DISTRICT OF COLUMBIA ~ DEPARTMENT OF HEALTH ~ ADAP
Roflumilast tablet (Daliresp®)
PRIOR AUTHORIZATION PROGRAM Request Form – <u>RENEWAL</u> Request (1 year maximum)

CLIENT'S NAME: _____ ADAP ID: _____
CLIENT'S DATE OF BIRTH: _____ ADAP Pharmacy: _____

DC ADAP Policy: Daliresp® (Roflumilast) is a selective phosphodiesteras-4 (PDE-4) inhibitor which leads to an accumulation of cyclic AMP (cAMP) within inflammatory and structural cells important in the pathogenesis of chronic obstructive pulmonary disease (COPD).
Limitations of use: roflumilast is NOT indicated for the relief of acute bronchospasm
Roflumilast is available as 250 mcg and 500 mcg tablets for oral administration.

Daliresp® requires prior approval for coverage. Allow up to 96 hours for completion of request.

Please fax (1) supportive medical letter of necessity (2) applicable diagnostic tests including forced expiratory volume in 1 second (FEV_1) and FEV_1/forced vital capacity (FVC) ratio

Indication for Use: Roflumilast is indicated to reduce the risk of COPD exacerbations in patients with severe COPD associated with chronic bronchitis and a history of exacerbations

Criteria for use:

Please complete and check all that apply:

1. Medical Provider is experienced in the care of COPD, or in consultation with a pulmonologist.
   YES □ NO □
2. Client has severe or very severe COPD according to the prescribing physician and clinical data (e.g. FEV_1 <50% of predicted and/or FEV_1/FVC ratio ≤70%).
   YES □ NO □
3. Client has a history of COPD exacerbations requiring systemic corticosteroids within the past 6 months.
   YES □ NO □
4. Client is currently receiving a long-acting beta2-agonist (LABA), e.g. salmeterol, fomoterol.
   YES □ NO □
5. Client is currently receiving a long-acting muscarinic antagonist (LAMA) e.g. tiotropium.
   YES □ NO □
6. Client is currently receiving an inhaled corticosteroid (ICS), e.g., fluticasone.
   YES □ NO □
7. Client is adherent to current COPD regimen.
   YES □ NO □
8. Client has moderate to severe hepatic impairment.
   YES □ NO □
9. Client has a history of depression with suicidal behavior/ideations.
   YES □ NO □

10. Client is currently receiving a strong CYP3A inducers, e.g. rifampin, carbamazepine, phenytoin

    YES □ NO □

11. **Client has documented clinical and laboratory data that indicated improvement in COPD based on the client's health status and reduction in symptoms (e.g., as evidenced by the COPD Assessment Test (CAT) or the modified Medical Research Council Dyspnea Scale .**

    YES □ NO □

Recommended dosage and administration: 250 mcg once daily for 4 weeks, followed by 500 mcg once daily. **Note:** An initial dose of 250 mcg once daily is recommended for the first 4 weeks of treatment in an attempt to improve tolerability. However, this is not considered a therapeutic dose and the effect of this approach on long-term tolerability is uncertain.

Physician's signature: _____ Date: _____

Physician's Name (Print): _____Phone #: _____Fax #: _____

Fax Completed Form to Clinical Pharmacy Associates Inc.
Fax: 1 (888) 971-7229 Phone: 1 (800) 745-0434 ext. 150 Attention: Prior Approval Program

Approval: YES □ NO □ Date_____ Initials_____ Office use only Reason for denial _____