

Medical Policy: ALFERON N® (interferon alfa-n3)

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.216	August 16, 2023	

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The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as “EmblemHealth”), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

Definitions

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 initial 8 week course.

Dosing Limits [Medical Benefit]

Max Units (per dose and over time):

- 160 billable units per 56 days

Guideline

I. Initial Approval Criteria

Alferon N 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 acuminata

- a. Patient must be 18 years of age and older; **AND**
- b. Patient must have a diagnosis of refractory or recurring external condylomata acuminata; **AND**
- 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 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 acuminata	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

Code	Description
J9215	Injection, interferon, alfa-n3, (human leukocyte derived), 250,000 IU

Applicable NDCs

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

ICD-10 Diagnoses

Code	Description
A63.0	A63.0 Anogenital (venereal) warts

Revision History

Company(ies)	DATE	REVISION
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EmblemHealth & ConnectiCare	8/16/2023	Annual Review: no criteria changes. Removal of "CCI ONLY" from policy name
EmblemHealth & ConnectiCare	3/17/2022	Transferred policy to new template
EmblemHealth & ConnectiCare	8/1/2019	Annual Review

References

1. Product Information: ALFERON N® 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.