PDL NEW DRUG REVIEW

Proprietary Name: Qnasl®
Common Name: beclomethasone dipropionate
PDL Category: Nasal Steroids

Comparable Products	Preferred Drug List Status
Fluticasone	Preferred
Nasonex	Preferred

Summary

Indications and Usage: Treatment of nasal 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: Non-aqueous nasal spray solution in propellant HFA, 80mcg per actuation. Each canister has 124 sprays, 4 of which are to be used for the initial priming.

Recommended Dosage: 320mcg (2 nasal sprays in each nostril) once daily; Max of 4 nasal sprays per day.

Common Adverse Drug Reactions: *Listed % incidence for adverse drug reactions = reported % incidence for drug minus reported % incidence for placebo.* The most commonly reported adverse events with Qnasl® were nasal discomfort (0.4%), epistaxis (0.7%), and headache (0.7%).

Nasal ulceration is another local nasal effect that has been reported. This was reported by 1 of 415 patients treated with Qnasal® in a 52 week safety trial (vs none in the placebo group). If this event occurs during Qnasl® use, treatment should be discontinued. While *Candida* infections have not been reported with Qnasl®, they have been in previous trials of an aqueous formulation of beclomethasone. If this infection occurs, Qnasl® should be discontinued. Glaucoma has also been reported with intranasal steroids, including Qnasl®. In one 52-week safety study, 10 patients (5%) on Qnasl® had increased IOP vs 1 patient (2%) taking placebo. No instances of cataracts were reported during this trial, although they have been reported with intranasal steroid use.

Contraindications: In those with a history of hypersensitivity to beclomethasone dipropionate and/or any other inactive ingredient.

Manufacturer: For Teva Respiratory, LLC; By: 3M Drug Delivery Systems.

Analysis: Beclomethasone dipropionate, the active ingredient of Qnasl® is an anti-inflammatory steroid in a non-aqueous solution. As with other intranasal steroidal inhalers, certain warnings do exist with use. One such warning is the effect on the hypothalamic-pituitary-adrenal axis. If changes occur, the dosage of Qnasl® should be discontinued slowly. Effects on growth also occur, so routine monitoring of growth should be done in the pediatric population.

One dose-ranging trial and two randomized placebo controlled efficacy trials were performed to establish FDA approval. In the dose ranging trial, three doses of beclomethasone (320mcg/day, 160mcg/day, and 80mcg/day) were compared with placebo. Only the 320mcg/day dose was statistically significantly more effective than placebo. In the efficacy trials, beclomethasone was significantly more effective for reducing reflective and instantaneous Total Nasal Symptoms Scores (rTNSS and iTNSS) as compared with placebo.

There is no evidence at this time to support that Qnasl® is more efficacious or safer than the currently available, more cost effective medications. Therefore, it is recommended that Qnasl® 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] Qnasl [package insert]. Horsham, PA: Teva Respiratory, LLC; 2012.