COPD agents PA criteria
Striverdi, Arcapta, Serevent, Trelegy

1. Is the requested drug Serevent (salmeterol), Arcapta (indacaterol) or Striverdi (olodaterol)
   a. Yes – Go to question 2
   b. No – Go to question 7

2. Does the member have a diagnosis of COPD?
   a. Yes – Go to question 5
   b. No- Go to question 3

3. Does the member have a diagnosis of asthma?
   a. Yes - Deny- Cat 5 -*Use of long acting bronchodilators for the treatment of asthma without a concomitant long-term asthma control medication, such as an inhaled corticosteroid, is contraindicated. Formulary LABA / ICS combination inhalers are AirDuo, Dulera and Symbicort and are subject to prior authorization and will be approved only for members whose asthma is not adequately controlled on inhaled corticosteroids alone despite regular use (80% or better compliance to therapy). Use of LABA with separate ICS inhaler is not least costly option.*
   b. No – Go to question 4

4. Does the member have a diagnosis of exercise induced bronchospasm?
   a. Yes – Deny Cat 5 - *Because LABAs may disguise poorly controlled persistent asthma, use of LABAs for exercise-induced bronchospasm is discouraged by the Asthma Guidelines.*
   b. No – Deny Cat 3- *Medication is being prescribed outside the FDA approved use.*

5. Is the request for Striverdi (olodaterol)
   a. Yes – May approved for 12 months
   b. No – Go to question 6

6. Is the request for Serevent (salmeterol) or Arcapta (indacaterol) where member had an inadequate response to preferred formulary LABA, olodaterol (Striverdi)?
   a. Yes – Approve for 12 months
   b. No – Deny Cat 5 – *Member has not had an inadequate response to preferred agent.*

7. Is the drug requested Trelegy? (Fluticasone, umeclidinium and vilanterol)
   a. Yes – Go to question 8
   b. No – Evaluate request for clinical appropriateness of request

8. Does the member have a diagnosis of COPD?
   a. Yes – Go to question 9
   b. No – Deny Cat 3 – *Medication is being prescribed outside of FDA approved use*

9. Is Trelegy being prescribed in member currently using LAMA, LABA and ICS therapy OR does member require escalation of therapy to reduce exacerbations of COPD?

    a. Yes- May approve for up to 12 months
    b. No – Evaluate for clinical appropriateness of request, possible Cat 5 denial.

Daliresp (Roflumilast)

1. Does the member have a diagnosis of severe COPD (group D) with associated bronchitis and a history of exacerbations?
    a. Yes – Go to question 2
    b. No – Deny Cat 3- *Medication is being used outside of FDA approved indication.*

2. Does member have an FEV_1 < 50% of predicted, chronic bronchitis and at least one hospitalization for an exacerbation in the previous 12 months?
    a. Yes- Go to question 3
    b. No – Deny- Not medically appropriate – *Member does not meet GOLD guidelines for use of roflumilast.*

3. Has member developed continued exacerbation despite treatment with maximally tolerated inhaled therapies (a long acting beta agonist, long acting muscarinic antagonist AND inhaled corticosteroid taken on a regular basis i.e. 80% of the time or more)? **Note ICS may be stopped in member at risk for pneumonia**
    a. Yes – Go to question 4
    b. No- Pharmacist and/or Medical Director evaluate for clinical appropriateness/CAT 5 denial

4. Has member used azithromycin or another macrolide antibiotic, as appropriate?
    a. Yes – Go to question 5
    b. No - Pharmacist and/or Medical Director evaluate for clinical appropriateness/CAT 5 denial

5. Does the member has a history of depression?
    a. Yes - Pharmacist and/or Medical Director evaluate for clinical appropriateness/CAT 5 denial

    The FDA has added a warning that roflumilast may be associated with an increase in adverse psychiatric reactions and should be used with caution in patients with a history of depression

    b. No – Go to question 6

6. Does the dosing follow FDA approved dosing guidelines? (see below)

250 mcg once daily for 4 weeks, followed by 500 mcg once daily, in combination with maximally tolerated inhaled therapy as additional agent for exacerbation reduction in high-risk COPD patients

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.

a. Yes – May approve for 6 months
b. No – Deny Cat 3- *Medication is being used outside FDA approved dosing*

Renewal Criteria

1. Has the member been compliant with both roflumilast and maximally tolerated inhaled therapies?

(Roflumilast has a limited benefit on lung function. Thus, the medication should be used as add-on, maintenance therapy to prevent exacerbations rather than to improve other COPD outcomes)

a. Yes- Go to question 2
b. No – Pharmacist or Medical Director to evaluate for clinical appropriateness of continued therapy

2. Has member experienced a reduction in frequency and/or severity of COPD exacerbations?

a. Yes – May approve for up to a maximum of 12 months
b. No – Deny Cat 5 – *Medication has not proven therapeutically affective in reducing COPD exacerbations for this member.*