primary coverage patients in the study. We will then determine the average payments for each of a small number of easily coded procedure types. These payments will then be imputed to all other access procedures on non-Medicare primary pay patients (private, HMO, Canadian).

24.7 Payments for Hospitalizations

Coordinators will be asked to report the dates of all hospitalizations (overnight stays) of any type for all study patients (Form #303) or date of admission and date of discharge (or date of in hospital death). The study PIs will be asked to identify the major indication for the hospitalization from a short list of major categories of events. Payments for hospitalizations of all study patients will be estimated in terms of the Medicare payment for the relevant Diagnosis-related Group (DRG) – which Medicare uses to determine payment for hospital admissions. DRGs are built on the basis of: primary diagnoses, secondary diagnoses (for complicating co-morbidities), whether a surgical procedure was performed, and the type of surgical procedure.

The assigned DRG will be available in the case of Medicare primary patients directly from Medicare claims data. We will obtain hospitalizations by DRG directly from HMOs. From Canadian centers, we will obtain the length of stay and primary reason from relevant ICD9/10 diagnostic codes and can derive from them the appropriate Medicare DRG codes. We will determine the average DRG payment for each major category of hospitalization type from the above patients, and impute an average DRG payment for hospitalizations of patients not in one of the above groups.

24.8 Summary

Assuming that frequent hemodialysis is shown to be medically effective, it will be essential to estimate the medical care costs of patients receiving frequent in comparison to standard hemodialysis. Most of the effort to make these estimates will not fall on the study coordinators. A major effort has been made to avoid burdening coordinators with collection of these data. But accurate reporting of certain data by the coordinators will be needed: occurrence of hospitalizations and access procedures, use of injectable medicines, and the special issues in home hemodialysis.