Rapid Flu Tests in the Outpatient Setting

Description of Procedure or Service

Rapid flu tests refer to an immunoassay that evaluates the presence of influenza virus A and/or B in nasal swabs, washes, or aspirates within 4 hours, and are an alternative to the gold standard diagnostic test of viral isolation with the use of tissue cells, which may require several days for results. Rapid confirmation of the presence of influenza virus may be useful in determining whether or not to initiate antiviral therapy (i.e., amantadine, rimantadine) or the more recently available neuraminidase inhibitors (i.e., oseltamivir, zanamivir), all of which are effective only if initiated within 48 hours of symptom onset.

Table 1: Commercially Available Rapid Flu Tests

<table>
<thead>
<tr>
<th>Test Name</th>
<th>Flu Type Detected</th>
<th>Time for Result (minutes)</th>
<th>Laboratory Setting</th>
</tr>
</thead>
<tbody>
<tr>
<td>Directigen Flu A</td>
<td>A only</td>
<td>15</td>
<td>Hospital or referral lab</td>
</tr>
<tr>
<td>Directigen Flu A + B</td>
<td>Detects and distinguishes A, B</td>
<td>15</td>
<td>Hospital or referral lab</td>
</tr>
<tr>
<td>FLU OIA</td>
<td>Detects A, B but does not distinguish</td>
<td>15</td>
<td>Hospital or referral lab</td>
</tr>
<tr>
<td>QuickVue</td>
<td>Detects A, B but does not distinguish</td>
<td>10</td>
<td>Physician’s office*</td>
</tr>
<tr>
<td>ZstatFlue</td>
<td>Detects A, B but does not distinguish</td>
<td>30</td>
<td>Physician’s office*</td>
</tr>
</tbody>
</table>

*These tests are "CLIA-waived" such that the physician’s office is not required to undergo additional regulation if these tests are performed in an office setting. CLIA-waived tests may also be performed in a hospital or referral laboratory.

The Directigen Flu A + B test is the only rapid test available that distinguishes between influenza A and B. This distinction may be important when considering which antiviral therapy to initiate. For example, aman-
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tadine and rimantadine are only effective against influenza A, while the more recently available oseltamivir and zanamivir are effective against both influenza A and B.

Evidence Based Guideline for Rapid Flu Tests in the Outpatient Setting

Rapid flu tests may be appropriate in the urgent care center, hospital, emergency room setting, or as part of community surveillance program to determine the prevalence of influenza.

The rapid flu test can be considered medically necessary in appropriately selected patients who present with clinical symptoms and signs consistent with influenza disease. Published sensitivity and specificity of these tests range from 65-100%, positive predictive values range from 50-100% and negative predictive values range from 70-100%. One published study indicated an improvement in positive predictive value from 48% for clinical diagnosis (fever and cough) to 89% with a rapid flu test (Directigen Flu A+B) and 78% with viral culture. Negative predictive value improved from 83% to 92% in the same study with the rapid flu test. In this study, the sensitivities were considerably better in pediatric patients, while the false negative rates in adults were as high as 29%.

The pre-test probability of a given patient having influenza (based on clinical symptoms and signs) influences the diagnostic performance of the test in that patient. When the pre-test probability of influenza is higher, the predictive value of the test will improve. Such factors as clinical scenario (rapid onset of high fever, plus symptoms of cough, myalgia, sore throat, or headache), presence of known influenza in the community, and lack of prior effective influenza vaccination will improve the predictive value of the rapid flu test in such a patient. Therefore, the rapid flu test is best used in patients with a high clinical suspicion of influenza during the appropriate time of year.

The Infectious Diseases Society of America has published "Practice Guidelines for the Management of Community Acquired Pneumonia in Immunocompetent Adults" as updated in 2003, that includes a recommendation for use of the rapid flu tests for "rapid detection of influenza for epidemiologic purposes and/or treatment. Tests that distinguish between influenza A and B are generally preferred." Because of the low sensitivities of these tests, they indicate that, "...negative test results do not exclude the diagnosis and have not generally been proven to be superior to physician diagnosis based on the presence of fever and typical symptoms in the presence of an epidemic" but that, "some rapid tests can distinguish between influenza A and B strains, which may have therapeutic implications."

One postulated benefit of use of the rapid flu test is the reduction in inappropriate antibiotics in patients with viral infections. Some small studies have demonstrated that children who have a positive rapid flu test are less likely to undergo extensive diagnostic evaluations in the emergency room, less likely to receive antibiotics, and more likely to receive antiviral therapy than those who either did not have the test, or in whom the test was negative. Although these studies were performed in the emergency room setting, it is possible that these benefits will accrue to appropriately selected patients seen in the office or outpatient setting as well.

Medical Evidence regarding Rapid Flu Tests in the Outpatient Setting indicates it is not recommended in the following situations:

Not applicable.

Benefits Application

Please refer to certificate for availability of benefit. This guideline relates only to the services or supplies described herein. Benefits may vary according to benefit design; therefore certificate language should be reviewed before applying the terms of the policy.
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Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable codes: 87804

Medical Term Definitions

Immunoassay
a process that measures and identifies a specific biological substance such as an antigen

Scientific Background and Reference Sources


Policy Implementation/Update Information

4/7/05 New policy issued. Rapid Flu Tests in the Outpatient Setting are considered investigational. Testing performed in the ER or Urgent Care settings does not apply to this policy. Specialty Matched Advisory Panel [MPAG] review on 03/10/2005 with no changes made to policy criteria. MPOC review and discussion on 02/14/05. References added. Notification 4/7/2005. Effective 6/16/2005.

9/1/05 Due to additional research of peer-reviewed literature, rapid flu tests will now be covered when medically necessary. "Policy, When covered, When not covered and Guidelines" sections revised to reflect the coverage change and rationale. References added.

8/21/06 Medical Policy changed to Evidence Based Guideline. (adn)

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