Measure #2: Disease Modifying Pharmacotherapy for ALS Discussed

Amyotrophic Lateral Sclerosis

Measure Description

Percentage of patients with a diagnosis of amyotrophic lateral sclerosis with whom the clinician discussed disease-modifying pharmacotherapy (riluzole) to slow ALS disease progression at least once annually.

Measure Components

<table>
<thead>
<tr>
<th>Numerator Statement</th>
<th>Patients with whom the clinician discussed disease-modifying pharmacotherapy (riluzole) to slow ALS disease progression at least once annually.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Denominator Statement</td>
<td>All patients with a diagnosis of amyotrophic lateral sclerosis.</td>
</tr>
<tr>
<td>Denominator Exclusions</td>
<td>• No exclusions applicable for this measure.</td>
</tr>
</tbody>
</table>

Supporting Guideline & Other References

The following clinical recommendation statements are quoted verbatim from the referenced clinical guidelines and represent the evidence base for the measure:

• Riluzole should be offered to slow disease progression in patients with ALS (Level A). ¹

• Riluzole 50 mg twice a day is reasonably safe and probably prolongs median survival by about two to three months in patients with amyotrophic lateral sclerosis. (No level of evidence listed.) This is a Cochrane review.²

• ALS patients should be offered treatment with riluzole 50 mg twice daily (Class 1A, GPP).³

• Patients treated with riluzole should be monitored regularly for safety (Class 1A, GPP).³

• Treatment should be initiated as early as possible after the patient has been informed of the diagnosis taking into account expected therapeutic benefits and potential safety issues (class 1A). Realistic expectations for treatment effects and potential side effects should be discussed with the patient and caregivers. (GPP)³

• Treatment with riluzole should be considered in PMA and PLS patients who have a first degree relative with ALS. (GPP)³


Measure Importance

Relationship to Riluzole is approved by the Food and Drug Administration (FDA) for slowing disease
desired outcome

progress in ALS, and it is the only currently available disease modifying pharmacotherapy for ALS. Riluzole was the subject of a practice advisory published by the American Academy of Neurology in 1997.1 The practice advisory recommended riluzole 50 mg BID to prolong survival for those with definite or probable ALS less than 5 years duration, with forced vital capacity (FVC) >60%, and without tracheostomy (Level A). Expert opinion suggested potential benefit for those with suspected or possible ALS with symptoms longer than 5 years, FVC >60%, and tracheostomy for prevention of aspiration only. Since 1997, 2 other controlled clinical trials have been published (Class I)2,3 and all of the available evidence has been reviewed.4 Riluzole has a modest beneficial effect in slowing disease progression (prolonged survival of 2–3 months) based on 4 Class I trials. The number needed to treat to delay 1 death until after 12 months was 11. However, 5 studies using large databases spanning 5 to 10 years have suggested that treatment with riluzole might be associated with a prolonged survival of 6 months (Class II)4, 10 months (Class III)5, 12 months (Class III)6, 14 months (Class III)7, or even 21 months (Class III)8. These cohort studies had longer-term follow-up than the clinical trials, but are subject to greater bias. After 10 years of patient experience, the drug appears to be safe but expensive. In fact, the cost does limit access to the drug for a significant portion of patients.4,10 Fatigue and nausea are known side effects. Riluzole is safe and effective for slowing disease progression to a modest degree in ALS (4 Class I studies).

References

10 Bryan WW, McIntire D, Camperlenzo L et al. Factors influencing the use of riluzole by ALS patients. 8th International Symposium on ALS/MND. November 1997 (abstract).

Opportunity for Improvement

Riluzole is currently the only available disease modifying pharmacotherapy available to slow down progression of ALS. Only 60% of patients are taking the riluzole in the United States, compared to nearly 100% in European countries (France, Italy, Germany).1 This utilization is improved compared to 45% in 1997, a rise that reflects increased awareness and experience of treating physicians.2 The cost is still a major factor for many patients. These data reflect the utilization of riluzole in large multidisciplinary clinics, and it is much lower in community-treated patients. Considerable misunderstanding exists around safety and efficacy, both for patients and physicians. More education is needed. The most influential factor in whether patients take riluzole is the knowledge and enthusiasm of the treating physician.3,4 ALS experts in a multidisciplinary clinic are most likely to adequately inform patients about this.
neuroprotective medication. Also, the more recent registry studies suggesting a much greater survival benefit have been impressive.3

References
4 Bryan WW, McIntire D, Camperlengo L et al. Factors influencing the use of riluzole by ALS patients. 8th International Symposium on ALS/MND. November 1997 (abstract).

| IOM Domains of Health Care Quality Addressed | Safe |
| Exclusion Justification | No exclusions relevant for this measure. |
| Harmonization with Existing Measures | There are no other measures currently available that are similar to this measure or need to be harmonized with this measure. |

Measure Designation

| Measure purpose | • Quality improvement |
| Type of measure | • Process |
| Level of Measurement | • Individual practitioner |
| Care setting | • Ambulatory Care |
| Data source | • Electronic health record (EHR) data |
| | • Administrative Data/Claims (inpatient or outpatient claims) |
| | • Administrative Data/Claims Expanded (multiple-source) |
| | • Paper medical record |

Technical Specifications: Administrative/Claims Data

Administrative claims data collection requires users to identify the eligible population (denominator) and numerator using codes recorded on claims or billing forms (electronic or paper). Users report a rate based on all patients in a given practice for whom data are available and who meet the eligible population/denominator criteria.

The specifications listed below are those needed for performance calculation. Additional CPT II codes may be required depending on how measures are implemented. (Reporting vs. Performance)

Denominator (Eligible Population)

| Diagnosis Codes: |
| 335.20 (amyotrophic lateral sclerosis) |

CPT E/M Service Code:
99201, 99202, 99203, 99204, 99205 (office-new patient),
99211, 99212, 99213, 99214, 99215 (office-established patient),
99241, 99242, 99243, 99244, 99245 (outpatient consult),
99304, 99305, 99306, 99307, 99308, 99309, 99310 (nursing facility),
99324, 99325, 99326, 99327, 99328, 99334, 99335, 99336, 99337 (domiciliary),
99341, 99342, 99343, 99344, 99345, 99347, 99348, 99349, 99350 (home visit)

<table>
<thead>
<tr>
<th>Numerator</th>
<th>Patients with whom the clinician discussed disease-modifying pharmacotherapy (riluzole) to slow ALS disease progression and the plan was updated at least once annually. Reporting Instructions:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Denominator Exclusions</td>
<td>All patients with a diagnosis of amyotrophic lateral sclerosis. Reporting Instructions:</td>
</tr>
<tr>
<td></td>
<td>• There are no exclusions for this measure. Do not report modifiers 1P, 2P or 3P with 4540F.</td>
</tr>
</tbody>
</table>