



Prior Authorization Approval Criteria
Department of Pharmacy Services

Generic Name: Nicotine Inhalation System

Brand Name: Nicotrol Inhaler

FDA Approved Uses: An aid to smoking cessation for the relief of nicotine withdrawal symptoms.

Therapeutic Class: Smoking Deterrent

Usual Dose: The initial dose should be individualized, with the patient self-titrating use to the level of nicotine replacement they require. Most successful patients in the clinical trials used from 6 to 16 cartridges per day, and patients should be encouraged to use at least 6 cartridges each day for at least the first 3 to 6 weeks of treatment.

Duration of Therapy: FCHP will only approve Nicotrol treatment for 3 months. This will be a onetime approval without any renewals.

Criteria for Use: *(bullet points below are all inclusive unless otherwise noted)*

- Patient must be part of the FCHP comprehensive behavioral smoking cessation program.
- Must have tried/failed all over the counter products including gum and patch dosage forms (separately and together)
- Must have tried/failed bupropion

Contraindications:

- Hypersensitivity to nicotine or menthol.

Not approved if:

- Patient has any contraindications to the use of Nicotrol.
- Patient does not meet the above stated criteria.

For Continuation of therapy:

- The patient must have stopped smoking by the fourth week of nicotine replacement therapy.

Rationale: Levels of nicotine achieved with the inhaler are lower than with some other nicotine replacement products, most closely comparable to the 2 mg nicotine gum.

*Manufacturer states that after 3 months Nicotrol can be tapered over 6 to 12 weeks. Use for longer than 6 months is not recommended

P&T Approval: _____ Date: _____