

MEDICATION COVERAGE POLICY

PHARMACY AND THERAPEUTICS ADVISORY COMMITTEE

POLICY:	Allergy Medications	LAST REVIEW:	2/09/2021
THERAPEUTIC CLASS:	Rheumatologic/Immunologic	REVIEW HISTORY:	2/20, 2/19, 9/17,
LOB AFFECTED:	MCL	(MONTH/YEAR)	9/16, 5/15, 9/14

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 12/2020)

Oral Agents					
Therapeutic Class	Generic Name (Brand Name)	Available Strengths	Fml Limits	Avg. Cost/Rx	Notes
Oral Antihistamines	Chlorpheniramine <i>Tablet, ER Tablet, Syrup</i>	IR: 4mg ER: 12mg Syrup: 2mg/5ml	-- -- --	\$2.68 -- --	
	Clemastine Fumarate <i>Tablet, Syrup</i>	IR: 1.34mg IR: 2.68mg	NF --	-- --	
	Cyproheptadine HCl <i>Tablet, Syrup</i>	IR: 4mg Syrup: 2mg/5ml	--	\$9.20 \$15.78	
	Diphenhydramine HCl <i>Capsule, Chew Tablet, Tablet, ODT, Elixir, Oral Solution, Syrup, Vial</i>	IR tab: 25mg IR cap: 25 mg IR cap: 50mg Chewable: 12.5mg ODT: 12.5mg Liquid: 12.5mg/5ml	--	\$3.20 \$3.14 \$2.44 -- \$4.25 \$4.08	
	Hydroxyzine HCl <i>(Atarax) Tablet, Syrup</i>	IR: 10mg IR: 25 mg IR: 50 mg Syrup: 10mg/5ml	--	\$4.63 \$5.21 \$6.81 \$10.53	
	Hydroxyzine Pamoate <i>(Vistaril) Capsule</i>	IR: 25mg IR: 50mg IR: 100mg	--	\$6.30 \$6.64 \$29.14	
	Promethazine HCl <i>Tablet, Syrup</i>	IR: 12.5mg IR: 25mg IR: 50mg Syrup: 6.25mg/5ml	--	--	
	Cetirizine HCl (Zyrtec) <i>Tablet, Oral Solution, Chewable Tablet, ODT, Capsule</i>	IR tab: 5mg IR tab: 10mg Soln: 1mg/ml (Rx) Soln: 1 mg/ml (OTC) Soln: 5mg/5ml Chew: 5mg Chew: 10mg ODT: 10mg IR cap: 10mg	-- -- -- -- NF NF NF NF NF	\$3.86 \$4.02 -- \$4.86 -- \$70.61 \$52.85 -- --	
	Fexofenadine (Allegra) <i>Tablet, ODT, Suspension</i>	IR: 30mg IR: 60mg IR: 180mg ODT: 30mg Susp: 30mg/5ml	--	-- \$26.06 \$15.18 -- \$57.80	
	Loratadine (Claritin) <i>Tablet, Oral Solution, Chewable Tablet, ODT</i>	IR: 10mg Soln: 5mg/5ml Chew: 5 mg ODT: 10 mg	-- -- NF NF	\$8.60 \$8.43 -- --	

	Desloratadine <i>(Clarinx) Tablet, Syrup, ODT</i>	IR: 5mg Syrup: 0.5 mg/ml ODT: 2.5mg ODT: 5 mg	--	\$14.32 -- -- --	
	Levocetirizine <i>(Xyzal) Tablet, Solution</i>	IR: 5mg Chewable: 5mg Soln: 2.5mg/5ml	--	\$4.82 \$52.14 --	
Oral Antihistamine & Decongestant Combinations	Phenylephrine/ Promethazine <i>Syrup</i>	6.25-5mg/5ml	--	--	
	Phenylephrine/ Brompheniramine <i>Oral Solution</i>	2.5-1mg/5ml	--	--	
	Phenylephrine/ Chlorpheniramine <i>Oral Drops, Syrup</i>	Drops: 3.5-1mg/5ml Syrup: 15-1mg/5ml	--	--	
	Pseudoephedrine/ Brompheniramine <i>Oral Solution</i>	15-1mg/5ml 2.5-1mg/5ml	--	\$2.91 \$2.27	
	Pseudoephedrine/ Triprolidine <i>Tablet, Syrup</i>	IR: 2.5mg-60mg Syrup: 1.25-30mg/5ml	--	\$4.45 --	
	Pseudoephedrine/ Cetirizine <i>ER Tablet</i>	5mg-120mg	--	\$19.59	
	Pseudoephedrine/ Fexofenadine <i>ER Tablet</i>	60mg-120mg 180mg-240mg	PA	\$35.32 --	Reserved for treatment failure to Cetirizine and Loratadine.
	Pseudoephedrine/ Loratadine <i>ER Tablet</i>	5mg-120mg 10mg-240mg	--	\$21.73 \$15.09	
	Pseudoephedrine/ Desloratadine <i>ER Tablet</i>	2.5mg-120mg	NF	\$361.44*	
Leukotriene Receptor Antagonists	Montelukast <i>Tablet, Chewable Tablet</i>	IR: 10mg Chew: 4mg Chew: 5mg	QL	--	Limit 1 per day
	Montelukast <i>Granules</i>	Granules: 4mg	NF	--	Formulary alternative = Montelukast tablets, chewable tablets
Therapeutic Class	Generic Name (Brand Name)	Available Strengths	Fml Limits	Avg Cost/Rx	Notes/Restriction Language
Nasal Agents					
Nasal Antihistamine	Azelastine HCl <i>(Asterlin)</i>	137mcg (0.1%)	--	\$12.26	
	Azelastine HCl <i>(Astepro)</i>	205.5mcg (0.15%)	--	\$32.85	
	Olopatadine <i>(Patanase) Solution</i>	665 mcg (0.6%)	NF	--	
Nasal Corticosteroids	Flunisolide	25mcg	ST	\$47.84	Step therapy to an adequate trial (7-14 days) of any 2 (two) first-line agents (fluticasone, budesonide, triamcinolone).
	Fluticasone propionate <i>(Flonase)</i>	50mcg (Rx)	--	\$13.52	
	Fluticasone propionate <i>(Flonase)</i>	50mcg (OTC)	--	\$8.04	

	Fluticasone furoate (Flonase Sensimist)	27.5mcg	NF	--	
	Fluticasone propionate (Xhance)	93 mcg	PA	\$527.24	Reserved for Chronic Rhinosinusitis with Nasal Polyposis with the supporting documentation/clinical findings. Must have tried and failed Sinus rinse plus steroid nasal sprays and nasal antihistamine for minimum of 12 weeks evidenced by pharmacy fill history.
	Triamcinolone (Nasacort)	55mcg (OTC)	--	\$15.54	
	Beclomethasone (Beconase AQ)	42mcg	--	--	
	Beclomethasone (Qnasl)	40 mcg	NF	--	
	Beclomethasone (Qnasl)	80mcg	ST	\$249.90	Step therapy to an adequate trial (7-14 days) of any 2 (two) first-line agents (fluticasone, budesonide, triamcinolone) AND flunisolide.
	Budesonide (Rhinocort Allergy)	32mcg	--	\$15.70	
	Ciclesonide (Omnaris, Zetonna) Aerosol Solution, Suspension	Solution: 37 mcg Susp: 50 mcg	NF NF	--	
	Mometasone (Nasonex)	50mcg	ST	\$153.90	Step therapy to an adequate trial (7-14 days) of any 2 (two) first-line agents (fluticasone, budesonide, triamcinolone) AND flunisolide.
Nasal Vasoconstrictors	Oxymetazoline HCl (Afrin)	0.05%	--	\$3.94	
	Phenylephrine HCl Nasal Drops, Nasal Spray	Drops: 0.125%		\$4.88	
		Drops: 1%	--	--	
		Spray: 0.25%		\$5.08	
	Spray: 0.5%		\$5.08		
	Spray: 1%		\$4.03		
Combination Nasal Sprays	Azelastine HCl/fluticasone propionate (Dymista, Ticalast) Nasal Spray, Nasal Kit	Spray: 137mcg-50mcg (0.1%-0.037%) Kit: 137mcg-50mcg (0.1%-0.037%) + sterile saline wash (0.9%)	NF	--	Formulary alternative = Astelin + Flonase nasal sprays as separate agents
Other	Cromolyn Sodium (Nasal crom) Spray	5.2 mg (4%)	--	\$10.43	
	Ipratropium (Atrovent) Solution	21 mcg (0.03%)	--	\$27.12	
		42 mcg (0.06%)	--	\$30.57	
	Sodium Chloride (Ocean Nasal) Spray	0.65%	NF	\$2.88	

Injectable Agents					
Epinephrine	Epinephrine HCl (Adrenaline) Ampule	1:1,000 (0.1%)	--	--	
	Epinephrine (Generic epinephrine) Auto-Injector	0.3mg/0.3ml 0.15mg/0.3ml	-- --	\$255.54 \$285.79	MCA-- Restricted to no more than two (2) auto-injectors per dispensing and two (2) dispensing in any 12-month period.
	Epinephrine (Epipen 2-Pak, Epipen Jr 2-Pak) Auto-Injector	0.3mg/0.3ml 0.15mg/0.3ml	NF	\$415.92 \$415.92	
Diphenhydramine	Diphenhydramine HCl Vial	50mg/ml	NF	\$2.24	
Dupilumab (Dupixent)	Dupilumab	200MG/1.14ML 300 mg/2 ml	PA	--	Must be prescribed by a specialist. Reserved for Chronic Rhinosinusitis with Nasal Polyposis with the supporting documentation/clinical findings such as nasal endoscopy or CT scan. Treatment failure/intolerance to Xhance X 12 weeks, in addition to saline nasal rinse, first line nasal steroid and nasal antihistamine sprays for 3 months with a history of or requiring surgery.
PA = Prior Authorization; QL = Quantity Limit; NF = Non-Formulary; AL = Age Limit; QL = Quantity Limit					

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 HPSJ 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, Allegra (Fexofenadine), Clarinex (Desloratadine), Xyzal (Levocitrizine)

- Coverage Criteria: None
- Limits: None
- Required Information for Approval: N/A
- Other Notes: None
- Non-Formulary: Loratadine chewable tablet, ODT

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
- Non-Formulary: Montelukast Granule Packets

Nasal Anticholinergics

Atrovent (Ipratropium) 0.03% and 0.06% spray

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

Nasal Antihistamines

Astelin (Azelastine) 137 mcg, Astepro (Azelastine) 205.5 mcg

- Coverage Criteria: None
- Limits: None
- Required Information for Approval: None
- Other Notes: None

Intranasal Corticosteroids

Flonase (Fluticasone), Xhance (Fluticasone), Beconase AQ (Beclomethasone), Nasacort 24hr (Triamcinolone), Rhinocort Allergy (Budesonide)

- Coverage Criteria: None
- Limits: None
- Required Information for Approval: N/A
- Other Notes: None
- Non-Formulary: Ciclesonide, Fluticasone furoate (Flonase Sensimist)

Xhance (Fluticasone)

- Coverage Criteria: Reserved for Chronic Rhinosinusitis with Nasal Polyposis
- Limits: None
- Required Information for Approval: Reserved for Chronic Rhinosinusitis with Nasal Polyposis with the supporting documentation/clinical findings. Must have tried and failed Sinus rinse plus steroid nasal sprays and nasal antihistamine for minimum of 12 weeks evidenced by pharmacy fill history.
- Other Notes: None
- Non-Formulary: Ciclesonide, Fluticasone furoate (Flonase Sensimist)

Nasarel (Flunisolide)

- Coverage Criteria:** Flunisolide is step therapy to 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 2 first-line intranasal steroids.
- Other Notes:** None

Qnasl (Beclomethasone), Nasonex (Mometasone)

- Coverage Criteria:** Qnasl and Nasonex step therapy to 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

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, Auvi-Q

Biologic Agents

Dupilumab (Dupixent) 200 mg/1.14 ml, 300 mg/2 ml

- Coverage Criteria:** Must be prescribed by a specialist. Reserved for Chronic Rhinosinusitis with Nasal Polyposis. Treatment failure/intolerance to Xhance X 12 weeks, in addition to saline nasal rinse, first line nasal steroid and nasal antihistamine sprays for 3 months with a history of or requiring surgery
- Limits:** None
- Required Information for Approval:** Supporting documentation/clinical findings such as nasal endoscopy or CT scan. Clinical documentation of treatment failure/intolerance to Xhance X 12 weeks, in addition to saline nasal rinse, first line nasal steroid and nasal antihistamine sprays for 3 months with a history of or requiring surgery
- Other Notes:** None

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.

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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

Update to Policy	HPSJ Coverage Policy – Rheum & Immuno – Seasonal Allergies 2017-09.docx	9/2017	Johnathan Yeh, PharmD
Update to Policy	HPSJ Coverage Policy – Rheum & Immuno – Seasonal Allergies 2019-02.docx	2/2019	Matthew Garrett, PharmD
Update to Policy	HPSJ Coverage Policy – Rheum & Immuno – Seasonal Allergies 2020-02.docx	2/2020	Matthew Garrett, PharmD
Update to Policy	HPSJ Coverage Policy – Rheum & Immuno – Seasonal Allergies.docx	2/2021	Matthew Garrett, PharmD

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