

23. Billing

23.1 General Information

- A. **Background:** The Centers for Medicare and Medicaid Services (CMS) is jointly sponsoring with the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) two clinical trials to evaluate the effectiveness of more frequent hemodialysis sessions compared with conventional thrice-weekly hemodialysis. One of these trials compares daily in-center hemodialysis (6 times per week) with conventional in-center hemodialysis (3-times per week). The other compares nocturnal hemodialysis (6 times per week in the home) with conventional in-center hemodialysis. CMS has agreed to pay for covered subject care-related expenses for Medicare beneficiaries enrolled in these trials. For subjects enrolled in the experimental arms of these trials (more frequent in-center or nocturnal hemodialysis), CMS also authorizes payment for one additional composite for the duration of the trial. The duration of the daily in-center hemodialysis trial will be 12 months after subject enrollment.
- B. The duration of the **nocturnal hemodialysis** trial will be 14 months after subject enrolment. For subjects enrolled in the experimental arm of the nocturnal hemodialysis trial, CMS also authorizes additional home dialysis training payment at the composite payment rate plus \$20 for each training session incurred not to exceed 30 training sessions payment per patient. The standard Medicare deductibles and co-payments will apply to both composite rate payments and training session payments.
1. The provider needs to complete the **Attestation Form** for all beneficiaries qualified and enrolled in the ESRD Daily Trial (Attachments 1 and 2) and forward to their respective fiscal intermediaries (FI).¹
 2. The provider will process claims following their normal billing procedures with the following exception: populate on the CMS billing **Form UB-92** (Attachment 3), Form Locator (FL) 63 or the 837I equivalent on the 72X Type of Bill (TOB) with “**Trial 49**” for dialysis services provided to the trial beneficiaries.
 3. The FIs shall process claims for payment, with **Trial 49 populated in FL 63** in accordance with standard Medicare claims processing rules.
 4. For **home hemodialysis** subjects enrolled in **Trial 49**, FIs shall follow the normal procedures in place to bill under **Temporary Method I**. This allows payment for home dialysis items and services on behalf of patients that have not filed a Form CMS-382 selection form.

Fiscal Intermediaries (FI)

The company that receives bills for Medicare, evaluates their appropriateness, and issues payment on behalf of Medicare

23.2 FREQUENTLY ASKED QUESTIONS

Answers to many questions regarding the billing procedures can be found under the change request section in the following link:

http://www.cms.hhs.gov/manuals/pm_trans/R145OTN.pdf

1. What are the eligibility criteria for patients for whom the 4th treatment will be paid by Medicare?

Medicare payments will be made for a 4th treatment for those subjects enrolled in either the nocturnal or in-center frequent hemodialysis trials in the experimental arm (6 times or more per week hemodialysis) and who otherwise would qualify for Medicare reimbursement for hemodialysis. A provider must fill out an attestation (see the link above) that the patient is enrolled in the trial and provide the Medicare identification number (HIC) for the patient. Only participating facilities listed in the addendum above who have their Medicare provider ID are eligible.

2. How many patients will have their 4th treatment paid by Medicare?

Currently the instructions to the fiscal intermediaries do not limit on the number of patients who we will pay for. The protocol calls for 250 patients (altogether) in the experimental arms of the trials. For the time we can say no more than 250 patients, as this is the maximum called for under the protocol. The attestation must include an enrollment date and expected termination date. After the termination date for each patient, no additional payment for a 4th treatment will be made, unless they otherwise qualify through medical necessity.

3. Are Medicaid patients under 65 yrs of age in that group?

Medicaid patients will not be paid by Medicare unless they are dual-eligibles and Medicare is the primary payer. Medicare patients under 65 who otherwise would qualify for Medicare reimbursement for hemodialysis are eligible.

4. Are private insurance patients under 65 and the first 33 months of their ESRD in that group? Are those patients who, within the study period, will become either 65 or exhaust their 33 month benefit within that group?

Medicare cannot pay for any patients who would not otherwise qualify for Medicare reimbursement for their hemodialysis. This means private pay

patients in their first 33 months of ESRD would not qualify. The same applies to Canadian patients enrolled in the trial.

5. Medicare needs to assign a specific billing code for this study and the 4th treatment. What is that code?

The attached link contains very detailed instructions concerning this issue. There is no special code, but trial 49 must be referenced.

6. What role will the intermediaries play?

The intermediaries will receive the attestations and be responsible for checking a website (to be established) that will update the list of participating facilities as needed. The intermediaries will work with CMS information services to produce a regular report that will be sent to ORDI at CMS describing the patients who are receiving the 4th treatment. CMS will check this list against a list of patients to be sent to them that includes patient HIC, name, and participating facility to safeguard our system against fraud and abuse.

7. How will contact information be obtained for the intermediaries and within CMS for billing related questions? Will specific point persons be assigned by these entities?

Each provider should know who their intermediary is. There is no specific contact for billing questions.

8. What about reimbursable medications? Any additional payments by Medicare/Medicaid?

Medicare limits on reimbursable medications remain the same as under existing rules. No extra payments for those items will be made under this trial.

9. What about transportation? What is being proposed for the three additional days?

Medicare will not pay for transportation for hemodialysis, except if an ambulance is warranted due to medical condition (not an ambulette) -- these rules are the same for all Medicare patients irrespective of participation in the trial.

23.3 POTENTIAL BILLING ERRORS

1. Ensure that **Attestation Forms** are completed and forwarded to the Fiscal Intermediaries for all patients that are part of the study.
2. Injectable medications will not be reimbursed for the fourth, fifth and sixth treatment of each week.
3. Nurses need to be well informed about the medication guidelines and not automatically administer medications.
4. Data Entry Clerks need to be aware of the patients and the drug administration policy as part of this study to ensure that information is entered correctly.
5. Billing Clerks must be aware of those patients that are part of the study to ensure that the billing is done correctly.