**Medication Policy Manual**

**Policy No:** dru318

**Topic:** Nicotine products:
- nicotine oral inhaler (Nicotrol®)
- nicotine nasal solution (Nicotrol NS®)

**Date of Origin:** September 16, 2013

**Committee Approval Date:** January 13, 2017

**Next Review Date:** January 2018

**Effective Date:** February 1, 2017

**IMPORTANT REMINDER**

This Medication Policy has been developed through consideration of medical necessity, generally accepted standards of medical practice, and review of medical literature and government approval status.

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control.

The purpose of medication policy is to provide a guide to coverage. Medication Policy is not intended to dictate to providers how to practice medicine. Providers are expected to exercise their medical judgment in providing the most appropriate care.

**Description**

Nicotine-containing products, also known as nicotine replacement therapy (NRT), are used to treat nicotine withdrawal in people quitting smoking as part of a comprehensive smoking cessation program. Nicotine patches, gum, and lozenges are available as lower-cost generics. Nicotine oral inhaler (Nicotrol) and nicotine nasal solution (Nicotrol NS) are only available as branded prescription products. This policy applies only to branded nicotine-containing products that require a prescription.
Policy/Criteria

I. Most contracts require prior authorization approval of nicotine oral inhaler (Nicotrol) or nasal solution (Nicotrol NS) products prior to coverage. Nicotine oral inhaler (Nicotrol) or nasal solution (Nicotrol NS) may be considered medically necessary when used for smoking cessation (nicotine withdrawal) when at least two less costly FDA-approved nicotine-containing products (See Appendix 1) have been ineffective, not tolerated, or all are contraindicated.

II. Administration, Quantity Limitations, and Authorization Period
   A. OmedaRx considers nicotine oral inhaler (Nicotrol) and nasal solution (Nicotrol NS) to be self-administered medications.
   B. When prior authorization is approved, nicotine oral inhaler (Nicotrol) or nasal solution (Nicotrol NS) may be authorized for no more than two fills within 30 days (or 6 fills per 180 days), to allow for a maximum of 12 weeks (90 days) of therapy per 6 month period.
   C. Authorization may be reviewed at least every six months to confirm that current medical necessity criteria are met and that the medication is effective.

III. Use of nicotine oral inhaler (Nicotrol) or nasal solution (Nicotrol NS) is considered investigational when used for all other conditions, including but not limited to treatment of any condition other than nicotine dependence (smoking cessation).

Position Statement

Product Comparisons
- Nicotine replacement therapy (NRT) products are equally safe and effective, although they differ in how the medication is administered as well as the frequency of administration.
- The evidence does not support branded nicotine inhaler (Nicotrol) or nicotine nasal spray (Nicotrol NS) over many generic NRT options.
- Among the available NRTs, non-prescription (“over-the-counter,” OTC) nicotine transdermal patches, gum, and lozenges cover the needs of most patients and provide the best value. Branded prescription NRTs may be an option for patients when OTC options are ineffective, not tolerated, or contraindicated.
- Guidelines support the use of nicotine replacement therapy, without preference to any one option, as part of a comprehensive treatment plan.
- Repeated interventions are frequently required for long-term abstinence. Use of a comprehensive smoking cessation program, including but not limited to use of counseling, an internet-based program, or behavioral therapy, increases effectiveness of pharmacotherapies.
Policy Considerations

- This policy is based on the underlying premise that nicotine-containing products may be considered medically necessary as a replacement for nicotine in patients who are stopping smoking.

Clinical Efficacy

- Nicotine oral inhaler (Nicotrol) and nasal solution (Nicotrol NS) have not been proven in reliable clinical studies to be more effective than generic options for nicotine replacement therapy (NRT). [1]
- Nicotine transdermal products are used on a scheduled basis, whereas nicotine gum, lozenge, oral inhaler, and nasal solution are used as-needed for nicotine cravings.
- Among the “scheduled use” and the “as-needed” products, efficacy and safety of the available products are considered similar and are considered interchangeable within each group. [1]
- Treatment guidelines consider all nicotine replacement therapy options (patch, gum, lozenge, oral inhaler, and nasal spray) to all be equally effective first-line therapies. [1,2]
- All medication therapies should be used in combination with counseling for all smokers attempting to quit. [1,2]

Safety

- Nicotine replacement therapy has the same risks as tobacco nicotine addiction, such as cardiovascular risks. These risks should be weighed against the risk of using tobacco.
- Irritation, based on route of administration, is common. Inhaled products (both Nicotrol and Nicotrol NS) have a risk of bronchospasm as well as local irritation of the nose, mouth, and pharynx. Neither product should be used in patients with severe reactive airway disease.

Dosing

- Nicotine replacement therapies are generally recommended for 8 to 12 weeks of use. [1]
- Although some NRT therapies may be used for up to 6 months, it is unknown if use beyond 12 weeks of therapy is superior to shorter therapy. Use of nicotine transdermal patch beyond 8 weeks of use is not proven to be superior to longer therapy based on smoking abstinence rates. [1]
- Multiple quit attempts are frequently needed. Up to two treatment courses (“quit attempts”) per year may be covered as medically necessary. [2,3]
- Recommended dosage of nicotine oral inhaler (Nicotrol) is 6 to 16 cartridges/day. [4]
- Recommended dosage of nicotine nasal spray (Nicotrol NS) is 1 to 2 doses (2-4 sprays) per hour as needed for symptom relief (range 8 to 40 doses per day). [5]
### Appendix 1: Available Nicotine-containing Products

#### Over-the-counter (OTC)

<table>
<thead>
<tr>
<th>Route of administration</th>
<th>Available as: b</th>
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<tr>
<td>nicotine polacrilex oral gum</td>
<td>generics, NICOrelief®, Nicorette®, Thrive®</td>
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<tr>
<td>nicotine polacrilex oral lozenge</td>
<td>generics, Commit®, NICOrelief®, Nicorette®, Nicorette Mini®</td>
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<tr>
<td>nicotine transdermal system (“patches”)</td>
<td>generics, Nicotrol Step®, NicoDerm CQ Step®, Habitrol®</td>
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#### Prescription (Rx)

<table>
<thead>
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<th>Route of administration</th>
<th>How supplied (per box)</th>
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<tr>
<td>nicotine nasal spray 10 mg/mL (Nicotrol NS)</td>
<td>4 x 10 mL bottle (200 sprays per 10 mL)</td>
</tr>
<tr>
<td>nicotine oral inhaler 10 mg (Nicotrol)</td>
<td>168 cartridges</td>
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a Electronic cigarettes are not FDA-approved nicotine-containing products and will not be considered as part of this medication coverage policy.

b Generics include a variety of “store brand” products.

### Cross References

None

### Codes

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References


Revision History

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