



**Indian Health Service**  
**National Pharmacy and Therapeutics Committee**  
**Formulary Brief: Inhaled Corticosteroids**  
**-May 2019-**



**Background:**

In May 2019, the National Pharmacy and Therapeutics Committee (NPTC) reviewed the current respiratory disease guidelines and drug classes for both asthma and COPD to determine if changes to the IHS National Core Formulary were warranted. The National Core Formulary currently lists mometasone as the sole inhaled corticosteroid (ICS) product for use in asthma patients. Following the NPTC clinical review and discussion, **no modifications were made to the National Core Formulary.**

**Discussion:**

Asthma and COPD are significant respiratory diseases with prevalence rates in the American Indian/Alaska Native population of ~10% and 0.8%, respectively. Until the 1980s, bronchodilator therapy was the primary treatment for asthma. Once airway inflammation was determined to be the central pathophysiologic factor in all forms of asthma, inhaled corticosteroids supplanted bronchodilators as prophylactic treatment. Monotherapy with an ICS is no longer indicated in COPD, although ICSs have a place in therapy in combination with other medications. Inhaled delivery of steroids allows for a clinical benefit with decreased systemic adverse effects.

**Inhalational devices:**

There are several different devices for the delivery of inhaled medication<sup>1</sup>. The most common device is the pressurized multi-dose inhaler (pMDI) which is often used with spacers and valve holding chambers. There is also a breath-actuated pMDI that cannot be used with a spacer or valve holding chambers. Additionally, dry powder inhalers (DPI), soft mist inhalers, and nebulizers (jet and ultrasonic) are available. Coordination and inspiratory effort are the most important factors in choosing the device. Patients with poor inspiratory effort and coordination (often children and elderly) can use pMDIs with spacers or nebulizers most effectively. Studies show that properly chosen devices are equivalent in their effectiveness. Adherence and technique should be assessed at every visit and prior to any medication change<sup>2</sup>.

**Inhaled Corticosteroid monotherapy:**

**COPD:** Available evidence for the role of ICS in patients with stable COPD is conflicting and differs based on the outcome(s) measured. ICS for 6 months or more did not consistently reduce the decline in the forced expiratory volume (FEV1) rate or mortality. Exacerbations were reduced and quality of life improved. There was increased risk of oropharyngeal candidiasis and hoarseness. Rate of pneumonia was also increased<sup>3</sup>. Use of ICS in the management of COPD is typically adjunctive therapy, reserved for patients with moderate to severe airflow obstruction who have continued symptoms, repeated exacerbations, or severe exacerbations despite use of an optimized inhaled bronchodilator.

**Asthma:** All FDA-approved ICS medications show superiority to placebo for improving pulmonary function tests, decreasing need for rescue beta-2 agonist use, and reducing frequency of asthma exacerbations. Head-to-head ICS studies are limited, industry-sponsored, and often compare non-equivalent doses, making direct comparison of products difficult. Currently, there is moderate evidence to suggest that all ICS are equivalent<sup>4</sup>. Numerous studies show that low to moderate doses of ICS are best, especially with mild to moderate asthma. High doses should be reserved for severe asthma and generally help decrease oral steroid requirements in those cases<sup>5</sup>. Intermittent versus daily ICS use shows no difference in events requiring oral steroids or other serious adverse events. Other than a growth velocity reduction in the daily use group, all other end-points including pulmonary function, rescue beta-2 agonist use, and quality of life were better in the daily use group<sup>6</sup>. ICS use, when compared to anti-leukotrienes, promotes decreased exacerbations requiring oral steroids, and effect which is more pronounced in patients with moderate versus mild asthma<sup>7</sup>. Theophylline has been shown to be steroid-sparing when added to ICS, but has a high potential for serious adverse reactions and therefore needs to be monitored closely<sup>8</sup>. Common side effects of ICS include oral candidiasis (*recommend oral gargle and spit after use*), dysphonia, headaches, nasopharyngitis, and muscular complaints. Adverse steroid consequences are

possible, the most serious of which are adrenal suppression (e.g., doses of 1.5mg/day, 0.75mg/day with fluticasone), growth velocity suppression in children, and pneumonia in COPD patients<sup>9</sup>. Step-down dosing in controlled asthma in children is recommended, but not in adults.

Adherence is improved with once-daily dosing of medications versus twice-daily dosing as well as with fixed-combination therapy. Adherence education and reminders also improve adherence rates and lead to cost savings for healthcare organizations by virtue of fewer exacerbations and hospitalizations<sup>10</sup>.

There are six FDA-approved and available formulations of ICS currently in the United States for children 12 years and older and for adults: beclomethasone, budesonide, ciclesonide, fluticasone propionate, fluticasone furoate, and mometasone. None of these products are FDA-approved for patients under 1 year of age. Budesonide is available via nebulizer for children ages 12 months to 8 years. Beclomethasone breath-actuated MDI, fluticasone furoate DPI, fluticasone propionate pMDI and DPI, and mometasone DPI are approved for patients 4 years and older. Fluticasone propionate pMDI with spacer (+/- face mask) is most commonly used off-label for children under 4 years old. While budesonide DPI is the only pregnancy category B ICS currently available (i.e., the preferred ICS in pregnant patients), guidelines from the [American College of Obstetricians and Gynecologists](#) recommend against switching pregnant patients already controlled on a different ICS medication. Only fluticasone furoate and mometasone are FDA-approved for once-daily use. All other daily dosing is off-label. If dosing once daily, give at night to maximize benefit.

### Findings:

Inhaled corticosteroids remain a guideline-supported staple in the management of asthma but have a lesser, adjunctive role only in treating patients with more advanced COPD. Clinical differences between ICS products and inhaler devices appear minimal and non-significant. Evidence from published literature and internal pharmacoeconomic analyses offer a value-based decision opportunity which supports the retention of the currently-named ICS product, mometasone, to the National Core Formulary.

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*If you have any questions regarding this document, please contact the NPTC at [IHSNPTC1@ihs.gov](mailto:IHSNPTC1@ihs.gov). For more information about the NPTC, please visit the [NPTC website](#).*

### References:

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