

Wyoming Drug Utilization Review

Chronic Obstructive Pulmonary Disease: Steroid Options

Sam Blakeslee, PharmD Candidate 2019

Steroids are a class of immunomodulators; glucocorticoids and corticosteroids. They have the capacity to interrupt inflammation pathways in the human body. Steroids are used to treat inflammation caused by various diseases such as asthma, Crohns disease, and chronic obstructive pulmonary disease (COPD). Inhaled corticosteroids are used for chronic reduction in COPD exacerbations and symptoms.² Glucocorticoids are administered as short-term

oral therapy for patients with severe exacerbation.¹

Steroids are used in combination with long acting muscarinic receptor antagonists (LAMAs) and long acting beta agonists (LABAs) to further suppress the inflammation of the lung tissue.² Moderate use of inhaled steroids is reserved for patients who have failed other therapies and need additional drug support to improve quality of life.

Oral glucocorticoids are given to patients who are having exacerbation including coughing, low oxygen saturation, and an increase in production of phlegm.² They are given short-term to reduce the severity of the exacerbation, improve lung function, and improve the recovery of the patient. Systemic steroid use comes with adverse effects including: bone density loss, fungal infections, suppression of the adrenal system, cataracts, and bone fractures.¹

Inhaled corticosteroids (ICS) are preparations of steroids specifically formulated for inhalation therapy. ICS used in long-term therapy do not reduce mortality or improve COPD; they improve quality of life and reduce COPD complications. Discontinuation of long-term use of steroids has been shown to have a rebound effect in exacerbations and a reduction in FEV when patients are tapered off of their use.¹

ICS bronchodilator therapy can be started early in the management of COPD, based on the assessment of severity measured by degree of symptoms, history of exacerbations and outcome of spirometry; based on the GOLD (Global initiative for chronic obstructive lung disease) classification for Severity of Airflow Limitation.⁴ A patient, who is classified as GOLD group C and having persistent exacerbations, may add ICS to their therapy. Management of patients classified as GOLD group D may require ICS therapy to step-up to a regimen already including a LABA/LAMA.⁴

Inhalation steroids are administered via hydroflouralkanes (HFA) and dry powder inhalers (DPI). HFAs contain a steroid expelled by a propellant from inhaler device. HFAs require minimal training to use and can be used with patients' having limited hand coordination. DPIs require more dexterity and manipulation which may be difficult for some patients.

The charts on page 3 detail available ICS products and combinations.

Combination ICS and LABA products reduce the number of doses administered and may increase patient compliance. They come in formulations of both HFA and DPI. Triple therapy, LABA/LAMA/ICS, shows improved quality of life, improved lung functions, exacerbations, and symptoms of COPD.² Currently there is one product on the market for the indication of COPD with all three drug regimens.²

The step-up in inhaled therapy to LABA plus LAMA and then adding on ICS (triple therapy) can occur by various approaches as shown on page 3.¹ Standard treatment

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P&T Committee Meeting Update

The P&T Committee met for its quarterly business meeting on November 8, 2018.

Highlights of this meeting include:

The 72 hour emergency fill policy will be applied to buprenorphine products, allowing pharmacies to override the PA process in an emergency situation to get patients started on therapy.

Antipsychotic medications, including long-acting injectables, will be limited to 100% of labeled dose. Patients currently above 100% will be reviewed and grandfathered as appropriate. Concurrent use of long-acting injectables and oral agents will require prior authorization with the exception of initiation of the injectable.

Concurrent use of different dosage forms of sumatriptan will no longer be allowed.

Aimovig and Ajovy will require a three-month trial and failure of both an anticonvulsant and a beta blocker. Concurrent use of botox will not be allowed. The Aimovig starting dose will be limited to 70 mg as there is no

significant difference in efficacy, but a higher incidence of adverse effects with the 140 mg dose.

Orilissa, Mulpleta, Takhzyro, Lucemyra, and Palynziq will be limited to indication. Ilumya, Kevzara and Olumiant were referred to the Department of Health for cost analysis and PDL placement.

Baxdela will require a trial of Zyvox, ciprofloxacin or levofloxacin prior to approval.

Concurrent use of Lyrica and gabapentin will no longer be allowed. Both drugs will be limited to 100% of the labeled maximum.

The proposed prior authorization criteria and 2019 PDL will be posted for public comment at www.uwyo.edu/DUR. Comments may be sent by email to alewis13@uwyo.edu or by mail to: Wyoming Drug Utilization Review Board, Dept. 3375, 1000 E. University Avenue, Laramie, WY 82071. Comments should be received prior to December 15, 2018.

The next P&T Committee meeting will be held February 14, 2019 in Cheyenne. An agenda will be posted approximately two weeks prior to the meeting.

Chronic Obstructive Pulmonary Disease

for COPD in the past has been to administer a dose of salmeterol/fluticasone and add a daily dose of tiotropium.⁴

Head to head trials between ICS/LABA and LAMA/LABA indicate LAMA/LABA are preferred initial therapy for patients of COPD because of greater reductions in exacerbations and a lower risk of pneumonia.³ Additionally, ICS plus LABA together are more efficacious at treating COPD than either one alone.¹ Triple therapy should be reserved for the most advanced patients with COPD to improve quality of life and reduced exacerbations with minimal increased risk for pneumonia.

ICS have a role in treating patients with GOLD group C and D COPD. ICS are most commonly used in combination therapy to maximize their effectiveness.

References:

1. Global Initiative for Chronic Obstructive Lung Disease (GOLD). Global strategy for the diagnosis, management, and prevention of chronic obstructive pulmonary disease (2018 report). Available at: <https://goldcopd.org/gold-reports/>. Accessed: July 24, 2018.
2. Drugs for COPD. *Med Lett Drugs Ther.* 2017;59:57-62.
3. N Horita, Goto A, Shibata Y, et al. Long-acting muscarinic antagonist (LAMA) plus long-acting beta-agonist (LABA) versus LABA plus inhaled corticosteroid (ICS) for stable chronic obstructive pulmonary disease (COPD). *Cochrane Database Syst Rev* 2017; 10.
4. Nici L, Shaughnessy A, Trow TK, editors. COPD. In: *DynaMed [database online]*. Ipswich (MA): EBSCO Industries, Inc.;2018. Available from: <http://www.dynamed.com/>. Accessed: August 14, 2018.

ICS Products and Combinations

Inhalation corticosteroid	Formulation-HFA	Adult dosage
Beclomethasone dipropionate Qvar ² Qvar Redihaler ²	40, 80 mcg 40, 80 mcg	40-320 mcg bid 40-320 mcg bid
Ciclesonide- Alvesco ²	80, 160 mcg	80-320 mcg bid
Flunisolide- Aerospan HFA ²	80 mcg	160-320 mcg bid
Fluticasone propionate- Flovent HFA ²	44, 110, 220 mcg	88-880 mcg bid
Mometasone furoate- Asmanex HFA ²	100, 200 mcg	200-400 mcg bid

Inhalation corticosteroid	Formulation- DPI	Adult dosage
Budesonide- Pulmicort Flexhaler	90, 180 mcg	180-720 mcg twice daily
Fluticasone furoate- Arnuity Ellipta	100, 200 mcg	50-500 mcg daily
Fluticasone propionate- Flovent Diskus ArmonAir RespiClick	50, 100, 250 mcg 55, 113, 232 mcg	100-1000 mcg twice daily 55-232 mcg twice daily
Mometasone furoate- Asmanex Twisthaler	110, 220 mcg	220-880 mcg once daily in PM or 220 mcg twice daily

Combination ICS/LABA	Formulation- HFA	Adult dosage
Budesonide/formoterol- Symbicort ^{1,2}	160 mcg/4.5 mcg	2 inhalation twice daily
Mometasone furoate with Formoterol- Dulera ^{1,2}	100/5 mcg, 200/5 mcg	2 inhalation twice daily

Combination ICS/LABA	Formulation- DPI	Adult dosage
Fluticasone furoate/vilanterol- Breo Ellipta ^{1,2}	100/25 mcg	1 inhalation once daily
Fluticasone propionate with salmeterol- Advair Diskus ^{1,2}	250/50 mcg	1 inhalation twice daily

Combination ICS/LAMA/LABA	Formulation-DPI	Adult dosage
Fluticasone furoate/umeclidinium/ vilanterol- Trelegy Ellipta ²	100/62.5/25 mcg	1 inhalation once daily

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