

Digoxin Therapeutic Drug Assay

CPT: 80162

CMS National Coverage Policy

Coverage Indications, Limitations, and/or Medical Necessity

A digoxin therapeutic drug assay is useful for diagnosis and prevention of digoxin toxicity, and/or prevention for under dosage of digoxin.

Indications

Digoxin levels may be performed to monitor drug levels of individuals receiving digoxin therapy because the margin of safety between side effects and toxicity is narrow or because the blood level may not be high enough to achieve the desired clinical effect.

Clinical indications may include individuals on digoxin:

- With symptoms, signs or electrocardiogram (ECG) suggestive of digoxin toxicity
- Taking medications that influence absorption, bioavailability, distribution, and/or elimination of digoxin
- With impaired renal, hepatic, gastrointestinal, or thyroid function
- With pH and/or electrolyte abnormalities
- With unstable cardiovascular status, including myocarditis
- Requiring monitoring of patient compliance

Clinical indications may include individuals:

- Suspected of accidental or intended overdose
- Who have an acceptable cardiac diagnosis (as listed) and for whom an accurate history of use of digoxin is unobtainable

The value of obtaining regular serum digoxin levels is uncertain, but it may be reasonable to check levels once yearly after a steady state is achieved. In addition, it may be reasonable to check the level if:

- Heart failure status worsens
- Renal function deteriorates
- Additional medications are added that could affect the digoxin level
- Signs or symptoms of toxicity develop

Steady state will be reached in approximately 1 week in patients with normal renal function, although 2-3 weeks may be needed in patients with renal impairment. After changes in dosages or the addition of a medication that could affect the digoxin level, it is reasonable to check the digoxin level one week after the change or addition. Based on the clinical situation, in cases of digoxin toxicity, testing may need to be done more than once a week.

Digoxin is indicated for the treatment of patients with heart failure due to systolic dysfunction and for reduction of the ventricular response in patients with atrial fibrillation or flutter. Digoxin may also be indicated to treat other supraventricular arrhythmias, particularly with heart failure.

Limitations

This test is not appropriate for patients on digitoxin or treated with digoxin FAB (fragment antigen binding) antibody.

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The ICD10 codes listed below are the top diagnosis codes currently utilized by ordering physicians for the limited coverage test highlighted above that are also listed as medically supportive under Medicare's limited coverage policy. **If you are ordering this test for diagnostic reasons that are not covered under Medicare policy, an Advance Beneficiary Notice form is required.**

***Note—Bolded diagnoses below have the highest utilization**

Please refer to the Limitations or Utilization Guidelines section on previous page(s) for frequency information.

Code	Description
E03.9	Hypothyroidism, unspecified
I25.10	Atherosclerotic heart disease of native coronary artery without angina pectoris
I42.0	Dilated cardiomyopathy
I42.8	Other cardiomyopathies
I42.9	Cardiomyopathy, unspecified
I47.1	Supraventricular tachycardia
I48.0	Paroxysmal atrial fibrillation
I48.11	Longstanding persistent atrial fibrillation
I48.19	Persistent atrial fibrillation
I48.20	Chronic atrial fibrillation, unspecified
I48.21	Permanent atrial fibrillation
I48.91	Unspecified atrial fibrillation
I49.9	Cardiac arrhythmia, unspecified
I50.22	Chronic systolic (congestive) heart failure
I50.32	Chronic diastolic (congestive) heart failure
I50.9	Heart failure, unspecified
N18.30	Chronic kidney disease
N18.31	Chronic kidney disease, stage 3a
R53.83	Other fatigue
Z79.899	Other long term (current) drug therapy

To view the complete policy and the full list of codes, please refer to the CMS website reference

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