BI Respiratory Diseases Portfolio Prior Authorization Resources and Sample Forms

Dear Healthcare Professional,

The collection of resources in this document has been assembled to facilitate the prior authorization (PA) process that may be required by the health plans of some of your patients. On the following pages, you will find:

- PA Tips (page 2)
- PA Checklist (page 3)
- Sample Letters of Medical Necessity (pages 4-6)
- Appeal Tips (page 7)
- Appeal Checklist (page 8)

Although care has been taken to include a variety of background details in these resources, Boehringer Ingelheim offers no guarantee that the use of this information will result in successful submissions. Specific scenarios that you may encounter can vary considerably between patients and health plans, which can alter the PA outcome. These resources are examples only, and plan-specific forms must be submitted to complete the PA.

STIOLTO® RESPIMAT® (tiotropium bromide & olodaterol) INHALATION SPRAY

INDICATION for STIOLTO RESPIMAT

STIOLTO® RESPIMAT® (tiotropium bromide and olodaterol) Inhalation Spray is a combination of tiotropium, an anticholinergic, and olodaterol, a long-acting beta$_2$-adrenergic agonist (LABA), indicated for the long-term, once-daily maintenance treatment of patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and/or emphysema.

Important Limitations of Use

STIOLTO is NOT indicated to treat acute deterioration of COPD and is not indicated to treat asthma.

IMPORTANT SAFETY INFORMATION for STIOLTO RESPIMAT

CONTRAINDICATION

Use of a LABA, including STIOLTO RESPIMAT, without an inhaled corticosteroid (ICS) is contraindicated in patients with asthma.

STIOLTO is contraindicated in patients with hypersensitivity to tiotropium, ipratropium (atropine derivatives), olodaterol, or any component of this product.

In clinical trials and postmarketing experience with tiotropium, immediate hypersensitivity reactions, including angioedema (including swelling of the lips, tongue, or throat), itching, or rash have been reported. Hypersensitivity reactions were also reported in clinical trials with STIOLTO.

SPIRIVA® RESPIMAT® (tiotropium bromide) INHALATION SPRAY 2.5 mcg/puff

SPIRIVA® RESPIMAT® (tiotropium bromide) INHALATION SPRAY 1.25 mcg/puff

INDICATION for SPIRIVA RESPIMAT

SPIRIVA® RESPIMAT®, 2.5 mcg, is indicated for the long-term, once-daily, maintenance treatment of bronchospasm associated with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and emphysema, and for reducing COPD exacerbations.

SPIRIVA RESPIMAT, 1.25 mcg, is a bronchodilator indicated for the long-term, once-daily, maintenance treatment of asthma in patients 6 years of age and older.

SPIRIVA RESPIMAT is not indicated for relief of acute bronchospasm.

IMPORTANT SAFETY INFORMATION for SPIRIVA RESPIMAT

SPIRIVA RESPIMAT (tiotropium bromide) Inhalation Spray is contraindicated in patients with a hypersensitivity to tiotropium, ipratropium, or any component of this product. Immediate hypersensitivity reactions, including angioedema (including swelling of the lips, tongue, or throat), itching, or rash have been reported.

SPIRIVA RESPIMAT is intended as a once-daily maintenance treatment for COPD and asthma, and should not be used for the relief of acute symptoms, i.e., as rescue therapy for the treatment of acute episodes of bronchospasm. In the event of an attack, a rapid-acting beta2-agonist should be used.

Please see complete Important Safety Information for STIOLTO RESPIMAT on page 9 and and accompanying full Prescribing Information, Patient Information, and Instructions for Use for STIOLTO RESPIMAT. Please see additional Important Safety Information for SPIRIVA RESPIMAT on page 10 and accompanying full Prescribing Information for SPIRIVA RESPIMAT, including Instructions for Use.

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PRIOR AUTHORIZATION TIPS

TIPS FOR HANDLING PA REQUIREMENTS FROM HEALTH PLANS

PA requirements may vary depending on the patient's particular health plan and benefit design. Additional documentation may be required beyond what is listed below. If you have any questions that are not addressed here, contact the health plan directly.

IDENTIFY SPECIFIC CRITERIA OF THE HEALTH PLAN

- Plan-specific guidelines and requirements for treatment authorization must be completed

PROVIDE APPROPRIATE IDENTIFICATION NUMBERS

- The individual provider identification (ID) number should be used, rather than the group practice or facility provider number
- The patient's specific ID number can be obtained from his or her insurance card
- The correct ICD-10-CM codes that identify the patient's diagnosis should be used*
  - **Sample ICD-10-CM codes for COPD** may include: J40 (bronchitis, not specified as acute or chronic), J41 (simple and mucopurulent chronic bronchitis), J42 (unspecified chronic bronchitis), and J43 (emphysema)
  - **Sample ICD-10-CM codes for asthma** may include: J45 (asthma), and J45.21 (mild persistent asthma with acute exacerbation)

INCLUDE REQUIRED SUPPORTING DOCUMENTS

- If applicable, supporting documents requested for the PA should be submitted. An example of supporting documentation includes any associated laboratory testing
- Photocopies of the front and back of the patient's insurance card should be submitted

DETERMINE INCLUSION OF STATEMENT OF MEDICAL NECESSITY

- A statement of medical necessity may need to be included or resubmitted. This type of form is usually valid for 12 months, but plan-specific guidelines should be verified

MONITOR SUBMISSION DEADLINES

- Deadlines and overall timing of PA submissions can vary and should be followed

VERIFY PROCESS FLOW

- If the patient's plan does not respond with a decision after a standard business week, verify with the appropriate contact method (phone or email)

MAINTAIN A LOG OF ACTIVITY

- Everything submitted for the PA should be copied and stored. All communications with the plan should be logged or saved, along with the identity of the individual speaking on behalf of the plan

*These codes are presented for background information only. The appropriate codes that apply to each patient's diagnosis must be verified and submitted by the healthcare provider. Code inclusion here is not a guarantee of reimbursement or PA approval. ICD-10-CM codes have subclassifications that may apply to the specific disease state of a patient.

PRIOR AUTHORIZATION CHECKLIST

PA CHECKLIST

The PA checklist below should be used as a general guideline and cross referenced with the official requirements from the patient's insurer website, if available.

The following should generally be submitted as part of the PA process:

- ☐ Contact information for the sender and recipient, such as fax number or email address
- ☐ Completed prescription forms
- ☐ Front and back photocopies of the patient's insurance and/or prescription card, with all appropriate membership numbers visible
- ☐ Additional documentation, as required
  - ☐ Plan-specific PA form
  - ☐ The patient's history, physical findings, and diagnosis
  - ☐ Appropriate test results, which may include:
    - Spirometry
    - CT scan
    - Peak inspiratory flow rate based on In-Check™ Dial G16
  - ☐ Notes from the patient's chart
  - ☐ Hospital or emergency room notes, if applicable
  - ☐ Patient's authorization and notice of release of information

Confirm that the plan has received the submitted documents and verify information if any of the requirements are not clear.

Sample Letter of Medical Necessity for STIOLTO RESPIMAT

PLEASE NOTE: The following is a sample letter of medical necessity, which may be required by the patient's plan. Use your organization's letterhead and modify any content from this example as appropriate for your patient and his or her health plan. Consider including the suggested supporting documentation at the bottom of the sample.

[DATE]
[NAME OF HEALTH PLAN]
[NAME OF HEALTH PLAN CONTACT]
[HEALTH PLAN MAILING ADDRESS]

Patient: [FULL PATIENT NAME]
Subscriber ID: [#XXXXXXXX]
Subscriber Group ID: [#XXXXXXXX]
RE: Authorization for STIOLTO® RESPIMAT® (tiotropium bromide and olodaterol) Inhalation Spray

Dear Sir or Madam,

I am writing to you as the treating physician to demonstrate medical necessity to obtain authorization for STIOLTO RESPIMAT on behalf of my patient, [PATIENT NAME], who has chronic obstructive pulmonary disease (COPD). Please find included the prescribing information, which supports the use of STIOLTO RESPIMAT for COPD, as approved by the US Food and Drug Administration (FDA) on May 21, 2015. The approval was based on two pivotal, phase 3 trials that demonstrated statistically significant improvements in lung function (FEV_1) over tiotropium and olodaterol alone.

[Rationale for treatment: Include a brief description of the patient's disease state, prior treatments, and responses to those treatments, as well as a additional factors that may contribute to this issues such as age, overall health, and other factors that impact your treatment decision. The following information may be mentioned:

- GOLD 2019* recognized the role of inhaler selection as part of the assessment and adjustments recommendations for management of all COPD patients
- [Patient Name] has compromised lung function and may benefit from STIOLTO RESPIMAT. The RESPIMAT Inhaler is a slow mist inhaler that delivers medicine independent of inspiratory effort

If available, include appropriate lab values such as FEV_1 or CT scans.]

STIOLTO RESPIMAT is an inhalable therapy approved as a long-term, once-daily maintenance treatment of patients with COPD. Stiolto is not indicated to treat acute deterioration of COPD or to treat asthma. In my clinical judgment, [PATIENT NAME] is an excellent candidate for this COPD treatment and has been told about the benefits and risks of STIOLTO RESPIMAT.

To summarize, my patient, [PATIENT NAME], has COPD, which is a serious, but treatable, lung disease, and I am requesting approval for treatment with STIOLTO RESPIMAT. The goal of therapy is to improve lung function (FEV_1), which STIOLTO RESPIMAT has been shown to do consistently in clinical trials. Thank for your attention to and consideration of my request for the approval of STIOLTO to treat my patient for COPD.

Sincerely,
[PHYSICIAN NAME]

Included supporting documents [SUGGESTED]:

- STIOLTO RESPIMAT FDA approval letter and prescribing information
- STIOLTO RESPIMAT published clinical studies (phase 3 TONADO® 1 and 2 trials, DYNAGITO trial)
- Clinical and diagnostic records, laboratory results, and imaging scans within the last 6 months (unless noted as older)
- Patient authorization and notice of release of information

*Global Initiative for Chronic Obstructive Lung Disease. 2019 Report. www.goldcopd.org.

Sample Letter of Medical Necessity for SPIRIVA RESPIMAT for COPD

PLEASE NOTE: The following is a sample letter of medical necessity, which may be required by the patient's plan. Use your organization's letterhead and modify any content from this example as appropriate for your patient and his or her health plan. Consider including the suggested supporting documentation at the bottom of the sample.

[DATE]
[NAME OF HEALTH PLAN]
[NAME OF HEALTH PLAN CONTACT]
[HEALTH PLAN MAILING ADDRESS]

Patient: [FULL PATIENT NAME]
Subscriber ID: [#XXXXXXXX]
Subscriber Group ID: [#XXXXXXXX]
RE: Authorization for SPIRIVA® RESPIMAT® (tiotropium bromide) Inhalation Spray 2.5 MG

Dear Sir or Madam,

I am writing to you as the treating physician to demonstrate medical necessity to obtain authorization for SPIRIVA RESPIMAT (tiotropium bromide) Inhalation Spray on behalf of my patient, [PATIENT NAME], who has chronic obstructive pulmonary disease (COPD). Please find included the prescribing information, which supports the use of SPIRIVA RESPIMAT for COPD, as approved by the US Food and Drug Administration (FDA) in September 2014. SPIRIVA RESPIMAT is the only once-daily long-acting antimuscarinic agent in a slow moving mist indicated to reduce the risk of exacerbations and shown to reduce exacerbation-related hospitalizations.

The SPIRIVA RESPIMAT clinical development program included 10 placebo-controlled clinical trials in COPD. These trials included 6565 adult COPD patients (75% males and 25% females) 40 years of age and older. One of these trials, TIOSPIR™, is one of the largest clinical trials conducted in patients with COPD.

[Rationale for treatment: Include a brief description of the patient's disease state, prior treatments, and responses to those treatments, as well as additional factors that may contribute to this issue, such as age, overall health, and other factors that impact your treatment decision. The following information may be mentioned:

- GOLD 2019* recognized the role of inhaler selection as part of the assessment and adjustments recommendations for management of all COPD patients
- [Patient Name] has compromised lung function and may benefit from SPIRIVA RESPIMAT. The RESPIMAT Inhaler is a slow mist inhaler that delivers medication independent of inspiratory effort

If available, include appropriate lab values such as FEV_1 or CT scans.]

SPIRIVA RESPIMAT is an inhalable therapy approved as a long-term, once-daily, maintenance treatment of bronchospasm associated with COPD, including chronic bronchitis and emphysema, and for reducing COPD exacerbations. SPIRIVA RESPIMAT is not indicated for relief of acute bronchospasm. In my clinical judgment, [PATIENT NAME] is an excellent candidate for this COPD treatment and has been told about the benefits and risks of SPIRIVA RESPIMAT.

To summarize, my patient, [PATIENT NAME], has COPD, which is a serious, but treatable, lung disease, and I am requesting approval for treatment with SPIRIVA RESPIMAT. The goal of therapy is to improve lung function (FEV_1), which SPIRIVA RESPIMAT has been shown to do consistently in clinical trials. Thank for your attention to and consideration of my request for the approval of SPIRIVA RESPIMAT to treat my patient for COPD.

Sincerely,
[PHYSICIAN NAME]

Included supporting documents [SUGGESTED]:

- SPIRIVA RESPIMAT FDA approval letter and prescribing information
- SPIRIVA RESPIMAT published clinical studies (TIOSPIR™ results)
- Clinical and diagnostic records, laboratory results, and imaging scans within the last 6 months (unless noted as older)
- Patient authorization and notice of release of information

*Global Initiative for Chronic Obstructive Lung Disease. 2019 Report. www.goldcopd.org.

Sample Letter of Medical Necessity for SPIRIVA RESPIMAT 1.25 MG for Asthma

PLEASE NOTE: The following is a sample letter of medical necessity, which may be required by the patient's plan. Use your organization's letterhead and modify any content from this example as appropriate for your patient and his or her health plan. Consider including the suggested supporting documentation at the bottom of the sample.

[DATE]
[NAME OF HEALTH PLAN]
[NAME OF HEALTH PLAN CONTACT]
[HEALTH PLAN MAILING ADDRESS]

Patient: [FULL PATIENT NAME]
Subscriber ID: [#XXXXXXXX]
Subscriber Group ID: [#XXXXXXXX]
RE: Authorization for SPIRIVA RESPIMAT (tiotropium bromide) Inhalation Spray

Dear Sir or Madam,

I am writing to you as the treating physician to demonstrate medical necessity to obtain authorization for SPIRIVA RESPIMAT (tiotropium bromide) Inhalation Spray on behalf of my patient, [PATIENT NAME], who has asthma. Please find included the prescribing information, which supports the use of SPIRIVA RESPIMAT for long-term, once-daily maintenance treatment of asthma in patients 6 years and older, as approved by the US Food and Drug Administration (FDA) in February 2017. SPIRIVA RESPIMAT is the only long-acting muscarinic antagonist (LAMA) approved for use in patients aged 6 years and older with asthma. Other LAMA agents on formulary do not have FDA approval in asthma.

This FDA approval was based on efficacy and safety data from the clinical trials of almost 4,500 children and adults with asthma.

[Rationale for treatment: Include a brief description of the patient's disease state, prior treatments, and responses to those treatments, as well as a additional factors that may contribute to this issues such as age, overall health, and other factors that impact your treatment decision.

If available, include appropriate lab values such as FEV_1 or CT scans.]

SPIRIVA RESPIMAT is an inhalable therapy approved for the long-term, once-daily, maintenance treatment of asthma in patients 6 years of age and older. SPIRIVA RESPIMAT is not indicated for relief of acute bronchospasm. In my clinical judgment, [PATIENT NAME] is an excellent candidate for this asthma treatment and has been told about the benefits and risks of SPIRIVA RESPIMAT.

To summarize, my patient, [PATIENT NAME], has asthma, which is a serious, but treatable, lung disease, and I am requesting approval for treatment with SPIRIVA RESPIMAT. The goal of therapy is to improve lung function (FEV_1), which SPIRIVA RESPIMAT has been shown to do consistently in clinical trials. Thank for your attention to and consideration of my request for the approval of SPIRIVA RESPIMAT to treat my patient for asthma.

Sincerely,
[PHYSICIAN NAME]

Included supporting documents [SUGGESTED]:

- SPIRIVA RESPIMAT FDA approval letter and prescribing information
- UniTinA-asthma® clinical studies did not investigator Spiriva Respimat as monotherapy for asthma
- Clinical and diagnostic records, laboratory results, and imaging scans within the last 6 months (unless noted as older)
- Patient authorization and notice of release of information

APPEAL TIPS

TIPS FOR COMPLETING AN APPEAL OF TREATMENT DENIAL

These tips can be used as a reference for handling the most common denial issues. Keep in mind that the reason for denial may vary by plan, and the original denial document provided by the plan should be used as the primary point of reference for your response.

RECORD THE REASON FOR THE DENIAL

- Determine, in writing, what the reason for denial was. This should generally be explained in the denial letter from the health plan or in the explanation of benefits letter. If neither of these was received, they can be obtained from the insurer through the standard communication route (phone or email)

REVIEW THE APPEAL GUIDELINES

- A number of variables should be kept in mind for the appeal process, such as:
  - The deadline for the appeal
  - Fax number or mailing address where the letter should be sent
  - Number of appeals permitted
  - Required origin of appeal letter (from the patient or the physician)
- Keep in mind that some insurers have narrow windows of time during which an appeal may be filed, so prompt action is advised

GET IN TOUCH WITH THE REVIEW DEPARTMENT

- If you need additional clarification, you will likely find a telephone number for the review department in the denial letter. The reviewer may even agree with the treatment rationale during a telephone conversation, making a written appeal unnecessary

FORMULATE A WRITTEN APPEAL AND SUBMIT SUPPORTING DOCUMENTATION

- Most insurers require a written appeal either from the patient or physician. The written appeal is typically sent as a package and includes a letter plus any pertinent supporting documentation
- The appropriate medical documentation included in the written appeals package, such as clinical notes and related test results, may help support the case for coverage. The most recent, up-to-date information should be included in relation to the patient's case

VERIFY DETAILS OF PATIENT'S INSURER

- Some factors to consider in regard to the insurance include:
  - The type of insurance the patient has
  - The status of coverage for the treatment requested
  - State laws that may influence the treatment decision
- The patient may be asked to verify the details of the plan to see whether the treatment is covered. An independent external review may be an option, depending on the state in which the patient is located

CONFIRM THE STATUS OF THE SUBMISSION

- If no response has been received with 2 months of submission of the appeal package, contact the health plan to confirm it was received

BACK UP ALL DOCUMENTS

- Keep copies of all documents submitted with the patient's appeal, as well as all responses from the patient's plan. Include the contact information of the individual speaking on behalf of the plan

APPEAL CHECKLIST

The checklist below shows examples of supporting documents that may be needed as part of the appeal package. The criteria for document inclusion may vary between plans, so verification of the specific documents required, as listed in the denial letter or the insurer's overall requirements, is important.

COMMONLY REQUESTED DOCUMENTS

- ☐ Statement of medical necessity
- ☐ Patient authorization and notice of release of information
- ☐ Front and back photocopies of the patient's health plan and/or prescription card
- ☐ Denial letter and/or explanation of benefits
- ☐ Letter of appeal
- ☐ Supporting documentation
    - ☐ STIOLTO® RESPIMAT® (tiotropium bromide and olodaterol) Inhalation Spray
        - ☐ FDA approval letter and prescribing information
        - ☐ Published clinical studies (phase 3 TONADO® 1 and 2 trials, DYNAGITO trial)
    - ☐ SPIRIVA® RESPIMAT® (tiotropium bromide) Inhalation Spray 2.5 mcg/puff
        - ☐ FDA approval letter and prescribing information
        - ☐ Published clinical studies (TIOSPIR™ trial)
    - ☐ SPIRIVA® RESPIMAT® (tiotropium bromide) Inhalation Spray 1.25 mcg/puff
        - ☐ FDA approval letter and prescribing information
        - ☐ Published clinical studies (UniTinA-asthma® Program)
- ☐ Clinical and diagnostic records, laboratory reports, and imaging scans within the last 6 months (unless noted as older)
- ☐ Pulmonary function testing that verifies diagnosis (FEV_1)

STIOLTO® RESPIMAT®
(tiotropium bromide & olodaterol)
INHALATION SPRAY

STIOLTO RESPIMAT
IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS

LABA as monotherapy (without an ICS), for asthma increases the risk of asthma-related death, and in pediatric and adolescent patients, increases the risk of asthma-related hospitalizations.

Do not initiate STIOLTO in patients with acutely deteriorating COPD, which may be a life-threatening condition, or used as rescue therapy for acute symptoms. Acute symptoms should be treated with an inhaled short-acting beta2-agonist.

STIOLTO should not be used more often or at higher doses than recommended, or with other LABAs as an overdose may result.

If immediate hypersensitivity reactions occur, such as urticaria, angioedema, rash, bronchospasm, anaphylaxis, or itching, discontinue STIOLTO at once and consider alternative treatment. Patients with a history of hypersensitivity reactions to atropine or its derivatives should be closely monitored for similar hypersensitivity reactions to STIOLTO.

If paradoxical bronchospasm occurs, discontinue STIOLTO immediately and institute alternative therapy.

STIOLTO can produce a clinically significant cardiovascular effect in some patients, as measured by increases in pulse rate, systolic or diastolic blood pressure, and/or symptoms. If such effects occur, STIOLTO may need to be discontinued.

Use caution in patients with convulsive disorders, thyrotoxicosis, diabetes mellitus, ketoacidosis, in patients with known or suspected prolongation of the QT interval, and in patients who are unusually responsive to sympathomimetic amines.

Use with caution in patients with narrow-angle glaucoma. Instruct patients to contact a physician immediately if signs or symptoms of acute narrow-angle glaucoma develop.

Use with caution in patients with urinary retention especially in patients with prostatic hyperplasia or bladder-neck obstruction. Instruct patients to consult a physician immediately should any of these signs or symptoms develop.

Patients with moderate to severe renal impairment (creatinine clearance of <60 mL/min) should be monitored closely for anticholinergic side effects.

Be alert to hypokalemia and hyperglycemia.

ADVERSE REACTIONS

The most common adverse reactions with STIOLTO (>3% incidence and higher than an active control) were: nasopharyngitis, 12.4% (11.7%/12.6%), cough, 3.9% (4.4%/3.0%), and back pain, 3.6% (1.8%/3.4%).

DRUG INTERACTIONS

- Use caution if administering adrenergic drugs because sympathetic effects of olodaterol may be potentiated.
- Concomitant treatment with xanthine derivatives, steroids, or diuretics may potentiate any hypokalemic effect of olodaterol.
- Use with caution in patients taking non–potassium-sparing diuretics, as the ECG changes and/or hypokalemia may worsen with concomitant beta-agonists.
- The action of adrenergic agents on the cardiovascular system may be potentiated by monoamine oxidase inhibitors or tricyclic antidepressants or other drugs known to prolong the QTc interval. Therefore, STIOLTO should be used with extreme caution in patients being treated with these drugs. Use beta-blockers with caution as they not only block the therapeutic effects of beta-agonists, but may produce severe bronchospasm in patients with COPD.
- Avoid co-administration of STIOLTO with other anticholinergic-containing drugs as this may lead to an increase in anticholinergic adverse effects.

STIOLTO is for oral inhalation only.

The STIOLTO cartridge is only intended for use with the STIOLTO RESPIMAT inhaler.

Inform patients not to spray STIOLTO into the eyes as this may cause blurring of vision and pupil dilation.

CL-STO-10002 6.5.2019

Please see accompanying full Prescribing Information, Patient Information, and Instructions for Use for STIOLTO RESPIMAT.

SPIRIVA RESPIMAT
IMPORTANT SAFETY INFORMATION (continued)

Immediate hypersensitivity reactions, including urticaria, angioedema (including swelling of the lips, tongue, or throat), rash, bronchospasm, anaphylaxis, or itching may occur after administration of SPIRIVA RESPIMAT. If such a reaction occurs, discontinue SPIRIVA RESPIMAT at once and consider alternative treatments. Given the similar structural formula of atropine to tiotropium, patients with a history of hypersensitivity reactions to atropine or its derivatives should be closely monitored for similar hypersensitivity reactions to SPIRIVA RESPIMAT.

Inhaled medicines, including SPIRIVA RESPIMAT, may cause paradoxical bronchospasm. If this occurs, it should be treated with an inhaled short-acting beta2-agonist, such as albuterol. Treatment with SPIRIVA RESPIMAT should be stopped and other treatments considered.

SPIRIVA RESPIMAT should be used with caution in patients with narrow-angle glaucoma. Prescribers and patients should be alert for signs and symptoms of acute narrow-angle glaucoma (e.g., eye pain or discomfort, blurred vision, visual halos or colored images in association with red eyes from conjunctival congestion and corneal edema). Instruct patients to consult a physician immediately should any of these signs or symptoms develop.

Since dizziness and blurred vision may occur with the use of SPIRIVA RESPIMAT, caution patients about engaging in activities such as driving a vehicle, or operating appliances or machinery.

SPIRIVA RESPIMAT should be used with caution in patients with urinary retention. Prescribers and patients should be alert for signs and symptoms of urinary retention (e.g., difficulty passing urine, painful urination), especially in patients with prostatic hyperplasia or bladder-neck obstruction. Instruct patients to consult a physician immediately should any of these signs or symptoms develop.

Patients with moderate to severe renal impairment (creatinine clearance of <60 mL/min) treated with SPIRIVA RESPIMAT should be monitored closely for anticholinergic side effects.

The most common adverse reactions >3% incidence and higher than placebo with SPIRIVA RESPIMAT (placebo) in COPD trials were pharyngitis 11.5% (10.1%), cough 5.8% (5.5%), dry mouth 4.1% (1.6%), and sinusitis 3.1% (2.7%).

The most common adverse reactions >2% incidence and higher than placebo with SPIRIVA RESPIMAT (placebo) in asthma trials in adults were pharyngitis 15.9% (12.4%), headache 3.8% (2.7%), bronchitis 3.3% (1.4%), and sinusitis 2.7% (1.4%). The adverse reaction profile for adolescent and pediatric patients was comparable to that observed in adult patients with asthma.

SPIRIVA RESPIMAT may interact additively with concomitantly used anticholinergic medications. Avoid administration of SPIRIVA RESPIMAT with other anticholinergic-containing drugs.

Inform patients not to spray SPIRIVA RESPIMAT into the eyes as this may cause blurring of vision and pupil dilation.

CL-SVR-0047 2.15.2017

Please see accompanying full Prescribing Information for SPIRIVA RESPIMAT, including Instructions for Use.