

SmartPA Criteria Proposal

Drug/Drug Class:	Antihistamines/Decongestant Combinations – Low Sedating (2nd Generation) PDL Edit
First Implementation Date:	February 26, 2003
Proposed Date:	March 19, 2020
Prepared For:	MO HealthNet
Prepared By:	MO HealthNet/Conduent
Criteria Status:	<input type="checkbox"/> Existing Criteria <input checked="" type="checkbox"/> Revision of Existing Criteria <input type="checkbox"/> New Criteria

Executive Summary

Purpose: The MO HealthNet Pharmacy Program will implement a state-specific preferred drug list.

Why Issue Selected: The most common form of rhinitis is allergic, occurring in 20 to 40 million patients annually in the US alone. Allergic rhinitis (AR) symptoms range from mild to severe and patients may present with related conditions such as asthma and sinusitis. AR is characterized by nasal mucous membrane swelling and blockage, reflex sneezing, mucous hypersecretion, and often ocular manifestations including itching, tearing, and conjunctival redness. Airborne allergens are known to cause an IgE-mediated response of histamine, thereby beginning the histamine cascade, which creates the role for antihistamine therapy.

Total program savings for the PDL classes will be regularly reviewed.

Program-Specific Information:

Preferred Agents	Non-Preferred Agents
<ul style="list-style-type: none"> • Cetirizine Tabs OTC • Cetirizine Soln Rx • Cetirizine-D • Levocetirizine Tabs Rx • Loratadine RapDis Tabs/Soln/Tabs OTC • Loratadine-D 	<ul style="list-style-type: none"> • Alavert-D • Allegra® • Allegra-D® • Cetirizine Caps/Chew Tabs/Soln OTC • Clarinex® • Clarinex-D® • Claritin® • Claritin-D® • Desloratadine ODT/Tabs • Fexofenadine OTC and Rx • Fexofenadine-D • Levocetirizine Tabs OTC • Levocetirizine Soln/Tabs Rx • Loratadine Caps/Chew Tabs OTC • Quzyttir™ • Semprex-D® • Xyzal® • Zyrtec® • Zyrtec-D®

Type of Criteria: Increased risk of ADE
 Appropriate Indications

Preferred Drug List
 Clinical Edit

Data Sources: Only Administrative Databases

Databases + Prescriber-Supplied

Setting & Population

- Drug class for review: Antihistamines/Decongestant Combinations – Low Sedating (2nd Generation)
- Age range: All appropriate MO HealthNet participants

Approval Criteria

- Failure to achieve desired therapeutic outcomes with trial on 2 or more preferred agents
 - Documented trial period of preferred agents
 - Documented ADE/ADR to preferred agents
- For Clarinex syrup: participants aged 2 years or younger
- **For Quzuyttir: Clinical Consultant Review**

Denial Criteria

- Lack of adequate trial on required preferred agents
- Therapy will be denied if no approval criteria are met
- Claim exceeds maximum dosing limitation for the following (Dose Opt or 716 Criteria):

Drug Description	Generic Equivalent	Max Dosing Limitation
CHILD ZYRTEC 1 MG/ML SOLUTION	CETIRIZINE	10 mL per day
CHILD CETIRIZINE 5 MG CHEW TAB	CETIRIZINE	1 tablet per day
CETIRIZINE HCL 5 MG TABLET	CETIRIZINE	1 tablet per day
CETIRIZINE HCL 5 MG/5 ML SOLN	CETIRIZINE	10 mL per day
ZYRTEC 10 MG CHEWABLE TABLET	CETIRIZINE	1 tablet per day
ZYRTEC 10 MG LIQUID GELS	CETIRIZINE	1 tablet per day
ZYRTEC 10 MG ODT	CETIRIZINE	1 tablet per day
ZYRTEC 10 MG TABLET	CETIRIZINE	1 tablet per day
CLARITIN 10 MG REDITABS	LORATADINE	1 tablet per day
CHILD'S CLARITIN 5 MG TAB CHEW	LORATADINE	1 tablet per day
CLARITIN 10 MG LIQUI-GEL CAP	LORATADINE	1 tablet per day
CLARITIN 5 MG REDITABS	LORATADINE	1 tablet per day
LORATADINE 5 MG/5 ML SOLUTION	LORATADINE	10 mL per day
CLARITIN 5 MG/5 ML SYRUP	LORATADINE	10 mL per day
CLARITIN 10 MG TABLET	LORATADINE	1 tablet per day

Required Documentation

Laboratory Results:
 MedWatch Form:

Progress Notes:
 Other:

Disposition of Edit

Denial: Exception Code "0160" (Preferred Drug List)
 Rule Type: PDL

SmartPA PDL Proposal Form

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Default Approval Period

1 year

References

1. Drug Effectiveness Review Project – Drug Class Review on Newer Antihistamines, 2nd Generation. Center for Evidence-Based Policy, Oregon Health & Science University; April 2006/Updated May 2010/Evidence Scan February 2016.
2. Evidence-Based Medicine and Fiscal Analysis: “2nd Generation Antihistamines – Therapeutic Class Review”, Conduent Business Services, L.L.C., Richmond VA; January 2020.
3. Evidence-Based Medicine Analysis: “Non-Sedating Antihistamines”, UMKC-DIC; February 2020.
4. Lippincott, Williams, Wilkins. PDR Electronic Library, Montvale NJ; 2020.
5. USPDI, Micromedex; 2020.
6. Facts and Comparisons eAnswers (online); 2020 Clinical Drug Information, LLC.

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