PDL NEW DRUG REVIEW

Proprietary Name: Zetonna®
Common Name: ciclesonide
PDL Category: Nasal Steroids

Comparable Products	Preferred Drug List Status
Fluticasone	Preferred
Nasonex	Preferred

Summary

Indications and Usage: Treatment of symptoms associated with seasonal and perennial allergic rhinitis in adults and adolescents ≥12 years of age. This is a pregnancy category C medication. The safety and efficacy of use in children under the age of 12 have not been established.

Dosage Forms: Nasal aerosol in propellant HFA (non-aqueous): 37mcg/actuation; containing 60 actuations per canister.

Recommended Dosage: 1 actuation per nostril once daily; maximum total daily dose should not exceed 74mcg/day.

Common Adverse Drug Reactions: *Listed % incidence for adverse drug reactions = reported % incidence for drug minus reported % incidence for placebo.* The most common adverse events reported with Zetonna® include nasal discomfort (1.4%), headache (1.9%), and epistaxis (0.2%). Warnings with use of topical corticosteroids include risk of *Candida albicans* infection, impaired wound healing, glaucoma and cataracts, immunosuppression, and hypothalamic-pituitary-adrenal (HPA) axis effects (if use higher than recommended doses or in those susceptible at recommended doses).

Contraindications: In those with known hypersensitivity to ciclesonide or any of the inactive ingredients of Zetonna®.

Manufacturer: Sunovion Pharmaceuticals Inc.

Analysis: Ciclesonide, the active ingredient of Zetonna®, has high affinity for glucocorticoid receptors for its anti-inflammatory effects. There were 3 placebo-controlled trials to assess safety and efficacy for use in allergic rhinitis, one with perennial allergic rhinitis (PAR) and two with seasonal allergic rhinitis (SAR). The main efficacy outcome was the difference from placebo in the change from baseline of the average morning and evening reflective total nasal symptom score (rTNSS; the recording of 4 nasal symptoms [runny nose, nasal itching, sneezing, and nasal congestion] rated on a severity scale). Results suggest that ciclesonide was significantly more effective than placebo for reduction of rTNSS. In one SAR trial, the mean change from baseline with ciclesonide was -1.5 vs -0.5 with placebo ($p<0.001$). The reflective total ocular symptom score was also significantly reduced with ciclesonide vs placebo (results from one trial includes a -0.8 mean change vs -0.2 mean change with placebo; $p<0.001$). The rTNSS in the PAR study was also significantly reduced with ciclesonide (-2.0 mean change vs -1.3 mean change with placebo; $p<0.001$).

There is no evidence at this time to support that Zetonna® is more efficacious or safer than the currently available, more cost effective medications. Therefore, it is recommended that Zetonna® remain non-preferred and be available to the few who are unable to tolerate any preferred medications.

PDL Placement:

- ☐ **Preferred**
- ☒ **Non-Preferred**
- ☐ **Preferred with Conditions**

References

[1] Zetonna [package insert]. Marlborough, MA: Sunovion Pharmaceuticals Inc; 2012.