

MEDICATION COVERAGE POLICY

PHARMACY AND THERAPEUTICS ADVISORY COMMITTEE

POLICY:	Allergy Medications	LAST REVIEW:	9/12/2017
THERAPEUTIC CLASS:	Rheumatologic/Immunologic	REVIEW HISTORY:	9/16, 5/15, 9/14
LOB AFFECTED:	MCL	(MONTH/YEAR)	

This policy has been developed through review of medical literature, consideration of medical necessity, generally accepted medical practice standards, and approved by the HPSJ Pharmacy and Therapeutic Advisory Committee.

OVERVIEW

Many treatment modalities exist for the treatment of seasonal allergies. Each treatment modality has benefits and limitations depending on each patient's specific symptomatology. While allergen avoidance is the first-line treatment, some conditions may be hard to avoid (e.g. seasonal allergies, vasomotor allergies) and may require treatment with pharmacologic agents. The below criteria, limits, and requirements for certain agents are in place to ensure appropriate use of those agents.

Seasonal Allergy Medications Formulary Positioning: (Current as of 7/2017)

Oral Agents					
Therapeutic Class	Generic Name (Brand Name)	Available Strengths	Fml Limits	Avg. Cost/Rx	Notes
Oral Antihistamines	Chlorpheniramine Tablet, ER Tablet, Syrup	IR: 4mg ER: 12mg Syrup: 2mg/5ml Syrup: 2 mg/ml	-- -- -- NF	\$1.03 \$13.64 -- --	
	Clemastine Fumarate Tablet, Syrup	IR: 1.34mg IR: 2.68mg Syrup: 0.67mg/5ml	NF -- NF	-- -- --	
	Cyproheptadine HCl Tablet, Syrup	IR: 4mg Syrup: 2mg/5ml	--	\$23.76 \$20.27	
	Diphenhydramine HCl Capsule, Chew Tablet, Tablet, ODT, Elixir, Oral Solution, Syrup, Vial	IR tab: 25mg IR cap: 25 mg IR cap: 50mg Chewable: 12.5mg ODT: 12.5mg Elixir: 12.5mg/5ml Soln: 12.5mg/5ml Syrup: 12.5mg/5ml	--	\$0.51 \$0.45 \$0.38 -- -- \$2.62 \$4.82 --	
	Hydroxyzine HCl (Atarax) Tablet, Syrup	IR: 10mg IR: 25 mg IR: 50 mg Syrup: 10mg/5ml	--	\$5.66 \$4.05 \$18.15 \$9.83	
	Hydroxyzine Pamoate (Vistaril) Capsule	IR: 25mg IR: 50mg IR: 100mg	--	\$4.27 \$8.85 \$53.15	
	Promethazine HCl Tablet, Syrup	IR: 12.5mg IR: 25mg IR: 50mg Syrup: 6.25mg/5ml	--	\$3.51 \$1.74 \$8.44 \$5.88	
	Cetirizine HCl (Zyrtec) Tablet, Oral Solution, Chewable Tablet, ODT, Capsule	IR tab: 5mg IR tab: 10mg Soln: 1mg/ml Soln: 5mg/5ml Chew: 5mg Chew: 10mg ODT: 10mg IR cap: 10mg	-- -- -- NF NF NF NF NF	\$0.95 \$1.66 \$3.46 \$24.70 \$50.85 -- -- --	
	Fexofenadine (Allegra) Tablet, ODT, Suspension	IR: 30mg IR: 60mg IR: 180mg ODT: 30mg	NF PA PA PA	-- \$21.95 \$11.48 \$46.04	Reserved for treatment failure to Cetirizine and Loratadine.

		Susp: 30mg/5ml		\$18.37	
	Loratadine (Claritin) Tablet, Oral Solution, Chewable Tablet, ODT	IR: 10mg Soln: 5mg/5ml Chew: 5 mg ODT: 10 mg	-- -- NF NF	\$2.76 \$5.94 -- --	
	Desloratadine (Clarinex) Tablet, Syrup, ODT	IR: 5mg Syrup: 0.5 mg/ml ODT: 2.5mg ODT: 5 mg	NF NF NF NF	-- -- -- --	
	Levocetirizine (Xyzal) Tablet, Solution	IR: 5mg Soln: 2.5mg/5ml	NF NF	\$11.68 --	
Oral Antihistamine & Decongestant Combinations	Phenylephrine/Promethazine Syrup	6.25-5mg/5ml	--	\$11.80	
	Phenylephrine/Brompheniramine Oral Solution	2.5-1mg/5ml	--	\$2.67	
	Phenylephrine/Chlorpheniramine Oral Drops, Syrup	Drops: 3.5-1mg/5ml Syrup: 15-1mg/5ml	--	\$11.40	
	Pseudoephedrine/Brompheniramine Oral Solution	15-1mg/5ml	--	\$4.13	
	Pseudoephedrine/Tripolidine Tablet, Syrup	IR: 2.5mg-6mg Syrup: 1.25-30mg/5ml	--	\$4.76 --	
	Pseudoephedrine/Cetirizine ER Tablet	5mg-120mg	--	\$16.66	
	Pseudoephedrine/Fexofenadine ER Tablet	60mg-120mg 180mg-240mg	PA	-- \$33.28	Reserved for treatment failure to Cetirizine and Loratadine.
	Pseudoephedrine/Loratadine ER Tablet	5mg-120mg 10mg-240mg	--	\$13.47 \$5.84	
	Pseudoephedrine/Desloratadine ER Tablet	2.5mg-120mg	NF	\$361.44*	
Leukotriene Receptor Antagonists	Montelukast Tablet, Chewable Tablet,	IR: 10mg Chew: 4mg Chew: 5mg	QL	\$4.95 \$10.68 \$8.96	Limit 1 per day
	Montelukast Granules	Granules: 4mg	PA; QL	\$116.58	Restricted to patients under age 2. For patients above age 2, reserved for patients with documented inability to use chewable tablets. Limit 1 per day.
Therapeutic Class	Generic Name (Brand Name)	Available Strengths	Fml Limits	Avg Cost/Rx	Notes/Restriction Language
Nasal Agents					
Nasal Antihistamine	Azelastine HCl (Astellin)	137mcg (0.1%)	ST	\$49.88	
	Azelastine HCl (Astepro)	205.5mcg (0.15%)	NF	\$99.87	Formulary alternative = Azelastine 137 mcg (0.1%)
	Olopatadine (Patanase) Solution	665 mcg (0.6%)	NF	--	

Nasal Corticosteroids	Flunisolide	25mcg	PA	\$54.80	Reserved for treatment failure of an adequate trial (7-14 days) of any 2 (two) first-line agents (fluticasone, budesonide, triamcinolone).
	Fluticasone propionate (<i>Flonase</i>)	50mcg (Rx)	--	\$6.92	
	Fluticasone propionate (<i>Flonase</i>)	50mcg (OTC)	NF	\$13.59	
	Fluticasone furoate (<i>Veramyst</i>)	27.5mcg	NF	\$190.38	
	Triamcinolone (<i>Nasacort</i>)	55mcg (OTC)	--	\$13.06	
	Beclomethasone (<i>Beconase AQ</i>)	42mcg	NF	\$335.27*	Formulary alternative = Qnasl
	Beclomethasone (<i>Qnasl</i>)	40 mcg	NF	--	Formulary alternatives = Flonase, Nasacort, Rhinocort Allergy
	Beclomethasone (<i>Qnasl</i>)	80mcg	PA	\$190.81	Reserved for treatment failure of an adequate trial (7-14 days) of any 2 (two) first-line agents (fluticasone, budesonide, triamcinolone) AND flunisolide.
	Budesonide (<i>Rhinocort Allergy</i>)	32mcg	--	\$13.15	
	Ciclesonide (<i>Omnaris, Zetonna</i>) Aerosol Solution, Suspension	Solution: 37 mcg Susp: 50 mcg	NF NF	-- --	
Mometasone (<i>Nasonex</i>)	50mcg	PA	\$199.22	Reserved for treatment failure of an adequate trial (7-14 days) of any 2 (two) first-line agents (fluticasone, budesonide, triamcinolone) AND flunisolide.	
Nasal Vasoconstrictors	Oxymetazoline HCl (<i>Afrin</i>)	0.05%	--	\$1.11	
	Phenylephrine HCl <i>Nasal Drops, Nasal Spray</i>	Drops: 0.125%	--	\$2.98	
		Drops: 1%		\$3.55	
Spray: 0.25%		\$3.23			
Spray: 0.5%		\$3.17			
Spray: 1%	\$1.64				
Combination Nasal Sprays	Azelastine HCl/fluticasone propionate (<i>Dymista, Ticalast</i>) Nasal Spray, Nasal Kit	Spray: 137mcg-50mcg (0.1%-0.037%) Kit: 137mcg-50mcg (0.1%-0.037%) + sterile saline wash (0.9%)	NF	\$214.43* \$4,789.43*	Formulary alternative = Astelin + Flonase nasal sprays as separate agents

Other	Cromolyn Sodium <i>(Nasal crom) Spray</i>	5.2 mg (4%)	--	\$6.61	
	Ipratropium <i>(Atrovent) Solution</i>	21 mcg (0.03%) 42 mcg (0.06%)	NF	\$29.73 \$29.73	
	Sodium Chloride <i>(Ocean Nasal) Spray</i>	0.65%	NF	\$0.81	
Injectable Agents					
Epinephrine	Epinephrine HCl <i>(Adrenaline) Ampule</i>	1:1,000 (0.1%)	--	--	
	Epinephrine (<i>Generic epinephrine</i>) <i>Auto-Injector</i>	0.3mg/0.3ml 0.15mg/0.3ml	-- --	\$233.13 \$268.86	
	Epinephrine (<i>Epipen 2-Pak, Epipen Jr 2-Pak</i>) <i>Auto-Injector</i>	0.3mg/0.3ml 0.15mg/0.3ml	NF	\$613.42 \$531.71	
Diphenhydramine	Diphenhydramine HCl Vial	50mg/ml	NF	\$4.92	
PA = Prior Authorization; QL = Quantity Limit; NF = Non-Formulary; AL = Age Limit; QL = Quantity Limit *Based on AWP					

EVALUATION CRITERIA FOR APPROVAL/EXCEPTION CONSIDERATION

Below are the coverage criteria and required information for each agent. These coverage criteria have been reviewed approved by the HPSJ Pharmacy & Therapeutics (P&T) Advisory Committee. For conditions not covered under this Coverage Policy, HPSJ will make the determination based on Medical Necessity as described in HSPJ Medical Review Guidelines (UM06).

1st Generation Oral Antihistamines

Benadryl (Diphenhydramine), Periactin (Cyproheptadine), Chlor-Trimeton (Chlorpheniramine), Tavist (Clemastine) 2.68 mg Tablet, Hydroxyzine HCl, Hydroxyzine Pamoate, Promethazine HCl

- Coverage Criteria:** None
- Limits:** None
- Required Information for Approval:** N/A
- Other Notes:** None
- Non-Formulary:** Chlorpheniramine syrup; Clemastine 1.34 mg Tablet, 0.67 mg/ml Syrup

2nd Generation Oral Antihistamines

Claritin (Loratadine Tablet, Solution); Zyrtec (Cetirizine) Tablet, 1 mg/ml Solution

- Coverage Criteria:** None
- Limits:** None
- Required Information for Approval:** N/A
- Other Notes:** None
- Non-Formulary:** Loratadine chewable tablet, ODT; Cetirizine chewable tablets, ODT, capsules, 5 mg/5 ml solution; Desloratadine; Levocetirizine

Allegra (Fexofenadine) 60 mg Tablet, 180 mg Tablet; ODT, Suspension

- Coverage Criteria:** Fexofenadine is reserved for patient with treatment failure of both loratadine and cetirizine.
- Limits:** None
- Required Information for Approval:** Drug refill history showing trials of both loratadine and cetirizine and chart notes documenting an intolerance or treatment failure to Loratadine and Cetirizine.
- Other Notes:** None
- Non-Formulary:** Fexofenadine 30 mg Tablet

Oral Antihistamine Combination Agents

Phenylephrine/Promethazine, Phenylephrine/Brompheniramine, Phenylephrine/Chlorpheniramine, Pseudoephedrine/Brompheniramine, Pseudoephedrine/Tripolidine, Pseudoephedrine/Cetirizine, Pseudoephedrine/Loratadine

- Coverage Criteria:** None
- Limits:** None
- Required Information for Approval:** N/A
- Other Notes:** None

Pseudoephedrine/Fexofenadine

- Coverage Criteria:** PA Required. Fexofenadine is reserved for patient with treatment failure of both loratadine and cetirizine.
- Limits:** None
- Required Information for Approval:** Drug refill history showing trials of both loratadine and cetirizine and chart notes documenting an intolerance or treatment failure to Loratadine and Cetirizine.
- Other Notes:** None

Leukotriene Receptor Blocker

Singulair (Montelukast) Tablets, Chewable Tablets

- Coverage Criteria:** None
- Limits:** 1 tablet per day
- Required Information for Approval:** N/A
- Other Notes:** None

Singulair (Montelukast) Granule Packets

- Coverage Criteria:** Restricted to patients under age 2. For patients above age 2, reserved for patients with documented inability to use chewable tablets.
- Limits:** 1 packet per day
- Required Information for Approval:** N/A
- Other Notes:** None

Nasal Antihistamines

Astelin (Azelastine) 137 mcg

- Coverage Criteria:** Astelin is step therapy to failing a 14 day trial of formulary intranasal corticosteroids (e.g, fluticasone, flunisolide).
- Limits:** None
- Required Information for Approval:** Drug refill history showing trials of a formulary first-line intranasal corticosteroid in the previous month and chart notes documenting inadequate control of allergy symptoms with intranasal corticosteroids alone.
- Other Notes:** Consider use of oral antihistamines for a more convenient method of administration, or intranasal corticosteroids for increased efficacy over nasal antihistamines.
- Non-Formulary:** Azelastine 205.5 mcg (Astepro)

Intranasal Corticosteroids

Flonase (Fluticasone) Rx, Nasacort 24hr (Triamcinolone), Rhinocort Allergy (Budesonide)

- Coverage Criteria:** None
- Limits:** None
- Required Information for Approval:** N/A
- Other Notes:** None
- Non-Formulary:** Fluticasone OTC, Ciclesonide, Veramyst, Sensimist

Nasarel (Flunisolide)

- Coverage Criteria:** Flunisolide is reserved for treatment failure of an adequate trial (7-14 days) of any 2 (two) first-line agents (fluticasone, budesonide, triamcinolone).
- Limits:** None
- Required Information for Approval:** Drug fill history showing fills of Nasacort, Flonase, or Rhinocort Allergy
- Other Notes:** None

Qnasl (Beclomethasone), Nasonex (Mometasone)

- Coverage Criteria:** Qnasl and Nasonex are reserved for treatment failure of an adequate trial (7-14 days) of any 2 (two) first-line agents (fluticasone, budesonide, triamcinolone) AND flunisolide.
- Limits:** None
- Required Information for Approval:** Drug fill history showing trials of 2 (two) formulary first-line intranasal corticosteroid AND flunisolide
- Other Notes:** None
- Non-Formulary:** Beconase AQ (Beclomethasone)

Mast Cell Stabilizers

Nasal Crom (Cromolyn Sodium Nasal Spray)

- Coverage Criteria:** None
- Limits:** None
- Required Information for Approval:** N/A
- Other Notes:** None

Anaphylaxis Agents

Epinephrine (Epipen 2-Pak, Epipen Jr 2-Pak, Generic)

- Coverage Criteria:** None
- Limits:** None
- Required Information for Approval:** N/A
- Other Notes:** None
- Non-Formulary:** Epipen 2-Pak, Epipen Jr 2-Pak

Clinical Justification:

Allergen avoidance should be recommended to all patients. Take steps to reduce poor air quality in the home and make strides to eliminate the offending allergen. During allergy season, time outdoors should be limited. Patients should close windows, wash bedding frequently, and use vacuum cleaners with HEPA filters.

Oral allergy medications can provide symptom relief for the broadest range of allergy symptoms (rhinitis, conjunctivitis, itching). 2nd generation antihistamines are less sedating than first generation antihistamines and all 2nd generation oral antihistamines have approximately the same level of efficacy and work quickly. Intranasal corticosteroids also all have approximately the same level of efficacy. These medications may take up to a week or more to control symptoms, but are effective for a broad range of symptoms when used regularly. Please refer to Table 1 for age-specific restrictions for each agent. Ocular antihistamines are a good target for patients with conjunctivitis not controlled by an oral antihistamine alone. Ketotifen is dosed less frequently than Visine-A, and may be a more convenient option for patients.

REFERENCES


1. *Am Fam Physician*. 2010 Jun 15;81(12):1440-1446.
2. Seidman MD, Gurgel RK, Lin SY, et al. Clinical Practice Guideline: Allergic Rhinitis. *Otolaryngology—Head and Neck Surgery*. 2015;152(1S):S1-S43.
3. Wallace DV, Dykewicz MS, Bernstein DI, et al. The Diagnosis and Management of Rhinitis: An Updated Practice Parameter. *J Allergy Clin Immunol*. 2008;122(2 Suppl):S1-84.
4. Singulair [Package Insert]. Whitehouse Station, NJ. Merck & Co., Inc; 2012.

REVIEW & EDIT HISTORY

Document Changes	Reference	Date	P&T Chairman
Creation of Policy	Azelastine 05-07.doc	5/2007	Allen Shek PharmD BCPS
Update to Policy	INC Class review 5-07.doc	5/2007	Allen Shek PharmD BCPS
Update to Policy	NSAH 5-07.doc	5/2007	Allen Shek PharmD BCPS
Update to Policy	Ophthalmics Feb 08.doc	2/2008	Allen Shek PharmD BCPS
Update to Policy	Veramyst monograph 6-08.doc	6/2008	Allen Shek PharmD BCPS
Update to Policy	NSAH 9-16-08.doc	9/2008	Allen Shek PharmD BCPS
Update to Policy	ICS Review 9-16-08.doc	9/2008	Allen Shek PharmD BCPS
Update to Policy	ICS post P&T survey recap.doc	3/2009	Allen Shek PharmD BCPS
Update to Policy	Azelastine Monograph 5-17-11.docx	5/2011	Allen Shek PharmD BCPS

Update to Policy	Allergy Review 2014-09-16.docx	9/2014	Jonathan Szkotak PharmD BCACP
Update to Policy	Ophthalmic & Otic – Anti-Inflammatory Agents 2015-11.docx	11/2015	Johnathan Yeh, PharmD
Update to Policy	HPSJ Coverage Policy – Rheum & Immuno – Seasonal Allergies 2016-09.docx	9/2016	Johnathan Yeh, PharmD

Note: All changes are approved by the HPSJ P&T Committee before incorporation into the utilization policy

 **Please refer to Eye & Ear Inflammatory Disorders Coverage Policy for coverage criteria of ophthalmic antibiotic medications.**