The ICD-10 Code and Drug Development

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Why ICD-10 Codes are Needed

• “Section 201.57 of the Code of Federal Regulations mandates that the full prescribing information section of the physician label “must state that the drug is indicated for the treatment, prevention, mitigation, cure, or diagnosis of a recognized disease or condition, or of a manifestation of a recognized disease or condition, or for the relief of symptoms associated with a recognized disease or condition.”
Multiple entities have described a form of sarcopenia as a pathologic condition (not simply a natural process of aging) which requires recognition and treatment.

- The European Working Group on Sarcopenia in Older Persons
- Foundation for the National Institutes of Health Sarcopenia Project
- The International Working Group on Sarcopenia
- The Society on Sarcopenia, Cachexia, and Wasting Disorders

Several pharmaceutical companies are testing treatments targeting muscle mass and strength which could potentially be used to treat sarcopenia.
Lack of Pharmacotherapy

• Currently available interventions/treatments for sarcopenia do not include pharmacologic treatments.

• Some recognized treatments:
  – Physical therapy (PT)
  – Exercise not formally part of PT
  – Nutritional counseling and therapy
  – Nutritional supplements
Barriers to Pharmacotherapy

• No clearly recognized end-points to document efficacy
  – A single end-point will likely not be adequate
  – Endpoints must be clinical meaningful
  – If a drug is studied with methods that can’t easily be used clinically, it will be hard to write prescribing information

• No well-defined regulatory path
• No validated Patient Reported Outcome measures
• Lack of data distinguishing pathology from normal aging
• Need for biomarkers to identify patients
• No reimbursement strategy
Benefits of ICD-10

• Improve awareness of the condition and diagnosis by physicians.
  – diagnosis will likely increase once the code is established.

• Greater diagnosis would allow a broader picture of the affected population
  – allow for the recording of common comorbid conditions
  – could later allow for secondary treatment of sarcopenia in patient subsets to improve overall patient health
  – provide better understanding of mortality, morbidity, and health outcomes in affected patients
  – Could provide pharmacodynamic biomarkers for early clinical testing
Benefits of ICD-10

• A code can be recognized for inclusion in health records and patient registries.
  – will aid in gathering data to establish efficacy endpoints
  – provide important information to programs aimed at slowing the decline of muscle mass and delaying decline in function among a community dwelling population

• ICD data is also frequently used in reimbursement resource allocation decision-making by WHO member states. This is an important consideration when pursuing any drug development program.