I. Medication Description

Neuraminidase inhibitors are a class of antiviral drugs with activity against influenza A and influenza B viruses. Neuraminidase is an enzyme that breaks the bonds that hold new virus particles to the outside of an infected cell. Once the enzyme breaks these bonds, the new viruses are released from the host cell and can infect other cells. Neuraminidase inhibitors block the enzyme’s activity and prevent the new virus particles from being released, thereby limiting the spread of infection in the respiratory tract. When administered within 2 days of illness onset to otherwise healthy adults, zanamivir and oseltamivir can reduce the duration of uncomplicated influenza A and B illness by approximately 1 day. Relenza and Tamiflu are used for the treatment and prevention of seasonal influenza. The treatment course begins within 2 days of the onset of signs/symptoms of influenza and continues for a total of 5 days. These medications are not a substitute for annual vaccination.

II. Position Statement

- Coverage is provided immediately (without generating the prior authorization process) for a drug quantity sufficient for one 5-day treatment course (twice daily dosing) or one 10-day prophylactic regimen (once daily dosing) for seasonal influenza in any 180-day period for either Relenza® or Tamiflu®.
- Coverage of a greater drug quantity such as that needed for a longer course of preventative treatment is determined through a prior authorization process.

III. Policy

Coverage for Tamiflu or Relenza at additional quantities or greater duration is provided in accord with the following:
- Member remains severely ill after 5 days of treatment OR
- Member requires increased duration of prophylaxis for seasonal influenza in accord with both of the following:
  - The patient is at high-risk for complications of influenza, including:
    - Children under 2 years of age or adults 65 years of age or older
    - Healthcare workers or caretakers of high-risk patients who have not or cannot receive the vaccine
    - Persons with chronic pulmonary (including asthma), cardiovascular (except HTN alone), renal, hepatic, hematological (including sickle cell disease), metabolic disorders (including diabetes mellitus), or neurologic and neurodevelopmental conditions (including disorders of the brain, spinal cord, peripheral nerve, and muscle such as cerebral palsy, epilepsy, stroke, intellectual disability, moderate to severe developmental delay, muscular dystrophy, or spinal cord injury)
    - Immunosuppression: including that caused by medications, HIV/AIDS, or cancer
Women who are (or will be) pregnant during flu season or who are postpartum (within 2 weeks after delivery)
- Persons aged less than 19 years who are receiving long-term aspirin therapy
- American Indians/Alaska Natives
- Persons who are morbidly obese (BMI at least 40)
- Nursing home or long-term care facility residents
  - Member must be in a high-risk situation, including:
    - Insufficient vaccine supply
    - Allergy or intolerance to the influenza vaccine (e.g., history of Guillain-Barre Syndrome)
    - Insufficient time between vaccination and likely exposure to develop immunity (i.e., less than or equal to 2 weeks)
    - The presence of an active outbreak in an institutionalized facility among vaccinated or non-vaccinated residents
    - Circulating influenza viruses are different than the strains used to develop the vaccine

IV. **Quantity Limitations**

- Relenza: 20 powder blisters per 180 days
- Tamiflu 45mg or 75mg capsules: 10 capsules in 180 days
- Tamiflu 30mg capsules: 20 capsules in 180 days
- Tamiflu 6mg/mL suspension: 180mL in 180 days

V. **Coverage Duration**

Coverage is provided for up to 6 weeks of Tamiflu or up to 28 days of Relenza for use in prevention of influenza in high-risk patients/situations.

VI. **Coverage Renewal Criteria**

Each course of therapy needed will require a new request with supporting documentation.

VII. **Billing/Coding Information**

- Tamiflu 30mg, 45mg, 75mg capsules
- Tamiflu 6mg/ml powder for suspension (each bottle: 60ml)
- Relenza 5mg powder for inhalation (each box: 5 Rotadisks containing 4 blister pks each of zanamivir 5mg)

VIII. **Summary of Policy Changes**

- 6/1/11: Defined automatically allowed amount as 5 treatment days (twice daily dosing) or 10 prophylactic days (once daily dosing)
- 6/15/12: Dosing table updated, Contraindications for Relenza® added
- 6/15/13:
  - Dosing table updated
  - Contraindication for Tamiflu® added
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- clarification of what ages carry drug quantity limits added
  - 6/15/14: no policy changes
  - 7/1/15: formulary distinctions made
  - 12/15/15: no policy changes
  - 9/15/16: no policy changes

IX. References


The Plan fully expects that only appropriate and medically necessary services will be rendered. The Plan reserves the right to conduct pre-payment and post-payment reviews to assess the medical appropriateness of the above-referenced therapies.

Drug therapy initiated with samples will not be considered as meeting medical necessity for coverage for non-preferred or prior authorized medications.

The preceding policy applies only to members for whom the above named pharmacy benefit medications are included on their covered formulary. Members with closed formulary benefits are subject to trying all appropriate formulary alternatives before a coverage exception for a non-formulary agent will be considered.

The preceding policy is a guideline to allow for coverage of the pertinent medication/product, and is not meant to serve as a clinical practice guideline.