Digoxin Therapeutic Drug Assay (80162) - NCD 190.24

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.

Most Common Diagnoses (which meet medical necessity) *	
E03.9	Hypothyroidism
I11.0	Hypertensive heart disease with heart failure
125.10	Coronary artery disease
142.8	Non-ischemic cardiomyopathies
142.9	Cardiomyopathy
148.0 - 148.91	All types of atrial fibrillation

148.92	Atrial flutter
I50.1 - I50.9	Most types of heart failure
N18.9	Chronic kidney disease
Z79.899	Other long term (current) drug therapy

^{*}For the full list of diagnoses that meet medical necessity see the Digoxin Therapeutic Drug Assay National Coverage Determination 190.24 document.

The above CMS and WPS-GHA guidelines are current as of: 4/01/2024.