Overview of Medicare Coverage of Clinical Services
in the Long-term Oxygen Treatment Trial (LOTT)

Medicare is covering clinical services in the Long-term Oxygen Treatment Trial

In March 2006, the Centers for Medicare and Medicaid Services issued National Coverage Determination (NCD) 240.2.1 (CAG00296N) (http://www.cms.hhs.gov/mcd/viewncd.asp?ncd_id=240.2.1&ncd_version=1&basket=ncd%3A240%2E2%2E1%3A1%3AHome+Use+of+Oxygen+in+Approved+Clinical+Trials).
This NCD covers the home use of oxygen for Medicare beneficiaries with arterial oxygen partial pressure measurements from 56 to 65 mmHg or resting oxygen saturation above 88% who are enrolled in certain clinical trials sponsored by the National Heart, Lung, and Blood Institute (NHLBI). The LOTT is such a trial. Medicare will cover the costs of certain LOTT clinical services for Medicare beneficiaries enrolled in the trial; beneficiaries must have Part B coverage. This NCD provides the following advantages with respect to coverage for Medicare beneficiaries enrolled in the LOTT:

- Coverage is provided for the home oxygen prescribed in LOTT.
- Regional variation in interpretation of what constitutes "routine" costs associated with care provided per protocol is replaced by this NCD's definitions of coverage, providing one consistent interpretation for sites across the United States.
- "Non-routine" costs of care provided per protocol are covered under this NCD.
- The coding instructions for LOTT follow those of the Medicare Clinical Trial Policy. These are explained in more detail below.

What protocol procedures will Medicare cover for beneficiaries participating in the LOTT?

- Home oxygen
- Physician visits
- Spirometry
- Resting oximetry
- Six minute walk test with oximetry (EKG if needed to clear patient to complete six minute walk test)
- Hematocrit and hemoglobin blood draw and tests
- Serum cotinine blood draw and tests
- A1AT blood draw and test

All protocol required treatments and clinical procedures, including clinical procedures for eligibility, in concordance with the LOTT Protocol's specifications and calendar, are covered unless excluded as explained in the next section entitled "**What costs and LOTT protocol procedures are NOT covered by Medicare**".

What costs and LOTT protocol procedures are NOT covered by Medicare?

- Costs covered by NHLBI for any patient enrolled in the study are not covered by Medicare. For example, administration of the quality of life questionnaires is covered by NHLBI for all patients in the LOTT.
- Coinsurance and deductibles are not covered by Medicare. If the patient has Medigap insurance that covers Part B copayments and/or deductibles, these costs may be billed to the Medigap insurer. Many, but not all, Medigap policies cover Part B copayments and several

cover Part B deductibles. If the patient does not have Medigap insurance that covers Part B copayments and/or deductibles, the patient is responsible for these costs unless the provider has agreed to waive copayments and deductibles for LOTT services.

- Costs that do not fall into a Medicare benefit category are not covered by Medicare. For example, quality of life questionnaires do not fall into a benefit category and their administration is not covered by Medicare. However, doctor visits that include administration of such questionnaires may be billed to Medicare.
- Medicare does not cover data collection NOT used in the direct care or management of patients.

Are Medicare HMO patients able to participate in the LOTT?

Yes, Medicare HMO patients are able to participate in the LOTT. Medicare will cover LOTT services for beneficiaries with "ordinary", fee for service Medicare plans, as well as for beneficiaries with Medicare plans provided via Health Maintenance Organizations (HMOs), Preferred Provider Organizations (PPOs), Medicare Advantage, etc. The beneficiary must have Part B coverage. The LOTT provider will bill Medicare as if the beneficiary was a fee for service beneficiary. All Medicare beneficiaries, regardless of type of plan (fee for service, HMO, PPM, Medicare Advantage, etc), will be responsible for co-insurance and deductibles for LOTT clinical services covered by Medicare unless the provider has agreed to waive copays and deductibles for LOTT clinical services or the beneficiary has Medigap insurance that covers copays and/or deductibles for Part B services.

What are the instructions for billing for a Medicare covered service in the LOTT?

- Use the ICD–9-CM diagnosis code of **V70.7** in the second diagnosis code position (on all types of claims) and condition code **30** (on inpatient and outpatient facility claims) to show that the claim involves a clinical trial.
- Use the "**Q1**" modifier with the applicable procedure code **for routine clinical costs** (those paid under usual care, if no study was involved; for example, spirometry, oximetry, 6 minute walk, hemoglobin, hematocrit, serum cotinine, A1AT, home oxygen if the patient has deteriorated and become severely hypoxemic at rest) on physician/provider claims.
- Use the "**Q0**" (zero) modifier with the applicable procedure code **for non routine clinical costs** (the home oxygen itself while the patient is moderately hypoxemic at rest or during exercise) on physician/provider claims.
- The Certificate of Medical Necessity (CMN) is required for the initial claim for home oxygen submitted for each patient prescribed oxygen under the LOTT protocol. It is not required again for the duration of the patient's participation in LOTT.
- Use of the clinicaltrials.gov identifier for LOTT (NCT00692198) will facilitate claims processing and generation of the claims database for analytical purposes. Information on use of the clinicaltrials.gov identifier may be found at http://www.cms.hhs.gov/Transmittals/2008Trans/itemdetail.asp?filterType=dual,%20keyword&filterValue=clinical%20trial&filterByDID=0&sortByDID=2&sortOrder=descending&itemID=CMS1207575&intNumPerPage=10

What if a patient is not on Medicare, will other insurers provide this same coverage?

- This coverage decision applies **ONLY** to Medicare plans. This coverage decision applies to "ordinary" (fee for service) Medicare, as well as Medicare plans provided via Health Maintenance Organizations (HMOs), Preferred Provider Organizations (PPOs), Medicare Advantage, etc.
- If no law exists, some private insurers "follow the lead" of Medicare in their decisions about paying for clinical trials. Your billing office may wish to call or email their contact at the particular insurer, telling them that Medicare has made a special decision. Sending this Medicare coverage information will inform them of this CMS determination and may impact their decision on coverage.

Summary reimbursement table

This table outlines the specific study elements that are coved by Medicare (as well as those not covered by Medicare such as research questionnaires which are supported by study funds). It is available on the LOTT website (www.lottsite.org; click on Oxygen Providers and scroll down to Medicare billing instructions or click on Documents and scroll down to Medicare billing instructions).

For more information

- Billing offices may learn about Medicare's National Coverage Determination Clinical Trials Policy at: http://www.cms.hhs.gov/mcd/viewncd.asp?ncd_id=310.1&ncd_version=2&basket=ncd%3A310%2E1%3A2%3ARoutine+Costs+in+Clinical+Trials
- The procedures, including use of the Q0 and Q1 modifiers, are described in CMS Medlearn Matters Article No. MM5805 and Change Request 5805 dated 1/18/08, found in Transmittal 1418 of Medicare Pub. 100-04, Medicare Claims Processing: http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM5805.pdf and http://www.cms.hhs.gov/Transmittals/downloads/R1418CP.pdf.
- The link below has additional links to postings related to billing under the Clinical Trial Policy: http://www.cms.hhs.gov/Transmittals/2008Trans/itemdetail.asp?filterType=dual,%20keyword&filterValue=clinical%20research&filterByDID=0&sortByDID=2&sortOrder=descending&itemID=CMS1207579&intNumPerPage=10