Medicare Coverage Summary

Coverage Guidance[1]

Cystatin C is a low molecular weight protein produced by all nucleated cells in the body at a constant rate. Cystatin C is freely filtered by the renal glomerulus, completely reabsorbed by the proximal tubule, and then metabolized by the proximal tubule. It has been proposed and investigated as an improved marker of renal function and as a potential alternative to serum creatinine based estimated glomerular filtration rate (eGFR), as well as a biomarker for predicting cardiovascular risk.

Cystatin C is considered to be a potential alternative to serum creatinine for estimating GFR. GFR can be estimated (eGFR) from serum cystatin C utilizing an equation which includes the age and gender of the patient. Cystatin C eGFR may have advantages over creatinine eGFR in certain patient groups in whom muscle mass is abnormally high or low (e.g., individuals who are very elderly, malnourished, or have quadriplegia). Serum creatinine levels may also be influenced by diet (e.g., vegetarian or high protein diets) and medications that block distal tubule secretion of creatinine. Blood levels of cystatin C also equilibrate more quickly than creatinine. Therefore, serum cystatin C may be more accurate than serum creatinine when kidney function is rapidly changing (for example amongst hospitalized individuals).

Cystatin C levels have been reported to be abnormally elevated or decreased in some medical conditions (e.g., HIV disease and thyroid disease) and by some medications (e.g., corticosteroids). In clinical situations where confirmation of the eGFR by serum cystatin C is warranted, equations that combine serum cystatin C and serum creatinine provide a more precise eGFR than equations using serum cystatin C alone. **Estimation of GFR from serum creatinine remains the clinical standard worldwide.**

Covered Indications

Cystatin C testing is medically reasonable and necessary when all of the following are met:

- In adults with $eGFR_{creat}$ 45–59 ml/min/1.73 m2 (chronic kidney disease (CKD) stage 3A mildly to moderately decreased GFR) who do not have markers of kidney damage; **and**

- If confirmation is warranted
  - When GFR estimates based on serum creatinine are thought to be inaccurate; **and**
  - When decisions depend on a more accurate knowledge of the GFR, such as confirming a diagnosis of CKD, determining eligibility for kidney donation, or adjusting the dosage of toxic drugs that are excreted by the kidneys.

Limitations

The following are not reasonable and necessary and therefore will be denied:

- Measurement of Cystatin C to assess cardiovascular risk is considered investigational in the risk assessment and management of cardiovascular disease. Cystatin C is not covered

[1] Medicare LCD L37616

according to Title XVIII of the Social Security Act, §1861(xx)(1). Therefore, cystatin C measurement is considered not medically reasonable and necessary.

- Based on the Kidney Disease Outcomes Quality Initiative (KDOQI™) US Commentary on the 2012 Kidney Disease: Improving Global Outcomes (KDIGO) Clinical Practice Guideline for the Evaluation and Management of CKD, cystatin C testing is considered not medically reasonable and necessary for patients with following stages of CKD:
  - Stage 1 Kidney damage with normal or elevated GFR > 90 ml/min/1.73 m2
  - Stage 2 Kidney damage with mild decrease in GFR 60-89 ml/min/1.73 m2
  - Stage 3B Moderately to Severely decreased GFR 30-44 ml/min/1.73 m2
  - Stage 4 Severely decreased GFR 15-29 ml/min/1.73 m2
  - Stage 5 Kidney Failure GFR < 15 ml/min/1.73 m2

Ordering Provider Documentation Requirements[2]

- All documentation must be maintained in the patient's medical record and made available to the contractor upon request.
- Every page of the record must be legible and include appropriate patient identification information (e.g., complete name, dates of service(s)). The documentation must include the legible signature of the physician or non-physician practitioner responsible for and providing the care to the patient.
- The submitted medical record must support the use of the selected ICD-10-CM code(s). The submitted CPT/HCPCS code must describe the service performed.
- The medical record documentation must support the medical necessity of the services as directed in this policy.
- The laboratory or billing provider must have on file the physician requisition which sets forth the diagnosis or condition (ICD-10-CM code) that warrants the test(s).
- Examples of documentation requirements of the ordering physician/non-physician practitioner (NPP) include, but are not limited to, history and physical or exam findings that support the decision making, problems/diagnoses, relevant data (e.g., lab testing).
- Medical record documentation must support cystatin C test was performed on an adult patient with creatinine based eGFR 45–59 ml/min/1.73 m2 who does not have markers of kidney damage.
- Medical record documentation must clearly indicate the rationale which supports the medical necessity for performing eGFR by measurement of cystatin C (i.e. support GFR estimates based on serum creatinine are thought to be inaccurate and what decisions depend on more accurate knowledge of the GFR) and must reflect how the test result were used in the patient's plan of care.

[2] Medicare LCD A57643