

LOTT Summary Reimbursement Table

Note: When billing Medicare, please use the appropriate codes to identify the claim as associated with LOTT: use V70.7 in the 2nd diagnosis code position, use condition code 30 (on inpatient and outpatient facility claims), use the modifier indicated in the table below, and use the clinicaltrials.gov identifier for LOTT, NCT00692198. Medicare will cover the items and services considered routine as well as the investigational (non-routine items; the stationary and portable oxygen systems).

Coverage of Costs of LOTT Protocol Elements			
Protocol element	Timing of protocol element	Coverage	Modifier
Baseline and Randomization			
Physician visit including health history (includes MMRC dyspnea score) and limited physical exam (height/armspan; weight; vital signs; chest exam; edema assessment)	Pre randomization evaluation	Medicare	Q1
Room air resting oximetry	Pre randomization evaluation	Medicare	Q1
Room air 6 minute walk with oximetry (including EKG if needed to clear patient to complete 6 minute walk)	Pre randomization evaluation	Medicare	Q1
Spirometry, pre and post bronchodilator	Pre randomization evaluation	Medicare	Q1
Hemoglobin and hematocrit blood draw and test	Pre randomization evaluation	Medicare	Q1
Serum cotinine blood draw and test	Pre randomization evaluation	Medicare	Q1
A1AT blood draw and test (if not available by chart review)	Pre randomization evaluation	Medicare	Q1
Epworth Sleepiness Scale, Pittsburgh Sleep Quality Index, Hospital Anxiety and Depression Scale	Pre randomization evaluation	Study funds	n/a
Quality of Well-Being Scale, St George's Respiratory Questionnaire, SF-36v2 Questionnaire	Pre randomization evaluation	Study funds	n/a

Note: When billing Medicare, please use the appropriate codes to identify the claim as associated with LOTT: use V70.7 in the 2nd diagnosis code position, use condition code 30 (on in patient and outpatient facility claims), use the modifier indicated in the table below, and use the clinicaltrials.gov identifier for LOTT, NCT00692198. Medicare will cover the items and services considered routine as well as the investigational (non-routine items; the stationary and portable oxygen systems).

Coverage of Costs of LOTT Protocol Elements			
Protocol element	Timing of protocol element	Coverage	Modifier
Blood draw for DNA collection	Any time; preferably during Pre randomization evaluation, but may occur during followup	Study funds	n/a
Blood draw for serum and plasma collection and processing blood sample to serum	Pre randomization evaluation	Study funds	n/a
Treatment			
Stationary home oxygen system while the patient is moderately hypoxemic at rest (SpO ₂ > 88%)	Randomization through end of trial	Medicare	Q0 (investigational item)
Portable home oxygen system while the patient is moderately hypoxemic at rest (SpO ₂ > 88%)	Randomization through end of trial	Medicare	Q0 (investigational item)
Stationary home oxygen system if the patient deteriorates and becomes severely hypoxemic at rest (SpO ₂ ≤ 88%)	Through end of trial	Medicare	Q1 (routine item since patient is severely hypoxemic at rest)
Portable home oxygen system if the patient deteriorates and becomes severely hypoxemic at rest (SpO ₂ ≤ 88%)	Through end of trial	Medicare	Q1 (routine item since patient is severely hypoxemic at rest)
Visit to determine ambulatory oxygen dose	Just after randomization and as needed	Medicare	Q1

Note: When billing Medicare, please use the appropriate codes to identify the claim as associated with LOTT: use V70.7 in the 2nd diagnosis code position, use condition code 30 (on in patient and outpatient facility claims), use the modifier indicated in the table below, and use the clinicaltrials.gov identifier for LOTT, NCT00692198. Medicare will cover the items and services considered routine as well as the investigational (non-routine items; the stationary and portable oxygen systems).

Coverage of Costs of LOTT Protocol Elements			
Protocol element	Timing of protocol element	Coverage	Modifier
Routine Followup Post Randomization			
Adherence monitoring telephone contacts	1, 2, 3, 4 weeks and 2, 3, 4, 5, 6, 8, 10 months	Study funds	n/a
Adherence monitoring in person contacts	1, 2, 3, 4, 5, 6 years	Study funds	n/a
Adherence monitoring diaries (mailing and processing)	q2 months from randomization through end of trial	Study funds	n/a
Interim history telephone contacts	4, 8, 16, 20, 28, 32, 40, 44, 52, 56, 64, 68, 76, 80 months	Study funds	n/a
Physician visit including interim history (includes MMRC dyspnea score) and limited physical exam (weight, vital signs, chest exam, edema assessment) and ambulatory dose check (if assigned to oxygen)	1, 2, 3, 4, 5, 6 years	Medicare	Q1
Room air resting oximetry	1, 2, 3, 4, 5, 6 years and as needed to check need for oxygen prescription	Medicare	Q1
Room air 6 minute walk with oximetry (including EKG if needed to clear patient for 6 minute walk)	1, 2, 3, 4, 5, 6 years	Medicare	Q1
Spirometry, pre and post bronchodilator	1, 2, 3, 4, 5, 6 years	Medicare	Q1

Note: When billing Medicare, please use the appropriate codes to identify the claim as associated with LOTT: use V70.7 in the 2nd diagnosis code position, use condition code 30 (on in patient and outpatient facility claims), use the modifier indicated in the table below, and use the clinicaltrials.gov identifier for LOTT, NCT00692198. Medicare will cover the items and services considered routine as well as the investigational (non-routine items; the stationary and portable oxygen systems).

Coverage of Costs of LOTT Protocol Elements			
Protocol element	Timing of protocol element	Coverage	Modifier
Serum cotinine blood draw and test	1 year	Medicare	Q1
Pittsburgh Sleep Quality Index, Hospital Anxiety and Depression Scale	1, 2, 3, 4, 5, 6 years	Study funds	n/a
Quality of Well-Being Scale, St George's Respiratory Questionnaire, SF-36v2 questionnaire	1, 2, 3, 4, 5, 6 years	Study funds	n/a
Treatment Adjustment (visits/procedures designed for safety checks or for getting patient back on protocol treatment)			
Resting oximetry while on oxygen	As needed for those who develop severe resting hypoxemia	Medicare	Q1
Physician visits to assess need for oxygen or to assess safety of stopping oxygen	As needed	Medicare	Q1