



Medicaid Drug Use Criteria

Non-sedating Antihistamines

- Developed in March 1997.
- Revised June 2020; June 2018; July 2016; May 2016; September 2014; December 2012; March 2011; February 2011; January 2011; January 2008; April 2003; April 2002; April 2001; April 2000; March 1999; March 1998; August 1997.

Information on indications for use or diagnosis is assumed to be unavailable. All criteria may be applied retrospectively; prospective application is indicated with an asterisk [*]. The information contained is for the convenience of the public. The Texas Health and Human Services Commission is not responsible for any errors in transmission or any errors or omissions in the document.

Medications listed in the tables and non-FDA approved indications included in these retrospective criteria are not indicative of Vendor Drug Program formulary coverage.

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1 Dosage

Oral non-sedating antihistamines are FDA-approved for managing urticaria and allergic rhinitis. Nasal non-sedating antihistamines as monotherapy and combination therapy are FDA-approved for treating allergic rhinitis and vasomotor rhinitis. The oral non-sedating antihistamines desloratadine and acrivastine are

available only by prescription. Inhalational non-sedative antihistamines are also available only by prescription.

1.1 Adults

Maximum recommended daily dosages for available non-sedating antihistamines are summarized in Tables 1 and 2. Dosages identified in Texas Medicaid patient profiles exceeding these recommendations will be reviewed.

Table 1. Adult Maximum Recommended Daily Dosages for Non-sedating Antihistamines - Monotherapy

Treatment Indication	Drug Name	Dosage Form/ Strength	Maximum Recommended Dosage
perennial allergic rhinitis	azelastine (Astepro®, generics)	0.15% nasal solution – 205.5 mcg/spray	2 sprays per nostril twice daily
seasonal allergic rhinitis	azelastine (generics)	0.1% nasal solution – 137 mcg/spray	2 sprays per nostril twice daily
seasonal allergic rhinitis	azelastine (Astepro®, generics)		2 sprays per nostril twice daily
vasomotor rhinitis	azelastine (generics)		2 sprays per nostril twice daily
perennial or seasonal allergic rhinitis	cetirizine (Zyrtec®, generics)	**tablets, chewable tablets – 5 mg, 10 mg **orally disintegrating tablets - 10 mg **liquid filled capsule – 10 mg **solution – 1 mg/mL syrup – 1 mg/ mL	10 mg once daily
urticaria	cetirizine (Zyrtec®, generics)		10 mg once daily
chronic idiopathic urticaria	desloratadine (Clarinx®, generics)	tablets – 5 mg rapidly disintegrating tablets - 2.5 mg, 5 mg	5 mg once daily
perennial or seasonal allergic rhinitis	desloratadine (Clarinx®, generics)		5 mg once daily

allergic rhinitis	fexofenadine (Allegra®, generics, Allegra® ODT)	**tablets – 30 mg, 60 mg, 180 mg **orally disintegrating tablets - 30 mg **suspension – 30 mg/5 mL	60 mg twice daily or 180 mg once daily
chronic idiopathic urticaria	fexofenadine (Allegra®, generics, Allegra® ODT)		60 mg twice daily or 180 mg once daily
allergic rhinitis	levocetirizine (Xyzal®, generics)	**tablet – 5 mg **oral solution – 2.5 mg/5 mL	5 mg once daily in evening
chronic idiopathic urticaria	levocetirizine (Xyzal®, generics)		5 mg once daily in evening
perennial or seasonal allergic rhinitis	loratadine (Claritin®, Alavert®, Claritin Children's®, Claritin RediTabs®, generics)	**tablets – 10 mg **chewable tablets (Claritin Children's®) – 5 mg **rapidly disintegrating tablets (Claritin RediTabs®) – 5 mg, 10 mg **liquid-gel capsule – 10 mg **solution – 5 mg/5 mL	10 mg once daily
urticaria	loratadine		10 mg once daily
seasonal allergic rhinitis	olopatadine (Patanase®, generics)	0.6% nasal solution	2 sprays per nostril twice daily

- ** now over-the-counter
- ODT = orally disintegrating tablet

Table 2. Adult Maximum Recommended Daily Dosages for Non-sedating Antihistamines - Combination Therapy

Treatment Indication	Drug Name	Dosage Form/ Strength	Maximum Recommended Dosage
seasonal allergic rhinitis	acrivastine/ pseudoephedrine (Semprex®-D)	capsule (acrivastine 8 mg/ pseudoephedrine 60 mg/ capsule)	1 capsule up to 4 times daily (every 4-6 hours)
seasonal allergic rhinitis	azelastine/ fluticasone (Dymista®)	nasal suspension – 137 mcg/ 50 mcg per actuation	1 spray per nostril twice daily

perennial or seasonal allergic rhinitis	**cetirizine/ pseudoephedrine (Zyrtec-D®, generics)	12-hour tablets (cetirizine 5 mg/ pseudoephedrine 120 mg/ tablet)	1 tablet twice daily
seasonal allergic rhinitis	**fexofenadine/ pseudoephedrine (Allegra-D®, generics)	12-hour tablets (fexofenadine 60 mg/ pseudoephedrine 120 mg/ tablet)	1 tablet twice daily
seasonal allergic rhinitis	**fexofenadine/ pseudoephedrine (Allegra-D®, generics)	24-hour tablets (fexofenadine 180 mg/ pseudoephedrine 240 mg/ tablet)	1 tablet once daily
seasonal allergic rhinitis	desloratadine/ pseudoephedrine (Clarinet-D® 12 hour)	12-hour tablets (2.5 mg desloratadine/ 120 mg pseudoephedrine/ tablet)	1 tablet twice daily
seasonal allergic rhinitis	**loratadine/ pseudoephedrine (Claritin D® 12 Hour, Alavert®, generics)	12-hour tablets (loratadine 5 mg/ pseudoephedrine 120 mg/ tablet)	1 tablet twice daily
seasonal allergic rhinitis	**loratadine/ pseudoephedrine extended-release (Claritin D® 24 Hour, generics)	24-hour tablets (loratadine 10 mg/ pseudoephedrine 240 mg/ tablet)	1 tablet once daily

- ** now over-the-counter

1.2 Pediatrics

Oral non-sedating antihistamines are FDA-approved for use in pediatric patients for allergic rhinitis and chronic urticaria. Cetirizine and levocetirizine are FDA-approved for use in children 6 months of age and older with urticaria and seasonal allergic rhinitis. Desloratadine is FDA-approved for use in children 6 months of age and older with chronic idiopathic urticaria and perennial allergic rhinitis and 2 years of age and older for seasonal allergic rhinitis, and fexofenadine and loratadine are FDA-approved for use in children 2 years and older for allergic rhinitis. The nasal non-sedating antihistamine, azelastine 0.1% solution, is FDA-approved for use in children 2 years and older for seasonal allergic rhinitis treatment, while olopatadine, another nasal non-sedating antihistamine, is indicated for use in children 6 years and older for seasonal allergic rhinitis therapy. Azelastine 0.15% solution is approved for use in children 6 years and older for perennial allergic rhinitis;

azelastine 0.1% is FDA-approved for perennial allergic rhinitis treatment in children 6 months to 11 years. Azelastine 0.1% solution is also indicated for use in pediatric patients 12 years and older with vasomotor rhinitis. Safety and efficacy of oral non-sedating antihistamine/decongestant combination products have not been established in children less than 12 years of age. Maximum recommended pediatric dosages for available non-sedating antihistamines are summarized in Tables 3 and 4. Dosages identified in Texas Medicaid patients exceeding these recommendations will be reviewed.

Table 3. Pediatric Maximum Recommended Dosages for Non-sedating Antihistamines – Monotherapy

Treatment Indication	Drug Name	Dosage Form/ Strength	Maximum Recommended Dosage
perennial allergic rhinitis	azelastine (generics)	0.1% nasal solution – 137 mcg/ spray	6 months to 11 years: 1 spray per nostril twice daily
perennial allergic rhinitis	azelastine (Astepro®, generics)	0.15% nasal solution – 205.5 mcg/ spray	6 years to 11 years: 1 spray per nostril twice daily
			12 years to 17 years: 2 sprays per nostril twice daily
seasonal allergic rhinitis	azelastine (generics)	0.1% nasal solution – 137 mcg/ spray	2 years to 11 years: 1 spray per nostril twice daily
			12 years to 17 years: 2 sprays per nostril twice daily
seasonal allergic rhinitis	azelastine (Astepro®, generics)	0.15% nasal solution – 205.5 mcg/ spray	6 years to 11 years: 1 spray per nostril twice daily
			12 years to 17 years: 2 sprays per nostril twice daily
vasomotor rhinitis	azelastine (generics)	0.1% nasal solution – 137 mcg/ spray	12 years to 17 years: 2 sprays per nostril twice daily

perennial or seasonal allergic rhinitis	cetirizine (Zyrtec®, generics)	**tablets, chewable tablets – 5 mg, 10 mg **orally disintegrating tablets - 10 mg **liquid filled capsule – 10 mg **solution – 1 mg/mL syrup – 1 mg/ mL	6 months to 11 months: 2.5 mg once daily 12 months to 5 years: 5 mg once daily 6 years to 17 years: 10 mg once daily
urticaria	cetirizine (Zyrtec®, generics)		6 months to 11 months: 2.5 mg once daily 12 months to 5 years: 5 mg once daily 6 years to 17 years: 10 mg once daily
chronic idiopathic urticaria	desloratadine (Clarinetx®, generics)	tablets – 5 mg rapidly disintegrating tablets - 2.5 mg, 5 mg	6 months to 11 months: 1 mg (2 mL) once daily 12 months to 5 years: 1.25 mg (2.5 mL) once daily 6 years to 11 years: 2.5 mg once daily 12 years to 17 years: 5 mg once daily
perennial allergic rhinitis	desloratadine (Clarinetx®, generics)		6 months to 11 months: 1 mg (2 mL) once daily 12 months to 5 years: 1.25 mg (2.5 mL) once daily 6 years to 11 years: 2.5 mg once daily 12 years to 17 years: 5 mg once daily
seasonal allergic rhinitis	desloratadine (Clarinetx®, generics)		2 years to 5 years: 1.25 mg (2.5 mL) once daily 6 years to 11 years: 2.5 mg once daily 12 years to 17 years: 5 mg once daily

allergic rhinitis	fexofenadine (Children's Allegra® Allergy suspension, generics)	**suspension – 30 mg/5 mL	2 years to 11 years: 30 mg (1 teaspoon) every 12 hours 12 years to 17 years: 60 mg twice daily
chronic idiopathic urticaria	fexofenadine (Children's Allegra® Allergy suspension, generics)		6 months to 2 years: 15 mg twice daily 2 years to 11 years: 30 mg twice daily 12 years to 17 years: 60 mg twice daily or 180 mg once daily
allergic rhinitis	fexofenadine (Children's Allegra® Allergy ODT, generics)	**orally disintegrating tablets - 30 mg	6 years to 11 years: 30 mg (1 ODT) on tongue every 12 hours 12 years to 17 years: 60 mg (2 ODTs) on tongue every 12 hours
chronic idiopathic urticaria	fexofenadine (Children's Allegra® Allergy ODT, generics)		6 years to 11 years: 30 mg (1 ODT) on tongue every 12 hours 12 years to 17 years: 60 mg (2 ODTs) on tongue every 12 hours
allergic rhinitis	fexofenadine (Allegra®, generics)	**tablets – 30 mg, 60 mg, 180 mg	12 years to 17 years: 60 mg twice daily or 180 mg once daily
chronic idiopathic urticaria	fexofenadine (Allegra®, generics)		6 years to 11 years: 30 mg twice daily 12 years to 17 years: 60 mg twice daily or 180 mg once daily
allergic rhinitis	levocetirizine (Xyzal®, generics)	**tablet – 5 mg **oral solution – 2.5 mg/5 mL	6 months to 5 years: * 1.25 mg once daily in the evening 6 years to 11 years: 2.5 mg once daily in evening 12 years to 17 years: 5 mg once daily in evening

chronic idiopathic urticaria	levocetirizine (Xyzal®, generics)		6 months to 5 years: * 1.25 mg once daily in the evening 6 years to 11 years: 2.5 mg once daily in evening 12 years to 17 years: 5 mg once daily in evening
perennial or seasonal allergic rhinitis	loratadine (Claritin®, Alavert®, Claritin Children's®, Claritin RediTabs®, generics)	**tablets – 10 mg **chewable tablets (Claritin®) – 5 mg **rapidly disintegrating tablets (Claritin RediTabs®) – 5 mg, 10 mg **liquid-gel capsule – 10 mg **solution - 5 mg/5 mL	2 years to 5 years: 5 mg once daily (chewable tablets, solution/ syrup) 6 years to 17 years: 10 mg once daily or 5 mg every 12 hours
urticaria	loratadine		6 years to 17 years: 10 mg once daily or 5 mg every 12 hours
seasonal allergic rhinitis	olopatadine (Patanase®, generics)	0.6% nasal solution	6 years to 11 years: 1 spray per nostril twice daily 12 years to 17 years: 2 sprays per nostril twice daily

- ** now over-the-counter
- *OTC use only indicated in patients 2 years and older

Table 4. Pediatric Maximum Recommended Dosages for Non-sedating Antihistamines – Combination Therapy

Treatment Indication	Drug Name	Dosage Form/ Strength	Maximum Recommended Dosage
seasonal allergic rhinitis	acrivastine/ pseudoephedrine (Semprex® -D)	capsule (acrivastine 8 mg/ pseudoephedrine 60 mg/ capsule)	12 years to 17 years: 1 capsule up to 4 times daily (every 4-6 hours)
seasonal allergic rhinitis	azelastine/ fluticasone (Dymista®)	nasal suspension – 137 mcg/ 50 mcg per actuation	6 years to 17 years: 1 spray per nostril twice daily

perennial or seasonal allergic rhinitis	**cetirizine/ pseudoephedrine (Zyrtec-D®, generics)	12-hour tablets (cetirizine 5 mg/ pseudoephedrine 120 mg/ tablet)	12 years to 17 years: 1 tablet twice daily
seasonal allergic rhinitis	**fexofenadine/ pseudoephedrine (Allegra-D®, generics)	12-hour tablets (fexofenadine 60 mg/ pseudoephedrine 120 mg/ tablet)	12 years to 17 years: 1 tablet twice daily
seasonal allergic rhinitis	**fexofenadine/ pseudoephedrine (Allegra-D®, generics)	24-hour tablets (fexofenadine 180 mg/ pseudoephedrine 240 mg/ tablet)	12 years to 17 years: 1 tablet once daily
seasonal allergic rhinitis	desloratadine/ pseudoephedrine (Clarinet-D® 12 hour)	12-hour tablets (2.5 mg desloratadine/ 120 mg pseudoephedrine/ tablet)	12 years to 17 years: 1 tablet twice daily
seasonal allergic rhinitis	**loratadine/ pseudoephedrine (Claritin D® 12 Hour, Alavert®, generics)	12-hour tablets (loratadine 5mg/pseudoephedrine 120 mg/tablet)	12 years to 17 years: 1 tablet twice daily
seasonal allergic rhinitis	**loratadine/ pseudoephedrine extended-release (Claritin D® 24 Hour, generics)	24-hour tablets (loratadine 10 mg/ pseudoephedrine 240 mg/ tablet)	12 years to 17 years: 1 tablet twice daily

***now over-the-counter*

2 Duration of Therapy

There is no basis for limiting the duration of treatment for non-sedating antihistamines as patients may suffer from symptoms of allergic rhinitis or other chronic allergic conditions continually.

3 Duplicative Therapy

The concurrent use of two or more non-sedating antihistamines is not recommended. Additional therapeutic benefit is not experienced when several antihistamines are administered in combination. Patient profiles containing concurrent prescriptions for multiple non-sedating antihistamines will be reviewed.

4 Drug-Drug Interactions

Patient profiles will be assessed to identify those drug regimens which may result in clinically significant drug-drug interactions. Drug-drug interactions considered clinically significant for non-sedating antihistamines are summarized in Table 5. Only those drug-drug interactions classified as clinical significance level 1/contraindicated or those considered life-threatening which have not yet been classified will be reviewed.

Table 5. Non-sedating Antihistamine Drug-Drug Interactions

Target Drug	Interacting Drug	Interaction	Recommendation	Clinical Significance Level#
fexofenadine	antacids	adjunctive administration within 15 minutes of each other decreases fexofenadine bioavailability (AUC ↓'d 41%, Cmax ↓'d 43%), may reduce fexofenadine efficacy	space administration times	major (DrugReax) 2-major (CP)
fexofenadine	P-glycoprotein (P-gp) inducers (e.g., rifamycins, carbamazepine, fosamprenavir)	co-administration may decrease fexofenadine serum concentrations and reduce fexofenadine efficacy; drugs such as carbamazepine, rifamycins may activate P-gp transport in small intestine (fexofenadine is substrate of this transport) and decrease fexofenadine oral absorption	monitor for decreased fexofenadine therapeutic effects	3-moderate (CP)

fexofenadine	P-glycoprotein (P-gp) inhibitors (e.g., etravirine)	co-administration may increase fexofenadine serum concentrations, potentially resulting in enhanced pharmacologic and adverse effects	monitor for increased fexofenadine pharmacologic effects	major (DrugReax) 3-moderate (CP)
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loratadine	amiodarone	conjunctive administration may result in reduced loratadine metabolism and enhanced loratadine pharmacologic/adverse effects; amiodarone inhibits CYP3A4, loratadine metabolized by CYP3A4; rare reports of QT interval prolongation with drug combination	use cautiously together; QT interval monitoring recommended	major (DrugReax)
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- #CP = Clinical Pharmacology

5 References

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