MEDICAL POLICY STATEMENT			
Effective Date	**Next Annual Review Date**	**Last Review / Revision Date**	
05/15/2014	**05/15/2015**	**/ /**	
Author			
Trisha Holbrook PharmD RPH			

CSMG Medical Policy Statements are derived from literature based and supported clinical guidelines, nationally recognized utilization and technology assessment guidelines, other medical management industry standards, and published MCO clinical policy guidelines. Medically necessary services are those health care services or supplies which are proper and necessary for the diagnosis or treatment of disease, illness, or injury and without which the patient can be expected to suffer prolonged, increased or new morbidity, impairment of function, dysfunction of a body organ or part or significant pain and discomfort. These services meet the standards of good medical practice in the local area, are the lowest cost alternative and are not provided mainly for the convenience of the member or provider.

A. SUBJECT

Asthma and COPD Management Policy

- **Inhaled Short Acting Beta Agonist**
  - **Albuterol (ProAir, Ventolin)***
  - **Albuterol (Proventil)**
  - ***Albuterol solution****
  - **Levalbuterol HFA (Xopenex HFA)**
  - **Levalbuterol solution (Xopenex Solution)**
- **Inhaled Short Acting AntiCholinergic/AntiMuscarinic**
  - ***Ipratropium solution****
  - **Ipratropium (Atrovent)***
- **Inhaled Corticosteroid**
  - **Fluticasone (Flovent)***
  - **Budesonide (Pulmicort)**
  - **Ciclesonide (Alvesco)**
  - **Beclometasone (Qvar)***
  - **Mometasone (Asmanex)***
- **Inhaled Long Acting Beta Agonists**
  - **Formoterol (Foradil)***
  - **Salmeterol (Serevent)***
  - **Aformoterol (Brovana)**
  - **Formoterol solution (Perforomist)**
- **Inhaled Long Acting AntiCholinergic/AntiMuscarinic**
  - **Tiotropium (Spiriva)***
  - **Aclidinium (Tudorza)***
- **Xanthine Derivatives**
  - ***Aminophylline****
  - ***Theophylline****
- **Leukotriene Receptor Antagonist**
  - ***Montelukast* (Singulair)***
  - ***Zafirlukast* (Accolate)**
  - **Zileuton (Zyflo)**
- **Selective Phosphodiesterase 4 Inhibitor**
  - **Roflumilast (Daliresp)**

- **Combination SABA/SAMA**
    - ***Albuterol/Ipratropium**** **(DuoNeb)**
    - **Albuterol/Ipratropium (Combivent Respimat)***

- **Combination ICS/LABA Products**
    - **Fluticasone/Salmeterol (Advair)***
    - **Mometasone/Formoterol (Dulera)***
    - **Budesonide/Formoterol (Symbicort)***
    - **Fluticasone/Vilanterol (Breo)**
    - **Umeclidinium/vilanterol (Anoro)**

Legend: * = formulary Italics = generically available

B. BACKGROUND

The aim of asthma therapy is to maintain control of asthma with the least amount of medication and hence minimize the risk for adverse effects. The stepwise approach to therapy – in which the dose and number of medications and frequency of administration are increased as necessary and decreased when possible – is used to achieve this control. Since asthma is a chronic inflammatory disorder of the airways with recurrent exacerbations, therapy for persistent asthma emphasizes efforts to suppress inflammation over the long-term and prevent exacerbations.

COPD (chronic obstructive pulmonary disease) includes both emphysema and chronic obstructive bronchitis. COPD is the fourth leading cause of death in the United States and is the only common chronic illness for which mortality rates, social burden and economic burden continue to increase *(Global Initiative for Chronic Obstructive Lung Disease, 2011 [Guideline]).*

The patient selection criteria outlined was derived from the FDA-approved prescribing information for each of the above listed medication and the studies that were presented to the FDA in support of the pre-market approval application, and studies in the peer-reviewed published medical literature. CareSource also evaluated and took recommendations from the current guidelines presented by the multiple different organizations. The FDA label indication found in the manufacturer prescribing information and described below is Asthma and/or COPD. Coverage decisions for conditions other than the above FDA approved indications will be reviewed on a case by case basis if proven effective through research documentation. The requesting provider will need to support his exception request with the appropriate literature.

C. POLICY

CareSource will approve the use of **the Asthma or COPD agents listed above** and consider their use as medically necessary when the following criteria have been met for:

Asthma or COPD

Requests for other uses should be reviewed using CareSource Policy for Off-Label Use and Excluded Indications.

<u>Inhaled Short Acting Beta Agonist –Nebulizing solution</u>

Prior Authorization Criteria:

- Failure of a 30 day trial of albuterol nebulizing solution

OR

- Intolerance, side effects, or allergy to albuterol

Inhaled Short Acting Beta Agonist –Albuterol HFAs

Prior Authorization Criteria:

- Failure of a 90 day trial of albuterol (ProAir or Ventolin)
  AND
- A Clinical reason (supported by chart notes) why the non-formulary product would be effective

Inhaled Short Acting Beta Agonist –Non-Albuterol HFAs

Prior Authorization Criteria:

- Failure of a 30 day trial of albuterol (ProAir or Ventolin)
  OR
- Intolerance, side effects, or allergy to albuterol

Inhaled Corticosteroid

Prior Authorization Criteria:

- Failure of 30 day trials for 2 of the following 3: Flovent, Qvar, or Asmanex
  OR
- Intolerance, side effects, or allergy to all: Flovent, Qvar, and Asmanex

Inhaled Long Acting Beta Agonists

Prior Authorization Criteria:

- Failure of a 30 day trial of Foradil or Serevent
  OR
- Intolerance, side effects, or allergy to all: Foradil and Serevent

Leukotriene Receptor Antagonist

Prior Authorization Criteria:

- Failure of a 30 day trial of montelukast (Singulair)
  OR
- Intolerance, side effects, or allergy to montelukast (Singulair)

Selective Phosphodiesterase 4 Inhibitor

Prior Authorization Criteria:

- Documented Diagnosis of Stage 4 – Severe COPD
- Currently claim - within the last 30 days - of albuterol or levalbuterol
- Currently on – claim within the last 30 days – for
  - 2 of the following categories
    - ICS
    - LABA
    - Leukotriene Antagonist or Xanthine Derivative

    OR
  - ICS/LABA combination

Combination ICS/LABA Products

Prior Authorization Criteria:

- Failure of 30 day trials of 2 of the following 3: Symbicort, Dulera, or Advair

Note: Documented diagnosis and other therapies tried must be supplied on the prior authorization request form to be considered for approval.

Conditions of Coverage

Quantity Limitations	Per package inserts and UFFs
Authorization Period	Approved authorizations are valid for 12 months. Continued treatment may be considered when the member has shown biological response to treatment. ALL authorizations are subject to continued eligibility.
Data Required on Request	Diagnosis Treatment Failures

D. REVIEW / REVISION HISTORY

/ /

E. REFERENCES

Facts and Comparison: http://online.factsandcomparisons.com/index.aspx

Sveum R, Bergstrom J, Brottman G, Hanson M, Heiman M, Johns K, Malkiewicz J, Manney S, Moyer L, Myers C, Myers N, O'Brien M, Rethwill M, Schaefer K, Uden D. Institute for Clinical Systems Improvement. Diagnoais and Management of Asthma. Updated July 2012.

New York State Department of Health. Clinical Guidelines for the Diagnosis, Evaluation and Management of Adults and Children with Asthma. Updated July 2013.

Anderson B, Conner K, Dunn C, Kerestes G, Lim K, Myers C, Olson J, Raikar S, Schultz H, Setterlund L. Institute for Clinical Systems Improvement. Diagnosis and Management of Chronic Obstructive Pulmonary Disease (COPD). Updated March 2013.

Gold Board of Directors, Gold Science Committee, and invited reviewers. Global initiative for Chronic Obstructive Lung Disease. Updated 2013.

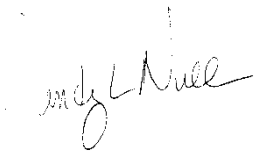
The medical Policy Statement detailed above has received due consideration as defined in the Medical Policy Statement Policy and is approved.

C Smith MD

Chief Medical Officer

5/20/2014

Date



5/20/2014

Director of Pharmacy Operations **Date**