

CMS Is Eyeing Part D Performance Measures

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WASHINGTON — Medicare intends to use performance measures to monitor cost, quality, and access issues related to the new prescription drug benefit, a research analyst said during a meeting of the Medicare Payment Advisory Commission.

But Medicare has not yet “determined what those measures will be and how they will be used,” said MedPAC analyst Cristi-

na Boccuti. The Centers for Medicare and Medicaid Services will be collecting a large amount of data on the new drug benefit—or Medicare Part D—including drug utilization and plan benefit information, to construct these performance measures, Ms. Boccuti said. In addition to the agency’s need for the data, “congressional agencies will need Part D data to report to the Congress on the impact of the drug benefit on cost, quality, and access,” she added.

MedPAC commissioners recommended

that the Health and Human Services department establish a process for the timely delivery of these data to interested parties. Individuals, employers, and government agencies currently use performance measures to evaluate how well health plans and pharmacy benefit managers manage drug benefits, Ms. Boccuti said.

To identify how policy makers could use these measures to monitor the Part D program, MedPAC convened a panel of 11 experts representing health plans, phar-

macy benefits managers (PBMs), employers, pharmacies, consumers, quality assurance organizations, and researchers. The panel analyzed measures such as cost control, access and quality assurance, benefit administration and management, and enrollee satisfaction.

Based on the panel’s findings, CMS plans to collect data on the following:

- ▶ Dispensing fees, generic dispensing rates, aggregate rebates, drug claims, and drug spending by plans and beneficiaries.
- ▶ Pharmacy networks, formularies (including prior authorization and exceptions), appeals rates, and drug utilization.
- ▶ Claims processing, including plans’ out-of-pocket calculations.
- ▶ Beneficiary satisfaction, grievances, call center operations, and disenrollment rates.

Measures to track beneficiary satisfaction—such as member satisfaction surveys and performance of customer service call centers—are common types of per-

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formance guarantees that health plans and PBMs offer to their clients, she said. CMS plans to conduct its own consumer satisfaction surveys to provide comparative plan

information to beneficiaries for making enrollment decisions. Also, plans will submit data on grievances filed, and call center performance measures such as abandonment rates and hold times.

MedPAC commissioner Nancy-Ann DeParle, a health care consultant in Washington and former head of CMS’ predecessor agency (the Health Care Financing Administration), asked whether CMS would be looking at these data at a physician level, in terms of who did the prescribing. “In our pay-for-performance discussions around physicians, [MedPAC indicated that] it would be useful to have this.” Ms. Boccuti noted that there is a prescriber code associated with each drug.

On the issue of collecting cost data, Ms. DeParle said that she wondered whether CMS would be able to assess whether particular plans were getting a “good deal” on the drugs they purchased. “Will they know by drug?” she asked. The agency will be collecting data on actual drugs and the spending associated with those drugs, “so there will be the ability to track how much was paid at the point of sale,” she said. ■



SPIRIVA® HandiHaler® (tiotropium bromide inhalation powder)

For Oral Inhalation Only
Brief Summary of Prescribing Information

INDICATIONS AND USAGE

SPIRIVA HandiHaler is indicated for the long-term, once-daily, maintenance treatment of bronchospasm associated with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and emphysema.

CONTRAINDICATIONS

SPIRIVA HandiHaler is contraindicated in patients with a history of hypersensitivity to atropine or its derivatives, including ipratropium, or to any component of this product.

WARNINGS

SPIRIVA HandiHaler is intended as a once-daily maintenance treatment for COPD and is not indicated for the initial treatment of acute episodes of bronchospasm, i.e., rescue therapy.

Immediate hypersensitivity reactions, including angioedema, may occur after administration of SPIRIVA. If such a reaction occurs, therapy with SPIRIVA should be stopped at once and alternative treatments should be considered.

Inhaled medicines, including SPIRIVA, may cause paradoxical bronchospasm. If this occurs, treatment with SPIRIVA should be stopped and other treatments considered.

PRECAUTIONS

General

As an anticholinergic drug, SPIRIVA may potentially worsen symptoms and signs associated with narrow-angle glaucoma, prostatic hyperplasia or bladder-neck obstruction and should be used with caution in patients with any of these conditions.

As a predominantly renally excreted drug, patients with moderate to severe renal impairment (creatinine clearance of ≤ 50 mL/min) treated with SPIRIVA should be monitored closely.

Information for Patients

It is important for patients to understand how to correctly administer SPIRIVA capsules using the HandiHaler inhalation device. SPIRIVA capsules should only be administered via the HandiHaler device and the HandiHaler device should not be used for administering other medications.

Capsules should always be stored in sealed blisters and only removed immediately before use. The blister strip should be carefully opened to expose only one capsule at a time. Open the blister foil as far as the STOP line to remove only one capsule at a time. The drug should be used immediately after the packaging over an individual capsule is opened, or else its effectiveness may be reduced. Capsules that are inadvertently exposed to air (i.e., not intended for immediate use) should be discarded.

Eye pain or discomfort, blurred vision, visual halos or colored images in association with red eyes from conjunctival congestion and corneal edema may be signs of acute narrow-angle glaucoma. Should any of these signs and symptoms develop, consult a physician immediately. Miotic eye drops alone are not considered to be effective treatment.

Care must be taken not to allow the powder to enter into the eyes as this may cause blurring of vision and pupil dilation.

SPIRIVA HandiHaler is a once-daily maintenance bronchodilator and should not be used for immediate relief of breathing problems, i.e., as a rescue medication.

Drug Interactions

SPIRIVA has been used concomitantly with other drugs commonly used in COPD without increases in adverse drug reactions. These include sympathomimetic bronchodilators, methylxanthines, and oral and inhaled steroids. However, the co-administration of SPIRIVA with other anticholinergic-containing drugs (e.g., ipratropium) has not been studied and is therefore not recommended.

Drug/Laboratory Test Interactions

None known.

Carcinogenesis, Mutagenesis, Impairment of Fertility

No evidence of tumorigenicity was observed in a 104-week inhalation study in rats at tiotropium doses up to 0.059 mg/kg/day, in an 83-week inhalation study in female mice at doses up to 0.145 mg/kg/day, and in a 101-week inhalation study in male mice at doses up to 0.002 mg/kg/day. These doses correspond to 25, 35, and 0.5 times the Recommended Human Daily Dose (RHDD) on a mg/m² basis, respectively. These dose multiples may be overestimated due to difficulties in measuring deposited doses in animal inhalation studies.

Tiotropium bromide demonstrated no evidence of mutagenicity or clastogenicity in the following assays: the bacterial gene mutation assay, the V79 Chinese hamster cell mutagenicity assay, the chromosomal aberration assays in human lymphocytes *in vitro* and mouse micronucleus formation *in vivo*, and the unscheduled DNA synthesis in primary rat hepatocytes *in vitro* assay.

In rats, decreases in the number of corpora lutea and the percentage of implants were noted at inhalation tiotropium doses of 0.078 mg/kg/day or greater (approximately 35 times the RHDD on a mg/m² basis). No such effects were observed at 0.009 mg/kg/day (approximately 4 times the RHDD on a mg/m² basis). The fertility index, however, was not affected at inhalation doses up to 1.689 mg/kg/day (approximately 760 times the RHDD on a mg/m² basis). These dose multiples may be overestimated due to difficulties in measuring deposited doses in animal inhalation studies.

Pregnancy

Pregnancy Category C

No evidence of structural alterations was observed in rats and rabbits at inhalation tiotropium doses of up to 1.471 and 0.007 mg/kg/day, respectively. These doses correspond to approximately 660 and 6 times the recommended human daily dose (RHDD) on a mg/m² basis. However, in rats, fetal resorption, litter loss, decreases in the number of live pups at birth and the mean pup weights, and a delay in pup sexual maturation were observed at inhalation tiotropium doses of ≥ 0.078 mg/kg (approximately 35 times the RHDD on a mg/m² basis). In rabbits, an increase in post-implantation loss was observed at an inhalation dose of 0.4 mg/kg/day (approximately 360 times the RHDD on a mg/m² basis). Such effects were not observed at inhalation doses of 0.009 and up to 0.088 mg/kg/day in rats and rabbits, respectively. These doses correspond to approximately 4 and 80 times the RHDD on a mg/m² basis, respectively. These dose multiples may be overestimated due to difficulties in measuring deposited doses in animal inhalation studies.

There are no adequate and well-controlled studies in pregnant women. SPIRIVA should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Use in Labor and Delivery

The safety and effectiveness of SPIRIVA has not been studied during labor and delivery.

Nursing Mothers

Clinical data from nursing women exposed to tiotropium are not available. Based on lactating rodent studies, tiotropium is excreted into breast milk. It is not known whether tiotropium is excreted in human milk, but because many drugs are excreted in human milk and given these findings in rats, caution should be exercised if SPIRIVA is administered to a nursing woman.

Pediatric Use

SPIRIVA HandiHaler is approved for use in the maintenance treatment of bronchospasm associated with chronic obstructive pulmonary disease, including chronic bronchitis and emphysema. This disease does not normally occur in children. The safety and effectiveness of SPIRIVA in pediatric patients have not been established.

Geriatric Use

Of the total number of patients who received SPIRIVA in the 1-year clinical trials, 426 were < 65 years, 375 were 65-74 years and 105 were ≥ 75 years of age. Within each age subgroup, there were no differences between the proportion of patients with adverse events in the SPIRIVA and the comparator groups for most events. Dry mouth increased with age in the SPIRIVA group (differences from placebo were 9.0%, 17.1%, and 16.2% in the aforementioned age subgroups). A higher frequency of constipation and urinary tract infections with increasing age was observed in the SPIRIVA group in the placebo-controlled studies. The differences from placebo for constipation were 0%, 1.8%, and 7.8% for each of the age groups. The differences from placebo for urinary tract infections were -0.6%, 4.6% and 4.5%. No overall differences in effectiveness were observed among these groups. Based on available data, no adjustment of SPIRIVA dosage in geriatric patients is warranted.

ADVERSE REACTIONS

Of the 2,663 patients in the four 1-year and two 6-month controlled clinical trials, 1,308 were treated with SPIRIVA at the recommended dose of 18 mcg once a day. Patients with narrow angle glaucoma, or symptomatic prostatic hypertrophy or bladder outlet obstruction were excluded from these trials.

The most commonly reported adverse drug reaction was dry mouth. Dry mouth was usually mild and often resolved during continued treatment. Other reactions reported in individual patients and consistent with possible anticholinergic effects included constipation, increased heart rate, blurred vision, glaucoma, urinary difficulty, and urinary retention.

Four multicenter, 1-year, controlled studies evaluated SPIRIVA in patients with COPD. Table 1 shows all adverse events that occurred with a frequency of $\geq 3\%$ in the SPIRIVA group in the 1-year placebo-controlled trials where the rates in the SPIRIVA group exceeded placebo by $\geq 1\%$. The frequency of corresponding events in the ipratropium-controlled trials is included for comparison.

Table 1. Adverse Experience Incidence (% Patients) in One-Year-COPD Clinical Trials

Body System (Event)	Placebo-Controlled Trials SPIRIVA (n=550)	Placebo (n=371)	Ipratropium-Controlled Trials SPIRIVA (n=356)	Ipratropium (n=179)
Body as a Whole				
Accidents	13	11	5	8
Chest Pain (non-specific)	7	5	5	2
Edema, Dependent	5	4	3	5
Gastrointestinal System Disorders				
Abdominal Pain	5	3	6	6
Constipation	4	2	1	1
Dry Mouth	16	3	12	6
Dyspepsia	6	5	1	1
Vomiting	4	2	1	2
Musculoskeletal System				
Myalgia	4	3	4	3
Resistance Mechanism Disorders				
Infection	4	3	1	3
Moniliasis	4	2	3	2
Respiratory System (upper)				
Epistaxis	4	2	1	1
Pharyngitis	9	7	7	3
Rhinitis	6	5	3	2
Sinusitis	11	9	3	2
Upper Respiratory Tract Infection	41	37	43	35
Skin and Appendage Disorders				
Rash	4	2	2	2
Urinary System				
Urinary Tract Infection	7	5	4	2

Arthritis, coughing, and influenza-like symptoms occurred at a rate of $\geq 3\%$ in the SPIRIVA treatment group, but were $< 1\%$ in excess of the placebo group.

Other events that occurred in the SPIRIVA group at a frequency of 1-3% in the placebo-controlled trials where the rates exceeded that in the placebo group include: *Body as a Whole*: allergic reaction, leg pain; *Central and Peripheral Nervous System*: dysphonia, paresthesia; *Gastrointestinal System Disorders*: gastrointestinal disorder not otherwise specified (NOS), gastroesophageal reflux, stomatitis (including ulcerative stomatitis); *Metabolic and Nutritional Disorders*: hypercholesterolemia, hyperglycemia; *Musculoskeletal System Disorders*: skeletal pain; *Cardiac Events*: angina pectoris (including aggravated angina pectoris); *Psychiatric Disorder*: depression; *Infections*: herpes zoster; *Respiratory System Disorder (Upper)*: laryngitis; *Vision Disorder*: cataract. In addition, among the adverse events observed in the clinical trials with an incidence of $< 1\%$ were atrial fibrillation, supraventricular tachycardia, angioedema, and urinary retention.

In the 1-year trials, the incidence of dry mouth, constipation, and urinary tract infection increased with age. Two multicenter, 6-month, controlled studies evaluated SPIRIVA in patients with COPD. The adverse events and the incidence rates were similar to those seen in the 1-year controlled trials.

In addition to adverse events identified during clinical trials, the following adverse reactions have been reported in the worldwide post-marketing experience: epistaxis, palpitations, pruritus, and urticaria.

DOSAGE AND ADMINISTRATION

The recommended dosage of SPIRIVA HandiHaler is the inhalation of the contents of one SPIRIVA capsule, once-daily, with the HandiHaler inhalation device.

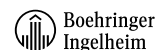
No dosage adjustment is required for geriatric, hepatically-impaired, or renally-impaired patients. However, patients with moderate to severe renal impairment given SPIRIVA should be monitored closely. SPIRIVA capsules are for inhalation only and must not be swallowed.

HOW SUPPLIED

The following packages are available:
carton containing 6 SPIRIVA capsules (1 blister card) and 1 HandiHaler inhalation device (NDC 0597-0075-06)
carton containing 30 SPIRIVA capsules (5 blister cards) and 1 HandiHaler inhalation device (NDC 0597-0075-37)

Rx only

59873/US/2 September 2004



Helping Seniors Navigate Medicare

A one-stop Web site offers older adults a host of user-friendly consumer health information. The site is sponsored by the nonprofit Medicare Rights Center and provides state and national information on how to get the most out of Medicare.

For more information, visit www.medicareinteractive.org/horizonhelp.