

Alferon N[®] (Interferon Alfa-n3)

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Medical Guideline Disclaimer

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Definition

Alferon N (interferon alfa-n3) is indicated for the intralesional treatment of refractory or recurring external condylomata acuminata in patients 18 years of age or older

Length of Authorization

Coverage will be provided for 8 weeks. Coverage may be renewed after 3 months after the intial 8 week course.

Dosing Limits

Max Units (per dose and over time) [Medical Benefit]:

- 160 billable units per 56 days

I. INITIAL APPROVAL CRITERIA

<u>Alferon N</u> may be considered medically necessary if one of the below conditions are met **AND** use is consistent with the medical necessity criteria that follows:

1. Condylomata acuminate

- a. Patient must be 18 years of age and older
- b. Patient must have a diagnosis of refractory or recurring external condylomata acuminate
- c. Patient must have an adequate trial and failure of a chemical agent (podophyllin, trichloroacetic acid, or 5-fluoruracil epinephrine gel) AND imiquimod with an inadequate

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response or significant side effects/toxicity or must have a contraindication to these therapies (Step protocol not mandated for Medicare members)

Limitations/Exclusions

N/A

II. RENEWAL CRITERIA

All prior authorization renewals are reviewed on a case-by-case basis to determine the Medical Necessity for continuation of therapy. Authorization may be extended for an additional 2-month course based upon chart documentation from the prescriber that the member's condition has recurred and requires additional treatment.

Dosage/Administration

Indication	Dose
Condylomata acuminate	 INTRALESIONAL injection of 0.05 mL (250,000 units)/wart twice
	weekly for up to 8 wk; MAX 0.5 mL/treatment session

Applicable Procedure Codes

Applicable NDCs

54746-0001-01	vial, 1 ml Interferon Alfa-N3 (Human) (Murine) (Avian) 5,000,000U/1mL, Solution for
	injection

Applicable Diagnosis Codes

ICD-10	ICD-10 Description
A63.0	A63.0 Anogenital (venereal) warts

References

- 1) Product Information: ALFERON N^(R) injection, interferon alfa N3 injection. Hemispherx Biopharma Inc, Philadelphia, PA, 2019.
- 2) Clinical Pharmacology Elsevier Gold Standard. 2019.
- 3) Micromedex[®] Healthcare Series: Thomson Micromedex, Greenwood Village, Co. 2019.