NEW UnitedHealthcare Requirements for Laboratory Testing

Effective Nov 1, 2017, UnitedHealthcare will start an online prior authorization/notification program for genetic and molecular/PCR testing performed in an outpatient setting for their fully insured UnitedHealthcare Commercial Plan members. Providers requesting laboratory testing will be required to complete the prior authorization/notification process. The process will require providers to indicate the laboratory and test name for genetic and molecular lab services within the following CPT ranges:

- 0001U
- 0004M-0008M
- 81161-81421
- 81423-81479
- 81507
- 81519
- 81545-81599

UnitedHealthcare has contracted with a vendor to provide an on-line system to obtain prior authorization/notification information and communicate UnitedHealthcare coverage decisions. Clinical information may be requested to determine if the request meets UnitedHealthcare’s clinical policy requirements for coverage; requests that meet UnitedHealthcare clinical criteria will be granted an authorization at the time of the request. Training opportunities and additional information about this program will be available on UnitedHealthcareOnline.com around Oct. 1, 2017.

Relative Contraindications for Platelet Transfusions

Platelets play an important role in primary hemostasis. Platelet transfusions are indicated therapeutically in treatment of bleeding due to critically decreased circulating platelet counts or functionally abnormal platelets. In general, prophylactic platelet transfusions are given at counts <10,000/μL in stable, non-bleeding patients, and at <50,000/μL in patients who are undergoing major invasive procedures or surgery.

In addition to a critical role in hemostasis at sites of endothelial trauma, there is emerging evidence to show that in certain clinical situations platelets may also mediate inflammation and pathologic thrombogenesis. The role of platelet transfusion in platelet consumptive or destructive disorders including thrombotic thrombocytopenic purpura/hemolytic uremic syndrome (TTP/HUS), idiopathic thrombocytopenic purpura (ITP), and heparin-induced thrombocytopenia (HIT) remains controversial. It has been hypothesized that platelet transfusions may potentially provoke fatal thrombotic events, particularly arterial ones, in TTP and HIT.

TTP is a primary thrombotic microangiopathy caused by severe ADAMTS13 deficiency (typically, activity <10%). It can be either acquired due to presence of an inhibitory autoantibody directed against ADAMTS13 or congenital. The principal histologic abnormality is proposed to be a platelet microvascular thrombus.

HIT is a life-threatening, immune-mediated complication of exposure to heparin (unfractionated or low molecular weight heparin) that occurs in up to 5% of patients exposed. The underlying physiology is due to the formation of a heparin-dependent anti-platelet factor 4 (PF4) immune complex resulting in immunologic platelet activation and thrombin generation, with subsequent thrombocytopenia and thrombotic risk.

ITP involves autoimmune destruction of platelets. The pathogenesis is related to a combination of increased platelet destruction and impaired platelet production caused by anti-platelet autoantibodies. The role of platelet transfusions in the management of ITP remains unclear. Transfused platelets have shortened survival in ITP similar to the patient’s
own platelets, suggesting that platelet transfusions may not be of clinical benefit in this condition.

Researchers at Johns Hopkins & Emory analyzed a comprehensive database of Nationwide Inpatient Samples to evaluate platelet transfusion practices in platelet consumptive disorders (Goel, R., et al. Blood 125.9 (2015): 1470-1476) and found that platelet transfusions are associated with higher odds of arterial thrombosis and mortality among TTP and HIT patients.

Use of platelets in such patients should be avoided except in life-threatening hemorrhage. Prophylactic transfusion before invasive procedures or surgery in these patients without thrombotic manifestations may be considered when the risk of bleeding is high.

**Challenges in Thyroid Stimulating Hormone Test**

Measurement of serum thyroid stimulating hormone (TSH) concentration is an indispensable tool for confirmation of thyroid function especially in patients with clinical symptoms resembling other disorders or if subtle. The primary use of this test is screening for thyroid dysfunction, evaluation of thyroid hormone replacement in primary hypothyroidism, and assessment of suppressive therapy in patients with follicular cell-derived thyroid cancer.

The testing methodology in the majority of non-reference laboratories for serum TSH determination is automated immunoassay. Over several decades, there has been a substantial improvement in the sensitivity of these assays due to use of monoclonal antibodies instead of polyclonal and development of non-competitive assays. The majority of currently available commercial immunoassays are capable of third-generation performance with markedly improved precision especially at TSH levels of 0.1 mIU/L.

Reference ranges for serum TSH levels established by testing laboratories are assay specific and therefore varied. Consequently, in clinics requesting tests from different laboratory or patients who regularly move between geographic locations, accurate interpretation of serum TSH levels can be a problem. A much needed establishment of a standard TSH reference range, however, has been challenging due to:

1. Sensitivity of the reference range to individuals present in the cohort, who can skew the upper limit, making the distribution non-Gaussian. For example, healthy elderly individuals, who may have upper limit of TSH twice that of young individuals.
2. Obesity induced increase in TSH levels independent of thyroid function, again skewing the TSH upper limit.
3. Inclusion of individuals with thyroid autoimmunity in the cohort, may also skew the upper limit.

Additional challenges in accurate interpretation of TSH tests is the heterogenous nature of the TSH molecule due to glycosylation. Monoclonal antibodies employed in various commercially available immunoassays therefore have limited and varying specificity in detecting TSH epitopes. And, since not all molecular forms of TSH are bioactive, clinical interpretation in patients with high TSH values can be difficult.

Finally, another source of uncertainty in thyroid function testing interpretation is the insensitivity of TSH population reference ranges in detecting individual thyroid function. This is mainly due to enormous differences between the population interval and individual variation, which is a result of much narrower intra-individual biological variation versus inter-individual variation. Consequently, in patients with TSH levels at the upper limit of the normal range, clinical judgement is imperative to rule out subclinical hypothyroidism.

To resolve issues with TSH reference ranges, the IFCC Committee for Standardization of Thyroid Function Tests (C-STFT) in collaboration with test manufacturers has undertaken the task of harmonization of TSH measurements. Recently, the C-STFT completed phase IV of these studies, which showed improvement in uniformity in reference range measurement across eight different commercially available immunoassays. However, this study also emphasized the need to understand that uniformity does not indicate that factors such as age, ethnicity, iodine intake etc. can be completely ignored while establishing reference ranges.

At Saint Luke's Hospital, TSH assay is a “third-generation” immunoassay, performed 24/7. The specimen requirement is 2 mL in serum gel or heparin tube.

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