

Policies Repository



Policy Title Levocetirizine (Xyzal®)

Policy Number FS.CLIN.33

Application of Pharmacy Policy is determined by benefits and contracts. Benefits may vary based on product line, group or contract. Some medications may be subject to precertification, age, gender or quantity edits. Individual member benefits must be verified.

This Pharmacy Policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety or FDA approval may have changed. If the Medical/Pharmacy Reviewer is aware of any new information on the subject of this document, please provide it promptly to the Medical/Pharmacy Policy Department. This information may include new FDA approved indications, withdrawals or other FDA alerts. This type of information is relevant not only when considering whether this Policy should be updated, but also when applying it to current requests for coverage.

Members are advised to use participating pharmacies in order to receive the highest level of benefits.

Policy **Levocetirizine (Xyzal®)** is indicated for the relief of symptoms associated with seasonal and perennial allergic rhinitis and the treatment of the uncomplicated skin manifestations of chronic idiopathic urticaria in adults and children 6 years of age and older.

The use of levocetirizine (Xyzal®) requires prior authorization (ie, clinical pharmacy and/or Medical Director review).

Policy Description **Levocetirizine (Xyzal®)**, the active (R) enantiomer of cetirizine (Zyrtec®), is an antihistamine that mediates via inhibition of H1 receptors. This effect has been documented in a variety of animal and human models and it is recorded to have a 2-fold affinity for the human H1 receptor than that of cetirizine through in vitro studies. However, the clinical effect of this 2-fold affinity is unknown. Levocetirizine (Xyzal®) has not shown to be superior in efficacy to the preferred agents for the approved indications or shown decreased sedation over other non-sedating 2nd generation antihistamines. In addition, long-term safety has not been established with the use of this drug.

Policy Guideline Inclusion **Levocetirizine (Xyzal®)** is approved when **all** of the following inclusion criteria are met:

- Documentation of a diagnosis of allergic rhinitis or urticaria
- Documentation of age greater than or equal to 6 years
- Documentation of a two week trial and failure of, or contraindication to, TWO of the following:
 - A cetirizine-containing product
 - A fexofenadine-containing product
 - A loratadine-containing product

Policy Guideline Exclusion **Levocetirizine (Xyzal®)** is denied when **any** of the following exclusion criteria are present:

- No documentation of a diagnosis of allergic rhinitis or urticaria

- No documentation of age greater than or equal to 6 years
- No documentation of a two week trial and failure of, or contraindication to, TWO of the following:
 - A cetirizine-containing product
 - A fexofenadine-containing product
 - A loratadine-containing product

Policy List of Applicable Drugs

Brand Name	Generic Name
Xyzal	levocetirizine

Dosing and Administration

Refer to the specific manufacturer's prescribing information for administration and dosage details for each specific agent.

Policy References

Facts and Comparisons. Xyzal® (Levocetirizine). [Facts and Comparisons Web site]. Available at: <http://online.factsandcomparisons.com/> [via subscription only]. Accessed April 1, 2009.

Micromedex® Healthcare Series [Internet database]. Xyzal® (Levocetirizine). Greenwood Village, CO: Thomson Micromedex. Available at: <http://www.thomsonhc.com> [via subscription only]. Accessed April 1, 2009.

Xyzal® [Package insert]. Bridgewater, NJ: sanofi-aventis US LLC; 2007. Also available online at: <http://www.xyzal.com/pdf/XYZAL.pdf>. Accessed April 1, 2009.

Policy Link to Related Policies

Printed

 05/04/2009 11:14:14

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