



Indian Health Service
IHS National Pharmacy and Therapeutics Committee
IHS National Supply Service Center



National Core Formulary Announcement:
Spiriva® (Tiotropium bromide inhalation powder)
September 2011

The IHS National Pharmacy and Therapeutics (NPTC) and the IHS National Supply Service Center (NSSC) would like to announce the addition of *Spiriva® inhalation powder* to the IHS National Core Formulary (NCF).

Background:

Spiriva® is a long-acting, inhaled anticholinergic agent indicated for the long-term, once daily, maintenance treatment of bronchospasm associated with COPD.¹ The NPTC completed a clinical review of the inhaled anticholinergic agents (ipratropium, ipratropium/albuterol combination and tiotropium) used in the treatment of chronic obstructive pulmonary disease (COPD) at its summer meeting, July 2011. At the time of review, the IHS NCF included the following agents for COPD use: Proventil HFA® (albuterol), Atrovent® (ipratropium), Serevent® (salmeterol) and Advair® (salmeterol/fluticasone).² In this meeting, the NPTC recommended the exploration of adding Spiriva to the NCF due to the following findings:

- The guidelines recommend a long-acting bronchodilator for moderate COPD and combining with an ICS for severe COPD.³
- Favorable response with Spiriva® on time to first exacerbation, number of exacerbations and severity of exacerbations, when compared to salmeterol.⁴
- Beneficial effects on lung function with Spiriva® when compared to salmeterol.⁴
- Combinations of long-acting maintenance therapy and short-acting rescue agents can be used in moderate to very severe COPD; recommended to use agents with differing mechanisms.³

In preparation for the July 2011 NPTC meeting, the NSSC underwent a Request for Quotes (RFQ) solicitation for sub-FSS (Federal Supply Schedule) pricing in order to maximize IHS' cost avoidance potential for the selected formulary medications. However, the RFQ was postponed due to pending acquisition regulations and thus the NPTC tabled the decision to the September 2011 meeting. The NSSC completed the RFQ and received sub-FSS pricing for Spiriva® inhalation powder that served as the pricing during the pharmacoeconomic analysis.

At the September 2011 meeting, Spiriva® was found to be an economically feasible addition to the NCF based upon a comparison of the daily average consumption (DACON) for each product.

Based upon the clinical and pharmacoeconomic data presented, the NPTC **ADDED** *Spiriva® inhalation powder* to the IHS NCF.

Procurement Information:

The pricing agreement will be in the form of a long-term temporary price reduction (TPR) that will be effective from 10/1/2011 to 12/31/2012. Continuation beyond 12/31/2012 is fully anticipated and will be negotiated at that time.

Product	Generic Name	NDC	Package Size	McKesson Item #
Spiriva®	Tiotropium Bromide	00597-0075-41	30 count	1771930

Cost Avoidance:

The Indian Health Care System will realize approximately **\$910,000** in annual cost avoidance by naming Spiriva® to the NCF and through the subsequent long-term temporary price reduction.

Note: Information within this document is current as of this writing and should not replace clinical judgment.

If you have any questions regarding the content of this announcement, please contact the NPTC at nptc1@ihs.gov or the NSSC at nssc1@ihs.gov.

References:

1. Spiriva HandiHaler (tiotropium bromide) inhalation powder: package insert. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc. 2010.
2. Indian Health Service National Core Formulary.
<http://www.ihs.gov/MedicalPrograms/NPTC/index.cfm?module=formulary&option=core> accessed June 7, 2011. .
3. Rodriguez-Roisin R AA, Bourbeau J, et al. . Global strategy for the diagnosis, management, and prevention of chronic obstructive pulmonary disease (updated 2010). Global Initiative for Chronic Ostructive Lung Disease. 2010 Dec. <http://goldcopd.org/>; accessed April 25, 2011.
4. Vogelmeier C, Hederer B, Glaab T, et al. Tiotropium versus salmeterol for the prevention of exacerbations of COPD. *N Engl J Med*. Mar 24 2011;364(12):1093-1103.

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