



Preferred Drug List

NEW DRUG REVIEW

Proprietary Name: Chantix™

Common Name: Varenicline

PDL Category: Nicotine Replacement Therapy

| <u>Comparable Products</u> | <u>Preferred Drug List/ Recommended Drug List Status</u> |
|----------------------------|--|
| Bupropion SR Tablets | Preferred |

Summary

Indications and Usage: Smoking Cessation

Mechanism of Action: Blocks alpha-4-beta-2 nicotinic acetylcholine receptors

Dosage Forms: Tablets; 0.5mg, 1mg

Recommended Dosage: Start 0.5mg once daily for 3 days, followed by 0.5mg twice daily for four days, then 1mg twice daily. Use for 12 weeks. If initial treatment leads to cessation, may continue for an additional 12 weeks (24 weeks total).

Common Adverse Drug Reactions: Nausea, vomiting, constipation, flatulence, sleep disturbance. An "Early Communication" from the FDA in November 2007 warned providers of suicidal thoughts and aggressive or erratic behavior associated with varenicline. In January 2008, Pfizer announced a plans to change the label warning of suicide risk.

Contraindications: Hypersensitivity to varenicline or any component of the compound

Manufacturer: Pfizer Inc.

Analysis: Chantix™ is non-nicotine containing smoking cessation aid that has been on the market since May, 2006. It exerts its pharmacologic effects by blocking alpha-4-beta-2 nicotinic acetylcholine receptors which is a different mechanism from existing treatments such as nicotine replacement products and sustained release bupropion. Some studies have shown Chantix™ to be 44% effective at helping patients reach their quitting goals by the end of 12 weeks of therapy. Meta-analyses published by BMC Public Health and Cochrane Database Systematic Reviews assert that Chantix™ is more effective than NRT or bupropion. While published studies show favorable efficacy, to date, all studies have been sponsored by the drug manufacturer, and some debate has been raised as to the definition of cessation, long term cessation rates, and study inclusion criteria. Due to the unique mechanism of action to aid in smoking cessation, it is recommended Chantix™ be added to the PDL as a preferred drug with conditions: a PA is required with confirmation of enrollment and ongoing participation in Quitline Iowa for members with nicotine dependence who are at least 18 years old.

IME Recommendation:

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| <input type="checkbox"/> Preferred Drug | <input type="checkbox"/> Recommended Drug |
| <input type="checkbox"/> Non-Preferred Drug | <input type="checkbox"/> Non-Recommended Drug |
| <input checked="" type="checkbox"/> Preferred Drug with Conditions | |