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## Cost-Effective Asthma Treatments for Uninsured or Underinsured Pediatric Patients

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#### ABSTRACT

Nurse practitioners should constantly compare a medication's potential effect with its associated cost, thus identifying the most cost-effective treatment plan. Such an approach is warranted for both pediatric and adult patients. Prescribing medications for children who are uninsured or underinsured can be especially challenging, particularly for those patients diagnosed with a chronic health condition requiring routine treatment and follow-up. Asthma can be such a chronic illness for which the cost associated with treatment may become a barrier to compliance with the treatment plan. Cost-effective treatment options for asthma in the pediatric patient are presented.

**Keywords:** asthma, cost-effective, medication, pediatric, underinsured, uninsured © 2012 American College of Nurse Practitioners

Figures 1 and 2 are available online at www.npjournal.org.

n 2010, 46.2 million Americans were living in poverty and 49.9 million did not have health insurance,<sup>1</sup> an increase of 900,000 since 2009. In addition, the percentage of Americans covered by private health insurance and employment-based health insurance has been decreasing since 2008.<sup>2</sup> Regrettably, the decreasing number of insured employees and rising costs of insurance rates have directly and negatively influenced the health of children who, consequently, are also uninsured.<sup>3</sup>

In 2010, 9.8% of children under the age of 18 in the United States were identified as uninsured, accounting for 7.3 million children.<sup>1</sup> Despite recent expansions of Medicaid and the Children's Health Insurance Program (CHIP), the number of uninsured US children has improved by only 1.7% since 2006.<sup>4</sup> Many of these uninsured children live in families whose income is below the federal poverty line and are 3 times less likely to visit health care providers.<sup>4</sup> Additionally, all underinsured pediatric patients are less likely to have their prescriptions filled than are children with adequate private insurance.<sup>5</sup>

Treating asthma patients under 18 years old costs an estimated \$3.2 billion per year.<sup>6</sup> Children from poor and low-income neighborhoods have a higher prevalence of asthma<sup>7</sup> and are 3 times more likely to experience acute exacerbations, necessitating more frequent emergency department (ED) visits and hospitalizations.<sup>8</sup> Consequently, health care providers must be able to offer uninsured or underinsured families costeffective treatment plans.<sup>9</sup> The purpose of this article is to review treatment plans for asthma management in pediatric patients and compare the cost and effectiveness of asthma medications.

#### **METHODS**

Multiple searches of electronic databases were conducted to identify studies related to the treatment of pediatric patients with asthma. Electronic databases included CINAHL, Medline, EBSCO, Clinical Pharmacology, Epocrates, Micromedex, UptoDate, and the Cochrane Library. An Internet search of government and professional organization Web sites were reviewed.

Inclusion criteria were English articles published in the past 5 years. Articles in which advanced treatment plans for asthma management or asthma medications not appropriate for use in pediatric patients were excluded. Search terms included asthma, cost, compliance, treatment, medication, guidelines, cost-related nonadherence, uninsured, pediatric, and children.

#### **REVIEW OF ASTHMA-RELATED COSTS**

Asthma is a chronic respiratory disease where inflammation and subsequent narrowing of small airways cause shortness of breath, coughing, wheezing, and chest pain. Episodes of impaired breathing can be caused by various triggers.<sup>10</sup> According to the Centers for Disease Control and Prevention,<sup>11</sup> an estimated 7.1 million children have asthma, making it the most common pediatric chronic illness in America.<sup>6,12</sup> Health care expenditures for children with asthma are 1.5 times greater than children without asthma.<sup>13</sup> In fact 75% of asthma-related costs are related to ED visits.<sup>14</sup> The economic burden of asthma includes direct costs, such as prescription costs and provider visits, or indirect costs, such as absenteeism from school.<sup>14,15</sup>

### REVIEW OF ASTHMA MANAGEMENT IN THE PEDIATRIC PATIENT

The National Heart, Lung, and Blood Institute<sup>16</sup> (NHLBI) outlines a stepwise pharmacological treatment plan of adjusting medication for children 0–11 years old with asthma until their symp-

toms are controlled (Figures 1 and 2). Before treatment, it is important to assess the severity of a child's asthma by collecting a complete history or spirometry testing results. Clinicians should then classify the severity of a patient's asthma symptoms while considering both current impairment and future risk.<sup>17</sup> Nurse practitioners (NPs) must also review symptoms such as

wheezing, use of short-acting beta agonists (SABAs), and interference with daily activities.

NPs can safely manage pediatric asthma patients for step 1 treatments.<sup>16</sup> If patients 0–4 years old are not well controlled in step 1, NPs may consider referring to a specialist for step 2 management, although this is not required.<sup>16</sup> However, the NHLBI does recommend an asthma specialist for step 3 management or higher for all patients 4 years and younger.<sup>16</sup> A specialist may be consulted at step 3 management for patients 5–11 years old, although an asthma specialist is required at step 4 for all patients 5–11 years old<sup>16</sup> (Figures 1 and 2).

#### Step 1

SABAs are the first line of therapy for children with intermittent asthma and include albuterol and levalubterol as needed. Referred to as rescue inhalers, SABAs have a quick onset and are used for acute exacerbations of asthma symptoms. As preventive medications, SABAs can also be administered 10 minutes before activities that commonly trigger symptoms, such as exercise.<sup>18</sup> Patients using SABA inhalers more than 2 times per week for at least 1 month or who are not adequately controlled should be advanced from step 1 to step 2 treatments as outlined in the National Asthma Prevention Program guidelines<sup>16</sup> (Figures 1 and 2).

#### Step 2

...an estimated

7.1 million children

have asthma,

making it the most common

pediatric chronic illness

in America.

Inhaled corticosteroids (ICSs) are recommended for long-term asthma control in pediatric patients with persistent asthma that is classified by symptom frequency, excessive SABA use, impairment of normal activity, limitations in normal activity, nocturnal awakenings more

> than once per week, and the use of oral glucocorticoids more than twice per year.<sup>16</sup> The preferred first-line therapy in this stepwise treatment category is to add a low-dose ICS to the patient's SABA therapy (Figures 1 and 2), such as beclomethasone, budesonide, fluticasone, or mometasone, although the choice of ICS depends on the child's age and the medication delivery mode (nebulizer versus inhaler). The addition of ICS

medications prevents lung function loss, improves quality of life, and reduces risk of severe exacerbations<sup>18</sup> for the patient with persistent asthma, consequently lowering the overall cost of asthma treatment.

There are a few alternative treatment options to ICS for patients requiring step 2 asthma therapy, although the treatment regimen is age dependent. Patients 0–4 years old are candidates for a leukotriene receptor antagonist (LTRA) (montelukast) in lieu of ICS, but in addition to continued use of SABAs (Figure 1). For patients 5–11 years old, the practitioner may consider prescribing theophylline or LTRA (montelukast or zafirlukast) as an alternative to ICS therapy but in addition to SABAs<sup>17</sup> (Figure 2).

While still listed as an alternative to ICS therapy, mast cell stabilizers (cromolyn) are no longer available in the US and so were not included for review. Likewise, theophylline is rarely used because of the potential for adverse side effects and drug interactions and was not included for review.

#### Step 3

For children requiring step 3 asthma management, treatment includes an SABA plus a medium-dose ICS (Figures 1 and 2). A medium-dose ICS is obtained by increasing the dosages of low-dose inhalers as recommended for the patient's age. If the practitioner wishes to avoid the medium-dose ICS, he or she may substitute a low-dose ICS plus a long-acting beta agonist (LABA) or LTRA.<sup>16</sup> Budesonide is currently the only approved ICS for patients age 0–4 years and is available as a nebulized treatment.<sup>19</sup> However, for children 5–11 years old, medium-dose ICS inhalers can be prescribed as part of a step 3 treatment plan, as long as the child can use an inhaler.<sup>16</sup> Although an option in step 3 treatment, theophylline was not included for review because of its potential for adverse side effects.

#### COMPARISON OF EFFICACY AND COST

#### SABA

SABAs are safe for children of all ages and can be dispensed as a nebulized treatment or hydrofluroalkane (HFA) inhaler. There is no significant difference between the SABA medications albuterol and levalbuterol<sup>20</sup> in efficacy, safety, or prevalence of adverse side effects.<sup>21</sup> Therefore, selection of SABAs should be made after considering medication cost.

The approximate cost of nebulized albuterol is \$43.99/box of the 0.63 mg/3 mL dose or \$53.82/box of the 1.25 mg/3 mL dose. The least expensive dosing option (0.083 mg/3 mL) can be purchased for about \$18.99/box. Comparably, levalbuterol is more than twice as expensive as albuterol at about \$132.87/box of the 0.31 mg/3 mL dose, \$148.23/box of the 0.63 mg/3 mL dose, or \$147.99/box of the 1.25 mg/3 mL dose <sup>22</sup> (Tables 1 and 2). Albuterol and levalbuterol are also available as an HFA inhaler. When administered via inhaler, albuterol is available as Proair (TevaRespiratory, Horsham, PA) at an approximate cost of \$44.99/inhaler, Ventolin (GlaxoSmithKline, Middlesex, United Kingdom) at about \$45.99/inhaler, or Proventil (Merck & Co., Inc., Kenilworth, NJ) at about \$55.99/inhaler. Somewhat comparable in cost, levalbuterol is available as Xopenex (Sunovion Pharmaceuticals Inc., Marlborough, MA) for about \$59.99/inhaler.<sup>22</sup>

#### **Inhaled Corticosteroids**

ICSs are the most potent asthma treatment available,<sup>17</sup> thus reducing bronchial hyperresponsiveness that, in turn, helps maintain and enhance lung function long term.<sup>23</sup> Because of potentially negative side effects, steroid use in the pediatric patient usually causes concern, although ICSs deliver steroids directly to the airways, causing fewer systemic side effects.<sup>17,24</sup> In children, daily use of ICSs is the most effective controller of persistent asthma symptoms and acute exacerbations.<sup>24–25</sup> However, ICSs are often underprescribed, despite the proven benefits in reducing asthma exacerbations.

There are currently 4 ICSs on the market for use in pediatric patients age 11 years and younger; however, the cost of treatment significantly increases when using an ICS in comparison to SABA alone. When selecting the most cost-effective and appropriate ICS for a child, consider age, ability of the patient to effectively use an inhaler, and compliance issues associated with frequency of dosing.

Beclomethasone (BDP) is prescribed starting at 1 puff twice per day for patients 5 years and older. BDP metabolizes into beclomethasone monopropriate (BMP) in the lung tissue and extrapulmonary tissue,<sup>23</sup> increasing local side effects that must be considered when prescribing to young children who have difficulty synchronizing inhaling with dispensing the medication. BDP is as effective as fluticasone (FP),<sup>26</sup> another ICS, although BDP usually causes less adrenal suppression.<sup>23</sup> The cost of BDP is about \$113.99/inhaler<sup>22</sup> (Table 2).

Budesonide (BUD) is the only ICS appropriate for patients as young as 1 year and can be administered via nebulizer or inhaler. Moreover, BUD has a low incidence of oropharyngeal side effects and is the least potent, systemically, compared with other ICSs.<sup>24</sup> The cost of BUD is approximately \$121.99/inhaler. For children who

Step 1: SABA Albuterol		Step 2 Preferred: SABA 1 Low-dose ICS SABA + Budesonide		Step 3 Consultation			
					HFA	Nebulized	Budesonide HFA
\$44.99/inhaler	\$18.99/box (0.083 mg/ 3 mL)	\$121.99/inhaler	\$205.99/box (.25 mg/2 mL)				
	or						
	\$43.99/box (0.63 mg/3 mL	)					
	or						
	\$53.82/box (1.25 mg/3 mL	)					
Levalbuterol		Step	2 Alternative:				
		SABA + LTRA (Montelukast)					
HFA	Nebulized	Montelukast granules	Montelukast chewable				
\$59.99/inhaler	\$132.87/box (0.31 mg/3 mL	\$169.05/box 4 mg )	\$166.91/bottle of 4 mg				
	or						
	\$148.23/box (0.63 mg/3 mL	)					
	or						
	\$147.99/box (1.25 mg/3 mL	)					

#### Table 1. Cost Comparison of Asthma Medications for Children 0-4 Years Old

SABA = *s*hort-acting beta agonist; ICS = inhaled corticosteroids; HFA = hydrofluroalkane; LTRA = leukotriene receptor antagonist. **Step 1 Recommendation**: Albuterol is the most cost-efficient option in both HFA and nebulized solution.

Step 2 Recommendation: SABA + budesonide is the preferred therapy. When age appropriate, budesonide HFA is the most cost-efficient option

cannot effectively use an inhaler, BUD is also available as a nebulized solution, costing about \$205.99/box for  $0.25 \text{ mg}/2 \text{ mL doses}^{22}$  (Tables 1 and 2).

FP has been established as a safe and effective medication to treat persistent asthma symptoms. With a low occurrence of both systemic and oral side effects, FP is often prescribed with twice daily dosing and has the greatest variety of dosing increments of any ICS. This variety may be advantageous for practitioners adjusting medication dosages for pediatric patients to achieve adequate symptom management, at the lowest possible prescribed dose. When compared with some of the newer HFA ICSs, FP has similar outcomes.<sup>23</sup> FP compared with BDP and BUD was equally effective in reducing exacerbation and appears to be more effective in improving morning peak flows.<sup>25</sup> Compared with BUD or BDP, FP can be prescribed at half the dose without significant clinical differences.<sup>25</sup> For a single inhaler, FP costs about \$119.99<sup>22</sup> (Table 2).

Mometasone furoate (MF) is the only ICS with once daily dosing. When inhaled, MF has less than 1% bioavailability and no absorption occurs through the digestive tract.<sup>23</sup> Furthermore, MF administered via dry powder inhaler is well tolerated and has similar effects compared to BDP. Comparatively, MF is equally as effective as FP and more efficacious than BDP and BUD.<sup>23</sup> MF costs approximately \$130.99/inhaler<sup>22</sup> (Table 2).

#### **OTHER ALTERNATIVE THERAPIES TO ICS**

Montelukast, an LTRA, is approved for patients 1 year and older. When compared with placebo, montelukast reduced asthma symptoms, but when compared with ICS or systemic steroids, it was not as effective in reducing seasonal asthma symptoms or preventing rescue medication use or unanticipated health care visits.<sup>21</sup> Although about a quarter of patients will have a greater benefit using montelukast, low-dose ICS appears to be more effective.<sup>27</sup> Available in

Step 1: SABA		Step 2 Preferred: SABA + Low-dose ICS		Step 3: SABA + Medium-dose ICS			
Albuterol HFA \$44.99/inhaler	Nebulized \$18.99/box (0.083 mg/3 mL) or \$43.99/box (0.63 mg/3 mL) or \$53.82/box (1.25 mg/3 mL)	Beclomethasone \$113.99/inhaler Budesonide \$121.99/inhaler Fluticasone \$119.99/inhaler Mometasone \$130.99/inhaler		Beclomethasone \$113.99/inhaler Budesonide \$121.99/inhaler Fluticasone \$119.99/inhaler Mometasone \$130.99/inhaler	3		
Step 2 Alternative:   Levalbuterol SABA + LTRA SABA + Low-dose ICS + LTRA							
HFA \$59.99/inhaler	Nebulized \$132.87/box (0.31 mg/3 mL) or \$148.23/box (0.63 mg/3 mL) or \$147.99/box (1.25 mg/3 mL)	lebulized LTRA: Montelukast LTRA: Zafirlu 132.87/box \$169.05/box \$89.99/60 tab (0.31 mg/3 mL) 4-mg granules 10-mg chew or or 148.23/box \$166.91/bottle (0.63 mg/3 mL) 4-mg chewable or 147.99/box		LTRA: Montelukast \$169.05/box 4-mg granules or \$166.91/bottle 4-mg chewable or LTRA: Zafirlukast \$89.99/60 tablets 10-mg chewable			
				<b>SABA</b> + Low of LABA: Formoterol \$175.99/inhaler	lose ICS + LABA LABA: Salmeterol \$180.99/inhaler		

#### Table 2. Cost Comparison of Asthma Medications for Children 5–11 Years Old

SABA = short-acting beta agonist; ICS = inhaled corticosteroids; HFA = hydrofluroalkane; LTRA = leukotriene receptor antagonist; LABA = long-acting beta agonist.

Step 1 Recommendation: Albuterol is the most cost-efficient option in both HFA and nebulized solution.

Step 2 Recommendation: Low-dose beclomethasone is the most cost-efficient option as adjunct treatment to SABA.

Step 3 Recommendation: Medium-dose beclomethasone is the most cost-efficient option as adjunct treatment to SABA.

granules, tablets, or chewables, montelukast costs about \$169.05 for 30 packets of the 4 mg granules.<sup>22</sup> The chewable tablets are slightly less expensive at a cost of about \$166.91 for 30 of the 4 mg dose<sup>22</sup> (Tables 1 and 2).

Another LTRA, zafirlukast, is approved for use in patients ages 5 years and older, has few side effects, and can be a good second-line choice in chronic asthma patients when ICSs are not available or well tolerated. However, long-term use shows some reduction of efficacy and rebound deterioration when the medication is stopped.<sup>28</sup> It is dosed as 10-mg tablets twice daily.<sup>19</sup> For 60 of the 10-mg tablets, zafirlukast costs around \$89.99<sup>22</sup> (Table 2).

Salmeterol and formoterol, LABAs, are used in combination with ICS. Because of risk of near fatal asthma attacks, the Food and Drug Administration (FDA) has advised against the use of LABA in treating mild asthma patients.<sup>29</sup> Despite FDA warning, once daily dosing of low dose FP with LABA is as effective as FP dosed twice daily and more effective than LTRA.<sup>30</sup> Adding an LABA is more effective for most patients than adding an LTRA or increasing to a medium dose inhaler.<sup>27</sup> Combined ICS with LABA (salmeterol/fluticasone, formoterol/budesonide, formoterol/mometasone) are approved only for children 12 years and older.<sup>19</sup> Formoterol costs \$175.99/ inhaler. Salmeterol is slightly more expensive, costing about \$180.99/inhaler<sup>22</sup> (Table 2).

#### **IMPLICATIONS FOR PRACTICE**

With so much at stake for the well-being of a pediatric patient, NPs can be influential in improving asthma outcomes through appropriate prescribing during the management of treatment plans. Optimum asthma control reduces medical costs overall and improves quality of life.<sup>14</sup> In order to keep costs at a minimum for patients, there must be a balance between affordability of medications and avoidance of exacerbations that lead to increased costs associated with hospitalization.

Most commonly, nonadherence to an asthma treatment regimen is a result of the complexity of treatment plans, low patient perception of need for treatment, dosing frequency, cost, and negative side effects.<sup>12</sup> The progression from step 1 to step 2 in a treatment plan includes increasing medication administration frequency from an as-needed basis to 1–4 times daily. As a result, costs associated with asthma treatment increase. Given the monthly cost incurred from ICS, many patients often forego this medication and continue to refill SABAs despite the need for longer-acting medications.<sup>15</sup> Generally speaking, patients who use SABAs alone are more likely to need ED services for acute asthma exacerbations, thus incurring a greater overall expenditure that could be otherwise reduced or prevented.

Practitioners need to encourage open-ended conversations with patients and parents related to compliance. As such, it is also helpful to inform patients and parents of prescription costs before their arrival at the pharmacy.<sup>12</sup> To assist patients in purchasing more expensive medications, NPs can facilitate finding online coupons, prescription assistance programs, and generic options when available.

#### **STEP 1 RECOMMENDATIONS**

Nebulized solutions, such as albuterol and levalbuterol, are equally as effective for patients with intermittent asthma. If there is, indeed, no significant difference in efficacy, safety, or adverse side effects,<sup>21</sup> then age should guide the provider's decision. Because albuterol nebulized solution is appropriate for children 0–11 years old, coupled with the fact that it is also significantly less expensive than leval-buterol, albuterol is the most efficacious option (Table 1). Both albuterol and levalbuterol are also available in an

inhaler form. However, because there is no significant difference between effectiveness, safety, or side effects of these medications, as well as the fact that all these inhalers are appropriate for use in children 4–11 years old, the most cost-effective choice would be albuterol (Tables 1 and 2).

#### **STEP 2 RECOMMENDATIONS**

If asthma symptoms are not controlled with SABAs alone, the patient is most effectively treated with step 2 guidelines. Based upon price alone, BDP (\$113.99/inhaler) is the most inexpensive option for ICS; however, FP, which is only slightly more expensive at \$119.99/inhaler, has more available dosing increments.<sup>22</sup> As such, FP may be the most cost-effective option for patients needing dosing adjustments without changing the medication itself. For patients who have difficulty following multiple daily dosing, MF (\$130.99)<sup>22</sup> may be an option because it is dosed once per day, although patients will pay slightly more for this medication when compared to any other ICS option (Table 2).

If low-dose ICS needs to be avoided, adding an alternative adjunct medication such as an LTRA can be considered. The provider can consider prescribing montelukast for 1–4 year olds and zafirlukast for 5–11 year olds.

#### **STEP 3 RECOMMENDATIONS**

For children 0–4 years old, consultation is required if step 2 asthma is not controlled with the use of a low-dose ICS. For children 5–11 years old, the most cost-effective option is to increase the ICS to a medium-dose range by increasing the number of puffs per day, the frequency, or the dosage. If an increase to a medium-dose ICS is not effective in controlling asthma symptoms, selecting a low-dose ICS with an LTRA or LABA may be helpful. The combined cost of a low-dose ICS with an LTRA (Table 2).

#### **LIMITATIONS**

Pediatric-based research comparing new HFA medications is lacking overall, making it difficult to determine efficacy among different types of inhalers. Also, research often does not identify which type of inhaler was studied, which may affect results. Additionally, because of individualization, differences in severity and response to medications and triggers may affect which medication a child will respond to, necessitating an individualized plan of care. The cost associated with any medication can change over time. Therefore, the medication costs listed in this article may not accurately reflect the costs associated with medications available in individual communities. However, we chose a national online pharmacy (drugstore.com) to collect cost-related information. As a national online pharmacy, drugstore.com is available to all patients regardless of location. A popular electronic medical reference program that also uses drugstore.com for price information, Epocrates, currently has 1.4 million subscribers and is a reference used by approximately 50% of providers.<sup>31</sup>

Finally, although there may be varied and subtle cost differences of asthma medications according to individual location, a review of various retail Web sites revealed that the least costly medication option was always the least costly, regardless of pharmacy.

#### **CONCLUSION**

NPs play a crucial role in assisting pediatric patients and families in asthma treatment adherence. NPs must not only educate patients about the disease but also stay informed of cost-effective treatment options currently on the market and explain these costs to families. As NPs consider the cost associated with asthma treatment, medication compliance may improve, thus decreasing other asthma-associated costs, such as hospitalizations.

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