PROTOCOL FOR PHARMACIST DISPENSING OF ALLERGIC RHINITIS THERAPIES v2

Approved 12/11/2019

PURPOSE

This protocol specifies the criteria and procedures for pharmacist(s) to initiate the dispensing of medications for symptomatic relief of allergic rhinitis.

PHARMACIST EDUCATION AND TRAINING

Prior to initiating the dispensing of allergic rhinitis therapies under this protocol, pharmacist(s) must have received education and training in the treatment of allergic rhinitis from a provider accredited by the Accreditation Council for Pharmacy Education, or by a comparable provider approved by the Kentucky Board of Pharmacy.

Provider of Training: _____

Date Training Completed: _____

CRITERIA

Pharmacist(s) authorized to initiate the dispensing of allergic rhinitis therapies will follow the most current practice guidelines for allergic rhinitis treatment.[1]

Inclusion criteria:

- Any individual, 12 years or older, who currently presents with one or more symptoms of allergic rhinitis:
    - nasal congestion
    - clear rhinorrhea
    - sneezing
    - itchy nose

Exclusion criteria:

- Individuals who are pregnant or lactating
- Children under 12 years of age
- Individuals presenting with any of the following:
    - Severe persistent allergic rhinitis
    - Symptoms of undiagnosed or uncontrolled asthma
        - Prolonged expiration and diffuse wheezing

[1] Wallace DV, Dykewicz MS, Oppenheimer J, Portnoy JM, Lang DM. Pharmacologic Treatment of Seasonal Allergic Rhinitis: Synopsis of Guidance From the 2017 Joint Task Force on Practice Parameters. Ann Intern Med. 2017;167:876–881. doi: 10.7326/M17-2203.

        - Cough
        - Difficulty breathing
    - Symptoms associated with sinusitis
        - Purulent discharge
        - Facial pain
        - Fever
    - Symptoms usually not associated with allergic rhinitis:
        - Loss of smell
        - Nasal obstruction without discharge or unilateral obstruction
        - Posterior discharge
        - Malaise
    - Earache
    - Recurrent epistaxis

MEDICATIONS

This protocol authorizes pharmacist(s) to initiate the dispensing of any medication approved by the FDA for treatment of allergic rhinitis or upper respiratory allergies included in the therapeutic classes listed below using the drugs and doses provided in the attached medication guide. Sufficient quantities to provide up to a 30-day supply of medication may be dispensed.

- Intranasal corticosteroids (INCS)
- Intranasal antihistamines
- Second generation oral antihistamines
- Oral decongestants
- Combination second generation oral antihistamines and decongestants

PROCEDURES FOR INITIATION OF THERAPY

Allergic rhinitis therapy initiation will follow current guidelines[1] and will be individualized based on relevant medical and social history, patient preferences, and consideration of contraindications and precautions of therapy as outlined below and in the attached medication guide.

<u>Relevant Medical and Social History</u>

- Past medical history
- Current medications
- Allergies and hypersensitivities

<u>Contraindications Precautions (see medication guide for details)</u>

- Known hypersensitivity
- Concurrent MAOI therapy

- Cardiovascular disease
- Uncontrolled hypertension
- Urinary retention
- Glaucoma
- Geriatrics

PROCEDURES FOR MONITORING AND CONTINUATION OR ADJUSTMENT OF THERAPIES

Follow-up monitoring and evaluation to determine effectiveness, adverse effects, and patient progress with therapy is required if therapy is to continue following the initial dispensation. If follow-up monitoring and evaluation indicates therapy continuation is warranted, medication refills may be authorized.

Should follow-up evaluation and monitoring indicate an adjustment in therapy is warranted, all procedures as outlined for initiation of therapies, including education, documentation and notification, will be followed.

EDUCATION REQUIREMENTS

Individuals, or their parent/guardian/caregiver, receiving allergic rhinitis therapies under the protocol will receive education regarding:

1. Nonpharmacologic recommendations to reduce allergic response.
2. Education specific to the individual medication(s) dispensed.

DOCUMENTATION

Pharmacist(s) shall document via prescription record each person who receives allergic rhinitis therapies under this protocol, including:

1. Documentation as required in 201 KAR 2:170 for the dispensing of prescription medication; and
2. Documentation that the individual receiving the allergic rhinitis therapy (or caregiver) was provided with the required education pursuant to this protocol
3. Documentation of the history and assessment, the plan of care implemented, and follow-up monitoring and evaluation.

NOTIFICATION

Pharmacist(s) shall ask all persons receiving allergic rhinitis therapies under this protocol for the name and contact information of the individual's primary care provider and shall provide notification of the medications dispensed under the protocol to the identified primary care provider within two (2) business days. Any individual affirmatively stating that the individual does not have a primary care provider may still have allergic rhinitis therapies under this protocol provided all other applicable requirements of the protocol are met.

[If directed by the authorizingprescriber, the pharmacist(s) shall provide written notification via fax or other secure electronic means to the authorizing prescriber of

persons receiving allergic rhinitis therapies under this protocol within 7 days of initiating dispensing]

TERMS

This protocol is effective as of the date parties execute this document. It shall remain in effect for a period of one year and shall automatically renew for successive one-year periods unless otherwise terminated by any party, with or without cause. Any termination without cause shall require prior notice to all parties of no less than sixty (60) days.

SIGNATURES

_____ _____

Prescriber Name Date

_____

Prescriber Signature

_____ _____

Pharmacist Name Date

_____

Pharmacist Signature

Medication Guide

Drug class	Generic	Brand	Formulation(s)	Indication	Dosage(s)	Pediatric dose	ADEs (frequent and/or clinically significant)	Contraindications	Notes
Instranasal Corticosteroids (INCS)	Budesonide	Rhinocort	nasal solution	allergy symptoms	Allergic rhinitis: Intranasal: One spray (32 mcg) in each nostril once daily (total daily dose: 64 mcg/day). Some patients who do not achieve adequate control may benefit from increased dosage. A reduced dosage may be effective after initial control is achieved (maximum dose: 4 sprays [128 mcg] in each nostril once daily [total daily dose: 256 mcg/day]).	Allergic rhinitis (Rx): Children ≥12 years and Adolescents: Refer to adult dosing.	headache, dry nose, epistaxis, bitter taste		
	Fluticasone Propionate	Flonase; Flonase Allergy Relief	nasal solution	allergy symptoms	Upper respiratory allergies (OTC): Intranasal: ClariSpray, Flonase Allergy Relief, Good Sense Nasoflow (fluticasone propionate): Initial: Two sprays (50 mcg/spray) per nostril once daily (200 mcg/day); after 1 week, may adjust to 1 or 2 sprays per nostril once daily (100 to 200 mcg/day). Do not use for more than 6 months unless instructed by health care provider.	Children ≥12 years and Adolescents: Refer to adult dosing.	headache, dry nose, epistaxis, bitter taste		
	Fluticasone Furoate	Flonase Sensimist	nasal solution	allergy symptoms	Initial: Two sprays (27.5 mcg/spray) per nostril once daily (110 mcg/day); after 1 week, may adjust to 1 or 2 sprays per nostril once daily (55 to 110 mcg/day). Do not use for more than 6 months unless instructed by healthcare provider.	Children ≥12 years and Adolescents: Refer to adult dosing.	headache, dry nose, epistaxis, bitter taste		
	Flunisolide (Rx only)	Apo-Flunisolide, Nasalide, Rhinalar	nasal solution	allergy symptoms	Intranasal: Two sprays (50 mcg) in each nostril twice daily (total daily dose: 200 mcg/day); may increase to 2 sprays in each nostril 3 times daily (total daily dose: 300 mcg/day); maximum dose: 8 sprays/day in each nostril (total daily dose: 400 mcg/day)	Children and Adolescents 6 to 14 years: One spray (25 mcg) in each nostril 3 times daily or 2 sprays (50 mcg) in each nostril twice daily; not to exceed 4 sprays/day in each nostril (total daily dose: 200 mcg/day) Adolescents ≥15 years: Refer to adult dosing.	headache, dry nose, epistaxis, bitter taste		
	Mometasone Furoate	Nasonex	nasal solution	allergy symptoms	Allergic rhinitis (seasonal and perennial): Intranasal: 2 sprays (100 mcg) in each nostril once daily (total daily dose: 200 mcg) Nasal congestion associated with seasonal rhinitis: Intranasal: 2 sprays (100 mcg) in each nostril once daily (total daily dose: 200 mcg) Seasonal allergic rhinitis (prophylaxis): Intranasal: 2 sprays (100 mcg) in each nostril once daily (total daily dose: 200 mcg); treatment should begin 2 to 4 weeks prior to the anticipated start of pollen season Rhinosinusitis, adjunctive treatment (acute) (off-label use): Intranasal: Intranasal corticosteroids such as mometasone are recommended by IDSA and AAO-HNS guidelines but no specific dosing recommendations are made. Alternatively, the following dosing recommendations have been made: 2 sprays (100 mcg) in each nostril twice daily (total daily dose: 400 mcg); if inadequate symptom control, may increase to 4 sprays (200 mcg) in each nostril twice daily (total daily dose: 800 mcg) (Nasonex Canadian product labeling 2013). Rhinosinusitis, treatment (acute, mild to moderate, uncomplicated) (off-label use): Intranasal: 2 sprays (100 mcg) in each nostril twice daily (total daily dose: 400 mcg); up to 15 days of treatment was studied (Meltzer 2005)	Allergic rhinitis (seasonal and perennial): Intranasal: Children ≥12 years and Adolescents: Refer to adult dosing. Seasonal allergic rhinitis (prophylaxis): Intranasal: Children ≥12 years and Adolescents: Refer to adult dosing.	headache, dry nose, epistaxis, bitter taste		
	Ciclesonide (Rx only)	Omnaris	nasal solution	allergy symptoms	Two sprays (50 mcg/spray) per nostril once daily; maximum: 200 mcg/day	Children ≥6 years and Adolescents: Refer to adult dosing.	headache, dry nose, epistaxis, bitter taste		
	Beclomethasone Diproprionate (Rx only)	Qnasl	nasal solution	allergy symptoms	Inhalation, nasal: Qnasl 80 mcg: Two inhalations (160 mcg) in each nostril once daily (maximum: 320 mcg daily)	Children ≥12 years and Adolescents: Qnasl 80 mcg: Refer to adult dosing.	headache, dry nose, epistaxis, bitter taste		
	Triamcinolone Acetonide	Nasacort Allergy	nasal solution	allergy symptoms	Two sprays (110 mcg) in each nostril once daily; once symptoms controlled reduce to 1 spray (55 mcg) in each nostril once daily (maximum: 2 sprays [110 mcg] in each nostril once daily). Discontinue therapy if adequate symptomatic relief is not observed within 3 weeks (1 week for OTC use).	Children ≥12 years and Adolescents: Refer to adult dosing.	headache, dry nose, epistaxis, bitter taste		

Medication Guide

Drug class	Generic	Brand	Formulation(s)	Indication	Dosage(s)	Pediatric dose	ADEs (frequent and/or clinically significant)	Contraindications	Notes
Intranasal Antihistamine	Azelastine (Rx only)	Astelin, Astepro	nasal solution	rhinitis	Perennial allergic rhinitis: Intranasal: Astepro (0.15% solution): Two sprays in each nostril twice daily. Seasonal allergic rhinitis: Intranasal: Astepro (0.1% or 0.15% solution): One or two sprays (0.1% solution) in each nostril twice daily or two sprays (0.15% solution) in each nostril once daily Azelastine [generic] 0.1% solution: One or two sprays in each nostril twice daily	Perennial allergic rhinitis: Intranasal: Astepro: Children ≥12 years and Adolescents: Refer to adult dosing. Seasonal allergic rhinitis: Intranasal: Astepro: Children ≥12 years and Adolescents: Refer to adult dosing. Azelastine [generic] 0.1% solution: Children ≥12 years and Adolescents: Refer to adult dosing.	bitter taste, headache, drowsiness, rhinitis exacerbation		
	Olopatadine (Rx only)	Patanase	nasal solution	rhinitis	Intranasal: 2 sprays into each nostril twice daily	Children >12 years: refer to adult dose	bitter taste, epistaxis, nasal mucosa ulcer		
2nd Generation Oral Antihistamine	Fexofenadine	Allegra, Mucinex Allergy	suspension, tablet	rhinitis	Twice daily formulations: 60 mg every 12 hours (maximum: 120 mg/day) Once daily formulations: 180 mg once daily (maximum: 180 mg/day)	Children ≥12 years and Adolescents: Refer to adult dosing.	Anticholinergic effects (dry mouth, blurred vision, urinary retention, constipation)		Take with water (not juice due to decreased absorption); avoid administration with aluminum or magnesium-containing products.
	Loratadine	Alavert, Claritin	tablet, capsule, solution, syrup	rhinitis	Oral: 10 mg daily once daily or 5 mg twice daily (RediTabs)	Children ≥6 years: Refer to adult dosing.	Anticholinergic effects (dry mouth, blurred vision, urinary retention, constipation)		
	Desloratadine (Rx only)	Clarinex	tablet, syrup	rhinitis	Oral: 5 mg once daily	Perennial allergic rhinitis, chronic idiopathic urticaria: Oral: Children ≥12 years and Adolescents: Refer to adult dosing. Seasonal allergic rhinitis: Oral: Children ≥12 years and Adolescents: Refer to adult dosing.	Anticholinergic effects (dry mouth, blurred vision, urinary retention, constipation)		
	Cetirizine	Zyrtec	capsule, tablet, solution, syrup	rhinitis	Oral: 5 to 10 mg once daily, depending upon symptom severity (maximum dose: 10 mg daily)	Children ≥6 years and Adolescents: Refer to adult dosing.	Anticholinergic effects (dry mouth, blurred vision, urinary retention, constipation)		
	Levocetirizine	Xyzal	tablet, solution	rhinitis	Oral: 5 mg once daily (in the evening); some patients with less severe symptoms may experience relief with 2.5 mg once daily; maximum dose: 5 mg/day	Allergic rhinitis (OTC only): Oral: Children ≥12 years and Adolescents: Refer to adult dosing.	Anticholinergic effects (dry mouth, blurred vision, urinary retention, constipation)		
Oral Decongestant	Phenylephrine	Sudafed PE	Tablet, solution	nasal congestion	10 mg every 4 hours as needed (maximum: 60 mg/24 hours)	≥12 years: Refer to adult dosing	tachycardia, increased BP, anxiety, insomnia, dizziness	Use with or within 14 days of MAO inhibitor therapy	Phenylephrine has low bioavailability (~38%). Use with caution in patients with cardiovascular disease and uncontrolled hypertension.
	Pseudoephedrine	Sudafed, Nexafed	Tablet, syrup	nasal congestion	Immediate release: 60 mg every 4 to 6 hours; Extended release: 120 mg every 12 hours or 240 mg every 24 hours; maximum: 240 mg per 24 hours	≥12 years and Adolescents: Refer to adult dosing	tachycardia, increased BP, anxiety, insomnia, dizziness	When used for self-medication: Use with or within 14 days of MAO inhibitor therapy	Use with caution in patients with cardiovascular disease and uncontrolled hypertension

Medication Guide

Drug class	Generic	Brand	Formulation(s)	Indication	Dosage(s)	Pediatric dose	ADEs (frequent and/or clinically significant)	Contraindications	Notes
2nd Generation Antihistamine/Pseudoephedrine Combination Products	Cetirizine/Pseudoephedrine	Zyrtec D	Tablet	Upper Respiratory Allergies	One tablet (cetirizine 5 mg/pseudoephedrine 120 mg) twice daily (maximum: 2 tablets [cetirizine 10 mg/pseudoephedrine 240 mg] per day)	Children ≥12 years and Adolescents: Refer to adult dosing.	Anticholinergic effects (dry mouth, blurred vision, urinary retention, constipation), tachycardia, increased BP, anxiety, insomnia, dizziness	When used for self-medication: Use with or within 14 days of MAO inhibitor therapy	Use with caution in patients with cardiovascular disease and uncontrolled hypertension
	Fexofenadine/Pseudoephedrie	Allegra D	Tablet	Seasonal Allergic Rhinitis	Fexofenadine 60 mg/pseudoephedrine 120 mg 12 Hour: One tablet twice daily. Fexofenadine 180 mg/pseudoephedrine 240 mg 24 Hour: One tablet once daily.	Children ≥12 years and Adolescents: Refer to adult dosing.	Anticholinergic effects (dry mouth, blurred vision, urinary retention, constipation), tachycardia, increased BP, anxiety, insomnia, dizziness	When used for self-medication: Use with or within 14 days of MAO inhibitor therapy	Use with caution in patients with cardiovascular disease and uncontrolled hypertension
	Loratadine/Pseudoephedrine	Claritin D	Tablet	Allergy symptoms	Loratadine 5 mg/pseudoephedrine 120 mg per tablet: One tablet every 12 hours, Loratadine 10 mg/pseudoephedrine 240 mg per tablet: One tablet daily (maximum: 1 tablet/day) (maximum: 2 tablets/day)	Children ≥12 years and Adolescents: Refer to adult dosing.	Anticholinergic effects (dry mouth, blurred vision, urinary retention, constipation), tachycardia, increased BP, anxiety, insomnia, dizziness	When used for self-medication: Use with or within 14 days of MAO inhibitor therapy	Use with caution in patients with cardiovascular disease and uncontrolled hypertension
	Desloratadine/Pseudoephedrine	Clarinex D	Tablet	Seasonal or Allergic Rhinitis	Desloratadine 2.5 mg/pseudoephedrine 120 mg every 12 hours; Maximum: Desloratadine 5 mg/pseudoephedrine 240 mg daily	Children ≥12 years and Adolescents: Refer to adult dosing.	Anticholinergic effects (dry mouth, blurred vision, urinary retention, constipation), tachycardia, increased BP, anxiety, insomnia, dizziness	When used for self-medication: Use with or within 14 days of MAO inhibitor therapy	Use with caution in patients with cardiovascular disease and uncontrolled hypertension

References: Lexi-Drugs [online database]. Hudson, OH. Accessed 2018 May 13.
Clinical Pharmacology [online database]. Tampa, FL. Accessed 2018 May 13.