

**A REVIEW OF THE COST-EFFECTIVENESS OF SUBLINGUAL  
IMMUNOTHERAPY (GRAZAX®) FOR THE PREVENTION OF SEASONAL  
GRASS POLLEN-INDUCED RHINOCONJUNCTIVITIS**



## Summary

1. GrazaX sublingual tablets contain standardised allergen extract of grass pollen. The therapeutic indication is for the treatment of grass pollen induced rhinitis and conjunctivitis in adult patients with clinically relevant symptoms and diagnosed with a positive skin prick test and/or specific IgE test to grass pollen.
2. In March 2007, Menarini Ireland Ltd submitted an economic evaluation on the cost effectiveness of GrazaX sublingual grass pollen extract for the management of allergic rhinitis to support its application for reimbursement under the Community Drugs Schemes. The cost effectiveness of GrazaX in the Irish Healthcare System was reviewed using standard criteria.
3. No clinical trial data has been presented on the use of GrazaX sublingual tablets for the treatment of seasonal allergic rhinoconjunctivitis beyond a second pollen season. Consequently the cost effectiveness of GrazaX was demonstrated using economic modelling. The main model was constructed on the basis of 3 years of treatment followed by 6 years of sustained effect.
4. Data was presented on the incremental cost effectiveness ratio (ICER) from the Health Services Executive (HSE) and societal perspectives. Assuming a one year time horizon the resulting ICER for GrazaX sublingual therapy vs symptomatic treatment was €6,226 per quality adjusted life year (QALY) from the HSE perspective. The ICERs obtained for the 3, 6 and 9 year time horizons were €1,637/QALY, €25,693/QALY and €17,075/QALY respectively. Analysis from the societal perspective at the one year time horizon demonstrated an ICER of €2,546/QALY. The incremental cost effectiveness at the 3, 6 and 9 year time horizons were €17,958/QALY, €2,014/QALY and €13,396/QALY.

5. The cost effectiveness of Grazax sublingual therapy was influenced by the time horizon assumption adopted in the model. Sensitivity analysis around the observed QALY gain was also presented. Fixing the QALY gain at the lower level of 0.2 the cost per QALY estimates at 1, 3, 6 and 9 years were €80,300/QALY, €73,724/QALY, €36,691/QALY and €24,381/QALY respectively (HSE perspective).
6. As expected the cost effectiveness of Grazax sublingual therapy is sensitive to price. From the base case HSE perspective at the one year time horizon the ICER for Grazax fell to €1,865/QALY, €7,453/QALY and €43,076/QALY following a 10%, 20% and 30% price reduction. Corresponding ICERs for the three year time horizon were €7,277/QALY, €2,865/QALY and €8,489/QALY.
7. Reimbursement of Grazax in the Irish Healthcare Setting could have a significant budgetary impact. Seasonal allergic rhinoconjunctivitis (hay fever) is estimated to affect 25 to 30% of the population. Approximately 52 to 90% are allergic to grass pollens which are usually prevalent from late May to mid August. Current estimates suggest that the cost of Grazax reimbursement could exceed €6 million per annum.
8. From the HSE perspective the current submission indicates ICERs of €6,226/QALY and €1,637/QALY at the one and three year time horizons respectively. This exceeds the cost effectiveness threshold of €45,000/QALY. If it is assumed the benefits of Grazax therapy are maintained over a 9 year time horizon, including the 3 year treatment period then the ICER is €17,075/QALY. However, there is currently no evidence to support this assumption. This review group considers that the cost effectiveness of Grazax remains to be established and this product cannot be recommended as value for money at this point in time.