RAPID INFLUENZA DIAGNOSTIC TESTING IN THE OUTPATIENT SETTING

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member’s specific benefit plan. This Medical Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

The section identified as “Description” defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as “Criteria” defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Medical Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Medical Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

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Description:

Rapid influenza diagnostic tests (RIDT), also known as rapid flu or point-of-care tests, refer to immunoassays that evaluate the presence of influenza virus A and/or B in nasal swabs, washes or aspirates within 30 minutes. These tests 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, which is effective only if initiated within 48 hours of symptom onset. Some tests use throat swab specimens to evaluate the presence of influenza virus A and/or B however, nasopharyngeal swabs, aspirate or washings have higher yields than throat swabs.
RAPID INFLUENZA DIAGNOSTIC TESTING IN THE OUTPATIENT SETTING (cont.)

Description: (cont.)

Several commercially available rapid flu tests can detect both influenza A and B viruses, while others can only detect influenza A. Presently, there are no tests that can distinguish between influenza A subtypes such as distinguishing between H1N1 and other influenza A strains.

Some of the RIDTs require hospital or laboratory referral testing while others are point of care tests that can be used in a physician’s office or other outpatient setting such as a health clinic. Positive and negative predictive values are dependent on the prevalence of influenza in the community. Once influenza activity has been documented in a geographic area, many individuals with uncomplicated illness consistent with influenza may be diagnosed clinically and not require testing.

Criteria:

➢ In the outpatient setting, rapid influenza diagnostic testing to detect influenza A and/or B is considered medically necessary with documentation of ALL of the following:

1. Individual is suspected of being infected with influenza A or B
2. Test is FDA-approved
3. Test is being used to help guide diagnostic and treatment decisions
4. Specimen is collected not later than 72 hours of illness
5. Specimen is a nasopharyngeal swab, aspirate or washing (not a throat swab)
RAPID INFLUENZA DIAGNOSTIC TESTING IN THE OUTPATIENT SETTING (cont.)

Resources:


4. CDC. Rapid Diagnostic Testing for Influenza Information for Clinical Laboratory Directors. Accessed 07/16/2010

FDA 510 (k) Premarket Notification for BD Directigen™ EZ Flu A+B Assay:

- FDA-approved indication: For the direct and qualitative detection of influenza A and B viral antigens from nasopharyngeal washes/aspirates, nasopharyngeal swabs and throat swabs of symptomatic patients. The Directigen EZ Flu A+B assay is a differentiated test, such that influenza A viral antigens can be distinguished from influenza B viral antigens from a single processed sample using a single device. The test is to be used as an aid in the diagnosis of influenza A and B viral infections. All negative test results should be confirmed by cell culture because negative results do not preclude influenza virus infection and should not be used as the sole basis for treatment or other management decisions.

FDA 510 (k) Premarket Notification for Alere BinaxNOW® Influenza A & B Card:

- FDA-approved indication: For the qualitative detection of influenza A and B nucleoprotein antigens in nasopharyngeal (NP) swab, nasal swab and nasal wash/aspirate specimens. It is intended to aid in the rapid differential diagnosis of influenza A and B viral infections. Negative test results should be confirmed by cell culture.
RAPID INFLUENZA DIAGNOSTIC TESTING IN THE OUTPATIENT SETTING (cont.)

Resources: (cont.)

FDA 510 (k) Premarket Notification for OSOM® Influenza A&B Test Model 190:

- FDA-approved indication: For the qualitative detection of influenza A and influenza B viral nucleoprotein antigens from nasal swab specimens in symptomatic patients. It is intended to aid in the rapid differential diagnosis of influenza A and/or B viral infections. The test is not intended for the detection of influenza C viruses. A negative test is presumptive and it is recommended these results be confirmed by cell culture. Negative results do not preclude influenza virus infection and should not be used as the sole basis for treatment or other management decisions.

FDA 510 (k) Premarket Notification for QuickVue® Influenza A+B Test:

- FDA-approved indication: For the rapid, qualitative detection of influenza type A and type B antigens directly from nasal swab, nasopharyngeal swab, nasal aspirate and nasal wash specimens. The test is intended for use as an aid in the rapid differential diagnosis of acute influenza type A and type B viral infections. The test is not intended to detect influenza C antigens. Negative results should be confirmed by cell culture; they do not preclude influenza virus infection and should not be used as the sole basis for treatment or other management decisions. The test is intended for professional and laboratory use.

FDA 510 (k) Premarket Notification for SAS™ FLUAlert A&B Test:

- FDA-approved indication: For detection of influenza A viral nucleoprotein antigens from nasal washes and nasal aspirates of symptomatic patients. The test is not intended for the detection of influenza type B viral antigen or influenza Type C viral antigen. This test is for professional use only. Negative results do not preclude infection with influenza A and should not be used as the sole basis for treatment or other patient management decisions. It is recommended that negative results be confirmed by cell culture.
RAPID INFLUENZA DIAGNOSTIC TESTING IN THE OUTPATIENT SETTING (cont.)

Resources: (cont.)

FDA 510 (k) Premarket Notification for TRU FLU®:

- FDA-approved indication: For detecting both influenza A and influenza B viral nucleoprotein antigens in human nasal wash, nasopharyngeal aspirate and nasal and nasopharyngeal swab samples in symptomatic patients. The test is not intended for the detection of influenza C viruses. A negative test is presumptive and it is recommended these results be confirmed by cell culture. Negative results do not preclude influenza virus infection and should not be used as the sole basis for treatment or other clinical management decisions.

FDA 510 (k) Premarket Notification for Remel Xpect® Flu A&B:

- FDA-approved indication: For the direct, qualitative detection of influenza A and influenza B viral antigens (nucleoprotein) from nasal wash, nasal swab and throat swab specimens from symptomatic patients. The test is intended as an aid in the rapid diagnosis of influenza A and influenza B viral infections. Negative tests should be confirmed by virus culture or an FDA-cleared influenza A and B molecular assay.

FDA 50K Summary for BioSign® Flu A+B, Status Flu A&B:

- FDA-approved indication: For detecting both influenza A and influenza B viral nucleoprotein antigens directly from human nasal swab, and nasopharyngeal aspirate/swab samples in symptomatic patients. It is intended to aid in the rapid diagnosis of influenza A and B viral infections. A negative test is presumptive and it is recommended these results be confirmed by viral culture. Negative results do not preclude influenza virus infection and should not be used as the sole basis for treatment or other clinical management decisions.

FDA 50K Summary for Sofia Influenza A+B FIA:

- FDA-approved indication: For detecting both influenza A and influenza B viral nucleoprotein antigens in nasal swab, nasopharyngeal swab and nasopharyngeal aspirate/wash specimens in symptomatic patients. It is intended for use as an aid in the rapid diagnosis of acute influenza A and influenza B viral infections. The test is not intended to detect influenza C antigens. A negative test is presumptive and it is recommended these results be confirmed by viral culture of FDA-cleared influenza A and B molecular assay. Negative results do not preclude influenza virus infection and should not be used as the sole basis for treatment or other clinical management decisions.